TAV-in-TAV: Future Considerations for Intermediate- and Low-Risk Patients

Challenges to the transcatheter management of severe aortic stenosis across a lifetime.

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ranscatheter aortic valve replacement (TAVR) has emerged as the standard of care for symptomatic severe aortic stenosis (AS) in patients at high risk for surgical aortic valve replacement (SAVR). 1,2-5 Five-year outcomes from randomized control trials (RCTs) have demonstrated comparable safety and efficacy of TAVR to SAVR in intermediaterisk patients, and outcomes from two RCTs in low-risk patients have recently prompted FDA approval of transcatheter aortic valve (TAV) prostheses—namely the Sapien 3/Ultra balloon-expandable valves (BEVs; Edwards Lifesciences) and Evolut R/Pro self-expandable valves (SEVs; Medtronic)—for use in all risk categories. 6-12

The expansion of TAVR to intermediate- and low-risk (ILR) patients has gained powerful momentum. This category comprises the largest proportion of patients with severe symptomatic AS, implying a leap in the pool of patients eligible for TAVR. The move beyond high-risk patients heralds the extension of TAVR to a younger population. In a series of patients who underwent isolated SAVR for AS between 1993 to 2004, 55% were 70 years old or younger. In both PARTNER 3 and the Evolut Low-Risk trial, mean age was approximately 74 years, with < 20% of patients in PARTNER 3 younger than the age of 70 years. In Patients with bicuspid valves, complex coronary artery disease, aortopathy, and multivalvular disease were also excluded from both

trials, highlighting the need for further RCTs to guide management within these subsets of the ILR group.

DURABILITY OF TRANSCATHETER AORTIC VALVES

The expansion of TAVR to younger patients presents a novel challenge for the heart team. Although candidates for TAVR generally have not lived long enough to experience structural valve deterioration (SVD), a significant subset of ILR patients will inevitably outlive their prostheses. With contemporary surgical aortic valves (SAVs), the incidence of reoperation for SVD at 5 years after SAVR is < 3%. At 10, 15, and 20 years after SAVR, the incidence reaches 5%, 10% to 20%, and 40% to 50% respectively. 14-17 In TAVs, the incidence of severe SVD at 5 years after TAVR has been comparable, with reintervention rates generally < 4%, although these findings are tempered by the competing risk of death in the early cohort of TAV recipients.^{2-4,6,18,19} Durability studies beyond 5 years will have greater implications given the increase in SVD seen in SAVs after this period.

In an early analysis of the Valve-in-Valve International Data registry, the median time to reintervention for SAV SVD was 8 years.²⁰ Assuming a similar timeline for TAVs, the management of SVD will be critical to the success of TAVR in patients with longer life expectancy. Redo-SAVR, the traditional standard of care for patients with SAV SVD, is associated with greater risk of opera-

tive mortality and major complications than primary SAVR.²¹ The technique of valve-in-valve TAVR within degenerated SAVs (TAV-in-SAV) was thus developed as an option for high-risk patients with SVD.

Although surgical replacement of degenerated TAVs may be a viable method of treating TAV SVD, extensive neo-endothelialization of chronically implanted TAVs (particularly SEVs) and the need for intensive endarterectomy may present a technical challenge.²² In 782 TAVR explants from the Society of Thoracic Surgeons (STS) registry, concomitant aortic repair was required in 45.8%, and 30-day postoperative mortality across all cases was 19.4%.²³ Although this sample is skewed toward those at higher operative risk, the possibility remains that surgical explantation will not be the optimal strategy for patients with anticipated TAV SVD. Considering that some patients will need more than one redo intervention, the optimization of valvein-valve TAVR in degenerated TAVs (TAV-in-TAV) will be critical to the success of TAVR as a routine method of bioprosthetic valve implantation through the lifetime of the ILR patient.

INSIGHTS FROM VALVE-IN-VALVE TAVR IN SURGICAL AORTIC VALVES

TAV-in-SAV has been shown to be an effective treatment for SAV SVD, achieving durable hemodynamic and functional improvement, lower stroke rates, and lower short-term mortality compared to redo-SAVR. The presence of severe baseline patient-prosthesis mismatch is a key risk factor for mortality at 30 days and 1 year, as well as for reintervention in the long-term after TAV-in-SAV. Savall host SAVs (label size < 20 mm or inner diameter < 21 mm) are also associated with increased mortality at 30 days, 1 year, and 8 years after TAV-in-SAV.³⁰

