

Radial Versus Femoral: Choosing the Best Option for Each Patient

Experts Sunil Rao, MD, and Timothy Sanborn, MD, discuss their opinions on access, pharmacology, patient selection, and the use of closure devices.



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What is the current standard regarding femoral access using closure devices versus radial access?

Dr. Sanborn: Currently, the femoral approach remains the predominant form of access for percutaneous coronary intervention (PCI), although use of the radial approach is increasing. The rationale for the radial approach includes improved patient comfort and mobility, as well as the potential for reduced complications.

Both approaches are being used in many laboratories across the country.

Two of the limitations of previously published randomized trials on the radial versus femoral approach include a low incidence of the use of bivalirudin and closure devices for the femoral approach. These factors could have contributed to higher bleeding complication rates with the femoral approach in these randomized trials. Reduced bleeding complications have been observed in a number of observational studies when bivalirudin and closure devices were used with the femoral approach.

Both approaches are feasible. There is still more femoral use than radial, but that is changing.

Dr. Rao: I agree that femoral access is still the predominant approach in the United States. The rate of radial use in the United States has increased from 1% to somewhere between 20% and 25%, and there has been a dramatic increase in the last 5 to 6 years. Based on the NCDR data, which lag a little bit, 75% to 80% of PCIs are femoral, and 20% to 25% are radial.

I think the closure device data are very interesting and send a message, but that message may be flawed. First, if you look at the randomized trials that had been published with closure devices, the data suggest that closure devices are associated with an increase in vascular complications. The big caveat is that the majority of closure devices that were studied are older-generation devices.

There has been tremendous evolution in vascular closure devices over time, so it's certainly possible that the newer ones are safer, and as Dr. Sanborn mentioned, the observational data suggest that there's an association between the use of closure devices and reduced bleeding.

In my opinion, the data are not updated enough for us to make a solid statement about vascular closure devices. What we can say is that certainly, in an observational sense, it does appear that closure devices are associated with a reduction in complications and in bleeding. The challenge that we have with those observational studies is that what we don't know what the denominator is (ie, how many patients didn't qualify for a closure device based on too low of a stick, too high of a stick, or disease at the entry site).

With some of the observational data, we are potentially looking at ideal cases that qualify for closure devices. In such ideal cases, I certainly think it is possible (and makes sense) that a closure device would work. The pessimist would look at that and say closure devices work best in patients who need them the least. I mean, it's possible that those patients are going to be so low risk that they don't need a closure device at all.

I don't think that the jury is in on closure devices saying that they're all bad. I do think that there is a lot more room for investigation in this particular area.

The most contemporary randomized trial that we have is the SAFE-PCI trial, which is a United States-based randomized trial of radial versus femoral access in women. There were a lot of limitations with the study, and it was stopped early. The femoral outcomes were fantastic, well below what we projected for the rate of complications, with a 65% closure device rate. Among patients who were undergoing either cardiac catheterization or PCI, despite the 65% closure device rate and 65% bivalirudin rate, the radial approach was still associated with a reduction in bleeding complications.

Having said that, the rates of overall complications were very low in that trial, which tells me that as an interventional cardiologist, you really have to know how to do both femoral and radial, and you have to know how to do both well. Achieving femoral access is not rocket science, but it is a science, and it all starts with making sure you're in the safe zone for arteriotomy to reduce those complications.

An experienced interventional operator can achieve excellent femoral outcomes. I think that in the kind of patient substrate that we're seeing in our cath labs these days, that interventional operator is probably going to be well served by being very proficient at radial access.

Dr. Sanborn: Yes, we have seen a number of publications going back to the initial meta-analyses that were done with the VasoSeal closure device which is no longer on the market.

Those meta-analyses and early trials are not relevant to today's newer closure devices. With some of the more recent observational studies (eg, the New England PCI registries, the analysis of the NCDR data by Steven Marso et al, and the ACUITY and HORIZONS data), we saw fewer bleeding complications with bivalirudin and the use of a closure device with the femoral approach. Now, not every patient can get a closure device, so that is important.

The other thing that has changed is that a lot of operators are starting to use micropuncture techniques rather than the conventional Seldinger technique with larger-bore needles. I think that will also decrease the risk of complications. The practice of femoral access has changed since many of the earlier studies.

Dr. Rao: Yes, that's right. I would really like to see a lot more data on those kinds of things because it makes a lot of sense. I have reviewed some of the literature, and it's very interesting because this is an area that a lot of people think is kind of boring compared with the latest and greatest devices, but from the patient's perspective, it is probably one of the most important things that we do—how do we achieve access?

If you look at the literature on micropuncture, for example, the data are composed of lower-quality studies. If anything, the data show that there is an association between micropuncture and increased vascular complications. Those studies are somewhat broad because they are primarily observational. The best way to achieve femoral access is to use ultrasound guidance. Unfortunately, not all of us have ultrasound available in our labs, and there is a learning curve associated with its use, as well.

I think that there is an evolution in the ways that we are achieving femoral access. There is also an evolution in the size of the sheath. This is not the old days where we were doing routine 8-F interventions; a lot of people nowadays are doing 5-F femoral intervention. That has to have an impact on the overall femoral bleeding rates.

