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STATE-OF-THE-ART REVIEW

Transcatheter Aortic Valve Replacement in Failed Transcatheter Bioprosthetic Valves

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ABSTRACT

Transcatheter aortic valve replacement (TAVR) is increasingly being performed in younger and lower surgical risk patients. Given the longer life expectancy of these patients, the bioprosthetic valve will eventually fail, and aortic valve reintervention may be necessary. Although currently rare, redo-TAVR will likely increase in the future as younger patients are expected to outlive their transcatheter bioprosthesis. This review provides a contemporary overview of the indications, procedural planning, implantation technique, and outcomes of TAVR in failed transcatheter bioprosthetic aortic valves. (J Am Coll Cardiol Intv 2022;15:1777–1793) © 2022 by the American College of Cardiology Foundation.

Transcatheter aortic valve replacement (TAVR) for the treatment of severe aortic stenosis has been approved in patients at low surgical risk based on the favorable outcomes of recent randomized clinical trials.[1,2] Consistently, a steady decrease in the mean age of patients undergoing TAVR has been reported.[3] Given the longer life expectancy of these patients, the long-term durability of transcatheter heart valves (THVs) is of critical importance because they are likely to outlive the bioprosthetic valve. Therefore, an increasing incidence of THV failure during extended follow-up is expected. Treatment options for a failed THV include surgical TAVR explant or transcatheter implantation of a second THV inside

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ABBREVIATIONS AND ACRONYMS

BASILICA = bioprosthetic aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction

BEV = balloon-expandable valve

CT = computed tomography

MEV = mechanically expanded valve

PPM = prosthesis-patient mismatch

PVL = paravalvular leak

SAVR = surgical aortic valve replacement

SEV = self-expanding valve

STJ = sinotubular junction

SVD = structural valve deterioration

TAVR = transcatheter aortic valve replacement

THV = transcatheter heart valve

the failing THV (redo-TAVR). The heart team decision between these 2 therapies should be tailored on the basis of the underlying mechanism of THV dysfunction, aortic root anatomy, the type of the initial THV implanted, and patients' clinical condition and procedural/surgical risk. Redo-TAVR has been shown to be a valid therapeutic option in selected patients, although challenges include higher rates of malposition, coronary obstruction, and impaired coronary access.[4,5] This review provides a comprehensive overview on the indications, procedural planning, implantation technique, and reported outcomes of redo-TAVR for THV failure.

HIGHLIGHTS

- Redo-TAVR will become more prevalent as TAVR is increasingly performed in younger patients with longer life expectancies.
- A multitude of clinical and anatomical factors need to be meticulously evaluated to determine candidacy and the feasibility of redo-TAVR in patients with transcatheter valve failure.
- Transcatheter heart valve selection, sizing, and the implantation technique remain under active investigation in redo-TAVR to minimize coronary obstruction risk while preserving access.
- Lifetime management of patients with aortic valve disease, including the possibility of redo-TAVR versus TAVR explant, should be part of any heart team discussion.

MECHANISMS OF FAILURE IN THVs

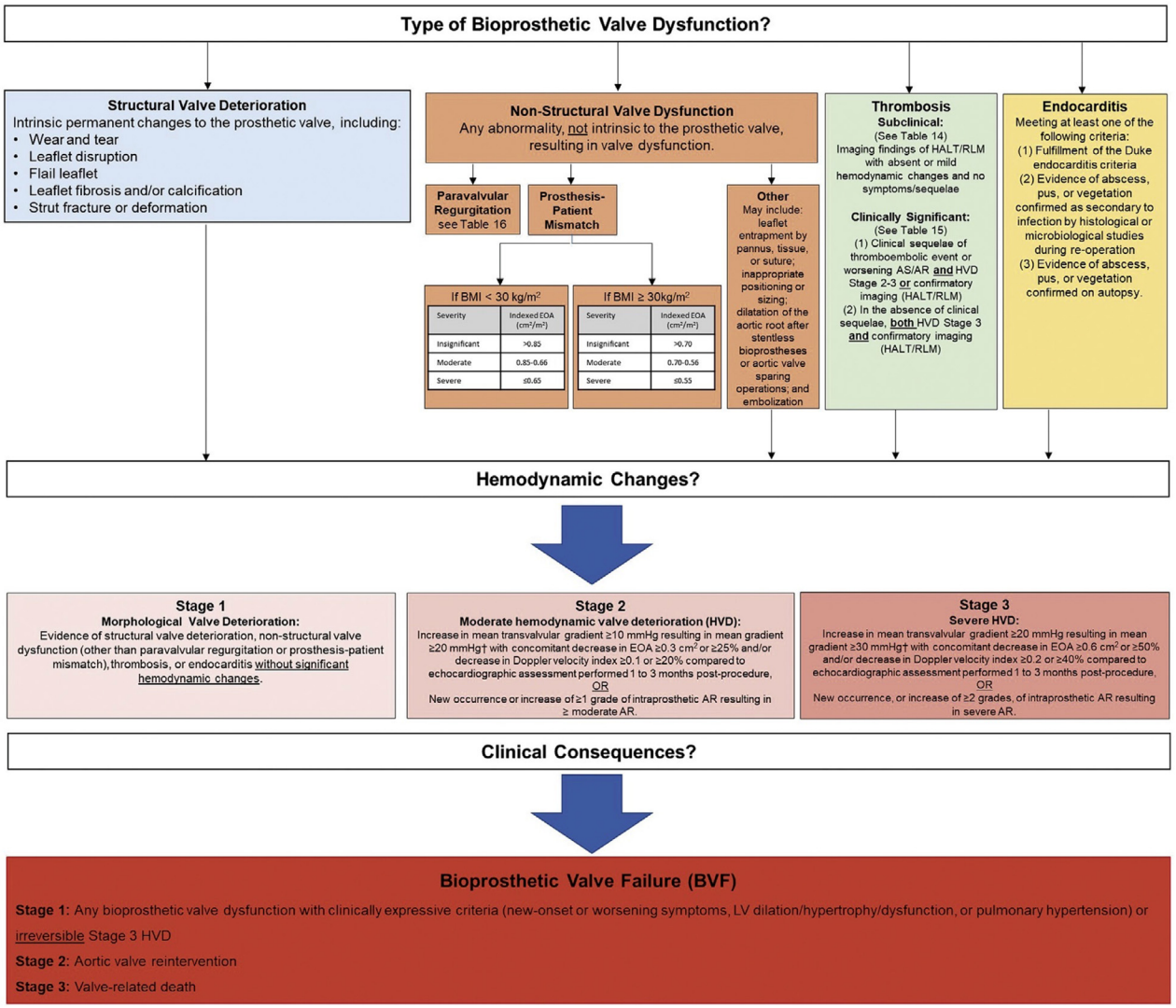
The Valve Academic Research Consortium writing group recently released their Valve Academic Research Consortium-3 update,[6] which represents the most up-to-date document regarding standardized definitions and clinical endpoints on bioprosthetic aortic valve dysfunction. According to the Valve Academic Research Consortium-3 criteria, 4 main mechanisms of bioprosthetic valve dysfunction for TAVR and surgical aortic valve replacement (SAVR) failure have been identified (**Figure 1**, top panel): 1) structural valve deterioration (SVD); 2) non-SVD; 3) valve thrombosis; and 4) endocarditis. SVD is commonly defined as an intrinsic irreversible change of the bioprosthesis structural elements caused by leaflet calcification, thickening, pannus formation, tear, or disruption. The resulting deterioration leads to stenosis and/or intraprosthetic regurgitation. Non-SVD is a bioprosthetic abnormality caused by extrinsic factors, which includes prosthesis-patient mismatch (PPM), paravalvular leak (PVL), device malpositioning, or abnormal frame expansion.

The stages of bioprosthetic valve dysfunction are as follows (**Figure 1**, middle panel): stage 1: morphologic valve deterioration; stage 2: moderate hemodynamic valve deterioration; and stage 3: severe hemodynamic valve deterioration. The Valve Academic Research Consortium-3 criteria also incorporate the definition for bioprosthetic valve failure, which is a patient-oriented clinical endpoint that considers relevant and clinically meaningful consequences of bioprosthetic valve dysfunction (**Figure 1**, bottom panel). Although SVD usually occurs late after the index TAVR, non-SVD, thrombosis, and endocarditis may mediate the early development of SVD. Comprehensive multimodality imaging studies, including transesophageal echocardiography and multidetector computed tomography, are prerequisites in diagnosing the mechanism of THV failure. The precise diagnosis of the THV failure mechanism is of utmost importance to plan the proper treatment because in some patients affected by non-SVD, a transcatheter approach is not indicated or even harmful (**Figure 2**).

