Crossover Balloon Approach for Vascular Closure After TAVR

Experts share their institutions' protocols for using this technique.

MICHAEL H. SALINGER, MD, FACC, FSCAI
Clinical Assistant Professor
University of Chicago Pritzker School of Medicine
NorthShore Medical Group
Evanston, Illinois
mhsalinger@comcast.net
Disclosures: Consultant and proctor for Boston Scientific's Lotus Valve and Edwards Lifesciences' Sapien Valve.

HYDE M. RUSSELL, MD
Cardiovascular Surgeon
NorthShore Medical Group
Evanston, Illinois
hrussell@northshore.org
Disclosures: None.

SUSHEEL KODALI, MD
Director
Structural Heart & Valve Center
Columbia University Medical Center/ New York-Presbyterian Hospital
New York, New York
sk2427@cumc.columbia.edu
Disclosures: None.

LOWELL SATLER, MD
Director
Cardiac Catheterization Laboratories
Section of Interventional Cardiology
MedStar Washington Hospital Center
Washington, DC
satlerlowell@gmail.com
Disclosures: None.

How much of a problem are vascular access site complications in transcatheter aortic valve replacement (TAVR)?

Dr. Salinger: Vascular complications and bleeding rates have consistently decreased over the years. Registry data from 2011 show vascular complications were represented in approximately 19% of the patients, while in 2015 it was down to 8%.[1] Some of the decrease in complications clearly represents improvement in technology, such as smaller devices, improvements due to increased operator experience, and likely also due to lower-risk patients being treated who have lower potential for complications. Still, vascular complications occur in 5% to 10% of patients with 5% to 10% transfusion rates, which still represents a real problem.

Dr. Kodali: Access site complications are a factor in the morbidity of the procedure, and although it's less than in the early days of TAVR, the rate of major vascular complications is still approximately 5% in recent studies, such as PARTNER II and SURTAVI. The complications aren't as severe as we had in the early experience with TAVR, such as iliac avulsion, but there are still major injuries occurring that require either covered stents or surgical repair, and transfusions are still an issue with rates around 5%.

Dr. Russell: Access site complications are a very real problem affecting 5% of all TAVR procedures. When they happen, significant morbidity can occur in patients, which increases procedure time, length of stay, transfusion rates, and affects overall experience. Rarely do these issues cause significant bleeding and ischemic complications. But to be clear, they are a real problem that we take very seriously.

Dr. Satler: Access site complications have become less frequent as sheath and delivery system size has been reduced. But when we do get a vascular complication, it can be catastrophic.

What factors influence your decision to start with the crossover approach?

Dr. Kodali: We're more conservative in that we do a crossover approach in most patients, approximately > 90%. We've debated whether it needs to be done routinely; while it may not need to be done in every patient, an angiogram to evaluate closure and assess for complications is mandatory in every patient, in my

opinion. Patients in whom I would absolutely utilize the crossover approach are those where the access site is calcified, the vessel size is borderline, and those patients with a higher risk of potential vascular complications.

Dr. Russell: Size and quality (ie, calcium, tortuosity) of the vessel are definite factors. Body habitus (ie, obesity) also has an impact on my decision. If getting control of the femoral artery would be a surgical challenge, I am always in favor of starting with a crossover wire. In our practice, we always have either the antegrade wire or the crossover wire in place for our first completion angiogram of the iliac artery after sheath removal so we can intervene if necessary. It's worth spending a few minutes to establish the crossover wire. I've never had a case where I regretted having one, but I have had a case where I regretted not having it in place.

Dr. Satler: We've been using very little crossover recently. There are two changes that have affected that decision-making process. First, we've seen a significant overall reduction in the incidence of vascular complications because of the introduction of smaller delivery systems. Second, the use of ultrasound-guided localization of the common femoral artery can dramatically reduce the vascular complication rate for access site issues.

Now when we do crossover, it's because we think there is a significant, increased risk of a vascular complication. It may be in a patient with vessels that are marginal in diameter, coupled with extensive calcium or tortuosity. However, probably in the last 100 TAVR cases that we've done, we have used crossover < 2% of the time. Having access to an expert peripheral interventionist is of paramount importance.

Dr. Salinger: We no longer use crossover for every case, but rather use a selective approach. We tend to look at a patient's size, and when we have a large patient with a deep femoral artery, we have a heightened concern for potential difficulty controlling a bleeding site with manual compression. In those patients, we usually start with a crossover. Some of the devices we use still require larger sheaths, and in those cases, we still start with the crossover.

Registry data have helped us learn that being female, and having significant peripheral vascular disease, tortuous arteries, and calcification are all predictors of potential vascular complication. In those cases, we're much more liberal in starting with the crossover at the beginning of the case. I believe it's much easier to put an 0.018-inch elective wire prophylactically across and down the side to be used for the large sheath size in a prophylactic fashion, than to scramble and try to do that in an emergency.

What are the limitations and advantages of radial access for crossover in TAVR?

Dr. Satler: Radial access is a problem because it does not allow you to deliver some of the larger balloons or covered stents. Because of these limitations, I do not consider the radial approach in case there is a problem.

You can consider the delivery of covered stents bareback, meaning placing the covered stent without any sheath delivery system. Selective angiographic visualization is replaced with the use of bony landmarks. I am unaware of using this approach through the radial artery.

