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Review

Degenerated Transcatheter Aortic Valve Replacement: Investigation and Management Options

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ABSTRACT

With the expansion of transcatheter aortic valve replacement (TAVR) to younger and lower-surgical-risk patients, many younger and less comorbid patients will be treated with TAVR and are expected to have a life expectancy that will exceed the durability of their transcatheter heart valve. Consequently, the number of patients requiring reintervention will undoubtedly increase in the near future. Redo-TAVR and TAVR explantation followed by surgical aortic valve replacement are the different therapeutic options in the event of bioprosthetic valve failure and the need for reintervention. Patients often anticipate being able to benefit from a redo-TAVR in the event of bioprosthetic valve failure after TAVR, despite the lack of long-term data and the risk of unfavourable anatomy. Our understanding of the feasibility of redo-TAVR is constantly improving thanks to bench test studies and growing worldwide experience. However, much remains unknown. In clinical practice, one of the heart team's objectives is to anticipate the

RÉSUMÉ

Le remplacement valvulaire aortique par cathéter (RVAC) a été élargi aux patients plus jeunes et présentant un risque chirurgical moindre, de sorte qu'un grand nombre de patients plus jeunes et présentant moins d'affections concomitantes seront traités par RVAC. Ces patients devraient alors avoir une espérance de vie supérieure à la durabilité de leur valve cardiaque transcathéter. Par conséquent, le nombre de patients qui auront besoin d'une réintervention augmentera sans aucun doute dans un proche avenir. La reprise du RVAC et l'explantation de la valve aortique transcathéter suivie d'une chirurgie de remplacement valvulaire aortique sont les différentes options thérapeutiques en cas de défaillance de la bioprothèse cardiaque et lorsqu'une réintervention s'impose. Les patients s'attendent souvent à ce qu'une reprise du RVAC leur soit bénéfique en cas de défaillance de la bioprothèse cardiaque après un RVAC, malgré l'absence de données à long terme et le risque de condition anatomique défavorable. Des

Over the years, transcatheter aortic valve replacement (TAVR) has become the routine therapy for symptomatic severe aortic stenosis in the elderly population across all surgical risk categories and is increasingly used in younger patients. As a result, the number of TAVR procedures in the United States in 2015 exceeded that of isolated surgical aortic valve replacement (SAVR), and in 2019, it even exceeded the total number of SAVR associated with other procedures (coronary artery bypass, surgical procedure on another valve).[1] The latest American Heart Association/American College of Cardiology guidelines give a class I indication for TAVR and SAVR between the ages of 65 and 80 years, and the 2021 European guidelines favour TAVR over the age of 75 years.[2,3] In 2021, 87.5% of US patients aged 65 to 80 years were treated with TAVR for their severe aortic stenosis, compared with fewer than 50% in 2015.[4]

With the expansion of TAVR to younger and lower-surgical-risk patients, TAVR penetration could reach 300 cases per million inhabitants in many countries, as is already the case in Germany.[5] Knowing that all transcatheter heart valves (THVs) are made from biological tissue, they are prone to structural valve deterioration (SVD) over time, and therefore, many younger and less comorbid patients are expected to have a life expectancy that will exceed the durability of their THV. Ultimately the number of patients requiring reintervention will undoubtedly increase.

Redo-TAVR and TAVR explantation followed by SAVR are the different therapeutic options in the event of bioprosthetic valve failure (BVF) and the need for reintervention. In this review, we address key definitions in the diagnosis of SVD and BVF, as well as patient selection and procedural planning for redo-TAVR to reduce periprocedural risk, optimise hemodynamic performance, and maintain coronary access. We also describe the bench testing and literature in the redo-TAVR and TAVR explantation fields.

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need to reaccess the coronary arteries and implant a second or even a third valve when life expectancy may exceed the durability of the transcatheter heart valve. In this review, we address key definitions in the diagnosis of structural valve deterioration and bioprosthetic valve failure, as well as patient selection and procedural planning for redo-TAVR to reduce periprocedural risk, optimise hemodynamic performance, and maintain coronary access. We describe the bench testing and literature in the redo-TAVR and TAVR explantation fields.

bancs d'essai et l'expérience croissante à l'échelle mondiale nous permettent de constamment parfaire notre compréhension en ce qui concerne la faisabilité d'une reprise du RVAC. Cependant, il reste encore de nombreuses zones d'ombre. En pratique clinique, un des objectifs de l'équipe cardiaque est d'anticiper le besoin d'accéder à nouveau aux artères coronaires pour y implanter une deuxième, voire une troisième valve lorsque l'espérance de vie peut dépasser la durabilité de la valve cardiaque transcathéter. Dans cette analyse, nous abordons les principales définitions relatives au diagnostic de détérioration structurale de la valve et à la défaillance de la bioprothèse cardiaque, de même que la sélection des patients et la planification de l'intervention pour une reprise du RVAC afin de réduire le risque périopératoire, d'optimiser l'efficacité hémodynamique et de maintenir un accès coronarien. Nous décrivons les bancs d'essai et la littérature concernant la reprise du RVAC et l'explantation de la valve aortique transcathéter.

