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Commentary: Should valve-in-valve transcatheter aortic valve replacement be first-line treatment for failed aortic bioprostheses?

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A recent analysis of the Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database published in the *Journal* showed an accelerated decline in mechanical valve use and a simultaneous increase in biological valve use in the aortic position, particularly in patients age <60 years.¹ It is well known that structural valve deterioration is related to 2 key factors—age at the time of implantation and time since implantation^{2,3}—and as such, given the findings from the STS dataset, we can expect to see more patients presenting with a failed bioprosthetic valve needing treatment. Traditionally, bioprosthetic valve failure could be

CENTRAL MESSAGE

Valve-in-valve transcatheter aortic valve replacement has evolved to become the preferred approach to managing failed aortic bioprostheses in selected patients.

treated only with redo surgical aortic valve replacement (SAVR), which is associated with at least double the risk compared with the index procedure.⁴ However, in recent years, transcatheter valve-in-valve (ViV) aortic valve replacement (TAVR) has emerged as a treatment option for failed bioprosthetic valves, despite limited clinical evidence to support its use over redo SAVR. Studies reported before 2020 were small and inadequately powered to detect differences in key clinical outcomes; even a meta-analysis of all available studies at the time included only 498 patients and found improved early morbidity and mortality with ViV TAVR compared with redo SAVR.⁵

However, in 2020, the publication of 3 large series using a combination of administrative and clinical datasets from Canada,⁶ the United States,⁷ and France⁸ confirmed what was observed in previous meta-analyses. Against this backdrop, in this issue of the *Journal*, Clark and Malaisrie⁹ review the current literature using the ViV TAVR approach

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for failed bioprosthetic valves and provide a balanced view of the benefits reported for ViV TAVR, along with the limitations of this approach and potential solutions. The authors critically interpret several registry and recent comparative studies that consistently show low mortality rates associated with TAVR ViV, in addition to reduced procedural-related complications such as prolonged ventilation, renal failure, and the need for blood transfusion or pacemaker insertion, along with decreased hospital length of stay. The majority of the studies highlighted in this review report short-term outcomes, with 2 notable comparative studies reporting long-term outcomes at 4- and 5-year follow-ups.^{6,8} Importantly, the authors also identify key challenges of a ViV approach: coronary obstruction, patient–prosthesis mismatch, and durability. The study also highlights novel approaches, such as the BASCILICA procedure in which the bioprosthetic aortic cusp is intentionally lacerated to prevent iatrogenic coronary artery obstruction, fracturing of the implanted bioprosthetic valve to prevent patient–prosthesis mismatch, and the ongoing PARTNER 3 AVIV Trial to examine durability.

Although Clark and Malaisrie's review is concise, there are some points that warrant further discussion. First, most of the ViV studies in the literature are observational studies, which are susceptible to treatment allocation bias. Patients in the ViV arm likely had favorable anatomy that led to excellent results, highlighting the importance of optimal patient selection. The landmark registry study by Webb and colleagues¹⁰ reported a 2.7% rate of 30-day all-cause mortality for ViV TAVR; however, that study also excluded patients with a size <21 mm valve, mild paravalvular leak, or ejection fraction <20% and included only 23-mm and 26-mm SAPIEN XT valves, suggesting once again that highly selected population of patients were eligible for ViV. In addition, that study reported a 58.4% rate of severe patient–prosthesis mismatch on the first echocardiogram. The authors pointed to variable prognostic implications of valve hemodynamics in the literature, a developing area concerning the decision between ViV and redo SAVR. Furthermore, the ViV comparative studies in the literature tend to have older and higher-risk patient populations, precluding generalizability of their findings to younger patients. For example, the highlighted comparative studies in this commentary report a mean patient age of 72 to 76 years.^{6–8} Given the accelerated valve failure in younger patients² and the paucity of data on second ViV outcomes, redo AVR may be the preferential option, followed by a ViV when again necessary. We note that the literature continues to evolve around some of the limitations in ViV TAVR,¹¹ including the lack of data on long-term ViV durability in younger patients and the implications of patient–prosthesis mismatch.

Moving forward, there remain areas of uncertainty that warrant further research to further improve outcomes for

patients requiring reintervention for failed aortic bioprostheses. Although volume–outcome relationships for AVR have been well documented,¹² less is known about this relationship with respect to ViV TAVR and redo SAVR. Given that volume–outcome relationships tend to be more pronounced for complex procedures,¹³ specialized heart teams or centers of excellence will be important in the treatment of complex cases, such as failed homografts, stentless valves, and specialized techniques like BASCILICA. In addition, an ounce of prevention and greater understanding of the ViV procedural techniques may be key to improved outcomes in the future. Aortic root enlargement during the initial AVR to implant larger valves for future ViV has been shown to be safe,¹⁴ and the discovery of optimal ViV positioning relative to the aortic annulus for different valve types and sizes have demonstrated significant improvements in valvular hemodynamics.¹⁵

Overall, this is a valuable contribution by Clark and Malaisrie to further our understanding of the treatment of the difficult problem of failed bioprosthetic valves. While we await the randomized PARTNER 3 AVIV clinical trial results, clinicians will undoubtedly continue to favor this less invasive option. Understanding the limitations of this option, coupled with a multidisciplinary heart team approach, may be key to ensuring that the right patients receive the optimal treatment for their failed aortic biological prosthesis.

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Commentary: Management of bioprosthetic valve failure—strategic planning for the future

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We read with great interest the invited expert opinion by Clark and colleagues.¹ Treatment of bioprosthetic structural valve deterioration is an increasingly challenging clinical entity, and the authors are to be congratulated for their concise yet extensive overview. We agree with the authors' appraisal of existing literature in that the valve-in-valve transcatheter aortic valve replacement (ViV-TAVR) approach to structural valve deterioration appears to be associated with favorable outcomes over reoperative surgical aortic valve replacement (re-SAVR), at least in the short term. This is in contrast to the existing literature showing good long-term durability of re-SAVR, given that the implanted valve will generally behave similarly to the index

CENTRAL MESSAGE

Heart teams should systematically and strategically plan for the future when determining the choice of initial treatment strategy between transcatheter and surgical aortic valve replacement.

bio-

prosthesis.^{2,3} Furthermore, a recent French study demonstrated superior 5-year outcomes of lower cumulative event rates in the re-SAVR group, mainly attributed to fewer rehospitalizations for heart failure and lower pacemaker implantation rates.⁴ Unfortunately, all the studies comparing ViV-TAVR and re-SAVR are nonrandomized observational studies with limited long-term head-to-head follow-up and do not adequately risk-adjust for key clinical and anatomical confounders (eg, frailty, risk of patient–prosthesis mismatch, and coronary obstruction). Therefore, the need for a randomized control study has been debated, although it will be challenging because of the small population and the need for long-term follow-up. Given the superior short-term outcome and less invasiveness, we believe ViV-TAVR is here to stay, but the long-term outcome should be carefully assessed.

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