Based on these findings, implantation of the largest valve possible during primary intervention should be pursued to maximize a young patient's options for future valve-in-valve treatment. If SAVR is performed in a small annulus, consideration may be given to concomitant aortic root enlargement that may allow for a larger primary prosthesis without a significant increase in postoperative complications, mortality, or risk of aneurysm.³¹⁻³³ SAV prosthesis designs that allow for controlled expansion at the time of TAV-in-SAV may also become preferable for these patients. If TAV-in-SAV is indicated in a patient with baseline prosthesis-patient mismatch, fracture of the SAV ring using a high-pressure balloon can be used as a rescue strategy to improve the hemodynamic outcome.³⁴

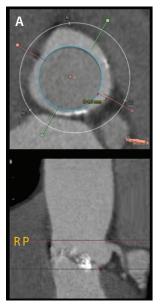
MITIGATING THE RISK OF CORONARY OBSTRUCTION AND IMPAIRED ACCESS

Coronary obstruction is uncommon after primary TAVR (< 1% incidence), but the risk is greater in TAV-in-SAV (2% to 4%).^{20,35} The primary mechanisms of obstruction are displacement of a calcified host leaflet in proximity to a coronary ostium and sinus sequestration. The consequences of obstruction are severe, with 30-day mortality over 40%.^{35,36} In patients undergoing TAV-in-SAV, a virtual transcatheter valve—to—coronary distance (VTC) < 4 mm measured via CT is sensitive and specific for the detection of patients at risk of obstruction.³⁶ TAV implantation within SAVs that are stentless or internally stented is also associated with increased risk of coronary obstruction.³⁶

In TAV-in-TAV, host TAV leaflets are less likely to cause ostial obstruction because the stent frame serves as a boundary for displacement. However, the host leaflets are pinned open during valve-in-valve implantation, forming a cylindrical "neoskirt" in the aortic root. If the top of the neoskirt is close to the sinotubular junction (STJ), it can seal or significantly impair flow into the adjacent coronary sinus—a devastating complication known as sinus sequestration. In cases in which the valve-to-STJ distance (VTSTJ) allows for adequate flow, access to coronary ostia for angiography may still be severely impaired. Furthermore, access can be further limited by the presence of two overlapping layers of stent frame or a commissural post adjacent to a coronary ostium.

Simulations of TAV-in-TAV in patients after primary TAVR suggest that the risk of sinus sequestration and impaired coronary access is significant. In an analysis of post-TAVR CT studies from 411 patients by Ochiai et al, TAV-in-TAV was considered at risk of causing sinus sequestration if the host TAVR commissure was above the level of the STJ with a VTSTJ < 2 mm in at least one coronary sinus.³⁷ Of 345 patients in the SEV cohort, 45.5% met this criteria, compared to 2% of 66 patients in the BEV cohort (P < .001).³⁷ Although the cutoff of 2 mm is likely more reflective of the risk of impaired coronary access (using a 6-F catheter) than obstruction, a modified criterion using a VTSTJ cutoff of 1 mm was still met by 13.6% and 1.7% of patients in the SEV and BEV groups, respectively (P < .001).³⁷

Analysis of post-TAVR angiography is similarly alarming. Nai Fovino et al performed coronary angiography in 137 patients after primary TAVR, deeming coronary access after TAV-in-TAV "feasible" if coronary cannulation was achieved below the "risk plane" (RP; the level under which the stent frame of the host valve would be covered by its neoskirt), "theoretically feasible" if achieved above the RP with a valve-to-aorta (VTA)



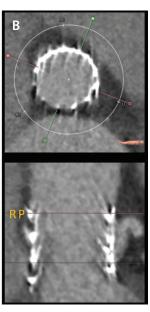


Figure 1. CT simulation of TAV-in-TAV in two patients with favorable (A) and unfavorable (B) anatomy.

distance > 2 mm, and "unfeasible" if the VTA was ≤ 2 mm.³⁸ Predicted coronary access after TAV-in-TAV was unfeasible in 38.5%, 41.1%, and 23.6% of patients after Evolut R/Pro, Acurate neo (Boston Scientific Corporation), and Sapien 3 implantation, respectively.³⁸ Unfeasible access was more frequently predicted in SEV host valves (P = .116).³⁸ This difference in risk between SEVs and BEVs, present by nature of stent frame height and position relative to the annulus, is further supported by analysis of CT examinations performed after TAV-in-TAV in 45 patients (15 in host BEV, 30 in host SEV) by De Backer et al. In this study, impaired access (defined as the presence of at least two of the following: RP above a coronary ostium, VTA > 3 mm, or < 3 mm between stent struts at the guide catheter crossing zone) was demonstrated in 65% of patients with host SEVs, compared to 17% of patients with host BEVs $(P < .001)^{.39}$