The Definition of Bioprosthetic Valve Dysfunction, Structural Valve Deterioration, and Bioprosthesis Valve Failure

Until recently in studies on SAVR, either survival without aortic valve reintervention or mortality related to the valve have been used as end points for long-term success. With this definition, we captured only the most severe cases of SVD and the patients who were well enough to undergo a reintervention. Indeed, the lack of a well-established definition of bioprosthetic valve dysfunction introduced confusion in the interpretation of the different trials and comparisons between the SAVR and TAVR data.[6] Furthermore, in clinical practice, yearly echocardiographic follow-up is often more routinely performed after TAVR than after SAVR, which may underestimate the real SVD in real-world SAVR cohorts.

The first standardised definition of bioprosthetic valve dysfunction was provided in 2017 by the European Association of Percutaneous Cardiovascular Intervention, the European Society of Cardiology (ESC), and the European Association for Cardio-Thoracic Surgery.[7] In 2021, the VARC-3 document provided a modified definition of bioprosthetic valve dysfunction which required not only hemodynamic changes but also permanent morphologic changes of the bioprosthesis before SVD could be confirmed. Hemodynamic changes can be related to causes other than SVD, and considering only the hemodynamic criteria may overestimate the incidence of true SVD.[6,8]

Briefly, bioprosthetic valve dysfunction includes 4 different categories: 1) SVD, meaning intrinsic permanent prosthesis changes (ie, wear and tear, leaflet disruption, flail leaflet, leaflet fibrosis, or calcification, strut fracture or deformation); 2) nonstructural valve deterioration (NSVD) which corresponds to paravalvular regurgitation, prosthesis-patient mismatch, and others (eg, leaflet entrapment, inappropriate positioning); 3) thrombosis; and 4) endocarditis. These entities are classified into 3 stages according to the hemodynamic changes, which are described in Figure 1. Finally, BVF is also divided into 3 stages and is an important patient-oriented clinical end point.

Valve Durability and Incidence of Failed THV

Surgical experience has shown us that the Achilles heel of bioprostheses is long-term durability. In the TAVR world, little data beyond 5 years exist. There are no data beyond 2 years in patients with bicuspid valves, who were excluded from the different randomised controlled trials.[8] TAVR was initially performed in elderly comorbid patients who often died from noncardiovascular causes, preventing long-term follow-up.

Indeed, data beyond 5 years from randomised controlled trials are still limited because the early population of high-risk patients from **P**lacement of **A**ort**i**c Tra**n**scathet**er** Valves (PARTNER) IA and inoperable patients from PARTNER IB had 5-year survival rates of 32% (37% when only transfemoral approach was considered) and 28%, respectively.[9,10] Importantly, the 5-year data of the low-risk PARTNER 3 trial were recently reported.[11] The significantly lower rate of the composite of death, stroke, and rehospitalisation in the TAVR group compared with the SAVR group (8.5% vs 15.1%; $P < 0.001$) at 1 year was attenuated at 5 years (TAVR: 22.8%; SAVR: 27.2%; $P = 0.07$).[11,12] Both groups were associated with low clinical event rates ($\sim$ 1%/y cardiovascular death, $\sim$ 1%/y stroke, $\sim$ 3%/y cardiovascular rehospitalisation). The hemodynamic performance of the Sapien 3 THV was similar to the surgical valves, with a BVF rate of 3.3% in the TAVR group and 3.8% in the SAVR group. In addition, at 5 years, 86.3% and 87.4% of the patients were alive with a durable valve in the TAVR and SAVR groups, respectively. Furthermore, 71.0% of the TAVR and 71.9% of the SAVR patients were alive with a Kansas City Cardiomyopathy Questionnaire score > 75.

Concerning post-TAVR survival trends, the all-comer Danish TAVR cohort, which consists of 2670 patients since 2007, provides important data on the impact of age and surgical risk on the survival rate.[13] The overall survival rate in that cohort was 58.1% at 5 years and 20.0% at 10 years, with more than half of the mortality being of cardiovascular cause. Age and surgical risk significantly affected survival. The survival of low-risk patients remained stable until 80 years of age, and one-third of the patients less than 75 years of age were still alive 10 years after TAVR. Finally, patients treated in the last