INDICATIONS FOR TAVR EXPLANTATION VERSUS REDO-TAVR

The decision to recommend redo-TAVR versus TAVR explant in a patient with THV failure depends on a multitude of factors (**Table 1**). Recent data from the United States suggest that redo-TAVR has lower 30-day mortality than TAVR explant.[7,8] However, there is a significant selection bias leading to one therapy over the other, such as anatomical feasibility and the patient's surgical risk. TAVR explant is technically more complex than the index or even redo-TAVR given the need to remove the compressed native aortic valve leaflets, the THV stent frame that usually gets adhered to the native tissue, and an increased risk of injuring adjacent cardiac structures requiring more extensive surgery (eg, mitral valve, aortic root, and ascending aorta).[9,10] In this regard, THVs with a long frame extending above the aortic root may increase the challenges for TAVR explant compared with shorter-frame THVs. Certain clinical

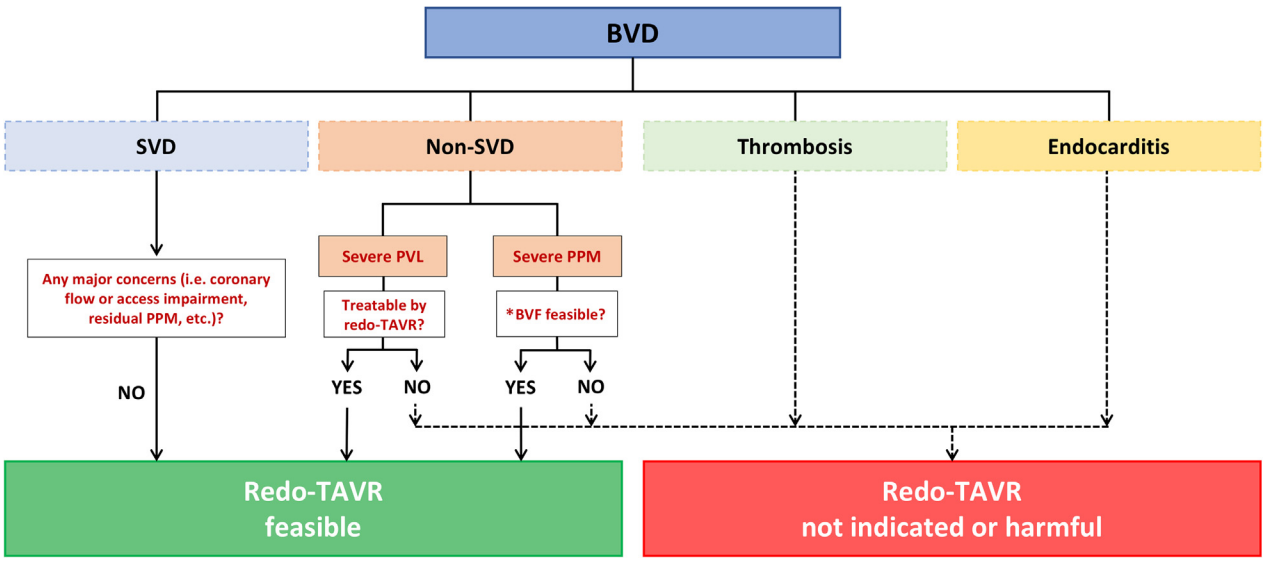
FIGURE 1 **BVD and BVF**



The figure summarizes the endpoints for both structural and nonstructural aortic bioprosthetic valve dysfunction (BVD) and illustrates the recommended decision tree for the classification of the etiology and severity of BVD. AR = aortic regurgitation; AS = aortic stenosis; BMI = body mass index; BVF = bioprosthetic valve failure; EOA = effective orifice area; HALT = hypoattenuated leaflet thickening; RLM = reduced leaflet motion.

conditions (eg, endocarditis, severe PPM, and the need for concomitant cardiac surgical procedures) may necessitate TAVR explant because redo-TAVR may not address the underlying issue. Patient and anatomical factors to determine the feasibility of redo-TAVR will also need to be considered before recommending the less invasive option as the default treatment. The timing between the index TAVR and failure is also important given that the durability will help predict the longevity of redo-TAVR, and in younger and lower surgical risk patients, TAVR explantation may be a more durable option in selected cases. Finally, the type of failing THV may be also relevant. If failure occurs early and surgery is not an option, operators may opt for redo-TAVR with a different THV type to increase the likelihood of better durability. However, because of the complex interplay of variables impacting THV failure and in the

FIGURE 2 Therapeutic Algorithm for Bioprosthetic Aortic Valve Dysfunction



*Balloon valve fracture/THV frame remodeling. PPM = patient-prosthesis mismatch; PVL = paravalvular leak; SVD = structural valve deterioration; TAVR = transcatheter aortic valve replacement; THV = transcatheter heart valve; other abbreviation as in Figure 1.

absence of evidence, the latter consideration remains speculative.

PREPROCEDURAL PLANNING AND PROCEDURAL ASPECTS OF REDO-TAVR

EVALUATING TYPES AND DIMENSIONS OF THVs. When planning redo-TAVR, it is important to consider the geometry of the failing THVs, which vary in terms of the shape and dimensions of the metallic stent frame, as well as the position of the leaflets within the frame. THVs can be classified as having short or tall stent frames and the leaflet position as intra- or supra-annular. THVs with a short stent frame (eg, a balloon-expandable valve [BEV] [Sapien/XT/3/Ultra (Edwards Lifesciences) or MyVal (Meril Life Sciences)] or a mechanically expandable valve [MEV] [Lotus (Boston Scientifics)]) are intra-annular valves. THVs with a tall stent frame can be supra-annular (eg, a self-expanding valve [SEV] [CoreValve (Medtronic), Evolut R/PRO/PRO+ (Medtronic), or ACURATE-neo/neo2 (Boston Scientific)]) or intra-annular (eg, SEV Portico/Navitor [Abbott Structural Heart]). Finally, some SEVs have an enclosed frame with intercalating cells (eg, CoreValve, Evolut R/PRO/PRO+, and Portico/Navitor), whereas others have an open frame (eg, Acurate Neo/Neo2, which have only stabilization arches).

Implanting a THV inside a failing THV pins the leaflets of the first valve in the open position.[5,11,12] This effectively turns part (or all) of the first valve into a covered cylindrical tube. The height of the covered tube is commonly referred to as the "neoskirt height."[5] The type of stent frame and the position of the leaflets directly impact the neoskirt height[9] (Figure 3). For example, when pinned open, the leaflets of a Sapien THV extend to the top of the stent frame; thus, the neoskirt height is essentially the same as the height of the frame. In contrast, when pinned open, the leaflets of an Evolut THV extend approximately two-thirds of the way up the stent frame. Therefore, the neoskirt height varies with THV size (eg, Sapien 20 mm vs 29 mm or Evolut 23 mm vs 34 mm). It may be possible in some patients to lower the neoskirt height for tall-stent frame supra-annular valves by deliberately implanting a short-stent frame THV lower inside the first THV and allowing the leaflets of the first to overhang rather than to be pinned fully open. This should be considered in procedural planning on a case-by-case basis, including considering the mechanism of the index THV failure.

The shape and stent type (ie, nitinol vs cobalt chromium) of the failing THV is also an important consideration and will determine the diameter of the covered tube formed during redo-TAVR. For example, the hourglass shape of the self-expanding

CoreValve/Evolut THV has a narrower waist that is smaller than the nominal size of the valve (eg, 34-mm Evolut has a 24-mm waist). This waist may be "pushed outward" toward the coronaries during redo-TAVR, particularly if a balloon-expandable THV is used and if it is sized to the patient's native annulus and/or to the inflow diameter of the failing THV. In contrast, the shorter-frame THVs (eg, Sapien, MyVal, or Lotus) have more rigid and cylindrical frames, which are less likely to expand significantly outward during redo-TAVR regardless of the type of second THV implanted. However, for the Sapien family and MyVal THVs, if the first valve is underexpanded and the anatomy (ie, dimensions and calcification) of the native annulus is permissive, overexpansion of the index THV can be attempted before implanting the second THV in order to avoid constraint of the second valve leading to suboptimal hemodynamics.

