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How to Assess the Feasibility of a Second Transcatheter Aortic Valve Replacement When the First Valve Fails

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Introduction

The 2020 American College of Cardiology/American Heart Association guidelines[1] for managing valvular heart disease changed the focus of aortic stenosis (AS) treatment from the determination of risk stratification and feasibility to shared decision-making with the patient regarding recovery goals and the potential need for valve reoperation. In the United States, patients older than 65 years of age with symptomatic, severe AS have the option of transcatheter aortic valve replacement (TAVR) or surgical aortic valve replacement. The European guidelines employ an age cutoff of 75 years,[2] which is more aligned with patients in the low-risk randomized controlled trials and the median age of low-risk patients in the Society of Thoracic Surgeons national database.[3] Currently, patients younger than 65 years of age with AS are the fastest-growing TAVR demographic in the Vizient Clinical Database, with 47.5% having undergone TAVR in 2021.[4] Given their young age and longer life expectancy, many patients will require a second valve in their lifetime. The patient's desire for a faster operation and quicker recovery must be balanced against the long-term objectives of the lifetime management of valvular heart disease.

For older patients, a single prosthetic valve may be all that is needed, but for patients in their 60s with an initial bioprosthetic valve, a second valve is likely to be needed, and for patients in their 50s, 3 valves could be required. Although there are many considerations when discussing the "best" first valve for a specific patient, such as age, comorbidities, aortic root anatomy, concomitant valve disease, and coronary reaccess, the feasibility of a second valve must be considered at the preplanning stage for the first valve, especially in the younger patient population.

Current Limitations

The treatment options for failed bioprosthetic valves are surgical removal, placing a prosthetic valve within the failed surgical valve (valve in valve), or redo TAVR. For redo surgical aortic valve replacement, 30-day mortality has ranged from 2.5% to 9%.[5,6] Surgical removal of a prosthetic valve has been associated with much higher risks, including an in-hospital mortality rate of 11.9%, a 30-day mortality of 13.1%, and a 1-year mortality rate of 28.5% in the EXPLANT-TAVR registry.[7] Importantly, 26.8% of patients presenting with failed prosthetic valves were

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not candidates for redo TAVR because of unfavorable anatomy. For redo TAVR, 30-day mortality rates of 0.7% to 4.6% have been reported.[6,8]

The challenge with redo TAVR is the creation of a continuous leaflet neoskirt, which acts like a covered stent and can directly occlude the coronary ostia or reach the level of the sinotubular junction. The neoskirt can compromise coronary flow, prevent access to the coronary arteries, or completely sequester the sinus. Coronary obstruction after valve-in-valve surgery was associated with more than 50% mortality in the VIVID registry.[9]

For well-selected patients, redo TAVR is associated with good short-term outcomes. The redo TAVR registry identified 212 consecutive redo TAVRs, with device success using Valve Academic Research Consortium–2 criteria being achieved in 180 patients (85.1%). Failures were the result of a residual high-gradient pressures of 20 mm Hg or greater (14.1%); valvular regurgitation (8.9%); and, in only 2 cases, coronary artery obstruction (0.9%).[8] What is unknown is how many patients were not selected to undergo redo TAVR because of an anticipated high risk of coronary artery obstruction resulting from unfavorable anatomy.

Abbreviations and Acronyms

AS	aortic stenosis
CT	computed tomography
TAVR	transcatheter aortic valve replacement

Recent Developments

The neoskirt height is unique to each valve manufacturer and valve size. Extensive benchtop research has delineated the heights of the fully pinned valve leaflets.[10,11] Redo TAVR feasibility can be assessed using computed tomography (CT) scanning on the basis of pinned leaflet height and root measurements. Table I details the steps to determine redo TAVR feasibility—most importantly, confirming that the valve-to–coronary