These findings underscore the importance of CT simulation at the time of both index valve implantation and reintervention to identify patients at risk of impaired coronary access or coronary obstruction with TAV-in-TAV, as well as guide the choice of prosthesis if TAVR is chosen over SAVR as the primary intervention. Figure 1A shows a patient with anatomy that is favorable to TAV-in-TAV. While the RP lies above the left main coronary ostium (as it will in the majority of patients), the VTSTJ distance is 4.3 mm, incurring low risk of sinus sequestration with ample space for coronary access. Figure 1B shows a patient after TAVR with

an exceedingly high risk of sinus sequestration by virtue of a neoskirt nearly apposed to the STJ.

RESCUE STRATEGIES FOR PATIENTS WITH THREATENED CORONARY ARTERIES

Although full effort should be made at the time of primary intervention to minimize risk to the coronaries during TAV-in-TAV, the development of rescue strategies for patients at established risk is equally crucial. Figure 2 shows a proposed approach to treatment of TAV SVD under both considerations.

In patients undergoing primary TAVR or TAV-in-SAV, BASILICA (bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction) can be used to maximize access to the coronaries. 40,41 There are clear barriers to its applicability in TAV-in-TAV. The likelihood of achieving adequate leaflet splay is reduced in TAV prostheses, and the splayed leaflet may end up obstructed by the newly implanted TAV. 42 A variation of BASILICA in which a balloon is inflated across the leaflet prior to laceration to maximize splay (balloon-assisted, or BA-BASILICA) has been described and may improve effective coronary protection. 43

By its nature, BASILICA is less effective when a commissural post is adjacent to the coronary ostium of interest. Although this is not an issue in primary TAVR or TAV-in-SAV due to preserved commissural alignment, conventional TAVR implantation does not reliably align TAV commissural posts with those of the native valve. In the referenced CT study by Ochiai et al, commissural overlap with a coronary ostium was present in 45.2% of SEVs and 11.3% of BEVs.³⁷ Development of alignment techniques, such as the "hat" marker technique demonstrated in Evolut valves by Tang et al in the ALIGN-TAVR study, may improve the utility of BASILICA in TAV-in-TAV.⁴⁴

The inevitable impact of future technologic developments on TAV-in-TAV cannot be discounted. While surgical explantation of complete TAVs may prove to be challenging, endovascular removal of degenerated TAV leaflets may circumvent the issue of neo-endothe-lialization while facilitating TAV-in-TAV.⁴⁵ Development of transcatheter devices designed to resect valve leaflets has already begun and may significantly expand the versatility of valve-in-valve TAVR.

CLINICAL OUTCOMES AFTER TAV-IN-TAV

Clinical experience with TAV-in-TAV for TAV SVD is thus far severely limited. In the Redo-TAVR registry, the mode of TAV SVD among 138 patients who underwent TAV-in-TAV more than 1 year after index TAVR was similar to that seen in SAVs (37% pure AS; 29.7% pure

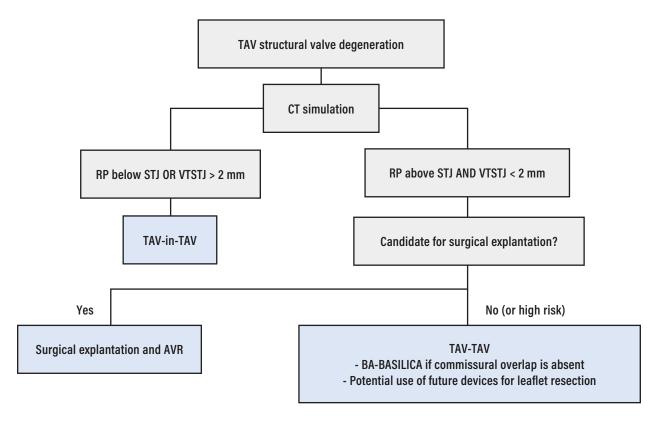


Figure 2. Treatment of TAV structural valve degeneration.