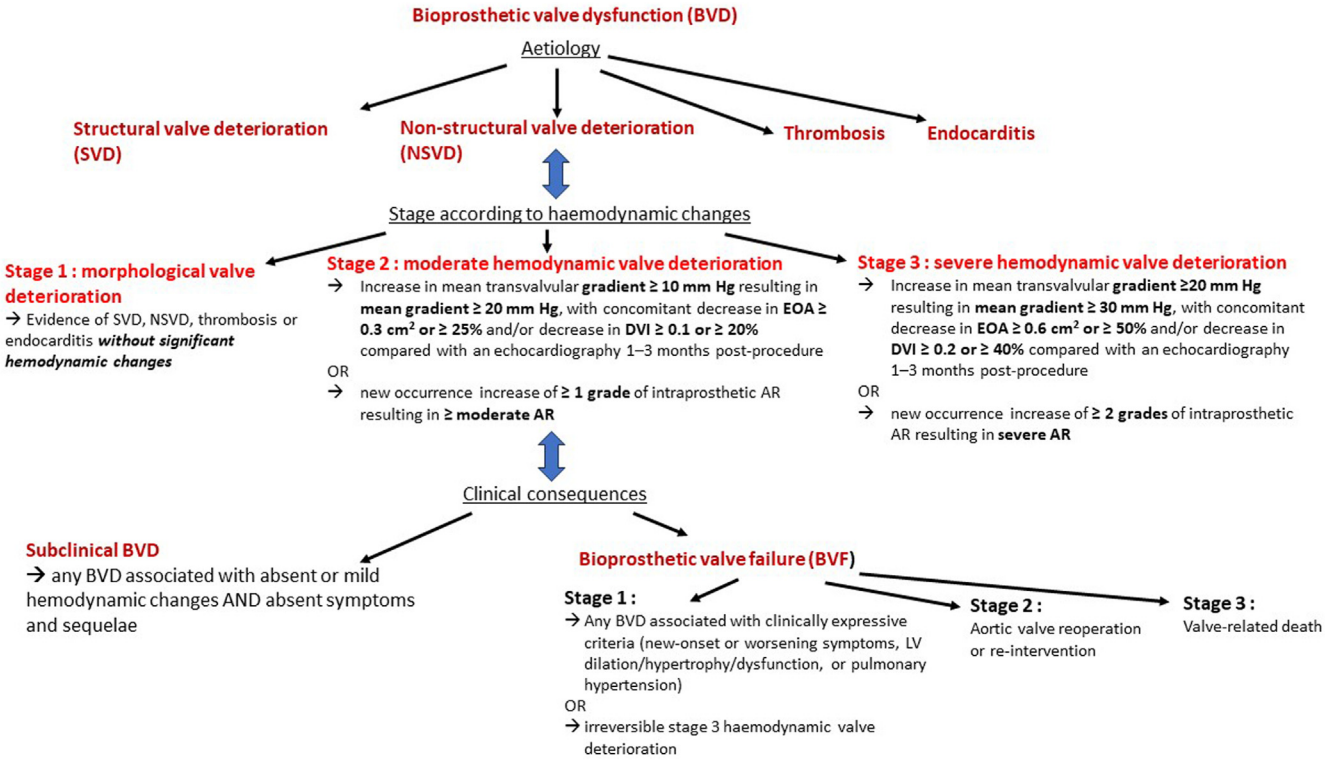

Figure 1. Bioprosthetic valve dysfunction classification and definition. AR, aortic regurgitation; BVD, bioprostetic valve dysfunction; DVI, Doppler velocity index; EOA, effective valve area; SVD, structural valve deterioration; NSVD, nonstructural valve deterioration.

period (2017-2021) had a modestly better 5-year survival rate (61.5%) than the patients treated from 2007 to 2011 (52.9%) and from 2012 to 2016 (56.3%), confirming the impact of better preprocedural planning, improved THV design, increased operator experience, and the selection of lower-risk and younger patients.[13]

The longest follow-up in a randomised controlled trial comes from the Nordic Aortic Valve Intervention (NOTION) trial, which randomised 120 patients to SAVR and 130 patients to TAVR using the nonrecapturable early-generation Medtronic CoreValve device. The 8-year results (52 TAVR and 39 SAVR still alive) were published in 2021,[14] and the 10 year-results (34 TAVR and 27 SAVR still alive) were presented at the 2023 ESC meeting.[15] Moderate and severe SVD at 10 years were significantly lower in the TAVR cohort (19.4% and 3.1%, respectively) than in the SAVR cohort (36% and 11%). Similar results were found when applying the modified SDV criteria (severe SVD in 0% and 5%, moderate SVD in 15.3% and 19.9% in the TAVR and SAVR cohorts, respectively). There was no significant difference in BVF. Of note, 34% of the SAVR valves were externally mounted leaflet bioprosthetic valves, known for early degeneration. One of them, the Trifecta valve (Abbott Vascular) was withdrawn by the manufacturer in 2023.

In summary, treatment of lower-risk and younger patients as well as improvement in technical aspects of the procedure (ie, pre-procedural planning, THV design, implantation technique), and operator experience and expertise are likely to result in improved long-term survival and THV durability.

Assessment of Bioprosthetic Valve Dysfunction

Each case with potential hemodynamic THV deterioration should be comprehensively assessed to 1) confirm the hemodynamic deterioration (ie, stenosis or regurgitation), 2) determine its stage, and 3) understand the etiology related to SVD.