TABLE 1 Potential Factors Affecting Candidacy of Redo-TAVR Versus TAVR Explant

	Redo-TAVR Favored	TAVR Explant Favored
Patient		
Age	Older	Younger
Comorbidities/frailty	Present/multiple	Absent/few
Surgical risk	High/extreme	Low/intermediate
Lifetime management of aortic valve reintervention	Likely only 1 reintervention	Likely >1 reintervention
Anatomical		
Risk of coronary obstruction	Low/moderate	Moderate/high
Coronary reaccess after redo-TAVR	Easy	Difficult
Mechanism of THV failure		
Endocarditis	Absent	Present
Severe PPM	Absent	Present
Moderate/severe PVL	Absent or PVL amenable to percutaneous treatment	Present or PVL not amenable to percutaneous treatment
Need for other cardiac surgical procedures	No	Yes
Timing of THV failure	Late	Early

PPM = prosthesis-patient mismatch; PVL = paravalvular leak; TAVR = transcatheter aortic valve replacement; THV = transcatheter heart valve.

EVALUATING CORONARY OBSTRUCTION RISK IN REDO-TAVR. Treatment of a failed bioprosthetic valve with TAVR has the potential for coronary obstruction, and cardiac computed tomography (CT) is routinely performed to determine this risk. The creation of a neoskirt, in particular its height, directly impacts the risk of potential coronary obstruction. The risk of coronary obstruction after redo-TAVR is influenced by several factors (**Figure 4**), including THV design, implant depth, commissural alignment, expansion of the index THV, and THV choice for redo-TAVR.

Design of the index THV. A THV design in which the leaflets are in a supra-annular position in a tall stent frame will create a higher neoskirt, which increases the potential risk for coronary obstruction.[11,13] Importantly, the neoskirt height can also vary across THV sizes and across different generations of the same THV platform.

Implant depth of the index THV. There has been an increasing desire to implant THVs higher to reduce permanent pacemaker rates,[14] but a high implant may impact the feasibility of redo-TAVR. If the neoskirt extends above the sinotubular junction (STJ) or the valve frame-to-STJ distance is <2 mm, redo-TAVR risks sequestering the sinus of Valsalva and causes coronary obstruction.[5,15] A lower implant of the index THV valve with the outflow portion below the STJ may facilitate redo-TAVR.

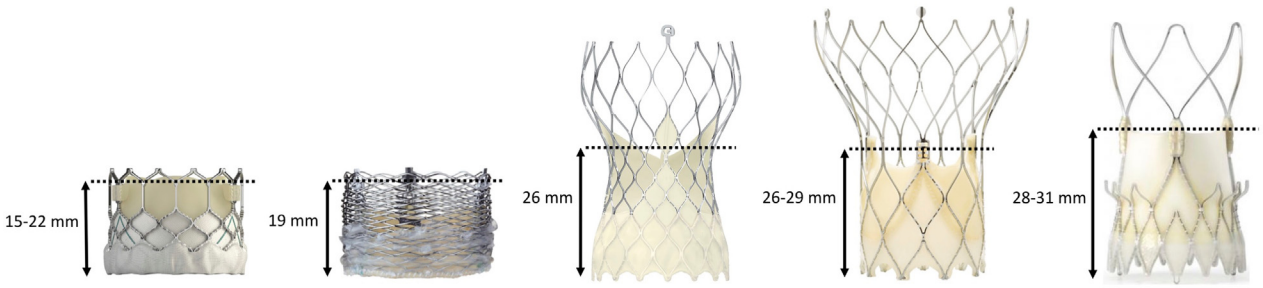
Commissural alignment. Consideration of commissural alignment of both the index THV and redo-THV is important to avoid coronary artery overlap with the index or second THV commissure.[16,17] Obtaining optimal commissural alignment is also important to allow leaflet modification techniques such as bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction (BASILICA) to be performed in case of high coronary obstruction risk with redo-TAVR.[13]

Expansion of the index THV. Redo-TAVR may lead to a greater expansion of a failed index CoreValve/Evolut THV and thereby reduce the space in the sinus of Valsalva, increasing the risk of sinus sequestration and coronary obstruction. Bench testing has demonstrated that the radius of the Evolut frame can expand by as much as 2.5 mm after the implantation of a Sapien 3 inside the Evolut THV.[18] This should be considered in terms of CT prediction of coronary obstruction in redo-TAVR.

Redo-TAVR THV choice and implant position. The THV choice for redo-TAVR can reduce the potential neoskirt height and mitigate the risk of coronary obstruction. A lower implantation of a short-frame THV into a tall-frame THV (eg, Evolut) will reduce the neoskirt height. In contrast, redo-TAVR with an Evolut into a failed CoreValve/Evolut THV would result in a high neoskirt and a potentially higher risk of coronary obstruction.[5]

Early reports have shown that redo-TAVR can be performed safely with a low risk of coronary obstruction.[4] The low rate of coronary obstruction likely reflects the robust ability to identify the risk of

FIGURE 3 The Risk Plane of Sapien 3, Lotus, Evolut R/Pro/Pro+, Portico, and Acurate Neo/Neo2 Transcatheter Heart Valves



coronary obstruction using CT-based preprocedural evaluation based on experience from TAVR in failed surgical valves. When the predicted risk of coronary obstruction is low, redo-TAVR can be performed safely. However, there is a large proportion of patients who are excluded from redo-TAVR because of an anticipated high risk of obstruction. Approximately half of the patients with a tall-frame valve may have a prohibitive risk of CT-predicted coronary obstruction.[19] Even with a short-stent frame THV, CT assessment has shown that the risk of coronary obstruction can be 21% because of the relationship of the neoskirt height of the index THV to the STJ.[11] Leaflet modification techniques such as BASILICA or dedicated leaflet cutting/removal devices may be required to facilitate successful redo-TAVR provided there is sufficient commissural alignment of the index THV.

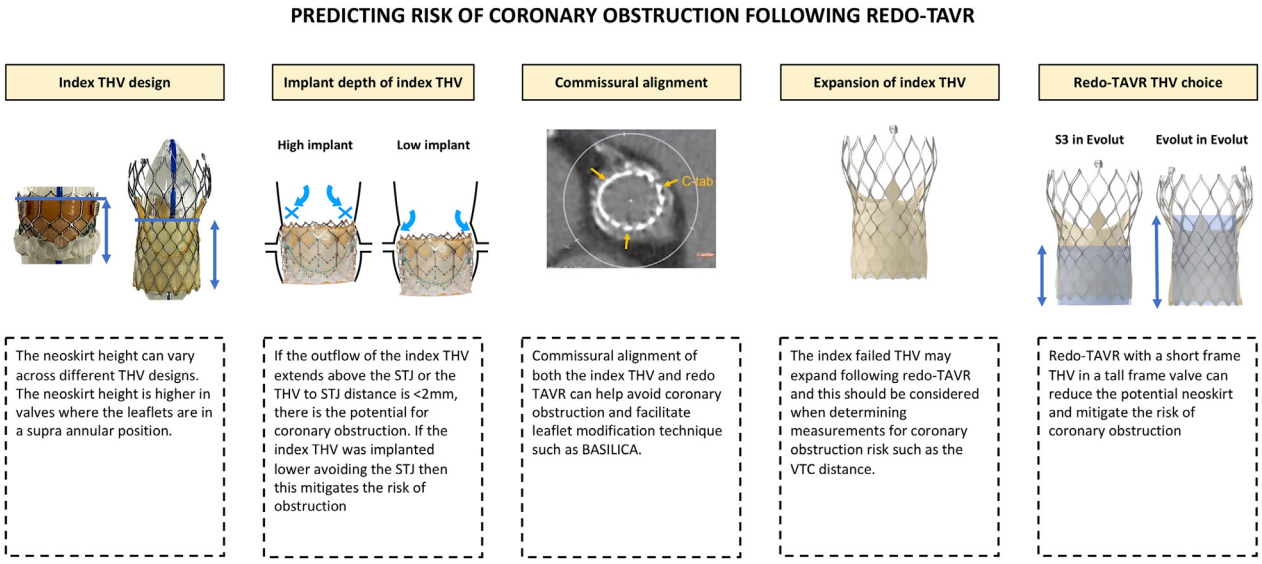
THV SELECTION IN REDO-TAVR. Currently, there is no solid evidence to guide THV selection for redo-TAVR.[4,20,21] The THV device selection in the context of redo-TAVR is determined by the type and positioning of the index THV, the failure mechanism, and the adjacent anatomical relationship. The stent frame height, leaflet position, presence of internal and/or external sealing fabric, and implant depth of the index THV should be evaluated in relationship to the dimensions of the left ventricular outflow tract (LVOT), native annulus, sinuses of Valsalva, STJ, and ascending aorta. Given the risk of impaired coronary access and coronary obstruction, the length of the stent frame of redo-THV that would extend beyond the level of the coronary ostia is relevant, particularly in the presence of a narrow sinus of Valsalva, STJ, and/or ascending aorta as well as a short distance of coronary ostia to the index THV frame.[15,22] Multimodality imaging including transthoracic/transesophageal echocardiography, coronary and aortic root angiography, and a cardiac CT scan is invaluable to determine the optimal THV and size selection. Table 2 suggests features to consider in THV selection in redo-TAVR.