TABLE I. Measurements to Define Redo TAVR Feasibility

Step	Procedure
1	Define the neoannulus as the inflow of the existing TAVR. The most ventricular-facing portion of the existing valve defines the neoannular plane. Set the centerline at the middle of the valve. Adjust for the blooming artifact by placing the dots in the middle of the metal. Trace the annulus, and select the second valve. Confirm valve sizing based on the manufacturer instructions for use.
2	Measure sinus of Valsalva diameters.
3	Define the left and right coronary artery heights from the neoannulus to the inferior edge of the coronary ostia.
4	Define the height of the sinotubular junction from the neoannular plane.
5	Select the sinotubular junction minimum and maximum. This measurement determines the risk of sinus sequestration.
6	Define the neoskirt height as pinned leaflet heights (based on benchtop testing).
7	Model virtual valves and implantation depth.
8	Measure valve-to–coronary artery, valve-to–sinotubular junction, and valve-to-aorta distances, and determine the risk of coronary artery obstruction or sinus sequestration.a If the neoskirt is below the coronary ostia or below the sinotubular junction and the valve-to–coronary artery distance is ≥4 mm, there is low risk of coronary obstruction. If the neoskirt extends to or above the sinotubular junction but the valve-to–sinotubular junction distance is ≥2 mm, there is low risk of coronary artery obstruction or sinus sequestration, but future coronary artery access may be challenging. For Evolut-in-Evolut valve procedures, if the valve-to-aorta distance is ≥2 mm, the risk of sinus sequestration is low, but future coronary artery access will be challenging.
9	Assess the alignment of the valve commissures to the native commissures; an angle <15° suggests that leaflet splitting will not be sufficient and an alternative treatment may be necessary.

TAVR, transcatheter aortic valve replacement.
Computed tomography measurements are often completed in the diastolic phase to better visualize the commissures.