Transthoracic echocardiography (TTE) is the cornerstone for the assessment of valve function and hemodynamics. The maximal and mean gradient across the THV can be determined with the use of the simplified Bernoulli formula, knowing that the formula may be controversial in the setting of bioprosthetic and small valves. The effective orifice area of the THV can be calculated with the use of the continuity equation. In addition, regurgitant orifice and regurgitant volume are both calculated with the help of the proximal isovelocity surface area method. Regurgitant volume may also be assessed with the use of the volumetric method.

The assessment of leaflet morphology and the structure of a THV is crucial. Transesophageal echocardiography offers better spatial resolution than TTE and superior temporal resolution than computed tomography (CT), thus providing a unique assessment of the morphology and motion of the prosthesis leaflets.

Leaflet thickening may be the result of thrombosis, usually in the form of hypoattenuated leaflet thickening (HALT), infection, inflammation, or calcification. In such cases, a reduced motion of 1 or more leaflets is typically observed. Figure 2 demonstrates an example of SVD secondary to infective endocarditis. On the other hand, mechanical degeneration is characterised by excessive leaflet motion, often

manifesting as prolapse or tearing. However, degeneration is more often characterised by thickening, restriction, and calcification.

Electrocardiography-gated CT is the criterion standard when suspecting valve thrombosis (HALT) owing to its higher spatial resolution, but it can also help assess paravalvular leaks and interchamber fistulas.

Management of Degenerated THV

TAVR explantation followed by SAVR and redo-TAVR (or TAV-in-TAV) are the different therapeutic options in the event of BVF and the need for reintervention. We describe the clinical worldwide experience with both approaches and bench test studies (focusing on Medtronic and Edwards THVs).

TAVR explantation followed by SAVR

TAVR explantation beyond 1 year can be technically complex, particularly for self-expanding valves that go up into the ascending aorta with dense endothelialisation of its upper portion in contact with the aortic wall.[16,17] It may lead to ascending aorta and aortic root replacement. In an analysis of the Society of Thoracic Surgeons (STS) database, patients with self-expanding devices required more frequent ascending aorta replacement than those with balloon-expandable THVs (18.2% vs 8.2%; $P = 0.009$).[18] However, the rate of aortic root replacement was similar (22.1% vs 18.9%; $P = 0.52$). TAVR explantation in the few days or weeks after implantation is easier than later when the endothelisation process is advanced.[16]

Analysis of a large multicentre American database including all patients who underwent TAVR from 2012 to 2017 showed that the overall incidence of TAVR explantation was low at 0.2% (n = 227; 71% from the 30th day to 12 months).[19] The average age of the cohort was 73.7 years, and 30-day and 1-year mortalities were as high as 13.2% and 22.9%, respectively.

More data are available in the international **Explant**ation After **T**ranscatheter **A**ortic **V**alve **R**eplacement Failure (EXPLANT-TAVR) registry, which included 269 patients in 42 centres from 2009 to 2020 (retrospective analysis, exclusion of reinterventions during index TAVR hospitalisation).[20] The mean age of patients was 72.7 ± 10.4 years and the median STS score at the time of TAVR explantation was 5.6% (interquartile range [IQR] 3.2%-9.6%) with a median time between TAVR and TAVR explantation of 11.5 months (IQR 4.0-32.4 months). The THVs explanted were Edwards THV in 50.9% and self-expanding or mechanically expandable THVs in 49.1%. The causes of TAVR explantation were endocarditis (43.1%), SVD (20.1%), paravalvular leak (18.2%), and prosthesis-patient mismatch (10.8%). A redo-TAVR was considered to be not feasible in as many as 26.8% of cases because of unfavourable anatomy. Aortic root replacement was performed in 13.4%, and 54.6% of cases had an associated cardiac procedure. Per-procedure mortality was only 0.7%, but the mortality and stroke rates were, respectively, 13.1% and 8.6% at 30 days and 28.5% and 18.7% at 12 months. Therefore, the risks associated with TAVR explantation were not negligible and similar to the large multicentre American database.[19] After adjustment, in multivariate analysis, the independent factors of 30-day mortality were a history of stroke (odds ratio [OR] 3.4, 95% CI 1.4-8.6), pulmonary hypertension (OR 2.8, 95% CI 1.1- 7.0), and an associated procedure on the mitral and/or tricuspid valve(s) during TAVR explantation (OR 3.8, 95% CI 1.5-9.4).

Jawitz et al. analysed 123 patients from the STS database who underwent TAVR explantation from 2011 to 2015 with a median age of 77 years (IQR 67-84 years) and median time from TAVR to explantation of 2.5 months (IQR 0.7-13 months).[21] Indications for reoperation were paravalvular leak (15%), SVD (11%), sizing or position issues (11%), and endocarditis (10%). The STS score was < 4% in 17% of cases, 4% and 8% in 24%, and > 8% in 59%. The 30-day mortality (17.1%) was higher than the expected mortality rate after conventional reoperation after SAVR. It reached 14% for patients at low surgical risk, 10% for those at intermediate risk, and 21% for those at high risk. The average operating time (321 min) was almost double the time reported for surgical reoperation of a degenerated surgical aortic bioprosthetic valve (~ 200 min). The median cardiopulmonary bypass time (146 min) was longer than the 111 min reported in a study of SAVR in patients who already had coronary artery bypass grafting.[22] Only 7% of patients required aortic root replacement.