THV SIZING IN REDO-TAVR. There are currently no sizing recommendations in redo-TAVR, and it depends on the native aortic root anatomy, the model and size of the index THV, and the second THV to be implanted. Meticulous CT analysis is necessary, including that of the preindex TAVR CT and the pre redo-TAVR CT. Table 3 lists the recommended anatomical measurements on CT, which may help to select the device type and sizing of the second THV in planning redo-TAVR.

Preindex TAVR CT. When feasible, the reason to acquire preindex TAVR CT is to examine the native aortic root, the annular and LVOT anatomies to determine if the first THV was properly sized, and the presence and severity of annular/LVOT calcification, which may explain certain mechanisms of THV failure (eg, PVL, THV deformation caused by severe calcification, or bicuspid anatomy). Although annular or aortic root injury has not been reported in redo-TAVR, it is theoretically possible that aggressive overexpansion of the index THV by the second THV may risk such injury, similar to aggressive balloon postdilatation after the index TAVR. Comparing the preindex TAVR with the postindex TAVR CT can also help determine if certain treatment options would be amenable to address the issue at hand, such as PVL closure, balloon dilatation of the first THV before redo-TAVR, and so on.

Pre-redo-TAVR CT. When evaluating the anatomy of the index THV, the internal dimensions are critical to determine the optimal device and size selection of the second THV. This is similar to knowing the true internal diameter in TAVR in surgical aortic valve procedures. However, unlike stented bioprostheses where the frame is usually circular, THV conforms to native anatomies and may not be circular after

FIGURE 4 Factors Impacting the Risk of Coronary Obstruction and Coronary Access Impairment After Redo-TAVR



BASILICA = bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction; STJ = sinotubular junction; TAVR = transcatheter aortic valve replacement; TVH = transcatheter heart valve; VTC = virtual transcatheter to coronary ostia distance.

implantation. If the dimensions of the index THV are smaller than the expected nominal dimensions, in selected cases and considering the native aortic root anatomy (eg, tricuspid vs bicuspid morphology, LVOT calcification, bulky leaflets, and so on), it may be advantageous to balloon dilate the first THV to further expand the internal dimensions before implanting the second THV, especially if a self-expanding device is considered as the second THV. It may also be necessary to determine a "projected" nominal dimension of the index THV to appropriately size the second THV.

Sizing of the second THV in redo-TAVR. In redo-TAVR, frame-to-frame interaction between the 2 THVs stabilizes the new valve and hence lessens the risk of device migration or embolization. However, valve migration may still happen if the second THV is undersized, mostly if it is inappropriately positioned (eg, deeper implantation at the inflow part of an Evolut THV where the valve internal dimensions are larger). Significant oversizing may not be required at all unless the failure mechanism is PVL, particularly if the index THV was undersized during the index TAVR. There are currently no generalized manufacturer sizing recommendations for redo-TAVR given the multitude of combinations of THVs that can occur. However, the following hypothetical proposals for sizing strategies of the second THV in redo-TAVR are shown in Figure 5:

1. If the index THV is a BEV or MEV and the planned second THV is a BEV, the recommended sizing will be the same as the index THV if it was a BEV. Depending on the internal dimensions of the index MEV, the BEV would be true sized or slightly upsized. However, based on bench testing, the implantation of an SEV (specifically the Evolut THV) in MEV seems preferable over a BEV in terms of the final hemodynamic performance and the risk of significant constraints against the BEV as a second THV.
2. If the index THV is a BEV or MEV and the planned second THV is an SEV, the recommendation would be to at least true size and perhaps even oversize with the SEV to avoid the risk of migration of the second THV within the first THV. However, one should caution in oversizing an intra-annular SEV as the second THV because it may risk under-expansion of the functioning portion of the valve and result in pinwheeling of the leaflets and potential early THV failure.
3. If the index THV is an SEV and the planned second THV is a BEV, depending on the SEV device type, the general recommendation would be to oversize with the BEV at least to the waist or inflow portion

TABLE 2 Potential Factors Affecting THV Selection for Redo-TAVR

	Balloon-Expandable THV	Self-Expanding THV
Small STJ/ascending aorta	+	−
Small SOV	−	±
Short distance coronary ostium to frame	±	−
PPM at index TAVR	−	+
High risk for elevated residual gradient	−	+

SOV = sinus of Valsalva; STJ = sinotubular junction; other abbreviations as in Table 1.

of the SEV to avoid risk of migration of the second THV within the first THV. However, because the narrowest portion of the SEV with an enclosed frame (eg, CoreValve/Evolut and Portico/Navitor) will expand with the BEV, native aortic annular dimensions at the preindex TAVR CT and implantation depth of the index THV should help guide the size selection of the second THV. Specific manufacturer recommendations when implanting a Sapien 3 in Evolut platforms are the following: Sapien 3 20 mm in the 23-mm Evolut, Sapien 3 23 mm in the 26-mm Evolut, Sapien 3 26 mm in the 29-mm Evolut, and Sapien 3 29 mm in the 34-mm Evolut.[18]

4. If the index THV is an SEV and the planned second THV is also an SEV, it depends on the model of the second THV. If both are the same, then a same-sized second THV can be implanted. However, if a different model is selected, it may be necessary to oversize the second THV to avoid the risk of migration of the second THV given the different radial force of the second THV relative to the first one. Although the implantation of an SEV in an SEV is theoretically feasible, it should be noted that SEV manufacturers recommend the use of a BEV within an SEV for redo-TAVR because of the risk of the first THV constraining the frame of the second THV, leading to suboptimal hemodynamic performance.

THV POSITION IN REDO-TAVR. There is no ideal THV design or implant position that would be considered optimal for all patients undergoing redo-TAVR. Rather, several factors will influence the target position of the second THV in redo-TAVR, including patient anatomy, the position of the failed index THV, the choice of the second THV, and the assessed risk of coronary access interference. The following factors must be considered when planning redo-TAVR:

1. If the failed THV has a short stent frame (BEV or MEV), the height of the neoskirt after redo-TAVR is relatively short. However, it has been reported that after redo-TAVR, the coronary arteries originated below the top of the neoskirt in 67% of cases with a failed Sapien THV.[23] When considering other factors that may impact coronary access (a distance of <2 mm between the THV and the aortic wall and misalignment of the stent frame struts affecting crossing with a catheter), CT modeling has predicted that coronary access will be without interference in 33% and technically impossible in 10% of cases after redo-TAVR for failed Sapien THVs. Although the inflow portion of the second THV would ideally be implanted at the same position as the failed THV, a lower position may be considered if the aforementioned risk factors for impaired coronary access are identified on preprocedural CT imaging. However, caution is needed when aiming at a lower implant of the second THV if the failure mode of the index THV is calcific degeneration, particularly when the leaflets are tall as typical in supra-annular SEV. The leaflets of the index THV may risk overhang or interfere with the leaflets of the second THV, risking residual functional prosthetic stenosis or affecting optimal leaflet function of the second THV.
2. In cases in which the failed THV has a tall stent frame, typical of SEVs, the neoskirt after redo-TAVR is higher, particularly if the degenerated valve has supra-annular leaflets. This may result in a higher neoskirt height, potentially increasing the risk of coronary obstruction, and may lead to more challenging coronary access in some patients. It has been predicted that after redo-TAVR for failed CoreValve/Evolut THVs, the coronary artery ostia will be below the top of the neoskirt in 90% of the cases, making coronary access uncomplicated in only 8% and impossible 27% of the time.[18,24] If the second THV also has a high stent frame, its implantation height will not change the length of the neoskirt and the preprocedural CT must be carefully analyzed for the possibility for coronary access before such a THV is chosen. Alternatively, a second THV with a short stent frame should be preferred. It should be noted that sometimes an SEV can be implanted rather deep, making the supra-annular leaflets more intra-annular. The preprocedural CT assessment would be helpful to determine the exact first THV implantation depth and neoskirt height relative to the coronary ostia to optimize the target position of the second THV.

