Perspectives on Access and Closure

A multispecialty panel's insights into current challenges and recent developments.

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In what ways does access affect closure decision making and effectiveness?

Dr. Schneider: Because the most common types of complications in all endovascular procedures are related to access, it is rewarding for all of us to start to see major progress made, new devices developing, and attention directed to this key area. The days of blind passage of an 18-gauge needle into an unsuspecting access artery are gone. For starters, we almost always choose our access site well ahead of time when we see the patient in the office. If there are questions about what the best approach might be, we usually obtain supplemental imaging to help us choose wisely.

Closure devices have been incorporated into our practice so thoroughly that it is almost difficult to recall what practice was like prior to their availability. There are a couple of key closure-related issues that lead the way. One is that hospital beds are at a premium in our isolated state (Hawaii), where there just are not enough for the population. So, a hospital stay being decreased, even for a few hours, is highly desirable. The other issue is that the patients and staff prefer closure due to comfort, convenience, and patient satisfaction.

Dr. van den Berg: A good quality access is mandatory to proceed with the use of any kind of closure device. I would rather refrain from using a closure device and perform manual compression when the puncture site is too low, the common femoral artery (CFA) is stenotic, or when other contraindications for the use of closure devices are present.

Dr. Arko: We perform almost all interventions with either a 6- or 7-F system in the periphery, and I routinely use a closure device. For pure diagnostics with a 5-F sheath without any anticoagulation, I typically use pressure alone. We are familiar with all the different closure devices and tend to use the MynxGrip (AccessClosure,

Inc., Mountain View, CA). For any access larger than 7 F, we use a suture-mediated device.

Dr. Ansel: In my view, there is no perfect closure device that is optimal for all patients. The vessel characteristics that may affect optimal closure are size, atherosclerotic process, and calcification. Patient characteristics such as depth of subcutaneous tissue, presence of scar or fibrous tissue, hypertension control, ability to follow directions, and anticoagulation status may all affect the choice of closure device.

Dr. Mustapha: Over the years, it has become apparent that access/closure decision-making and effectiveness depends on the patient's clinical status. Unique needs of the advanced peripheral arterial disease (PAD) patient have necessitated the adoption of newer approaches to access site selection. We have found having an exit strategy at the time of access reduces access complication rates significantly in complex PAD patients that are at high risk due to multiple comorbidities such as diabetes, hypertension, renal failure, vessel wall calcification, or obesity.

How have advances in access techniques and technologies (imaging included) affected your PAD practice in recent years?

Dr. Ansel: Since our group reported the first percutaneous pedal access in 2003, we have been proponents of nontraditional access when needed. The use of micropuncture techniques from various vascular beds such as tibial, popliteal, and superficial femoral arteries (SFA) has led to success in many cases where traditional access was either not possible or unsuccessful. We have also become much more aggressive about utilizing external ultrasound to facilitate access.

Dr. van den Berg: The fact that we can now safely perform a retrograde popliteal or pedal access has increased the number of patients that can be treated successfully. The use of ultrasound to guide the puncture is helpful for reducing complications and reducing radiation exposure to the operator.

Dr. Schneider: Independent of the development of closure methods, in the interest of decreasing access-related complications, several years ago we instituted the use of routine ultrasound guidance for all punctures, including routine retrograde femoral access. This has dovetailed nicely with our growing interest in closure. Ultrasound guidance permits the operator to precisely choose the site, guarantee that it is in the common femoral artery (CFA), and even avoid calcific lesions or stenoses that may have made closure difficult. Consequently, our complication rate has decreased, and our closure rate has increased.

We have also adopted the routine use of micropuncture for all punctures. In the femoral artery, I obtain a single shot of the needle position to make sure it is below the top of the femoral head. If the initial puncture is in an undesirable location, it is simple to pull it out and hold pressure for a couple minutes because it is a 21-gauge needle. Avoidance of retroperitoneal hematoma is key, and this is the best way to do it in my opinion.

The micropuncture wire is steerable and is particularly useful for entering the SFA after antegrade femoral puncture. When we are doing a retrograde femoral puncture ipsilaterally and distal to an iliac lesion, we use a long micropuncture catheter so that after the entry micropuncture wire is across the lesion, the position is maintained.

