Valve-in-Valve TAVI for Degenerated Surgical Prostheses

Transcatheter aortic valve implantation is being used in novel ways to treat degenerated surgical prostheses with promising results.

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Since the first transcatheter aortic valve implantation (TAVI) by Dr. Alain Cribier was reported in 2002, the field of TAVI has grown steadily and, at times, exponentially.[1] Surgeons and cardiologists have continued to innovate and broaden the range of applications for TAVI. Initially developed for aortic stenosis, TAVI has been performed by either a transfemoral or transapical approach. Subsequently, the transarterial approach has been expanded to transaxillary approaches, as well as transaortic approaches.[2] Although the access sites have been expanded, so have the indications. As the world's population ages, more patients will be deemed high risk or unsuitable for the standard of care, which continues to be surgical replacement. In these patients, TAVI has become an attractive alternative.

In the United States, the PARTNER (Placement of Aortic Transcatheter Valves) trial, which is evaluating the Edwards Sapien transcatheter heart valve (Edwards Lifesciences, Irvine, CA), has recently completed enrollment, and plans for a second phase of the trial are already underway. Outside of the United States, the Sapien valve and CoreValve (Medtronic, Inc., Minneapolis, MN) are commercially available for TAVI. Off-label use of the valve around the world continues to advance the growing field, and one of the frontiers of innovation is the use of TAVI in degenerated prostheses.

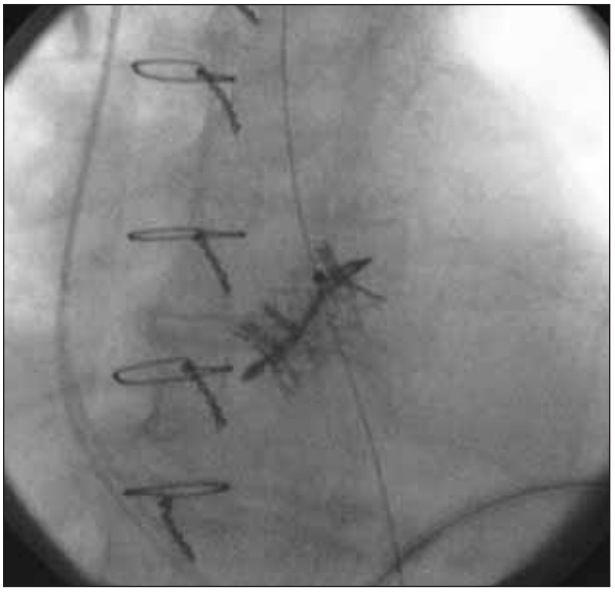

Figure 1. Sapien 23-mm valve within a Mitroflow 23-mm valve (Sorin Group USA, Inc., Arvada, CO). Reprinted with permission from Ferrari E et al. Which available transapical transcatheter valve fits into degenerated bioprostheses? Interact Cardiovasc Thorac Surg. 2010;11:83–85. Available at: http://icvts.ctsnetjournals.org. Copyright © 2010, ICVTS Online by The European Association for Cardio-Thoracic Surgery.[3]

The so-called valve-in-valve (VIV) procedure has been used in the aortic, pulmonary, mitral, and tricuspid position, and the preliminary results are promising. So promising, in fact, that many centers are using more bioprosthetic valves where a mechanical valve would have been placed previously due to the lack of a VIV option for mechanical valves. It is important to emphasize that the techniques and options for degenerated prostheses that are described in this article are considered an off-label use and are not currently available in the United States.

DEGENERATED AORTIC PROSTHESES

Currently, the Sapien valve is available commercially in 23-, 26-, and 29-mm sizes outside of the United States. For the PARTNER trial, only the 23- and 26-mm sizes are used. In the near future, a 20-mm valve will also be available. CoreValve is available outside of the United States in 26- and 29-mm sizes, and other sizes will surely become accessible.

Although aortic valve replacement remains the standard of care, TAVI has become an attractive alternative in older, high-risk patients. For younger patients with less risk, standard excision of a native valve and implantation of either a bioprosthetic or mechanical valve are still indicated. Mechanical valves require life-long anticoagulation, which carries the inherent risk of life-threatening hemorrhage. Alternatively, bioprosthetic valves do not require anticoagulation; however, they degenerate over time and may need to be replaced, necessitating a repeat operation with all of the associated risks.