A recent bench model systematically studied the neoskirt height, leaflet overhang, and performance after redo-TAVR with the Sapien 3 at different implantation depths in Evolut THVs.[18] Sapien 3 THVs

20, 23, 26, and 29 mm were deployed within Evolut THVs 23, 26, 29, and 34 mm, respectively. Importantly, because the Sapien 3 THV foreshortens mostly from the inflow part of the stent frame during deployment, alignment was done according to the outflow of this THV. Thus, the Sapien 3 THV was tested in 3 different positions: the outflow part of the stent frame at nodes 4, 5, and 6 of the Evolut THV reflecting the inflow part of the Sapien 3 THV approximately 4 mm below, at the same level, and 4 mm above, respectively, the inflow part of the Evolut THV (Figure 6).

The neoskirt height for the Evolut THV was shorter when the Sapien 3 outflow was positioned at node 4 compared with node 6 (16.3-19.9 mm vs 23.9-27.0 mm). Thus, a high Sapien 3 implant in an Evolut THV poses similar issues to redo-TAVR with an Evolut in an Evolut, whereas a low Sapien 3 implantation in an Evolut may facilitate future coronary access after redo-TAVR (if the leaflets of the original Evolut overhang). All configurations showed acceptable hydrodynamic performance (regurgitant fraction <20%) independently of the degree of leaflet overhang. However, for a 29-mm Sapien 3 in a 34-mm Evolut THV at a low position (node 4), the dimensions of the THVs made it such that there was minimal overlap of the PVL skirt of the Sapien 3 and the Evolut THV inflow, resulting in higher inter-THV leakage.

Thus, the risk of impossibility for coronary access after redo-TAVR is particularly high if the index THV has a high stent frame with a supra-annular position. Low implantation of a second THV with a short stent frame provides a shorter neoskirt, and despite a high degree of leaflet overhang, this seems not to impact the hydrodynamic performance of the second THV. Of note, all these considerations are based on bench testing, which included only normal THVs without degenerated leaflets. Also, it should be kept in mind that the implantation of a balloon-expandable Sapien 3 valve, particularly in the larger valve sizes, may results in outward expansion of the Evolut frame, by up to 2.5 mm in all directions, which may also increase the risk of coronary obstruction, making coronary access challenging.

TABLE 3 CT Measurements on Preprocedural Sizing in Redo-TAVR

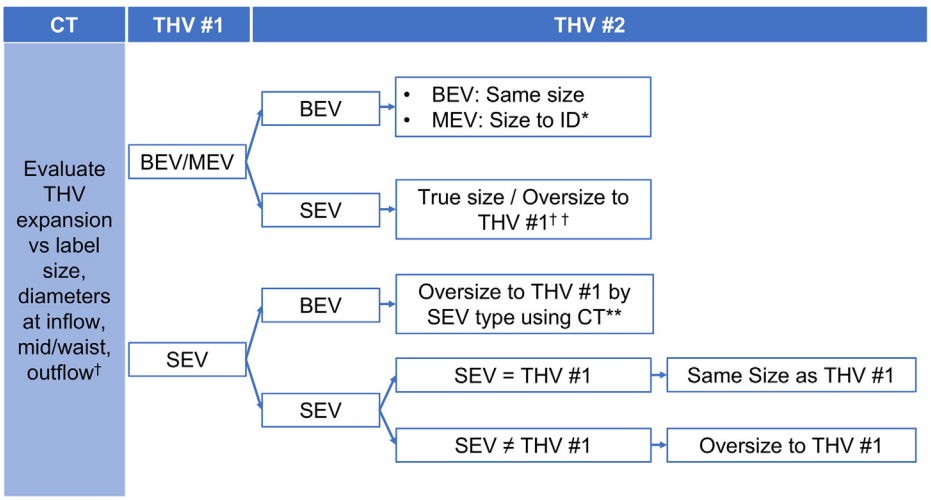
Preindex TAVR CT	Postindex TAVR CT
Annulus • Maximum diameter • Minimum diameter • Mean diameter • Area • Area-derived diameter • Perimeter • Perimeter-derived diameter • Eccentricity	THV #1 manufacturer model and size • % oversized/undersized to native annulus
LVOT • Maximum diameter • Minimum diameter • Mean diameter • Area • Area-derived diameter • Perimeter • Perimeter-derived diameter • Eccentricity	If THV #1 is BEV/MEV: 3 levels: inflow, midframe, outflow • Maximum internal diameter • Minimum internal diameter • Mean internal diameter • Internal area • Area-derived internal diameter • Internal perimeter • Perimeter-derived internal diameter • Eccentricity
Calcification • Annulus: location, severity • LVOT: location, severity • Leaflets: location, severity, presence of commissural fusion	If THV #1 is SEV: 3 levels: inflow, waist, outflow at commissural posts • Maximum internal diameter • Minimum internal diameter • Mean internal diameter • Internal area • Area-derived internal diameter • Internal perimeter • Perimeter-derived internal diameter • Eccentricity
Bicuspid valve • Morphology: Sievers type, raphe location and calcification	Proposed THV #2 model and size • Oversized % to THV #1 by area and perimeter to inflow and waist

BEV = balloon-expandable valve; CT = computed tomography; LVOT = left ventricular outflow tract; MEV = mechanically expandable valve; SEV = self-expanding valve; other abbreviations as in Table 1.

MANAGING CORONARY OBSTRUCTION RISK IN REDO-TAVR. If the patient is at high risk of coronary obstruction with redo-TAVR, 1 of the following options may be considered:

1. Surgery: 2 surgical options include explantation of the entire TAVR valve and implantation of a surgical prosthesis or leaflet removal of the index THV followed by redo-TAVR inside the original TAVR frame under direct visualization. The latter, surgical resection of prosthetic valve leaflets under direct vision, may provide a less technically challenging and potential bailout surgical solution in patients who may be at increased risk of TAVR explant, but the long-term durability of TAVR in a bare THV stent frame remains unknown.[25] After exposure to the failed THV is obtained from a transaortic approach, the degenerated valve leaflets are completely excised, and a TAVR under direct visualization is performed within the prior THV stent frame.
2. Leaflet modification: BASILICA has been used successfully to prevent coronary obstruction with TAVR in native aortic stenosis and degenerated surgical bioprosthetic aortic valves.[26,27] A large multicenter registry including 30 patients with severe native or bioprosthetic aortic valve disease at high or extreme risk for surgery and at high risk of coronary artery obstruction demonstrated real-world feasibility and safety of BASILICA, with 2.8% 30-day mortality and 2.8% 30-day stroke rate,[28] which is similar to outcomes in patients undergoing TAVR and not at risk of coronary

FIGURE 5 Proposed Sizing Strategy in Redo-TAVR



Given no current manufacturer recommendations are available on sizing in redo-TAVR, the following strategy is proposed. †In cases in which THV #1 was under/overexpanded, consider using the computed tomography (CT) THV internal dimensions instead of the label THV size, and if feasible, balloon dilate THV #1 before implanting THV #2. *For a mechanically expandable valve (MEV), one recommends sizing to the internal diameter (ID) of the stent frame. ††One may want to true size an intra-annular self-expanding valve (SEV) as THV #2 to avoid underexpansion and leaflet pinwheeling, risking early failure. **Sizing the balloon-expandable valve (BEV) inside the SEV depends on the SEV type. One may need to size based on the SEV inflow dimensions measured on CT, the waist of SEV if one exists, or to native pre-TAVR annulus. This is to reduce risk of THV #2 migration within THV #1 or annular injury from excessive oversizing. Abbreviations as in Figure 4.