Recently, Hawkins et al. reported all SAVRs with previous aortic valve intervention (29,306 previous SAVR, 1126 previous TAVR, 674 previous SAVR + TAVR) from the STS Adult Cardiac Surgery Database from 2011 to 2021.[23] The most common exclusion criteria were previous non-bioprosthetic valve, emergency TAVR explantation, and previous root replacement. The unadjusted operative mortality was the highest (17%) in the TAVR-SAVR group, whereas the operative mortality rate was 12% for the SAVR-TAVR-SAVR patients and 9% in the SAVR-SAVR patients. In a propensity-matched group with 433 SAVR-SAVR patients and 433 TAVR-SAVR patients, the operative mortality was significantly higher for TAVR-SAVR (11.3%) than for SAVR-SAVR (6.7%; $P = 0.02$), but the rate of major morbidity was not different between the groups (28% vs 24%; $P = 0.223$). However, the TAVR-SAVR patients had more renal failure and longer intensive care unit stays, with fewer patients discharged directly home.

In 2023, Fukuhara et al. reported the results from the State of Michigan after redo-TAVR (n = 54) and TAVR explantation (n = 34) from 2012 to 2019 in a cohort of 9694 TAVRs.[24] The number of reinterventions increased over time and, the contraindications for redo-TAVR were unfavourable anatomy (75%), need for other cardiac surgery (29%), other structural issues caused by the THV (18%; ie, mitral valve impingement, partial coronary obstruction, and ventricular septal defect) and endocarditis (12%). Importantly, in that series, the rate of concomitant procedure at the time of TAVR explant was high at 68% and corresponded with aortic repair (32%), mitral repair or replacement (29%), coronary artery bypass graft (21%), tricuspid repair (18%), and ventricular septal defect repair (3%). In an earlier study from the STS database assessing 784 patients with TAVR explantation, Fukuhara et al. found that the 30-day mortality was significantly lower after isolated TAVR explantation vs TAVR explantation and concomitant procedure (14.8% vs 23.8%; $P = 0.002$).[18]

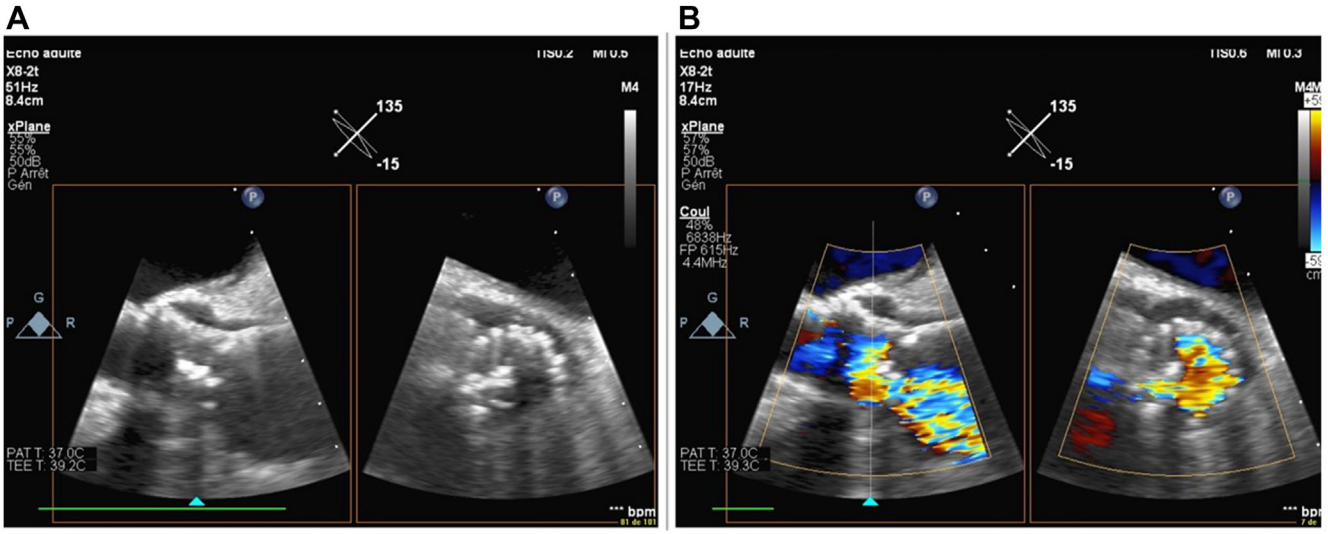

Figure 2. Example of structural valve deterioration secondary to infective endocarditis. (**A**) Transesophageal echocardiography: mid-esophageal biplane view focused on the aortic prosthesis in a patient who underwent transcatheter atrial valve replacement 2 years earlier. Note the prosthesis leaflet calcification that results in reduced prosthesis opening. (**B**) Same view with colour Doppler in systole showing colour Doppler aliasing and noncircular transprosthetic flow.