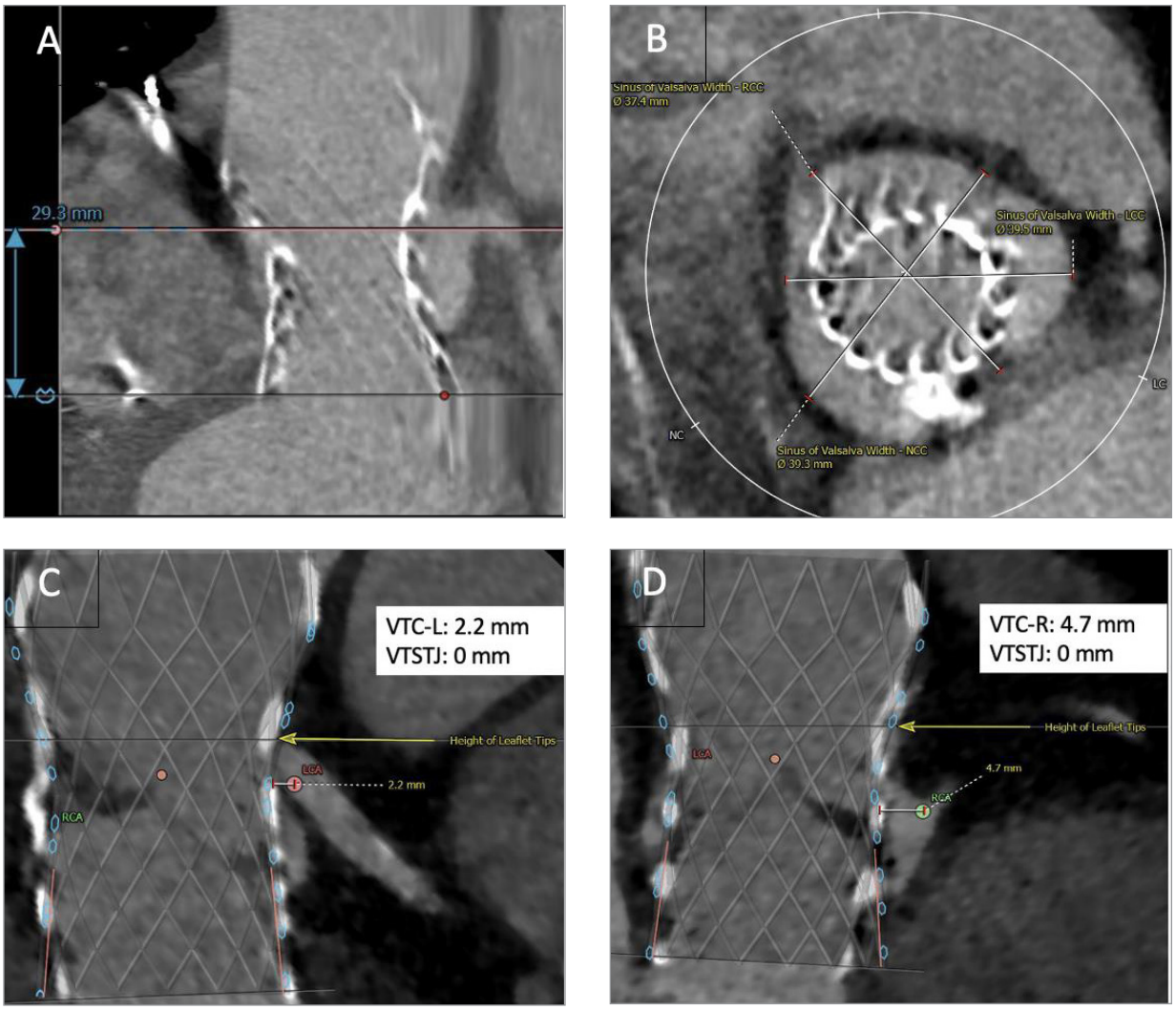

Fig. 1 Examples of redo TAVR analyses for a failed Evolut valve (Medtronic). Panels A and B demonstrate favorable anatomy for redo TAVR. **A**) The low implantation depth of the Evolut valve moves the neoskirt toward the ventricle. The height from the neoannulus plane to the left coronary artery is 29.3 mm, and the neoskirt will be below the coronary ostia, putting this patient at low risk for coronary artery obstruction. **B**) The sinus of Valsalva diameters are wide, with no risk of sinus sequestration in this patient. Panels C and D demonstrate unfavorable anatomy for redo TAVR. **C**) Although the Evolut valve is positioned low in the annulus, the neoskirt (black line) will reach the sinotubular junction thanks to a short sinus height. Here, the valve-to–coronary artery distance for the left coronary artery is only 2.2 mm and at risk for compromised coronary artery flow. The valve-to–sinotubular junction distance is 0 mm, putting this patient at risk for sinus sequestration. **D**) On the right, the valve-to–coronary artery distance is adequate at 4.7 mm, but the valve-to–sinotubular junction distance of 0 mm, the neoskirt extending to the aorta, and a valve-to-aorta distance of 0 mm predict sinus sequestration.

LCA, left coronary artery; LCC, left coronary cusp; NCC, noncoronary cusp; RCA, right coronary artery; RCC, right coronary cusp; TAVR, transcatheter aortic valve replacement; VTC-L, valve to left coronary artery; VTC-R, valve to right coronary artery; VTSTJ, valve to sinotubular junction.

artery distance is at least 4 mm and that the valve-to–sinotubular junction measurement is at least 2 mm, as demonstrated in Figure 1.

Because of the potential increased risk of encountering unfavorable aortic root anatomy with failed supra-annular valves, a CT simulation study was completed using the existing post-TAVR CT images from the Evolut Low Risk Trial (Medtronic).[12] The series evaluated the placement of a SAPIEN 3 valve (Edwards Lifesciences) within an Evolut valve at 4 locations, defined by the node level on the initial valve, as well as an Evolut-in-Evolut valve. Generally, the SAPIEN 3 valve was downsized by 1 size from the Evolut valve,

confirmed using CT measurements according to the SAPIEN 3 valve indications for use. The new Evolut valve was size-matched to the initial implant. The neoskirt height was defined by the inflow edge of the index valve to the outflow edge of the SAPIEN 3 valve or the fully pinned leaflet heights for the Evolut-in-Evolut valve. Redo TAVR was deemed to have low risk of coronary artery flow obstruction and coronary artery inaccessibility if the neoskirt was below the coronary ostia midpoint. Considering a valve-to–coronary artery distance of at least 4 mm, a valve-to–sinotubular junction measurement of at least 2 mm, and an additional measurement of valve-to-aorta distance (leaflets pinned at the aorta) of at least 2 mm for the Evolut-in-Evolut valve, redo TAVR in a failed Evolut valve was most feasible (80% of cases) if the SAPIEN 3 valve was placed with outflow at node 4. Notably, even with this optimized scheme, only 68% of patients were deemed to have easy coronary artery accessibility.

Beyond the specific anatomic root measurements (Table I), the implantation depth of the initial valve at the noncoronary cusp determined the feasibility of a redo TAVR; the higher the index valve, the greater the risk of not being able to place a second valve. This finding raises concerns because placing implants higher in the aortic annulus is preferred to avoid conduction disturbances and pacemakers. Per the Optimize PRO protocol, the target Evolut implant depth was 1 to 5 mm, with a mean depth of 3 mm.[13]

Future Directions

Transcatheter aortic valve replacement is now an acceptable treatment across all risk levels, and younger patients are receiving implants with the anticipation that during their lifetime, their valve will fail. More and more patients are presenting with failed prosthetic valves. With the possibility of an exponential increase in cases, the criteria for who can undergo redo TAVR and the optimal prosthetic valve implantation technique are poorly understood. Leaflet modification strategies may not be useful because leaflets trapped between the 2 prosthetic valve frames do not adequately splay to facilitate unobstructed blood flow to the coronary arteries. Although the current focus is on redo TAVR feasibility after failed TAVR, future patients will require a much more complex decision-making process whereby selecting and properly placing the first valve will facilitate the placement of the second valve. Computer simulation and artificial intelligence may ultimately guide these decisions, and active research is underway to develop guidance for the lifetime treatment of patients with AS.

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