In patients with degenerated aortic valves, numerous case reports have been published regarding the use of TAVI to avoid the risks of replacing the valve. Initially reported in 2008 by Walther and colleagues, an off-pump technique through a transapical approach was used.[4] An 82-year-old patient presented with heart failure caused by a degenerated 21-mm Carpentier-Edwards Perimount aortic heart valve (Edwards Lifesciences). A 23-mm Edwards Sapien transcatheter heart valve was implanted via a transapical approach. Postoperatively, the patient had no evidence of aortic insufficiency, low gradients with a maximum velocity of 2.1 m/s, and was discharged home in 11 days. At 3-month follow-up, the patient was asymptomatic with a well-functioning valve.

Azadani et al have performed several ex vivo studies evaluating VIV hemodynamics.[5,6] In two studies, homemade transcatheter valves were designed to imitate the 23-mm Edwards Sapien transcatheter heart valve. One study deployed these homemade valves within unaltered Edwards pericardial valves, and in the other study, within Carpentier-Edwards Perimount bioprostheses in which degeneration was simulated. In both studies,

Figure 2. CoreValve deployment within a bioprosthesis. Preprocedure severe aortic regurgitation (A). Fully deployed CoreValve prosthesis (B) with almost complete resolution of the aortic regurgitation (C). Reprinted from the Journal of the American College of Cardiology, 55/2, Khawaja MZ et al, Transcatheter aortic valve implantation for stenosed and regurgitant aortic valve bioprosthesis: CoreValve for failed bioprosthetic aortic valve replacements, 97–101, Copyright © (2010), with permission from Elsevier.[7]

there were acceptable gradients and minimal regurgitation when deployed within a 23-mm bioprosthesis. However, in the 21- and 19-mm bioprosthesis, the hemodynamics were unacceptable for implantation. Future in vitro and in vivo studies will be needed to specifically and methodically evaluate each bioprosthesis with VIV TAVI to demonstrate which size and valve works best.

Ferrari et al further explored the issue of "prosthesis-to-prosthesis" match.[3] Their group presented a case report of an 80-year-old patient with a degenerated 23-mm Mitroflow bioprosthesis that was causing severe aortic insufficiency who underwent transapical TAVI with a 23-mm Edwards Sapien transcatheter heart valve (Figure 1). Postoperatively, the peak and mean gradients were 18 and 10 mm Hg, respectively, and lacked significant regurgitation. The authors also raised several excellent points. VIV procedures have been performed in stented and unstented bioprostheses with good results. Furthermore, although 10% to 20% oversizing of prosthesis to annulus generally occurs in initial transfemoral or transapical TAVI, VIV procedures tend to undersize, and when a 23-mm valve was implanted in a bioprosthesis that was < 23 mm, the gradients tended to be unacceptably high despite good early clinical outcomes. Perhaps when the smaller-size transcatheter valves become available, VIV procedures will be more hemodynamically feasible in bioprosthetic valves smaller than 23 mm.

Kempfert et al recently reported a series of patients who underwent successful transapical VIV TAVI and had a significant reduction in transvalvular gradient.[8] The maximal gradient dropped from 74.1 ± 20.6 to 21 ± 8 mm Hg, and the mean gradient dropped from 40.2 ± 13.2 to 11 ± 4 mm Hg. There was minimal aortic regurgitation (either transvalvular or paravalvular) that was present in only two of the 11 patients after implantation. The investigators report that the metal frame of the degraded bioprosthesis serves

as an excellent landmark to guide positioning of the transapical VIV device. Also, the investigators believe that balloon valvuloplasty of the bioprosthesis helps guide placement and shows where the valve will be best seated to minimize the risk of embolization and migration. This case series is remarkable in that the investigators were able to use the transapical VIV procedure for a wide variety of degraded bioprostheses. Perhaps a more provocative point that was raised by the investigators is the prospect that the age of patients at which bioprosthetic valves will be encouraged over mechanical valves may begin to fall, knowing that this technology can be performed with good results.