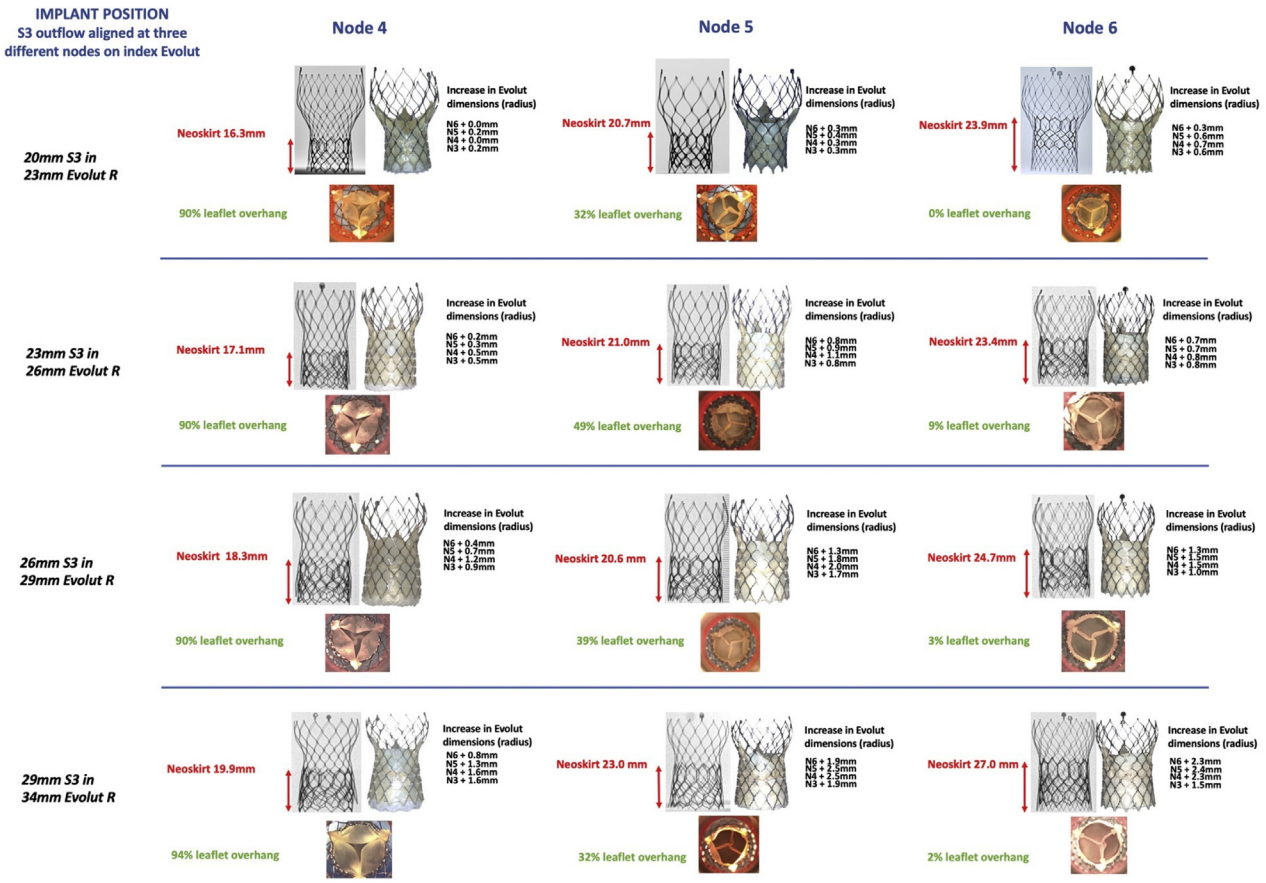
obstruction, thus providing an option for patients who would otherwise have a 40% to 50% 30-day mortality risk.[29] Unlike for snorkel/chimney stenting, there were no late complications associated with BASILICA.[26]

There are 3 problems posed by BASILICA in THV.[5] First, the THV stent frame may limit the outward excursion and hence the splay of the split leaflet away from the centerline laceration. Second, newer-generation THVs are designed with a redundant leaflet for better coaptation, which further limits the splay of these leaflets after BASILICA. Third, the THV commissures may be misaligned, with a commissural post in front of or adjacent to the threatened coronary artery. Most of these problems present a serious concern when the risk of obstruction is at the coronary ostium. However, when the risk is sinus sequestration, BASILICA may suffice in providing adequate flow into the sinus for coronary perfusion (**Figure 7**). Modeling suggests that most of the coronary obstruction risk is from sinus sequestration,[12] so BASILICA or similar leaflet management techniques will likely have a role in redo-TAVR procedures.

One technique to enhance leaflet splay during BASILICA is the so-called "balloon-assisted" BASILICA.[30] After traversal of the center and base of the TAVR valve leaflet with an electrified guidewire, the leaflet nadir is dilated with a 4- to 5-mm noncompliant balloon at high pressure. This theoretically increases leaflet splay and has been performed successfully in patients at high risk of coronary obstruction before redo-TAVR (**Figure 8**).

3. Leaflet removal: The CATHEDRAL (CATHeter Electrosurgical Debulking and RemovAL) procedure removes the entire prosthetic leaflet by electrosurgery based on the BASILICA concept. The advantage of this technique is even in THV with commissural misalignment, removing 1 or 2 of the index THV leaflets should be sufficient to avoid sinus sequestration and coronary obstruction during redo-TAVR. The disadvantage is the risk of inducing acute severe aortic regurgitation and hemodynamic instability, requiring immediate and expeditious implantation of the second THV to restore aortic valve competency.
4. Snorkel/chimney stenting: a snorkel/chimney stent would be crushed between the frames of the old and new TAVR valves and is likely not a feasible option in redo-TAVR unless the outflow of the index THV provides sufficient clearance for a snorkel/chimney stent to be deployed against the

FIGURE 6 **Redo-TAVR Test Configurations of Different-Sized S3 Within Evolut R THVs**



The neoskirt height, degree of leaflet overhang (%), and increase in the Evolut R radius (mm) at each node (N3 to N6) after redo-TAVR with Sapien 3 (S3) for each THV size are outlined. Abbreviations as in Figure 4.

second THV (eg, the first THV is a Sapien or ACURATE-neo valve and the coronaries can be cannulated by going on the outside of the first THV stent frame).

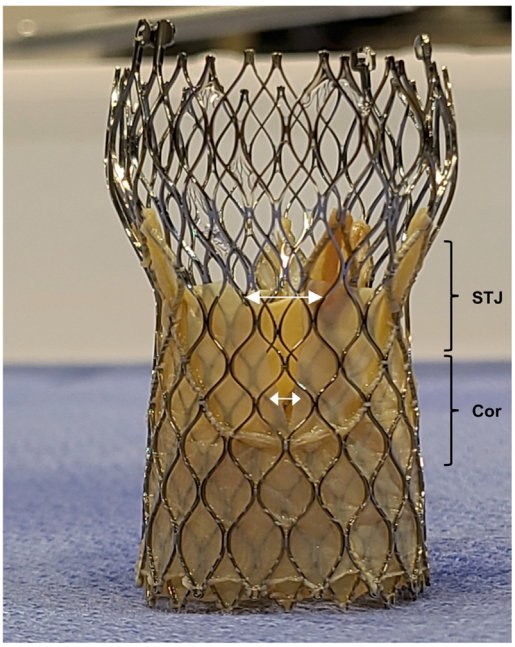
ANTITHROMBOTIC REGIMEN AFTER REDO-TAVR

There are currently no studies or data on an optimal antithrombotic regimen after redo-TAVR. Given the presence of native aortic valve leaflets, 2 THV stent frames, and THV neoskirt from the index THV and the potential lack of commissural alignment, the risk of sinus sequestration and hypoattenuating leaflet thickening may be higher than in index TAVR. Ideally, similar to TAVR in degenerated surgical prosthesis, lifelong aspirin plus a 3-month period of anticoagulation with warfarin may be considered, although the evidence supporting this regimen remains scarce. Until further studies are conducted in the redo-TAVR patient population, a case-by-case decision would be necessary to balance between the risks of valve thrombosis and bleeding, particularly because many redo-TAVR candidates are older people with a high bleeding risk.

CORONARY ACCESS AFTER REDO-TAVR

The inability to access the coronaries to perform coronary angiography and percutaneous coronary intervention after redo-TAVR is going to be 1 of the biggest limitations of performing redo-TAVR in patients with a longer life expectancy.[24,31-33] Data on the feasibility of coronary angiography after redo-TAVR are limited to CT analysis of theoretical feasibility after implantation of the first THV. It has been shown that coronary access would theoretically be unfeasible after redo-TAVR in 23.8%, 38.5%, and 41.1% of patients receiving a Sapien 3, CoreValve, or

FIGURE 7 Benchtop Redo-Transcatheter Aortic Valve Replacement With Evolut-in-Evolut With Bioprosthetic or Native Aortic Scallop Intentional Laceration to Prevent Iatrogenic Coronary Artery Obstruction



There is little splay at the typical level of the coronary artery (Cor) and adequate splay at the typical level of the sinotubular junction (STJ).