We use the upper extremity for access liberally and as needed, usually the brachial, in about 15% of our cases. This is especially true for visceral and renal cases. When the femoral access arteries are hostile, we have used upper extremity access to perform lower extremity revascularization.

Another big opportunity for us has been large-bore closure. It is rare for us now to use open exposure to do aortic stent graft placement. This has decreased the length of stay in our aortic practice and increased the patient satisfaction. Most of our patients go home the next day. We typically use two ProGlides (Abbott Vascular, Santa Clara, CA) for each femoral artery. The key is to select patients ahead of time with good examination results and imaging of the proximal femoral arteries. Then we use ultrasound to get the puncture in just the right place.

Dr. Mustapha: The progress in access techniques and technologies has advanced our PAD practice significantly over the last few years. We are now able to utilize alternative options, such as ultrasound-guided antegrade/retrograde access, which facilitates easier crossing, especially of long chronic total occlusion (CTO) segments that start in the SFA or popliteal and reconstitute in the tibial arteries.

Dr. Arko: We have used a variety of different access points including brachial, popliteal, and pedal. The use of ultrasound and the improvement of cross-sectional imaging can often readily determine the easiest point of access.

Is it realistic for all patients to be approached "endovascular first"? When are surgery or medical management better options than attempting exotic percutaneous access?

Dr. Ansel: Absolutes are really never appropriate. The endovascular specialist should always evaluate each particular patient's characteristics before offering endovascular, surgical, or medical treatment. For patients requiring an intervention, the amount of calcification, presence of a CTO, available conduit, renal function, and ability to tolerate or reliably take antiplatelet therapy all play important roles in the decision process. There are two angiographic characteristics that I do think should be strongly considered for surgical therapy before endovascular treatment: first, the patient with atherosclerotic occlusion of the mid, distal popliteal that extends into the tibial arteries. Until we have drug-coated balloons available in the United States, I do not feel we have the technology that reliably offers enough patency. So if a patient has good venous conduit and reliable runoff, surgical bypass would be the procedure of choice. Second, a long CTO of the SFA with very severe calcification, reasonable conduit option, and good surgical risk is typically best served by bypass. The aggressiveness of the intervention should also be placed in context of the clinical symptoms with more exotic access typically reserved for patients with critical limb ischemia (CLI).

Dr. Arko: I believe that when a patient requires an intervention, an endovascular-first approach first is reasonable. Clearly, there are some patients that I believe will warrant an open surgical repair, especially those that have an adequate autogenous conduit with extensive disease that extends to the tibials. However, the patients often have little autogenous tissue to offer; we think we are forced to proceed with an endovascular approach, even though open repair with an adequate conduit would be preferred.

Dr. van den Berg: I think most patients can be managed by an endovascular-first approach. In cases of CLI, medical management is not a stand-alone option at all. In cases where the exotic access uses a potential distal anastomotic site for a bypass, I always consider (in a multidisciplinary manner) the option of a bypass first prior to performing a distal access; the vascular surgeons hardly ever prefer to perform a distal bypass in these often critically ill patients.

Dr. Schneider: "Endovascular first" is driven mostly by the desire for the lower morbidity of less invasive reconstructions. If the magnitude of the endovascular reconstruction is increased by the complexity and risk of the vascular access, it might change the equation used to decide which therapy plan is best. However, this scenario is not very common. If the access plan is made and carried out deliberately and meticulously and the operator is paying close attention, the likelihood of safety and success is high.

Dr. Mustapha: It depends. If the CFA and profunda are involved, the answer is no. These patients should always be evaluated for surgical therapy first. If the CFA and profunda are not involved, then endovascular first is an appropriate approach as long as vascular bypass remains an option. Medical management is a good option for those patients who do not have Rutherford 4 or above and do not have good distal targets. The risk of making the situation worse is higher in these patients, so medical management has been shown to be a better option in the long term. Of course, hybrid procedures are always a feasible approach for patients with a combination of CFA, profunda, and other vascular conduit involvement.

When should challenging access either be abandoned or not attempted altogether?