Dr. Salinger: It's not only the large sheath access, which is the site for potential bleeds, but also the contralateral femoral imaging access site can bleed as well. Using radial access for your imaging can decrease the bleeding complications from your imaging access site. However, radial access for crossover does limit some interventions you could do in an emergency. The radial artery is smaller and requires you to be able to place a long shuttle sheath, such as a Pinnacle (Terumo Interventional Systems), to advance long-shafted devices (eg, balloons, low-profile endographs, and/or covered stents) to treat iliac complications. While there are advantages up front using radial access for imaging, it can make procedures for femoral vascular complications or iliac complications more difficult.

Dr. Kodali: We've used radial access for crossover in a reasonable number of patients. There is an advantage to radial access use. I don't know the specific numbers, but we talk about vascular complication rates of 5% to 7%, and a certain number of those complications are on the nonlarge sheath side. If you can avoid accessing the contralateral groin, the risk of a vascular complication decreases; that's the real advantage of radial crossover.

In addition, for patients in whom crossover from the contralateral groin is difficult, such as those in whom the iliac bifurcation angle is acute, the common iliacs are heavily calcified, or there is an endograft or prior stent, balloon protection from the radial approach may be the only option. The disadvantage is the logistics of the procedure; it's slightly more complicated. You need to have longer balloon catheters. If there's a major complication and you need to use a covered stent, you can't do it with radial access because it would require a 9-F sheath, and thus it would require either converting to surgical repair or obtaining contralateral groin access to facilitate placement of a covered stent.

Do you consider a crossover balloon inflation for hemostasis or stenosis a complication?

Dr. Russell: No. Not if it is effective! Additional interventions such as stenting a dissected vessel or a covered stent for hemostasis would be considered a vascular complication requiring intervention, but balloon inflation alone is simply an internal form of manual compression in my mind and does not equate with a complication by itself.

Dr. Salinger: The short answer is no. We do not want to discourage operators from getting an optimal closure result by labeling the use of a crossover balloon as a de facto complication. If there is an event that requires a covered endograft or a covered stent for a vascular perforation, then labeling the event as a complication appears appropriate.

Dr. Kodali: No, because it's just a balloon inflation to get hemostasis or to help "tighten the knot." I don't see that as a major complication. I haven't seen any acute or late complications related to balloon occlusion.

Dr. Satler: No. We would consider it a complication when we have to upgrade to a covered stent during the procedure.

Do you have any additional insight related to crossover at your practice that you would like to share?

Dr. Salinger: We have found we can usually place a supportive 0.018-inch wire, such as a V-18 (Boston Scientific Corporation), and use an 0.035-inch-compatible, over-the-wire balloon and advance that bareback without a sheath, making things a little less complicated. We can even use that 0.035-inch lumen over-the-wire balloon to do imaging with the guidewire still left in place, allowing us to maintain wire position as a safety measure in the iliac and femoral artery while assessing closure.

We believe it's possible to simplify crossover by omitting the extra step of trying to advance a larger, stiffer, more cumbersome sheath over the aortic bifurcation, and instead just advance instrumentation bareback over the 0.018-inch extra support wire, including covered stents, and use distal injections through the 0.035-inch device to assess results.

There has been some recent evolution in endografts and covered stents for iliac disease. Gore & Associates has a highly flexible, balloon-expandable sheath, with highly flexible endografts called the Viabhan VBX. It comes in sizes from 5 to 10 mm in diameter and lengths of 12 to 13 mm, up to lengths of 70 and 80 mm. The device is indicated for iliac disease with apparently very high patency rates. In the event of a complication and the need to cross over, the device is highly trackable and flexible and can be advanced from the contralateral side using the crossover technique, as well as via the ipsilateral approach. I would anticipate these newer devices to emerge as important tools when dealing with an iliac or femoral complication.

When you do use the crossover technique and wire, such as the V-18 extra support wire, you really must be careful about the distal tip. It's a somewhat stiff instrument. We often put a large J-tip on it to make it a little safer, but even so, there have been perforations of the superficial femoral artery (SFA), formation of SFA pseudoaneurysms, and local bleeding from the tip of these otherwise "protective wires."

The issues regarding the distal tip of the crossover wire are often "off-screen" outside the imaging field, so the operator doesn't see it visually and must subconsciously be thinking about where the tip of the wire is: Is it in a safe position? Is the attempt to provide a measure of safety going to result in a complication instead? That's one caveat to using these smaller, stiffer crossover wires as a prophylactic tool.

When we have bleeding from the access site and we put in our Perclose closure devices (Abbott Vascular), we find that placing a balloon internally and just inflating it to low pressures can sometimes finish cinching up the knot a bit tighter and seal the bleeding or provide a period of internal compression and seal the vessel. We've also found, through limited experience, that if you inflate the balloon when there is continuous mild bleeding from the access site and the balloon has not stopped the bleeding when you deflate it, that you can reinflate the balloon while injecting Surgicel (Ethicon) against the inflated balloon and use the gel matrix to seal the vessel and the access tract.

Dr. Kodali: We do crossover because although the vascular complication rates are low, the skill set of crossing over is an important one to have. It allows us to manage most vascular complications percutaneously. We do approximately 400 cases a year and we'll probably put in three to five covered stents a year to treat major vascular injury.

From a training perspective and to manage these cases, crossover is a technique that's important to learn and maintain. If you are going to push the limits of vascular access, you are going to have these complications. We're 95% transfemoral, so sometimes we're going to push these limits.

Dr. Satler: If the iliacs are challenging, it's probably wiser to consider an alternative access earlier, such as the subclavian or transcaval. ■

1. Grover FL, Vemulapalli S, Carroll JD, et al. 2016 Annual Report of the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry. J Am Coll Cardiol. 2017;69:1215-1230.