ACURATE-neo THV,[15] whereas another study found coronary access was technically impossible in 27% and 10% for CoreValve and Sapien platforms, respectively.[23] Similarly, it has been reported that impaired coronary access could occur in more than half of redo-TAVR cases with a higher risk with supra-annular valves.[22] Anatomical factors that will impede coronary access include narrower STJ width and height, coronary arteries originating below the neo-skirt height of the first THV, a THV frame-to-aortic wall distance <2 mm, and misaligned THV commissures.[15,23]

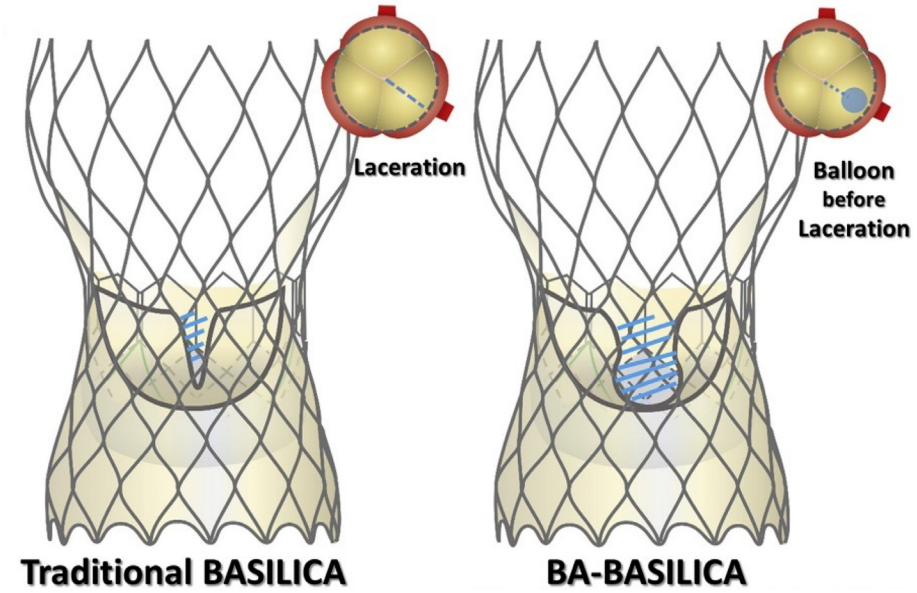
Commissural alignment of the first THV, especially with THVs with supra-annular leaflets and a tall stent frame, is essential to facilitate coronary access after TAVR.[17] Patient-specific commissural alignment of the Evolut, Portico, and Acurate THV platforms can be reliably performed in most patients by using the coronary cusp overlap fluoroscopic view to optimize neocommissural orientation.[34] Furthermore, optimal neocommissural alignment of the index THV is essential for leaflet modification techniques (eg, BASILICA and dedicated leaflet laceration/removal devices) to be effective in preventing coronary obstruction and maintaining coronary access in redo-TAVR, especially in patients with high-risk anatomies. Indeed, commissural alignment of the index THV has become an important issue, and all next-generation balloon-expandable and self-expanding THVs are likely to incorporate features to easily achieve this. Commissural alignment of the second THV is likely to be important to maintain coronary access, especially when the second THV has a tall stent frame and/or supra-annular leaflets and when leaflet modification of the first THV has been performed. Commissural alignment may prevent THV-THV stent frame misalignment that would otherwise reduce open cell gaps and space for catheter engagement. Furthermore, coronary cannulation after redo-TAVR will potentially be more challenging and require advanced techniques that need to be widely taught. The development of specialized guiding catheters with dedicated curves and steerability will also be useful. Currently, the following techniques can be useful for coronary access after redo-TAVR: 1) downsizing the guiding catheters by one-half size; 2) considering intubation with a diagnostic catheter and then exchanging to guide the catheter with 2 long support coronary wires; 3) nonselective wiring of the coronary artery; 4) using a microcatheter or dual-lumen catheter to place a more supportive wire; and 5) liberally using guide catheter extensions and considering anchoring the balloon in the coronary if there is difficulty in advancing guide catheter extension into the ostium.[5,35,36]

CLINICAL OUTCOMES AFTER REDO-TAVR

Real-world data on redo-TAVR remain scarce. TAVR-in-TAVR comprised 0.46% of 133,250 TAVR procedures in the 2012 to 2017 Medicare database and 0.33% of 63,876 procedures in the Redo-TAVR international registry, the 2 largest series yet reported.[4,7] Generally, in appropriately selected patients, redo-TAVR was relatively safe and effective, with low rates of procedural complications and substantial symptomatic improvement. Survival at 30 days seems comparable to that reported in other valve-in-valve TAVRs in selected patients at intermediate to high surgical risk (mortality, 2.9%-6.0%; stroke, 1.4%-1.8%; and pacemaker, 4.2%-9.6%) yet lower at 1 year (13.5%-22%), which could be attributable to the high competing risk of mortality in this population.

Both series included all redo-TAVR procedures, meaning that some patients were not treated for SVD but rather early after the first valve was implanted for procedural failure (eg, because of PVL). Accordingly, the median interval from the index to redo-TAVR was

FIGURE 8 Balloon-Assisted BASILICA



The leaflet splay theoretically increased after balloon augmentation at the traversal site before laceration. BASILICA = bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction; BA-BASILICA = balloon-assisted bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction.

only 5 months (Medicare) and 33 months (Redo-TAVR registry). Mortality at 30 days was substantially lower in patients undergoing redo-TAVR beyond 1 year from the index TAVR in whom SVD (vs suboptimal first THV implantation) was the most probable cause of failure (1.5% vs 5.4%, respectively). Mortality was also lower in those who underwent their first TAVR during 2015 to 2017 compared with earlier (2012-2014) years (4.6% vs 8.7%, $P = 0.049$). Device success was achieved in 85%, and most failures were attributable to high residual gradients (14.1%) or regurgitation (8.9%). Although the use of subsequent self-expanding THV seems to be associated with higher device success caused by lower redo-TAVR residual gradients (10.3 [8.9-11.7] vs 15.2 [13.2-17.1] mm Hg, $P < 0.001$), neither the initial or the subsequent THV type (balloon expandable vs self-expanding) had an impact on redo-TAVR safety (71%-76% in different THV-in-THV type combinations, $P = 0.590$) or mortality (0%-2.3%, $P = 0.499$).[3] Compared with a matched group undergoing TAVR explantation, redo-TAVR was associated with lower 30-day mortality (6.2% vs 12.3%, $P = 0.05$), whereas 1-year mortality was similar (21.0% vs 20.8%, $P = 1.000$).

Importantly, both studies were observational and thus carried a risk of unmeasured bias. The population examined consisted of highly selected patients who, first, survived to the second procedure and, second, were deemed anatomically suitable for redo-TAVR. It is unknown how many patients died before redo-TAVR could be attempted, how many were declined caused by anatomical concerns, and how many chose to decline reintervention. The low rate of coronary obstruction observed (0.9%) could be the result of meticulous preprocedural planning in highly experienced centers and caused by older THV designs and a historically deeper implant depth (most failing bioprostheses were first-generation SEVs [37%] or second-generation BEVs with a relatively short frame [24%]). Lastly, because neither study looked at younger patients or had long-term follow-up, none of these data address the lifetime management strategy for TAVR patients with longer life expectancies.

TAVR EXPLANT

In patients in whom redo-TAVR is not feasible or suboptimal, TAVR explant remains the only option in those who are deemed surgical candidates. TAVR explant is more technically complex and carries a higher risk than index SAVR. A study of all U.S.

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TABLE 4 Summary of Reported TAVR Explant Studies

First Author (Ref. #)	Study Period	N	Top Indications for Explant (%)	Outcomes (%)
Hirji et al[37]	1/2012-12/2017	227T	THV failure (79.3) Endocarditis (20.7)	30-day: mortality: 13.2 30-day stroke: 5.7 1-year mortality: 22.9
Jawitz et al[38]	7/2011-3/2015	123	Other (21.1) PVL (15.5) SVD (11.4) Endocarditis (9.8)	30-day mortality: 17.1 30-day stroke: 3.3
Fukuhara et al[8]	1/2012-12/2019	34	AI/PVL (50) SVD (38) Need for other cardiac surgery (18) Endocarditis (12)	30-day mortality: 15 30-day stroke: 0
Brescia et al[10]	1/2012-12/2019	46	Procedure-related failure (34.8) PVL (28.3) SVD[a] (26.1) Need for other cardiac surgery (26.1) Endocarditis (13.0)	30-day mortality: 20 30-day stroke: 4
Bapat et al[9]	11/2009-9/2020	269	Endocarditis (43.1) SVD (15.2) PVL (10.7) Other (9.7) PPM (6.3)	30-day mortality: 13.1 30-day stroke: 8.6 1-year mortality: 28.5 1-year stroke: 18.7

[a]Includes prosthetic stenosis and insufficiency.