Dr. Mustapha: We face this question on a daily basis, especially when dealing with elderly CLI patients with diabetes and renal failure. A decision to attempt intervention in this subset of patients has to be heavily weighted prior to attempting due to the higher risk of complications. In limb salvage cases, we should proceed with a clear plan from access to closure. Of course, there are limited situations when a patient is not a candidate for endovascular revascularization. Patients with advanced Rutherford 6, osteomyelitis involving the calcaneal bone, and poor distal vascular tree should not be attempted.

Dr. Arko: Challenging access should be abandoned when you feel that the risk of doing something to harm the patient outweighs the benefit of doing something positive. This situation typically comes with experience, unfortunately.

Dr. van den Berg: I am of the opinion that challenging access should only be reserved for patients with CLI. In patients with intermittent claudication, one should be very reluctant in using any fancy access technique.

Dr. Schneider: If there is a high chance of a puncture site thrombosis due to juxtaposed disease, don't use that puncture site.

Dr. Ansel: Physician expertise and Rutherford class should play a large role.

In challenging access cases, how worried are you about increased radiation exposure? What are you doing in your practice to reduce this, and how does this affect your decision making?

Dr. Ansel: We pay far too little attention to both patient and health care staff radiation exposures. I think many don't pay the proper attention to it because they are goal-driven to a successful procedure. However, there are important ways of reducing radiation exposure. Using radiation-absorbing pads and needle extenders to keep your exposure minimal, especially to your hand, are important. For carotid, heart, and valve patients, there are new rooms available that will be almost radiation free for the operator, helping to reduce radiation exposure and orthopedic risk.

Dr. Schneider: We use ultrasound guidance to obtain access. When we begin fluoroscopic imaging, we use shielding. We also use sheath lengths and extension tubing selectively to help move the operator away from the radiation field.

Dr. van den Berg: Distal punctures are almost always performed using ultrasound-guided techniques. When not possible, I always try to keep my hands outside of the direct beam, using image collimation, and using fluoroscopy only with the needle in place without holding the needle myself. Currently, needle extension devices are available that allow for moving the needle under fluoroscopy, without the risk of putting the operator's hand in or close to the direct x-ray beam.

Dr. Arko: For a challenging access case, I am not as worried about increased radiation. For direct access, I typically use ultrasound to limit my exposure.

Dr. Mustapha: I'm not worried about increasing radiation exposure. In fact, we have found radiation exposure to be lower in cases utilizing alternative access for a few reasons.

We use ultrasound for access in 100% of our cases and to perform the majority of wire and catheter advancements. Also, CTO crossing in the infrainguinal vessels is performed primarily under ultrasound guidance. I understand this practice is not common; however, I think it should be the preferred way to perform complex cases.

What do you value most in a closure method?

Dr. Arko: I value a system and protocol that is simple, effective, and allows the patient to readily become ambulatory. I have had success with the ProGlide, MynxGrip, and Angio-Seal (St. Jude Medical, Inc., St. Paul, MN). Those are the three primary closure devices that I use in varying degrees.

Dr. Schneider: Reliability, suture closure for large bore, and simplicity decrease failure modes (both device-related and operator-related).

Dr. van den Berg: A closure device should be fast, reliable, reproducible, and applicable to the large majority of cases.

Dr. Mustapha: I most value the ability to obtain hemostasis in obese patients, high-grade sticks, and popliteal access. These are known to have higher complication rates if hemostasis is not achieved properly. I truly value the benefit of closure devices in antegrade access. We have demonstrated high closure success in our institution by utilization of fluoroscopy and ultrasound-guided closure. The improvement in currently available closure devices allows us to obtain access and closure in diseased vessels that previously were avoided due to risk of complications.

Dr. Ansel: I wish we did not call these devices *closure devices*—it sets the expectation of finality at the end of the procedure. I have seen physicians try to prove the macho power of a closure device by having a patient get up off the table and walk. While this may be nice theater, it sends the wrong message. Personally, I would rather have these classified as sheath removal devices that assist in hemostasis. In our labs at Riverside, we mandate manual compression for 5 to 10 minutes after placement of a closure device to assist in hemostasis. This step has led to a significantly reduced risk of complication and improved patient comfort after the procedure. We also instituted a nurse-administered access ooze protocol utilizing epinephrine/lidocaine, which has led to far fewer complications, increased patient satisfaction, and reduced physician calls.