Ultimately, TAVR explantation years after implantation is technically more demanding than standard SAVR owing to the longer operating times and higher rates of complications and 30-day mortality. The latest generation of THVs, with their external sealing skirts, can increase tissue development and potentially add challenges to TAVR explantation. In addition, compared with SAVR, during TAVR explantation, the risk of aortic root replacement after THV stent dissection/deinsertion and the risk of anterior mitral leaflet injury are higher. Overall, the 30-day mortality after TAVR explantation varies from 11% to 23.8% in the series described above, with the highest mortality rate found in the group of TAVR explantation associated with concomitant procedures.[18-21,23] The concept of the volume-outcome relationship applies to this potentially challenging surgery.[25] In the 2023 Michigan report, 12% of the cardiac surgeons have been exposed to TAVR explantation with a median of only 1 procedure per surgeon (IQR 1-2, range 1-10 per surgeon) at 10 hospitals representing 30% of the cardiac centres in the state.[18] The 30-day mortality rate after TAVR explant has the potential to decrease when treating lower-risk and younger patients by more experienced and exposed surgeons to this surgery.

However, TAVR explantation is the criterion standard therapy for THV endocarditis or thrombosis, significant paravalvular leak, patient-prosthesis mismatch, or in the context of unsuitable anatomy for redo-TAVR.

Redo-TAVR

Redo-TAVR has emerged as an alternative therapy for BVF in the lifetime management of aortic stenosis, particularly for patients at high surgical risk. Although TAV-in-SAV has already proved to be safe and effective in the treatment of degenerated surgical valves,[26] data on the use of THV in degenerated THV prostheses (redo-TAVR) are still scarce and do not exceed 12 months.

Redo-TAVR requires a tailored approach for each patient, taking into account the risk and pitfalls of implanting a second THV in a THV. Similarly to TAV-in-SAV procedures, in addition to the difficulty of reaccessing the coronary arteries and the risk of coronary obstruction, there is a risk of leaflet thrombosis and patient-prosthesis mismatch, especially for valves smaller than 23 mm, which leads to an increased mean gradient. To reduce patient-prosthesis mismatch, routine pre- and postdilation are typically performed. Sapien THVs can be dilated to a diameter that is approximately 3 mm larger than nominal.[27] However, for valves smaller than 23 mm or when expecting a patient-prosthesis mismatch, TAVR explantation remains the best approach when surgery can be reasonably undergone.

The preprocedural planning is of utmost importance and requires a very good knowledge of the THV-specific characteristics as well as the patient's individual anatomy and position of the index THV in relation to the anatomy. Importantly, the balloon-expandable Sapien THV is the only device that is approved in the USA and Europe for redo-TAVR.

Current implantation recommendations favour high implantation during the initial TAVR, intending to reduce the risk of conduction disorders. However, this approach may be unfavourable for future redo-TAVR, because a high THV is more likely to cause coronary occlusion during redo-TAVR by occluding the entire sinus of Valsalva, particularly when the sinuses of Valsalva are at the lower size limit required for the initial TAVR. Indeed, data have shown that many redo-TAVR combinations could be at risk of coronary obstruction or sinus sequestration. Bench test studies provide information on the best combinations of valves to perform a redo-TAVR and how to position the second THV. They also provide critical insight into the implications of creating a double stent layer and neoskirt that can complicate coronary reaccess and reduce the flow in the sinuses of Valsalva in

diastole. The concepts of leaflet overhang and neoskirt need explanation before discussing CT analysis, bench test studies, and worldwide experience.

Leaflet overhang

Leaflet overhang corresponds to the extent of index THV leaflets that are entrapped by the second THV. Indeed, it contributes to the orifice blockage considering the inward flexing of the unpinned portion of the initial THV leaflets. The lower the second THV is implanted, the higher the percentage of leaflet overhang there will be. It may affect valve performance, durability, and coronary access.

Neoskirt

Neoskirt corresponds to the height of the covered tube which is formed by the leaflets of the initial failed THV with its leaflets blocked in an opened position by the second THV. The height of the neoskirt varies according to the index THV, the design of the second THV, and the height of the initial implantation. It can be measured from 15.4 mm in the case of a balloon-expandable valve in a balloon-expandable valve to 31.6 mm in the case of a balloon-expandable valve positioned high in a self-expanding valve.[28,29] The functional neoskirt corresponds to the height of the neoskirt that is situated above the annular plane and thus is influenced by the initial THV implantation depth. The height of the neoskirt has important implications for the periprocedural risk for coronary obstruction and future coronary access.

Importance of CT Scan Analysis

CT scan analysis of the valve and aortic root is paramount for planning TAVR procedures, and even more so for redo-TAVR. Indeed, when considering redo-TAVR, the CT scan of the initial TAVR as well as the one with the BVF should be carefully assessed. Figures 3 and 4 show an example of redo-TAVR with an Edwards Sapien S3 in a degenerated Evolut THV.