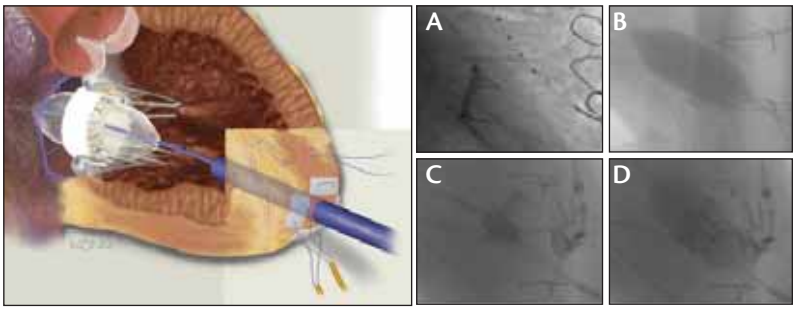

Figure 3. Technique for transapical mitral VIV implantation shows the cuffed valve being deployed within the bioprosthesis (cut away). A pigtail catheter in the apex during preoperative angiography (A). The xenograft commissural posts are marked by the radiopaque nickel-cobalt alloy wire form, with the support ring also visible. Intraoperative fluoroscopy shows balloon valvuloplasty (B), positioning the transcatheter valve (a few millimeters atrially beyond the support ring) (C), and deployment (D). Reprinted from The Annals of Thoracic Surgery, 87/3, Cheung A et al, Transapical transcatheter mitral valve-in-valve implantation in a human, e18–20, Copyright © (2009), with permission from Elsevier.[9]

There has been some speculation that the Edwards Sapien valve may be better suited than the CoreValve for VIV procedures[8]; however, other investigators have reported success with the device. Khawaja et al published a case series of four patients who underwent VIV TAVI in the aortic position using the CoreValve device.[7] In this case series, a single VIV device was placed into a 21-mm aortic bioprosthesis and had a high postprocedure peak gradient of 50 mm Hg. Also, one of the valves was placed into an aortic homograft with acceptable results (Figure 2).

Other interesting approaches that have been recently reported include a transaxillary VIV implantation and a transsubclavian VIV implantation into an aortic homograft.[10,11]

DEGENERATED MITRAL PROSTHESES

There is a slowly growing body of experience in performing transapical TAVI for degenerated mitral prostheses. Cheung and colleagues reported the first successful case in 2009[9] of an 80-year-old patient who had undergone coronary artery bypass grafting and mitral valve replacement with a 25-mm Carpentier-Edwards Perimount Plus 6900P valve (Edwards Lifesciences). The patient presented back with symptomatic prosthetic valve stenosis and was deemed too high risk for a repeat mitral valve replacement. After approval from the Institutional Review Board, the patient was consented for a transcatheter VIV procedure. The initial approach was via a right thoracotomy through the left atrium, but the valve could not be crossed. A transapical approach was then employed, and a 26-mm Cribier-Edwards 9000MIS valve (Edwards Lifesciences) was implanted. The patient survived for 47 days with a functioning valve, without transvalvular or paravalvular leak, and with a 3-mm Hg mitral gradient. It is of note that a fabric cuff was used around the valve to minimize paravalvular leak (Figure 3).

Other groups have performed transapical VIV procedures for degenerated mitral bioprostheses with similar success.[12] Recently, at the International Society for Minimally Invasive Cardiothoracic Surgery meeting in Berlin, Germany, Cheung et al presented data on seven high-risk patients with degenerated mitral valve bioprostheses who underwent transapical VIV implantation.[13] In all cases, a 26-mm Edwards Sapien transcatheter valve was used, and the longest follow-up was out to nearly a year. Six of the seven patients are alive and well with a reduction of mean gradient from 12.9 ± 5.4 to 8 ± 1.3 mm Hg. In addition, the valve area improved from 0.7 ± 0.4 to 1.7 ± 0.4 cm^2. The short-term results were excellent; however, the long-term outcomes remain to be seen.

Webb and colleagues also recently published their varied experience with transcatheter VIV procedures for degenerated bioprosthetic valves in the aortic (10), mitral (seven), pulmonary (six), and tricuspid (one) positions via a variety of access approaches.[14] The mitral and aortic VIV procedures were performed through a transapical or transarterial approach, whereas the pulmonary valves used a percutaneous transvenous approach. The tricuspid transcatheter valve was implanted via a right intercostal surgical approach to promote coaxial placement of the new valve. As with the initial experience of a mitral VIV procedure, the investigators first attempted aortic VIV

implantation via a transfemoral route but found a transapical approach to be better suited. Consequently, the authors report that a transapical approach to degraded mitral and aortic bioprosthetic valves offers direct and coaxial access to facilitate successful deployment. The 30-day mortality rate in these 24 high-risk patients was 4.2%. Furthermore, implantation was considered successful with immediate restoration of satisfactory valve function in 23 of the 24 patients. The vast majority of patients in this group also benefited from a great increase in exercise tolerance and a significant reduction in heart failure symptoms.

