Expert Perspectives in Valve-in-Valve Therapy

A cardiothoracic surgeon and an interventional cardiologist share their perspectives on the potential complications, trouble-shooting techniques, and expanding use for ViV therapy.

WITH ANSON CHEUNG, MD, AND DANNY DVIR, MD

Perspectives presented in these expert physician interviews include descriptions of investigational and off-label techniques. Information presented is strictly for educational purposes.

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What can you tell us about your practice?

Dr. Cheung: I am Clinical Professor of Surgery and Surgical Director of the Cardiac Transplant Program of British Columbia at The University of British Columbia, St. Paul’s Hospital in Vancouver, British Columbia, Canada. Currently, I am the President of the International Society of Minimally Invasive Cardiothoracic Surgery. I have more than 17 years of experience and perform more than 250 cases per year. Our center is on the forefront of cardiac surgery, having performed the first transfemoral and transapical transcatheter aortic valve replacement (TAVR) in 2005. With more than 1,000 surgical aortic valves implanted using all of the approved surgical valves, I think the key advantage of valves with externally mounted leaflets is that they have better hemodynamics than valves with internally mounted leaflets. They have a bigger effective orifice area because it opens to a full circle, which allows for the biggest area and the lowest gradient.

When placing surgical valves, what considerations should be taken to ensure accurate placement near the coronary ostium?

Dr. Cheung: Surgical valves have three valve struts, and you want to make sure that the struts are not in front of the coronary artery by having them bisect both the left and right coronary ostium.

What steps might be taken during implantation to prevent coronary occlusion in case a future valve-in-valve (ViV) procedure is performed?

Dr. Cheung: It is important that suture placement is not too high above the annulus and that the valve is not excessively oversized.

Are there any considerations that are particular to the Trifecta GT valve? What about the Replica sizer?

Dr. Cheung: The Trifecta Replica sizer (Abbott) reflects the actual valve size and geometry. Again, it is very important not to excessively oversize the valve.

In general, surgical valves all come with a circular sizer on one end of the handle and something almost like a Replica sizer on the other end. Most people would use the circular sizer to make sure that it goes through the left ventricular outflow tract as one of the guides, and then they use the other side to measure how it fits supra-annularly.

For the majority of other companies, the sizer is not an exact replica of the actual valve; you use it to...
As one of the first to report on ViV use, what can you tell us about your experience performing these procedures? Are there particular techniques that you would recommend?

Dr. Cheung: We performed our first aortic ViV in 2007, which I think was one of the first or the second such procedures in the world. We now have extensive experience, having...
performed somewhere between 200 to 300 aortic ViV procedures to date. One of the things that we have found is that it’s very important to find out the original surgical valve size and type. The reason is that we need to know the geometric dimension of that surgical valve to plan for the proper size or type of TAVR valve to be used for the ViV. In general, the previous operative report will list the original valve’s serial number, type/model, and size. If this information is absent, all surgical valve patients receive a certificate or valve card from the manufacturer with the relevant device information listed. If all of that fails, you could always perform fluoroscopy in order to view the fluoroscopic markers, which should provide some information to indicate the type of valve used.

What should be included in the ViV armamentarium to provide the best possible outcomes for the patient?

Dr. Cheung: It is important to have a full complement of TAVR valve sizes and type available to best match each patient’s anatomic requirements and the previous valve in place. Very importantly, you don’t want to place a new TAVR valve that is too large inside of a smaller old surgical valve. In this situation, the new TAVR valve cannot be fully expanded, therefore resulting in high residual transvalvular gradient. The TAVR ViV may fail prematurely because the material is restricted and the valve leaflet does not properly open. The ViV procedure will likely fail earlier if the valve is not fully expanded.

What is your strategy for managing valve-in-Valve Trifecta if a ViV procedure is needed?