Pre–index TAVR CT analysis

If the preindex CT is available, it permits the evaluation and sizing of the native aortic annulus and root and particularly the identification of unfavourable characteristics such as severe annulus or left ventricular outflow tract calcifications, bicuspid anatomy, anatomy with narrow sinuses of Valsalva, or low coronary ostia.

Indeed, small anatomy presents significant challenges for redo-TAVR owing to the potential higher risk of coronary obstruction or flow impairment as well as patient-prosthesis mismatch.

Pre–redo-TAVR CT analysis

Pre–redo-TAVR analysis is crucial to evaluate the commissural alignment and position of the index THV in relation to the surrounding structures and hence the feasibility of redo-TAVR.[30] A systematic step-by-step approach (Table 1) can help to plan redo-TAVR.[30] It is essential to understand the characteristics (self-expanding vs balloon-expandable, supra- or intra-annular), design (frame/struts, skirt and leaflets), and size of the initial THV. Assessment of the index THV expansion is also important. Measurements should be performed at every stent frame node level to evaluate the neosinus, specifically the valve-to-coronary, valve-to-sinotubular junction for both the left and right coronary sinuses, and valve-to-aorta (VTA) at the neoskirt plane in cases of Evolut-in-Evolut (Fig. 5). It is important to be aware that the neoskirt-to-aorta distance can be shorter than the VTA distance, depending on the second THV size and index THV expansion. Indeed, it has been shown that implantation of a balloon-expandable valve inside a failed Evolut THV can result in up to a 5-mm increase in the Evolut THV diameter, particularly if the balloon-expandable valve is implanted high in the self-expandable valve.[31]

Access to the Coronary Arteries and Risk of Coronary Obstruction

When the THV covers the coronary ostia, as is frequently the case after supra-annular valve implantation, access to the coronary arteries after the initial TAVR may already be challenging, and it becomes even more difficult when a THV commissure is in front of the coronary ostium.

Research using post-TAVR or post–redo-TAVR CT scans is an important element in assessing the risk of sinus sequestration and coronary access failure.[32-34] In the Evolut Low-Risk trial, 204 patients underwent high-quality post-TAVR CT scans, which were analysed with the use of 3Mensio software (Pie Medical Imaging) after virtual Sapien S3 (in different positions) and Evolut THV implantation to assess the feasibility of redo-TAVR.[32] When a Sapien S3 valve was implanted in an Evolut THV, the analysis predicted that 80% of the patients would have a low risk of coronary flow compromise. The most favourable coronary access was achieved when the Sapien S3 valve was implanted at node 4. However, when Evolut-in-Evolut redo-TAVR was performed, only 29% of the patients were considered to be at low risk for coronary flow compromise, and all cases were predicted to be challenging or at high risk of coronary access failure. Figure 6 displays the risk stratification for coronary flow compromise as reported by Grubb et al.[32]

Using post-TAVR CT scans, Ochiai et al. assessed the risk of coronary obstruction associated with the sinus of Valsalva sequestration during redo-TAVR in a cohort of 66 Evolut THV and 345 Sapien 3 THV cases.[33] They used specific CT scan criteria to predict this risk, including THV commissures rising above the sinotubular junction or a distance between the THV and the sinotubular junction < 2 mm. They showed that CT scans allowed the identification of a risk of sinus sequestration at 1 or both coronary ostia in 45.5% of Evolut cases (39.4% for the left ostium and 24.2% for the right) and 2% of Sapien 3 cases (2% for the left ostium and 0.6% for the right ostium). This risk was even higher when the height of the sinuses of Valsalva was low.

Another study assessed coronary access according to post–redo-TAVR CT scans from 45 patients. It revealed that the coronary ostia were located below the upper part of the neoskirt in 90% of supra-annular Medtronic THV cases and in 67% of intra-annular Edwards valve cases.[34] Using various criteria, such as the relationship between the coronary ostia and the neo-skirt, a distance < 3 mm between the THV and the aortic wall, and misalignment of the bioprosthetic