I do think it's time for our community as a whole to start focusing on the basics again. It is always great to talk about these fantastic devices that are coming out, and that's incredibly important. But for people who deal with trainees by focusing on the fundamentals, just like we help the fellows develop good habits in the interventional lab, we need to make sure they learn how to achieve access in an appropriate way, regardless of whether it's radial or femoral.

What future additional studies need to be conducted regarding the latest device iterations?

Dr. Sanborn: Well, I think a lot of people have concluded if you really wanted to do a closure device randomized trial, it would be prohibitive. I don't think you're going to see a randomized trial of closure devices. The devices are always changing, and we have newer devices now compared to when many of the previous analyses were performed. So, I think getting comfortable with a closure device (or maybe several) is important—again, paying attention to good technique, looking at the femoral head with fluoroscopy, and possibly using micropuncture to avoid multiple sticks or sticks with large bores.

Dr. Rao: I agree. I don't think it's going to be possible to do a randomized trial of closure devices in PCI or, for that matter, diagnostic catheterization. The outcomes have just gotten too good. If you were to do a randomized trial of closure devices you would have to do it in a patient population that's undergoing a procedure where the vascular complication rate is quite significant. That is usually in the structural space.

There may be a lot of interest because with the latest iterations in the aortic valve devices (ie, smaller French sizes), it looks like transfemoral is superior to transapical, so there's going to be a lot more transfemoral aortic valve implantations. In that setting, it seems like the perfect area to explore the role of some of these closure devices, particularly with preclosure and so forth.

A problem that we have in any procedural field, not just in interventional cardiology, is that the iteration of these devices is so rapid that it is difficult for the studies to keep up. For example, we've seen that PCI versus open surgery studies originally used balloon angioplasty, but by the time the study came out, everyone was using bare-metal stents. So, another study of bare-metal stents was conducted, and by the time that came out, everyone was using drug-eluting stents.

This is a very challenging area, and it gets to one of the fundamental clinical issues in the procedural field, which is about patient selection. With a randomized trial, by virtue of the randomization, you are really applying one strategy to a group of people. But that's not how we practice at the bedside. How we really practice is we look at the patient in front of us and we try to assess what's the best approach for this patient.

If you have a patient who, for example, is a very high bleeding risk, you're probably going to be better off using bleeding avoidance strategies, whether that's radial if you're a proficient radial operator, or the use of targeted anticoagulants to reduce the bleeding risk. That's where I think we are going to achieve the best

outcome, when the patient that's in front of you is a candidate for the approach that you want to use.

What patient populations benefit most from either access route, and what patients benefit most from the use of closure devices?

Dr. Sanborn: Certainly, the patient population in which I will shy away from using femoral access is obese patients. I would rather use radial access in those patients than worry about achieving access and then also gaining successful manual compression or closure device placement afterward.

Dr. Rao: I agree. Very obese patients are going to be much more comfortable with radial access.

I think there are two groups of interventionists right now in the United States—three if you count the ones who just don't want to adopt radial—and that's fine. There are people like me, sort of radial first in every patient, and that's just what we've become comfortable with. There are also folks who are a little bit more discretionary about the patients in whom they use radial. I think obese patients are going to be the group in which all of us can agree that radial is probably the way to go.

With respect to closure devices, it's interesting, because you add another layer to the patient selection. It's not only about the patient that's in front of you, but it's also about making sure that the arteriotomy is in the right anatomical location so that the patient qualifies for a closure device.

Dr. Sanborn: Yes, in those situations, fluoroscopy can help a lot. As I'm training fellows, I always emphasize the use of fluoroscopic guidance. I want to make sure they are over the femoral head. Often they'll say, "Well, I think I'm going to put the needle here." When I have them check it, we find that it is 2 cm below the femoral head, or maybe it's even above the inguinal crest.

We must continue to encourage the use of good fluoroscopic techniques. We've learned this from published studies, and many of the experts in the field talk about this repeatedly at all the major cardiology meetings. Make sure you're in the right spot; palpation certainly helps, but checking it with fluoroscopy is probably one of the key aspects of a good femoral access case.

Dr. Rao: Absolutely. In fact, the person who taught me how to do angioplasty, Dr. Jess Peters, used to tell me, "Never rely on the inguinal crease, creases lie to you." That's absolutely true. You'll go for the inguinal crease, and you'll realize that you're an entire four finger breadths

below the femoral head, and the next thing you know, the patient develops a hematoma on the table.

What are the challenges operators face in determining which access route to use?

Dr. Rao: I would say that the number one challenge is a lack of familiarity or proficiency with the radial approach. If you haven't done many radial cases or if you have not attended any kind of training course, you probably shouldn't be using radial for primary PCI. That's the wrong setting in which to start learning how to do radial.

All of us had a learning curve when we first started using radial; you just have to accept that when you start doing it, cases are going to take a little bit longer. But you want to choose your patients very carefully.

Dr. Sanborn: The other thing to mention is that the catheterization laboratory team also has to be experienced with radial.