Dr. Cheung: I think all ViVs should go through the same evaluation process, specifically in terms of preoperative imaging. This preoperative imaging should include an aortogram to assess coronary flow and potential obstruction (Figure 1). Additionally, all patients should undergo a CT scan of their aortic root to measure the height of the left coronary artery (Figure 2), the height of the right coronary artery in relationship to the surgical valve, and also the virtual transcatheter heart valve (THV) to coronary (VTC) dis-
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Are most ViV procedures performed inside a surgical valve?

Dr. Dvir: Yes, the majority of ViV procedures are performed inside failed conventional surgical valves. It is less common to perform ViV procedures for failed transcatheter heart valve (THV) devices. However, there are cases in which acute ViV procedures are performed in a THV because there is malposition or complication, and a second valve becomes necessary, but this is not the conventional ViV procedure.

The conventional ViV procedure is commonly performed in patients with a failed surgical valve after implantation or after only ring implantation. In 85% of cases, aortic ViV procedures are performed in fully, conventional stented surgical valves and approximately 15% of ViV procedures are performed in stentless surgical valves.

In general, the mitral ViV field has been approved by the US Food and Drug Administration (FDA) in the past year. The need to treat failed, sutureless deployment surgical valves continues to grow rapidly. In addition, performing mitral valve-in-ring procedures is also becoming more common. Although it is still off-label in the United States, many patients have had mitral valve repair with ring implantation and are counted among the valve-in-ring procedures.

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In which surgical valves have you performed ViV?

Dr. Dvir: I have managed the ViViD registry, the ViV international database, since 2010, so I have had the opportunity to review the reports on what is happening with THV devices across different medical centers. I don’t believe there is a surgical valve that was in clinical use that was not eventually determined for use in ViV procedures. There are older surgical valves, such as the Carpentier-Edwards valve (Edwards Lifesciences), Hancock II (Medtronic), Mosaic (Medtronic), Epic (Abbott), and Mitroflow (Sorin Group) valves presenting for ViV procedures. We also commonly see more recently utilized surgical valves, such as Magna-Ease (Edwards Lifesciences), Trifecta (Abbott), and Perceval (Sorin Group), in addition to many other valves.

Stentless valves that we see present for ViV procedures include the Freestyle (Medtronic), the Freedom Solo (Sorin Group), or the Toronto SPV heart valves (Abbott). In fact, even very rarely utilized surgical valves, such as the BioPhysio valve (Edwards Lifesciences), which was only implanted in a very small number of patients, have presented for ViV procedures.

We’ve probably seen all surgical valves that have been implanted in at least a few patients who eventually present for a ViV procedure.

When performing ViV procedures, what are the primary considerations for techniques and proper placement of the THV?

Dr. Dvir: We used to think that in a ViV procedure the placement of the THV device was less of a concern because the risk for paravalvular leakage is not as high as it is with conventional TAVR, but we were wrong.

One of the limitations of ViV procedures is elevated postprocedural gradients. For the past 2 years, we have known that the position of the THV, especially during ViV procedures, is a crucial parameter. THVs need to be implanted relatively high (within the valve) in order to have good expansion of the functional portion of the valve. This is why positioning in ViV procedures is a very important part of the procedure, especially when we want to seek optimal hemodynamics.

Another significant limitation of ViV procedures is a concern for coronary obstruction when deploying the new valve. The failed valve can cause an anatomic complication in which the leaflet of the failed valve may deflect and may obstruct flow in the aortic ViV space. In the mitral ViV space, it can also be of concern for causing left ventricular outflow tract obstruction.

Are there certain patients in whom you would not perform ViV procedures?

Dr. Dvir: We know how to identify patients at risk for these complications and who are not optimal candidates for ViV procedures. The issue of elevated postprocedural gradient or residual stenosis is another ViV complication to consider.