AR; 32.6% mixed). 46,20 SEVs accounted for 61% of host TAVs and 50% of implanted TAVs. 46 Device success was achieved in 85.5% of patients. 46 At 30 days, there were two deaths, one stroke, 16 cases with residual mean gradients > 20 mm Hg, four cases of valve malposition, and one case of coronary obstruction. In 172 patients who underwent TAV-in-TAV for TAV SVD in the TRANSIT registry, mode of failure was skewed toward aortic regurgitation (AR; 33% pure AS, 56% pure AR, 11% mixed).⁴⁷ SEVs accounted for 61% of implant TAVs, and device success was achieved in 79% of cases.⁴⁷ Mortality was 7% and 10% at 30 days and 1 year, respectively, with no incidences of coronary obstruction.⁴⁷ Although these findings are encouraging, the patients in both studies were likely chosen carefully based on clinical factors including CT simulation, thus falsely lowering the incidence of complications such as coronary obstruction. Further studies including RCTs are clearly needed.

DEVISING A LIFETIME STRATEGY AT THE TIME OF PRIMARY INTERVENTION

The nature of the index valve implantation has clear and lasting implications on future eligibility for TAV-in-TAV or TAV-in-SAV that must be considered when planning the primary intervention. Figure 3 shows

a proposed approach to initial valve implantation in ILR patients with severe, symptomatic trileaflet AS; this is an expansion and modification of the approach proposed by Tarantini et al for younger patients based on coronary access.⁴⁸

Although the decision between mechanical and biologic prosthesis entails a complex balance of the benefits of durability with risks of stroke and bleeding, the mortality benefit of mechanical valves does not clearly extend to patients older than 55 years. 49 Thus, this is a reasonable age above which to consider a biologic prosthesis. For patients younger than 65 years, there are yetinsufficient data describing outcomes after TAVR, and a strong recommendation for TAVR in this group cannot be made until further studies are performed. The reality is that many patients will likely have a strong preference for TAVR over SAVR, and shared informed decision-making will be paramount. Conversely, for patients older than 80 years, the benefit of TAVR over SAVR with regard to mortality, stroke risk, major bleeding, and recovery clearly outweighs the unlikely need for reintervention.5 For patients aged between 65 and 80 years, CT simulation of TAV-in-TAV in the proposed TAV should be performed, including measurement of the VTC, simulation of the RP formed through the

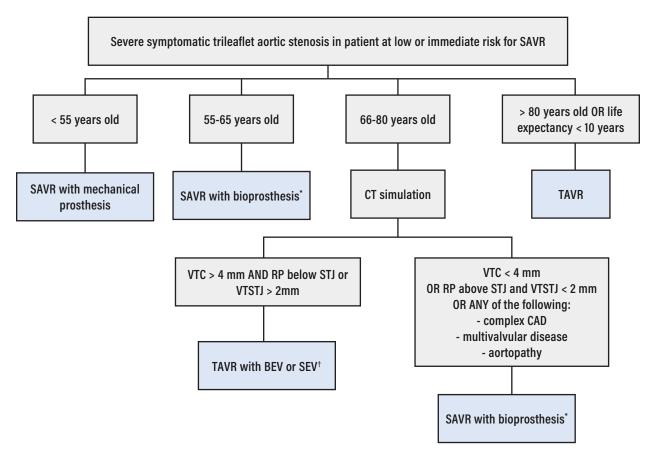


Figure 3. Treatment of severe symptomatic AS in patients at low or intermediate risk for SAVR. *Avoid stentless valves or valves with externally mounted leaflets; if annulus < 23 mm or will not accommodate > 21 mm prosthesis, consider aortic root enlargement. †Consider commissural alignment using "hat" orientation.

top of the host valve neoskirt, and measurement of the VTSTJ. In patients with VTC > 4 mm and either RP below the STJ or RP above the STJ with VTSTJ > 2 mm, TAVR is a reasonable choice as the primary intervention, with anticipated TAV-in-TAV at the time of SVD. If an SEV is chosen as the initial prosthesis, use of the "hat" marker technique should be considered to minimize neocommissure-coronary overlap. If all aforementioned criteria are not met with either a BEV or SEV, SAVR should be performed as the primary intervention, with consideration of concomitant aortic root enlargement and avoidance of a stentless or internally stented prosthesis.

The landscape of AS management will continue to transform through experience with TAV-in-TAV and TAVR in ILR patients. As TAVR expands to patients with increased longevity, the importance of developing a "lifetime strategy" at the time of primary intervention, with consideration to both native valve AS and anticipated SVD, cannot be overstated. Finding the ideal primary intervention for younger patients is no

straightforward endeavor, particularly considering the yet-unknown risks of TAV explantation. For patients with TAV SVD at risk of sinus sequestration, the current and future rescue strategies will play a key role in the expansion of TAV-in-TAV. Above all, individualized and shared decision-making in conjunction with a heart team approach will remain of utmost importance in optimizing clinical outcomes.

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