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EDITORIAL COMMENT

TAVR in Prior Valve-Sparing Aortic Root Replacement

Critical Factors to Consider to Achieve Successful Outcomes*

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Transcatheter aortic valve replacement (TAVR) is now indicated in patients with symptomatic severe aortic stenosis across the entire surgical risk spectrum. However, TAVR in pure native aortic insufficiency (AI) remains an off-label procedure, and surgical aortic valve replacement (SAVR) remains the gold standard. In younger patients with pure native AI, efforts have been made to preserve the native valve with surgical repair rather than replace the valve with an artificial substitute. Valve-sparing aortic root replacement (VSARR) was introduced more than 2 decades ago as an alternative to a conventional composite valved graft with a mechanical or bioprosthetic valve in patients with trileaflet aortic valve (TAV), severe AI, and root aneurysm requiring replacement. VSARR allows for correction of aortic root pathologic changes with preservation of the native aortic valve and function. Over the past 2 decades, the operation has been adopted worldwide and when performed by experienced surgeons has resulted in acceptable mid- and long-term outcomes (1,2). VSARR alleviates the need for anticoagulation with mechanical valves and, depending on the type of prosthesis implanted, minimizes the risk of valve-related complications such as bleeding, thromboembolism, or structural valve degeneration. Although these factors make VSARR appealing, there is an inherent risk of reoperation because of recurrent AI or aortic stenosis (AS) (3). This is more so in bicuspid aortic valve (BAV) and associated aortopathy, where aortic valve repair to restore native valve function and minimize AI can be technically more complex, and outcomes after VSARR, even in expert hands, may not be as durable as in TAV (4).

In this issue of *JACC: Case Reports*, Koren et al (5) describe the case of a 59-year-old woman who presented with severe bicuspid AI after VSARR and underwent successful TAVR after heart team discussion and patient preference. The procedure was performed via a transfemoral approach, with no residual paravalvular leak and minimal residual gradients, and the patient experienced an expeditious recovery. Although the report demonstrates the feasibility of TAVR in severe AI after VSARR, the first question lies more on why the patient already experienced mild to moderate AI after the initial operation and how that affects early VSARR failure and need for reintervention.

VSARR IN BICUSPID VALVES HAVE DURABILITY, AND EARLY AI PREDICTS EARLY FAILURE

Compared with TAV, there is heterogeneity in the mechanism of AI in patients with BAV, which may result from a dilatation and distortion of root geometry, restriction or calcification of conjoint cusp, cusp prolapse or fenestration, or a combination of these, requiring different types of cusp repairs and efforts to restore the root geometry at the time of VSARR. However, BAV repair has been accompanied by a higher rate of recurrent and progressive AI as a result of, among other factors, cusp calcification, or the need for cusp reconstruction using a pericardial patch (4), as observed in this case, with persistence of mild

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to moderate AI after the procedure. Also, the number and location of raphes and the extent of their fusion may affect the durability of the repair. Progressive AI has been associated with a higher rate of reoperation after VSARR in patients with BAV than in those with TAV (6). TAVR can be particularly challenging in the setting of AI after VSARR in patients with BAV (**Figure 1**).

TAVR IN PURE AI AND PRIOR VSARR SHOULD BE PERFORMED IN EXPERT CENTERS

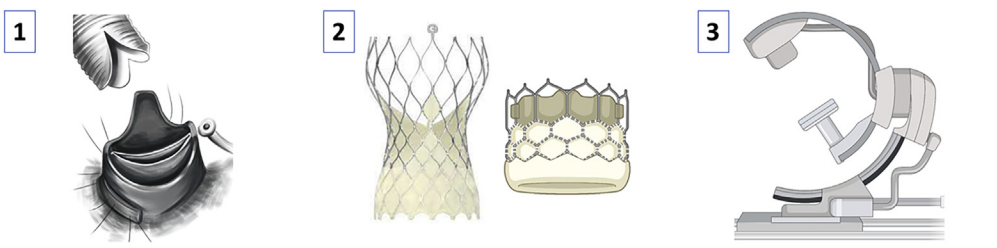
Although TAVR has emerged as the preferred treatment option in patients with symptomatic severe AS across all surgical risks, the use of TAVR for pure native AI presents additional unique challenges. From a technical standpoint, 2 main factors challenge TAVR in patients with pure AI: the absence of a calcified native valve apparatus to anchor the transcatheter heart valve (THV) and the frequent coexistence with aortic root and ascending aorta dilatation. Potential risks for TAVR in this setting are associated with malpositioning resulting from inadequate sealing, valve embolization, or significant residual paravalvular aortic regurgitation. In addition, oversizing of the THV in an attempt to compensate for deficient anchoring involves a risk of valve dislocation, conduction disorders, and annular rupture. Despite these concerns, not all patients are candidates for surgery because some have comorbidities or are deemed at high risk for surgery. Several studies have described successful off-label use of TAVR in native AI (7-10), but there remains a scarcity of literature on TAVR after valve-sparing aortic root surgery, which further complicates the procedure.