We see too many cases of aortic ViV procedures (and, in some cases, mitral ViV procedures) that finish with suboptimal hemodynamics. Too many cases have a mean gradient across the aortic valve of > 20 mm Hg at follow-up. The underexpansion of the newly implanted THV appears to be causing that. As a result, it would seem if you have a small and stenotic surgical valve that fails, those patients would be less suitable for aortic ViV procedures, especially if they are good candidates for redo surgery in which the operator can implant a larger surgical valve.

We know that not only leaflet thickening, but also clinical thrombosis of the newly implanted valve, is a common adverse event of ViV procedures. The potential for anticoagulation to improve the hemodynamics after aortic ViV procedures, and the need to do it systematically or only in a selected group of patients, is currently being studied.
What is your technique for deployment to manage those concerns?

Dr. Dvir: We can describe two techniques that are used for preventing these adverse events. First, residual stenosis after open ViV procedures is relatively common. One important technique is the need to implant the valve as high as possible without malposition of the device. In cases at risk for elevated gradients, you may consider using a device that has supra-annular valve function.

A new technique being performed increasingly over the past year is called bioprosthetic valve ring fracture (BVF). BVF includes inflating a noncompliant balloon either before or after a ViV procedure, in order to fracture the ring of the surgical valve, which relieves the underexpansion of the TAVR valve to be deployed. However, this technique does have some safety concerns and is being studied with a proposed matched comparison.

Coronary obstruction is another notorious and problematic complication of aortic ViV procedures. With conventional TAVR procedures, we see that the risk of coronary obstruction is < 1%. With aortic ViV procedures, that risk is approximately 3%. In some surgical valves and stented valves with externally mounted leaflets (such as Mitroflow and Trifecta), that risk increases further.

Patients who have coronary obstruction have very poor clinical outcomes. Data from the VIVID registry have shown that the early mortality after coronary obstruction was approximately 50%. Therefore, we must identify patients at risk for coronary obstruction and do the best we can to prevent it. If it does occur, we need to know how to manage it optimally.

For years the main technique to prevent coronary obstruction was to deploy a coronary stent outside of the coronary ostia toward the sinotubular junction in order to deflect that leaflet. However, the use of coronary stents is associated with too many adverse events and suboptimal durability. In addition, stent use in that location can cause a significant challenge when going back toward the coronary tree in order to perform coronary intervention.

As a result, there is a need to modulate that leaflet, which brought about the BASILICA technique. The BASILICA technique is a result of understanding that the mechanism of obstruction is mainly the leaflet of the failed valve and the need to modulate that leaflet in order to prevent obstruction (Figure 1). It was first performed in 2017 at the University of Washington by myself, and was brought about through collaboration with a team at the National Heart, Lung, and Blood Institute led by Robert Lederman, MD.

The technique was described and presented at Transcatheter Cardiovascular Therapeutics (TCT) 2017. Six months since the first procedure, there have been 17 successful cases using the BASILICA technique, with an investigational device exemption trial about to start in the United States.

Based on the VIVID registry, are there certain surgical valves that work better than others for ViV procedures?

Dr. Dvir: There is no specific surgical valve or THV device that is obsolete for ViV procedures. For ViV procedures we want cases that will result in proper hemodynamics and to prevent any complication. In general, most ViV procedures are very successful. Many patients have a relatively good survival and, when reviewing the different analyses performed, we can see very significant improvements in the cases, such as in the 6-minute walk test and KCCQ scores.

The majority of patients do not have complications after the procedure. It must be understood we are talking about the minority of patients who are at risk for certain complications; we must identify them and consider alternative strategies. You need to identify whether, in a specific patient, a particular valve may be at risk for complications during a ViV procedure. It is important to understand that the majority of surgical valves used are not at risk for complication when performing ViV procedures.

Although stentless valves may be at greater risk for coronary obstruction, it does not mean we cannot perform ViV procedures in stentless surgical valves. When we acknowledge that a surgical valve, such as Mitroflow, is considered at risk for coronary obstruction, it does not mean that we cannot perform ViV procedures in Mitroflow valves. In fact, within the VIVID registry, the Mitroflow valve is relatively common in ViV procedures, with the majority of those cases being successful.

