Paravalvular Leak in Aortic and Mitral Valve Disease

CLD talks with Nish Harshadkumar Patel, MD, about his presentation at Baptist Health's Echocardiography and Structural Heart Symposium, which took place September 27th-28th in Coral Gables, Florida.

Can you tell us about paravalvular leak after transcatheter aortic valve replacement (TAVR)?

Commercially available devices now have a skirt around the valve, so the issue of paravalvular leak after TAVR has reduced substantially compared to when TAVR was initially approved in 2011. While the most recent generations, including the Sapien 3 Ultra Resilia (Edwards Lifesciences), Evolut FX+ (Medtronic), and the Navitor valve (Abbott), all have a skirt around the stent frame, there are still occasions where paravalvular leak is an issue, especially in patients with a bicuspid aortic valve and significant calcium at the annulus or left ventricular outflow tract (LVOT). No matter which valve you use, these patients most likely will end up with paravalvular leak. The goal in these patients is to achieve a level of mild or less, because we know that a mild or less level of paravalvular leak does not have any significant clinical impact on patient outcome. When the level is moderate or higher, that is when issues arise.

If a patient does have mild paravalvular leak after TAVR, what then?

Mild paravalvular leak has to be monitored. However, there are scenarios where patients have mild paravalvular leak right after the procedure or on the day-one echocardiogram, but as time passes, the paravalvular leak actually resolves as the valve becomes part of the body. There is tissue growth around the valve that can resolve some of the minor leak that is present. Patients undergoing TAVR with a bicuspid aortic valve, with a calcified leaflet and calcified raphe, the conjoined area of 2 adjacent defective leaflets, should also undergo monitoring. Over a period of time, the calcium may continue to press on the frame of the transcatheter valve, which sometimes can cause recoil of the stent frame and result in late paravalvular regurgitation. In these patients, the leak may be trace or mild right after the procedure, but a year later, due to recoil, it may develop further.