Dr. Rao: That's absolutely true. That's a great point.

Dr. Sanborn: It's not just the operator, it's the whole team, the nurses, the technicians, and the people that are going to be checking the radial bands afterward. We just recently changed from one observation unit to another, and it's important that those nurses know how to monitor the radial bands. Just yesterday, I had a patient who started bleeding because the nurse let the pressure up too early.

I think the whole team has to be experienced in radial. There are courses your team can attend; make sure your team goes to those. I think it is beneficial for a cath lab today to be able to have both approaches available.

What complications does the use of closure devices add to the patient course?

Dr. Sanborn: I think closure devices can decrease bleeding. The other aspect here involves the pharmacologic treatment. I'm a big proponent of bivalirudin as compared to the heparin IIb/IIIa approach. Put the two together, bivalirudin plus a closure device, and I think you can get bleeding complication rates that are really comparable to the radial approach.

I also think that sterile technique is not emphasized enough. One of the things I do is I change my gloves and put some extra Betadine on the site before putting in a vascular closure device. Infection is a complication that is increased with the use of closure devices as compared to manual compression. If you take appropriate precautions, the result should be a very low incidence.

Dr. Rao: There's a learning curve associated with closure devices, as well. There are different closure devices that have different degrees of efficacy at sealing the arteriotomy.

I think it's important to get comfortable with one or two devices to make sure that you know exactly how they behave and when it's appropriate to use them.

What directions will femoral and radial access take in the future?

Dr. Rao: Well, I don't think femoral is going to go away, and it shouldn't. We are doing things in the cath lab today that I just couldn't imagine when I was in training. Specifically, transcatheter procedures for valves are going to continue to evolve, and some of those procedures are just going to require large-bore access. Femoral is not going away.

Where is radial going to end up? I'm not really sure. I have to admit that I'm surprised that it's gotten this far, maybe it will end up at 50%. Maybe we will be a 50% country where coronary cases are predominantly being done by radial access for the straightforward procedures, and we'll have a small group of dedicated radial operators who are using radial even for complicated procedures like chronic total occlusions and left veins.

As catheter-based therapies evolve well beyond the vascular space and into the structural space, good femoral technique is going to continue to be important.

Dr. Sanborn: As we continue to see closure devices, as well as the pharmacology evolve, we are going to see improved results with femoral access.

Dr. Rao: It all adds up to good news for our patients because as people continue to pay attention to cath lab fundamentals, that can only result in good things.

How do current approaches to PCI anticoagulation influence outcomes of femoral versus radial access?

Dr. Sanborn: I think we are seeing more use of bivalirudin and less use of glycoprotein IIb/IIIa inhibitor based on some of the recent large-scale trials, such as ACUTY and HORIZONS-AMI. With that, there are fewer bleeding complications with the femoral approach. It could be very close to the rate seen with the radial approach.

Dr. Rao: The interaction between pharmacology and radial access is yet unknown. We recently saw the presentation of the HEAT PPCI trial, which generated a lot of controversy. It's a primary PCI trial in ST-elevation myocardial infarction with 85% radial use and no difference in bleeding between bivalirudin and a heparin-alone strategy. Maybe it's because of the high rate of

radial usage that the bleeding difference between the two pharmacological strategies was neutralized.

There are several ongoing trials that will try and address this interaction between the access sites and pharmacology. We have some observational data, of course; for example, the EASY B2B trial, another primary PCI trial, which is all radial and comparing heparin alone versus bivalirudin. There is also the MATRIX trial, which is a huge study with 10,200 patients who have acute coronary syndromes, both with and without ST elevation and randomized to radial versus femoral access, heparin $\pm$ glycoprotein IIb/IIIa inhibitor versus bivalirudin.

We're going to see a lot more data on this particular question in the next few years. I think we're going to end up with, or at least I hope we end up with, a series of strategies that we can pick and choose from and tailor to the clinical setting for the patient who is in front of us. Because, at the end of the day, it's really about what you decide to do at the bedside and what you're good at doing to make sure that you get the best outcomes.

Dr. Sanborn: Your comment about the use of bivalirudin in the radial approach is important because bivalirudin probably has the biggest impact compared to heparin plus glycoprotein IIb/IIIa inhibitor when you are

using the femoral approach; there is less of an impact with the radial approach.

What take-home points would you like to impart to our readers?

Dr. Sanborn: Operators should be experienced in both approaches because both are going to be necessary in the future. As Dr. Rao said, the femoral approach is not going away. Also, stay on top of the pharmacology with PCI and which pharmacologic agents are best for which approach.

Dr. Rao: The other important message for people who work in the cath lab is to never fall into the trap of digging your heels in with one strategy because things continue to change and devices evolve, approaches evolve, and pharmacology evolves. Look at the literature with an objective eye and decide what's best. That may be different from what you're doing now, and we've got to get comfortable with that approach because this is a field that's rapidly changing and we've got to keep up.

Dr. Sanborn: I tell my fellows that cardiology changes about every 6 months.

Dr. Rao: That's right, and that's why I think most of us do it, because we like that; it keeps things exciting. ■