Transcatheter pulmonary valve implantation is occurring in three centers in the United States under the COMPASSION (Congenital Multicenter Trial of Pulmonic Valve Regurgitation Studying the Sapien Interventional THV) trial. Enrollment has been completed in the safety and efficacy phase, and the results are forthcoming. Outside of the United States, the experience with this technique is greater. A study of 59 consecutive patients who received stent-mounted bovine jugular vein was reported in 2005, showing excellent results.[15]

The Melody transcatheter pulmonary valve (Medtronic, Inc.) is also being implanted into degrading pulmonary homografts.[16] Zahn and associates reported on the first 30 patients in which implantation was attempted. Successful placement of the stent-mounted bovine jugular vein occurred in 29 of the patients. Peak systolic gradient acutely dropped from 37.2 ± 16.3 to 17.3 ± 7.3 mm Hg, and pulmonary regurgitation was no more than mild in those 29 patients. A single patient suffered from conduit rupture requiring urgent surgery, and a distal pulmonary artery perforation occurred due to a guidewire, but overall, the initial results were promising. Furthermore, at 6-month follow-up, the gradient remained low at 22.4 ± 8.1 mm Hg.

RESCUE TECHNIQUES DURING IMPLANTATION

When implanting a transcatheter valve, regardless of the type of valve, a variety of potential complications and pitfalls can arise. Some complications, such as aortic root rupture, are currently unmanageable through transcatheter means. There are subsets of adverse events that can be managed via transcatheter techniques by skilled and knowledgeable operators. Significant perivalvular leak in TAVI is an uncommon but feared event. The mechanism of successful TAVI involves pushing the native (or bioprosthetic in the case of VIV procedures) valve against the aortic annulus and wall. Due to the distribution of calcium, this occurs unevenly. When this happens, small areas of paravalvular leak can be present, most of which have little clinical significance.

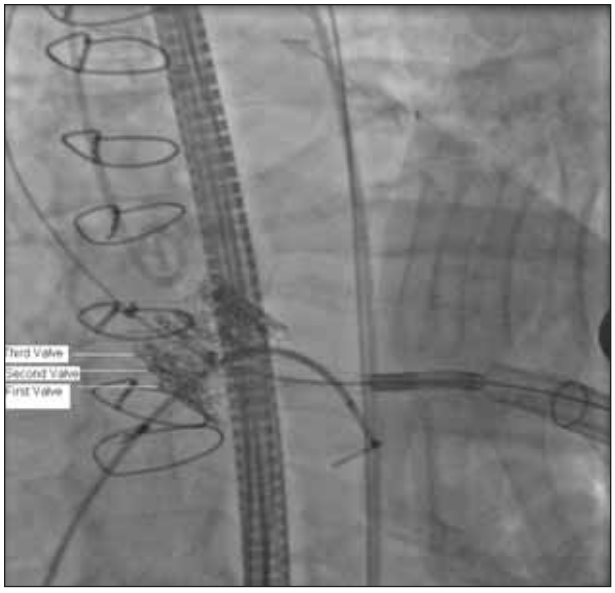

Figure 4. The three TAVI valves are seen within each other.

However, there are times when the paravalvular leak is significant. This can rarely be resolved with balloon post-dilatation. It was also reported that placing a second transcatheter valve of the same diameter within the first valve, a modified VIV technique, can also significantly reduce the paravalvular leak.[17] Transvalvular leak can also be significant. If this occurs, a second or even third valve may be placed within the first with successful resolution of aortic regurgitation (Figure 4). Furthermore, rescue from early failure does not need to be performed with an identical valve. A report of an Edwards Sapien valve that was used to treat a regurgitant CoreValve aortic prosthesis in a VIV fashion has also been reported.[18]

CONCLUSION

In a rapidly progressing field, transcatheter VIV technology is at the forefront of this growth. Although it has only recently been introduced as a viable option, the potential for such technology seems substantial. Given the current technology, it appears that a transapical approach for VIV procedures in the aortic and mitral position offers better control and positioning when compared to a transarterial approach. It is also apparent that valve hemodynamics are better when VIV TAVI is performed in a degraded bioprosthetic > 23 mm. In the United States, where further studies are needed before commercialization, the future of transcatheter valves may follow suit behind innovative surgeons and cardiologists around the world, where the only limit to further development is imagination and engineering. ■

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