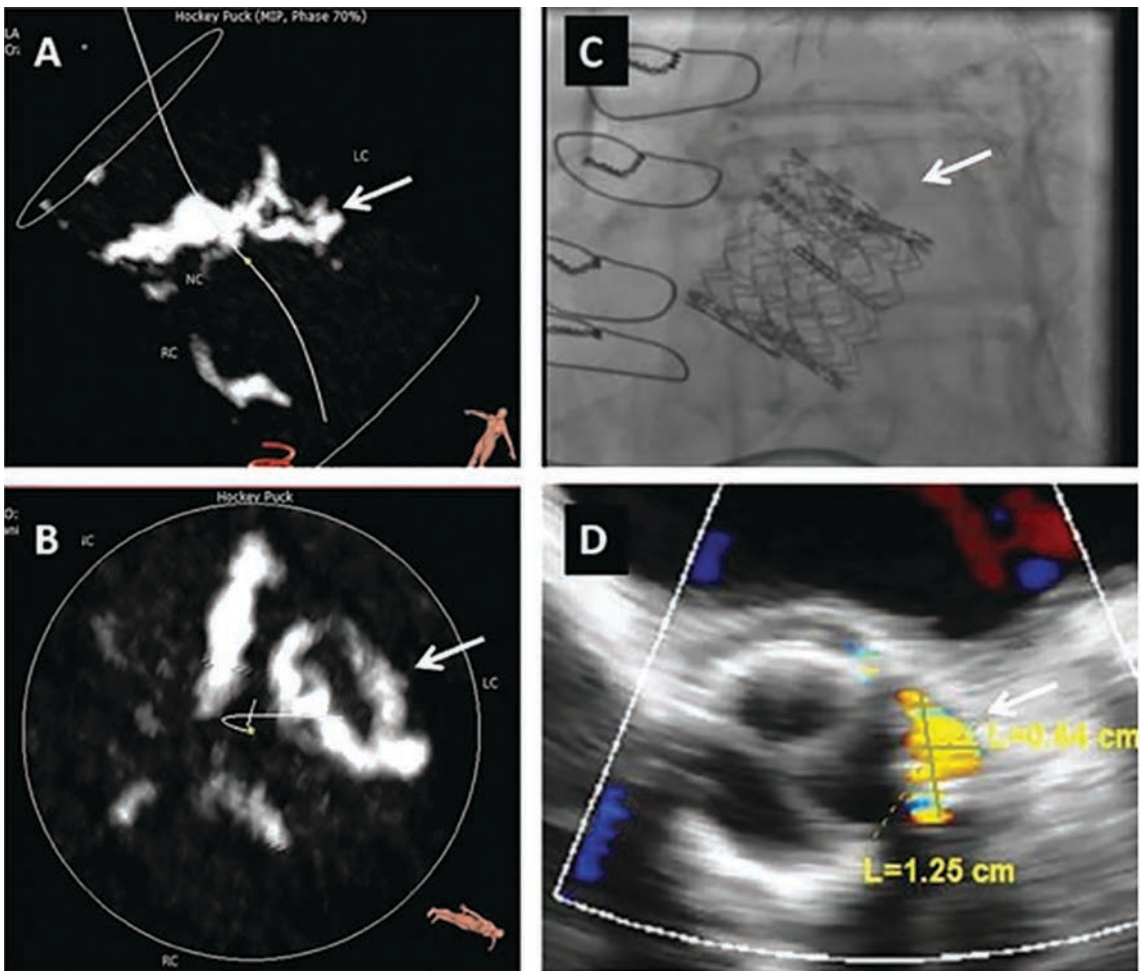

Figure. Transcatheter valve in transcatheter valve (TV-inTV) for paravalvular leak (PVL) caused by bulky calcium. (A, B) A preprocedural computed tomography revealed bulky calcium at the left coronary cusp corresponding to the PVL site. (C) TV-in-TV procedure was performed. The second valve (more ventricular) seemed to be slightly deformed at the calcification site; the position might also have been too ventricular for the device skirt to cover the PVL. (D) A follow-up transesophageal echocardiogram after TV-in-TV still showed the PVL (arrows indicate the location of calcification).

Reprinted with permission from Okuyama K, et ak. Percutaneous paravalvular leak closure for balloon-expandable transcatheter aortic valve replacement: a comparison with surgical aortic valve replacement paravalvular leak closure. J Invasive Cardiol. 2015 Jun;27(6):284-290.

How does valve positioning during the TAVR procedure help avoid paravalvular leak?

You don't want to position the valve too low, where the skirt is not at the annulus, because that means the leak will be significantly greater. If the coronary artery heights are lower, operators may try to implant the valve slightly lower, but obviously you don't want to place the valve too low, such that you miss the skirt. If you miss the skirt, there is a higher chance of paravalvular leak. For the self-expanding valves (the Evolut and Navitor valves), this is more of a concern if the LVOT, a structure just below the annulus, is larger than the annulus. Also, if the aortic valve itself does not have significant calcium, the valve may dive into the LVOT and then you are going to miss that skirt — it won't be at the annulus. As a result, we tend to find that the patient experiences significant paravalvular valve leak on the table, and then we have to put in another valve to fix it. In general, the standard approach is to size and place the valve according to the annulus and LVOT measurements, making sure that the valve is placed in such a way that the skirt covers the annulus and LVOT. This helps ensure that the risk of anything greater than mild paravalvular leak is extremely low. For balloon-expandable valves, we worry about paravalvular leak if there is calcium at the annulus or LVOT, and sizing is in the gray zone. Let's say you could put in either an expanded 23 millimeter (mm) valve or an under expanded 26 mm valve. We typically will use an undersized 23 mm valve and try to expand it with a greater volume in the balloon. The goal is to prevent paravalvular leak while making sure that the patient won't have a complication such as annular rupture.

You mentioned tissue growth after placement of the valve. Are there any risks around that?

In the structural space, we have seen that most of the tissue growth happens around the valve; we haven't yet had any cases where tissue grows within the valve.

What about the risk of thrombus formation?

We are facing an issue with thrombus formation, referred to as hypoattenuated leaflet thickening (HALT), which causes the motion of the leaflets to

We can perform an advance simulation of the patient's TAVR on a computed tomography (CT) scan, allowing us to predict the risk of paravalvular regurgitation and other TAVR-related complications such as coronary artery obstruction and annular rupture. These are the complications, as implanters, that keep us awake at night when we are planning procedures for some of our high-risk patients.

be restricted, and this is referred to as hypoattenuation affecting motion (HAM). We need to learn which patients are high risk for thrombus formation and proactively place them on anticoagulation. It is a common phenomenon that patients undergo catheter-based valve replacement and experience an increased gradient later on. An imaging assessment will usually demonstrate thrombus formation at the leaflet. It usually resolves after placing the patient on anticoagulation, but we don't know how long the anticoagulation should be continued. If we stop the anticoagulation, would the thrombus return? This is an evidence-free zone at the moment. The majority of these patients are also high risk for bleeding, meaning lifelong anticoagulation is not a good strategy.