In addition, when saying that the results of performing ViV procedures in small surgical valves (label sizes 19 mm and 21 mm) are inferior, it does not mean that a patient with a 19-mm surgical valve cannot have a successful procedure. Physicians’ need to understand the considerations around the procedure for that particular patient to manage that case properly. I cannot say in a general way that all the valves of a specific type,
or all very small valve sizes, are not well managed with ViV procedures. It is case-specific for each patient.

**Would that also apply to whether the surgical valve had externally mounted leaflets or internally mounted leaflets?**

**Dr. Dvir:** Yes, certain valves with externally mounted leaflets are associated with increased risk for a coronary obstruction. However, the majority of these surgical valves are being treated well with ViV procedures around the world. Most of these procedures are successful.

If there is a case at risk for coronary obstruction, that case should be identified with proper imaging. If that patient cannot have redo surgery, there is a likelihood the patient may be a candidate for the BASILICA technique performed on the leaflet that may cause an obstruction, followed by a ViV procedure. However, more data are needed to support the use of the BASILICA technique.

**What is prosthesis patient mismatch (PPM) and why is it important for ViV?**

**Dr. Dvir:** The size of the implanted valve sometimes is too small for certain patients. The patient body size sometimes has a discrepancy with the valve that you can implant during surgery. We recognized that throughout the 1980s, some patients had valves implanted that were too small for their body size.

In general, patients with severe PPM are typically more symptomatic, have a higher need for reoperation, and have a shorter time until reoperation than those who do not have severe PPM. Severe PPM is also associated with an increased rate of degeneration of a valve; therefore, it may not be healthy for certain valves to have PPM. In addition, when patients with severe PPM need redo implantation with a ViV procedure, their results are suboptimal compared with those who do not have severe PPM.

We see many clinical challenges and suboptimal results in patients with severe PPM. Today, it is widely accepted that patients should have as large an implanted valve as possible in order to increase the longevity of a specific valve, as well as enable successful ViV procedures in the future, if necessary.

**What have you learned about the importance of imaging for ViV procedures?**

**Dr. Dvir:** The need for imaging in ViV procedures is a bit different than in conventional TAVR. With conventional TAVR, the anatomy of the patient needs to be learned meticulously in order to select the optimal size of the device. But in ViV procedures we are treating a valve that was manufactured by the industry. We know everything about that particular valve.

For example, if you have a failed Magna 25 valve (Edwards Lifesciences), it is not necessary to image the sizes of that particular valve to decide about the sizing during the procedure. Although imaging for ViV procedures may be less important for sizing for the procedure, it is vital in assessing the capability of performing a safe transfemoral access. It is also important in order to assess the risk for mechanical complication, such as coronary obstruction or left ventricular outflow tract obstruction.

**How have the data regarding ViV procedures changed your approach to treating patients with compromised aortic valves?**

**Dr. Dvir:** We recently published new standardized definitions of what is structural valve degeneration (SVD) in *Circulation.* SVD should be defined as a spectrum like all valvular disease because it is not a binary phenomenon. It is not that the patient either has a failed valve or a well-functioning valve. Usually, the valve becomes narrowed or regurgitant gradually.

In our article, we described a staging system: stages 1, 2, and 3. Stage 1 is for conditions that make a valve prone to early degeneration. Stage 2 is for moderate stenosis or regurgitation. Stage 3 is for severe stenosis or regurgitation. Some degenerated valves should be treated before they have severe stenosis or severe regurgitation. Valves that have moderate stenosis and moderate regurgitation, are stage 2SR. These patients are sometimes symptomatic and improve clinically when the new valve is deployed.

A patient’s ability to improve with a procedure and the risk for that patient must always be considered. We have done lots of research and today we know many things that we didn’t know before. We just need to identify cases at risk for adverse events well and to treat them appropriately.