As corroborated by this case report, preprocedural computed tomography angiography (CTA) evaluation is critical for proper THV bioprosthesis selection and sizing. Unlike TAVR in pure native AI, in VSARR the aortic root issue has been replaced by a synthetic Dacron graft, with the native aortic valve commissures sutured to the graft. Given that the continuity between the left ventricle and the aortic root is now supported only by sutures, aggressive oversizing and expansion with a balloon-expandable THV may risk disrupting this suture line and risk annular rupture. Balloon valve fracture of a BioBentall aortic root replacement by inflating a balloon at high pressure has been associated with aortic root rupture and death. Although balloon inflation of a balloon-expandable THV generates a lower pressure, this risk cannot be underestimated. The investigators reporting this case come from an expert TAVR center and had conducted meticulous preprocedural and intraprocedural planning, and they are to be congratulated for their excellent outcome with this patient. However, just as VSARR, especially in BAV, should be done by expert centers and surgeons, TAVR for pure native AI, particularly in the rare occasion of prior VSARR, should also be performed only by expert TAVR centers and operators.

DEDICATED TAVR SYSTEMS FOR PURE AI: A SAFER ALTERNATIVE TO EXISTING SYSTEMS

Outcomes of TAVR in pure native AI have improved with newer device iterations. Self-

FIGURE 1 Factors to Consider in TAVR With Prior Bicuspid Valve Repair and Valve Sparing Aortic Root Replacement



Factors to consider in transcatheter aortic valve replacement (TAVR) with prior valve sparing aortic root replacement with pure native bicuspid aortic insufficiency.

expanding THV, particularly CoreValve and more recently Evolut (Medtronic) were favored initially because they were thought to facilitate safe anchoring by oversizing without increased risk for annular disruption, whereas the more recent Evolut THV allows for recapturing and repositioning to optimize implant depth and radial force against the native anatomy. Early results were unfortunately suboptimal (11). The latest generation balloon-expandable and self-expanding TAVR systems have showed improved outcomes, but relatively high procedural complications and mortality rates have remained (10).

Novel devices featuring repositionability, self-positioning geometry, and specific fixation mechanisms have the potential to improve the performance of TAVR in patients with native pure AI. The JenaValve THV (JenaValve Inc) is currently the only device with the Conformité Européenne mark for the treatment of AI. It is made of a self-expanding nitinol stent with a trileaflet porcine pericardial valve, and it features a clipping mechanism that anchors positioning feelers into the native aortic annulus, which allows anchoring without relying on annular calcification or the need for oversizing. Early experience with the JenaValve has been promising (10,12) and is currently expanded in the ALIGN-AR EFS (Safety and Effectiveness/Performance of the Transfemoral JenaValve Pericardial TAVR System in the Treatment of Patients With Symptomatic Severe Aortic Regurgitation; NCT02732704) trial evaluating the safety and performance of the transfemoral JenaValve in the treatment of symptomatic severe AI.

SUMMARY

As demonstrated by the current case report, with appropriate preparation and planning and a collaborative multidisciplinary team approach, TAVR can be a reasonable treatment option for severe bicuspid AI in patients deemed to be at high or extreme risk for surgery. Importantly, despite initial encouraging data, larger studies, longer follow-up times, and further development in device technology are necessary to advance the expansion of TAVR to patients with pure native AI.

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REFERENCES

1. Kari FA, Doll K-N, Hemmer W, et al. Survival and freedom from aortic valve-related reoperation after valve-sparing aortic root replacement in 1015 patients. *Interact Cardiovasc Thorac Surg*. 2016;22:431–438.

2. David TE, David CM, Ouzounian M, Feindel CM, Lafreniere-Roula M. A progress report on reimplantation of the aortic valve. *J Thorac Cardiovasc Surg*. 2021;161:890–899.e1.

3. Patlolla SH, Saran N, Dearani JA, et al. Outcomes and risk factors of late failure of valve-sparing aortic root replacement. *J Thorac Cardiovasc Surg*. 2020;S0022-5223326684.

4. Ouzounian M, Feindel CM, Manlhiot C, David C, David TE. Valve-sparing root replacement in patients with bicuspid versus tricuspid aortic valves. *J Thorac Cardiovasc Surg*. 2019;158:1–9.

5. Koren O, Patel V, Kaewkes D, et al. Transcatheter aortic valve replacement for bicuspid aortic insufficiency after valve-sparing aortic root replacement. *J Am Coll Cardiol Case Rep*. 2021;3:1798–1802.

6. Karciauskas D, Mizariene V, Jakuska P, et al. Early and long-term results of aortic valve sparing aortic root reimplantation surgery for bicuspid and tricuspid aortic valves. *Perfusion*. 2019;34:482–489.

7. Alharbi AA, Khan MZ, Osman M, et al. Transcatheter aortic valve replacement vs surgical replacement in patients with pure aortic insufficiency. *Mayo Clin Proc*. 2020;95:26552664.

8. Anwaruddin S, Desai ND, Szeto WY, et al. Self-expanding valve system for treatment of native aortic regurgitation by transcatheter aortic valve implantation (from the STS/ACC TVT Registry). *Am J Cardiol*. 2019;124:781–788.

9. Rawasia WF, Khan MS, Usman MS, et al. Safety and efficacy of transcatheter aortic valve replacement for native aortic valve regurgitation: a systematic review and meta-analysis. *Catheter Cardiovasc Interv*. 2019;93:345–353.

10. Yoon S-H, Schmidt T, Bleiziffer S, et al. Transcatheter aortic valve replacement in pure native aortic valve regurgitation. *J Am Coll Cardiol*. 2017;70:2752–2763.

11. Testa L, Latib A, Rossi ML, et al. CoreValve implantation for severe aortic regurgitation: a multicentre registry. *EuroIntervention*. 2014;10:739–745.

12. Seiffert M, Diemert P, Koschyk D, et al. Transapical implantation of a second-generation transcatheter heart valve in patients with non-calcified aortic regurgitation. *J Am Coll Cardiol Intv*. 2013;6:590–597.

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