Can you tell us more about the concerns around mitral paravalvular leak?

Mitral paravalvular leak occurs more often after surgery, particularly when surgeons work in a very calcified mitral valve. These are nightmare cases, because it is very difficult for surgeons to suture the valve, and the risk of paravalvular regurgitation is higher. Paravalvular leak in these patients can happen much later, anywhere from three to five years later, or sometimes even 20 years later. It may be because the sutures don't hold up — they may break — or sometimes it may be a result of dehiscence of the valve, so it is very important to find out the etiology of the paravalvular leak in the mitral valve space. We do have a catheter-based solution where we can put in an Amplatzer vascular plug and close the leak, using transesophageal echocardiogram guidance. In the mitral space, you want to close any leak completely, because if even a small leak is present, it can cause hemolysis and hemolytic anemia.

So eliminating even mild paravalvular regurgitation is more important in mitral valve disease patients than aortic valve patients.

Yes. In the mitral space, if we place a transcatheter valve, the concern for paravalvular regurgitation remains, because the mitral valve is saddle-shaped and the transcatheter valve that we put in is a circular valve. The majority of existing transcatheter mitral valve replacement (TMVR) valves are in the research phase and none are FDA approved (the MitraClip [Abbott], which is FDA approved, is a transcatheter edge-to-edge repair, or TEER, procedure). The FDA hasn't approved the indication of putting a TAVR valve into a mitral stenosis due to mitral annual calcification (MAC), although multiple studies have been done. The FDA has approved catheter-based mitral valve replacement in a preexisting surgical mitral valve or surgical mitral valve ring. If the surgical valve or ring is failing, you can place a catheter-based Sapien aortic valve. We can put it in the surgical mitral ring or in a surgical mitral valve, but in these cases, the risk of mitral paravalvular leak is low because there is already a frame in place. A paravalvular leak can occur with a valve-in-ring procedure, especially if you are putting a valve into an incomplete ring. The mitral valve surgical rings come in several different sizes and shapes. One more common ring is the Physio or Physio II ring (Edwards Lifesciences), which is a complete, semi-rigid ring, so a valve can be percutaneously placed with greater certainty that you are not going to create any paravalvular leak. If the ring is incomplete, however, the risk of paravalvular leak is much higher.

Can you share how the planning process for heart valve patients at Baptist Health South Florida has benefited from artificial intelligence?

I am excited about technology we are using from DASI Simulations, which is a company that has created their own AI-based algorithm that is FDA approved and reimbursed by CMS. We can perform an advance simulation of the patient's TAVR on a computed tomography (CT) scan, allowing us to predict the risk of paravalvular regurgitation and other TAVR-related complications such as coronary artery obstruction and annular rupture. These are the complications, as implanters, that keep us awake at night when we are planning procedures for some of our high-risk patients. We have trialed this technology at Baptist and are planning to implement it into our workflow. We can simulate anything from a

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valve-in-valve analysis or even a TMVR analysis. After using the simulation to determine the best outcome, we can tell our patients that their risk of any particular complication related to TAVR is substantially lower. Let's say we are planning to use a 26 mm Sapien valve or 29 mm Evolut valve. We can perform a simulation for each valve and determine the chances of a complication with either in a particular patient. Informed consent is more meaningful, because rather than just providing the patient a generic percentage risk from the trials, the simulation calculates individual risk. The heart team discussion is more informed as well. There are some patients who would be relatively low risk for surgery, for example. We can perform the simulation and let these patients know if surgery may be a better option, and at Miami Cardiac and Vascular Institute, we have the privilege of working with surgeons who can perform minimally invasive surgery. ■

Baptist Health's 42nd Annual Echocardiography and Structural Heart Symposium will take place September 26-27, 2025.

More information is available at:

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