Besides early hemostasis, low levels of reduced inflammation are important to me so that the resultant closure may have less fibrous tissue formation or infection.

Which patient or case factors affect how you decide which closure option to use?

Dr. van den Berg: I typically use one type of plug-mediated closure device. The decision to use a closure device is dictated by the size of the introducer;

4 and 5 F are always closed by manual compression. Fortunately, the majority of cases below the inguinal ligament can be managed with 4-F devices (at least in Europe). Also, in cases when an ipsilateral access is anticipated within a short time range (< 2 weeks)—for example, antegrade SFA treatment after retrograde common iliac artery treatment—I would refrain from using my preferred (plug-mediated) device, and go for manual compression.

Dr. Schneider: There are sutures, clips, and plugs. The plugs may be only in the access tract or anchored from inside the artery. For routine femoral access up to 6 or 7 F, I like to use a plug that is anchored inside the artery. In larger-bore access, sutures are desirable. One disadvantage of suture placement is the need for relatively blind advancement of the insertion tip. If there is an iliac lesion or implant, this can be a problem, and I don't like to do it. Calcified arteries or scarred arteries can also be treated with collagen plugs, but I usually add supportive manual pressure for a few minutes. If I have punctured the artery near a threatening femoral lesion, I do my best to limit the size of the access once this is recognized, and I usually hold it by hand afterward.

Dr. Mustapha: Deciding which device to use depends primarily on the access site and whether calcified plaque is present at the access site. Perivascular scar tissue and obesity also contribute to device selection. Factors that prevented us from placing closure devices in the past are no longer complete obstacles. We now have multiple closure options to marry with site selection.

Dr. Ansel: Patient characteristics include depth of subcutaneous tissue, presence of scar or fibrous tissue, hypertension control, ability to follow directions, and anticoagulation status. Patients with hypertension, poor compliance, and a small amount of subcutaneous tissue are typically closed with a suture-based system. Larger patients, smaller sheaths, and less anticoagulation are more likely to be closed with a device that sits on top of the vessel. However, I must say that some of the newer technologies are closing the gap on this differential, and anticoagulation status is playing less of a role in the decision process.

Dr. Arko: For smaller and more calcified vessels, I tend to use MynxGrip. For larger holes, I tend to use the ProGlide. For those with standard closures, I use the MynxGrip as well. For those with a significant amount of anticoagulation on board or with hypertension, I tend to use Angio-Seal or ProGlide.

How does the nature of your practice (facility type, staff on hand) influence your decision making in closure methods?

Dr. Mustapha: While the use of closure devices hasn't been shown to decrease the rate of complications overall, we use a lot of closure devices in our practice. Initially, we did so due to limited staffing and lack of experienced sheath pullers. However, since instituting this practice, we have appreciated a lower complication rate, especially in antegrade access cases.

Dr. van den Berg: The nature of my practice does not influence the decision-making; clinical factors are the main drivers in deciding on the choice of closure method.

Dr. Ansel: The most frequent complication of our percutaneous procedures is access related. I personally take responsibility for closing almost all of my own sites, especially if a more exotic puncture was utilized. I attempt hemostasis in the lab on almost all of the patients.

Has your group tracked the short- and long-term economic elements of various closure options? To what degree do the device cost and current reimbursement factor into your closure planning?

Dr. Ansel: Our institution certainly takes economic elements into account. However, patient comfort and decreasing complications continue to be our areas of major focus. We recently standardized our entire process—staff education, method of obtaining routine access, and prompt feedback on any variances from the norm and the health care professional responsible for vascular hemostasis. This led to an immediate and measurable improvement in our procedural outcomes.

Dr. Mustapha: Device cost and reimbursement does not affect our closure planning and device selection; the decision is operator dependent. We are in the process of evaluating this at our institution.

Dr. van den Berg: In the case of an outpatient treatment, all material/equipment used during a procedure is reimbursed (in Switzerland), and therefore there is no financial limitation in this group of patients. For hospitalized patients, however, we receive a flat rate based on the diagnosis-related group, and thus the device cost becomes a relative, but not a limiting, issue. ■