AI/PVL = aortic insufficiency/paravalvular leak; PPM = prosthesis-patient mismatch; SVD = structural valve degeneration; other abbreviations as in Table 1.

patients undergoing TAVR from 2012 to 2017 using the Center for Medicare and Medicaid Services database revealed a 0.2% incidence of TAVR explant.[37] However, 30-day mortality was high at 13.2%, and 1-year mortality was 22.9%. This finding was confirmed by using the Society of Thoracic Surgeons database to study 123 patients who underwent TAVR explant from July 2011 to March 2015.[38] An increased observed-to-expected mortality ratio was found across all surgical risk categories. Furthermore, an increasing trend of TAVR explant from 2012 to 2019 in the Michigan statewide database has been reported, including an increasing proportion of patients needing valve reintervention after TAVR requiring explant.[8] Most explant patients (75%) had unfavorable anatomy for redo-TAVR, with a 30-day mortality of 15% and an observed-to-expected mortality ratio of 1.8. The same group also recently reported its statewide experience of 46 TAVR explants (0.4% incidence), a majority of which (71%) were SEVs.[10] The operative mortality in this group was 20%, and the 3-month survival rate was only 73% ± 14%.

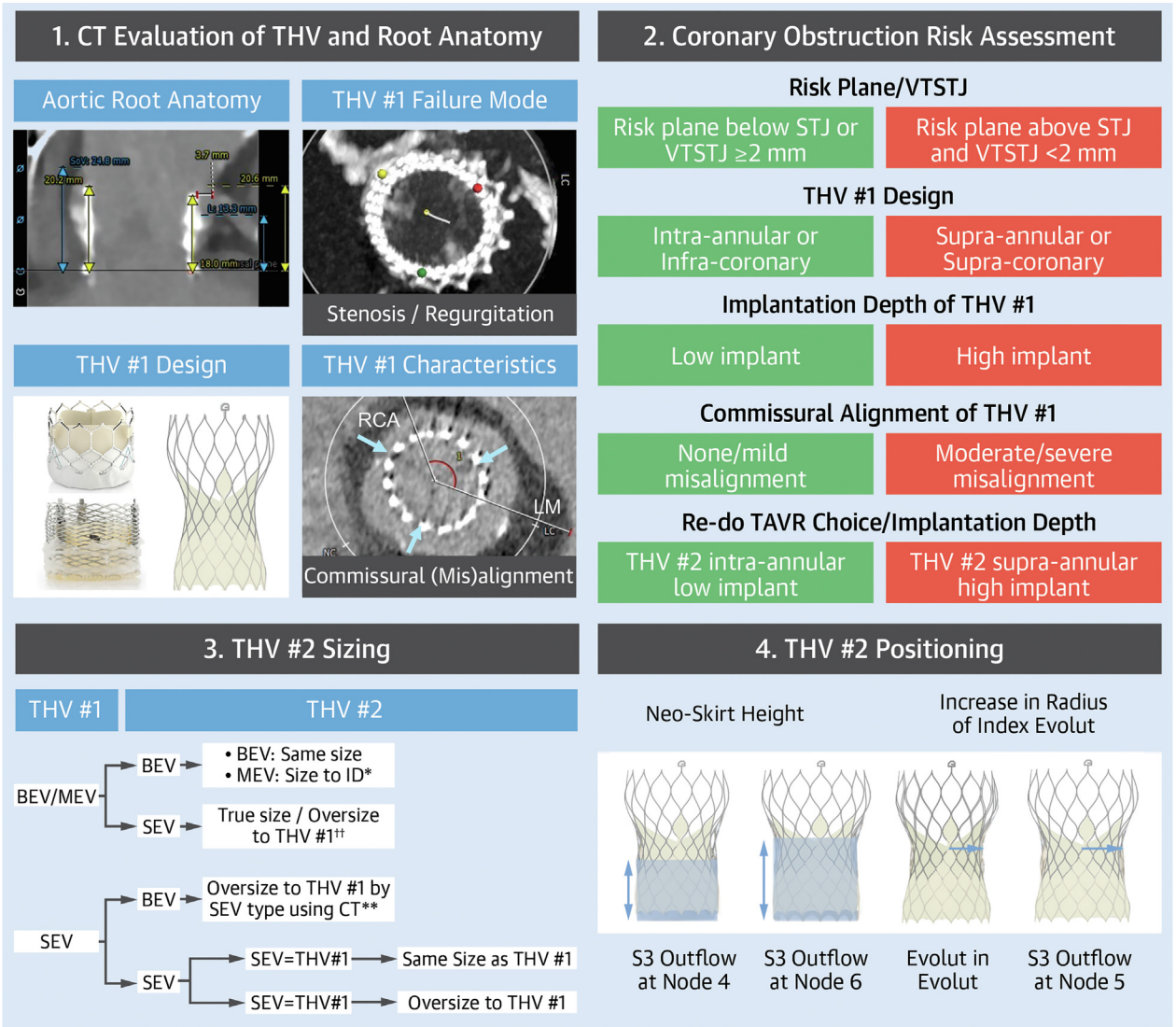
The international EXPLANT-TAVR registry reported midterm outcomes of TAVR explant, including 269 patients who had explant from November 2009 to September 2020.[9] The proportion of BEVs and SEVs were similar, with 43.1% caused by endocarditis, 20.1% structural valve degeneration, 18.2% PVL, and 10.8% PPM. Redo-TAVR was deemed not feasible in 26.8% of patients. Concomitant cardiac procedures were performed in 54.6% of patients. The group also reported high 30-day and 1-year mortality rates of 13.1% and 28.5%, respectively, but also high 30-day and 1-year stroke rates of 8.6% and 18.7%, respectively.

Table 4 summarizes the reported characteristics and outcomes of TAVR explant. The overall findings showed that TAVR explant is a more complex operation with higher observed than expected mortalities. Although there is undoubtedly a learning curve associated with TAVR explant and outcomes will likely improve with experience, the data thus far should prompt a comprehensive heart team discussion on the lifetime management of patients who prefer index TAVR to SAVR, especially those who are not anatomically suitable for redo-TAVR and would require TAVR explant in the future.

CONCLUSIONS

The current review encompasses the most relevant and contemporary information on the topic of redo-TAVR for failed transcatheter bioprosthetic aortic valves. It discussed different aspects of preprocedural planning including patient selection, coronary obstruction risk assessment, THV selection, and positioning (Central Illustration) and reported contemporary outcomes for both redo-TAVR and TAVR explant. Further in vitro and in vivo investigations will be necessary to further standardize

CENTRAL ILLUSTRATION **Steps to Consider in Transcatheter Aortic Valve Replacement in Failed Transcatheter Bioprosthetic Valves**



Tarantini G, et al. J Am Coll Cardiol Intv. 2022;15(18):1777–1793.

Key steps to consider in transcatheter aortic valve replacement (TAVR) in failed transcatheter bioprosthetic valves. (Step 1) Post-index TAVR computed tomography evaluation of basal aortic root anatomy and transcatheter heart valve (THV) #1 design, characteristics, and failure mode. (Step 2) Assessment of coronary obstruction risk considering the most relevant anatomical and device-related impacting factors, including the risk plane, valve frame to sinotubular junction, THV #1 design/implantation depth/commissural alignment, THV #2 design/implantation depth. (Step 3) THV #2 sizing based on the type and size of THV #1. (Step 4) THV #2 positioning based on coronary obstruction risk. BEV = balloon-expandable valve; CT = computed tomography; ID = internal diameter; LM = left main; MEV = mechanically expandable valve; S3 = Sapien 3; SEV = self-expanding valve; THV = transcatheter heart valve; VTSTJ = valve frame to sinotubular junction.

preprocedural planning, sizing, implantation techniques, and coronary obstruction mitigation and management strategies and to evaluate long-term outcomes of redo-TAVR.

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Dr Tarantini has received lecture fees from Medtronic, Edwards Lifesciences, Abbott, and Boston Scientific. Dr Sathananthan is a consultant to Edwards Lifesciences, Medtronic, and Boston Scientific.

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