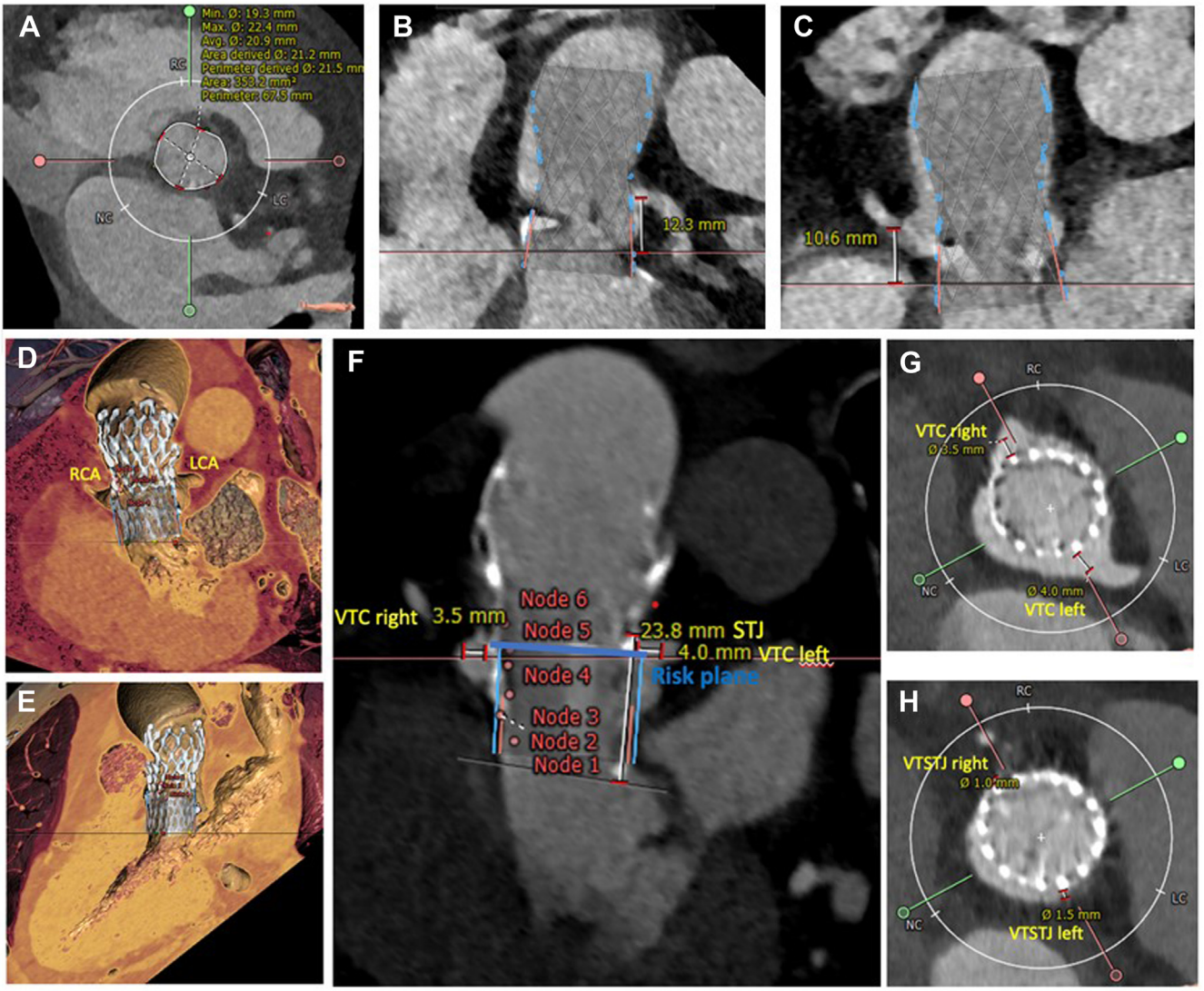

Figure 3. (**A-C**) Pre—index TAVR computed tomography (CT), measurements of the annulus and aortic root, and simulation with a 26-mm Medtronic Evolut transcatheter heart valve (THV). (**D-H**) Pre—redo-TAVR CT scan analysis with the failed 26-mm Evolut R with simulation using a 23-mm Edwards Sapien S3. If the Sapien S3 THV is implanted at node 4, the risk plane (top of the neoskirt) is just below the coronary ostia, which is very important in this case with short valve-to-coronary (VTC) and valve-to-sinotubular junction (VTSTJ) distances. LCA, left coronary artery; RCA, right coronary artery; STJ, sinotubular junction; TAVR, transcatheter atrial valve replacement.

commissures, the risk of coronary access failure was identified in 27% of cases after initial Medtronic THV implantation and in 10% of cases after initial Edwards THV implantation.[34]

Leaflet Modification Techniques

In the context of degenerated surgical aortic prosthetic valves, several publications have demonstrated the feasibility of the BASILICA (**B**ioprosthetic or Native **A**ortic **S**callop **I**ntentional **L**aceration to Prevent **I**atrogenic **C**oronary **A**rtery Obstruction During TAVR) procedure to reduce the risk of coronary obstruction.[35] However, technical complexity limits its use. A new device, the ShortCut system, appears promising as it may facilitate the technique of leaflet modification.[36] Nevertheless, in the context of redo-TAVR, there is limited clinical experience. Bench test studies using the Evolut R, Sapien XT, Sapien 3, and Lotus THVs showed a lower success rate of the BASILICA procedure compared with surgical aortic bioprosthetic valves.[37] An effective leaflet splay was demonstrated for the Sapien XT and Lotus valves, but BASILICA procedures on the Sapien 3 and the Evolut THVs were associated with a less effective leaflet splay. For the Evolut THV, leaflet splay was achieved only high above the annulus. In addition, the commissure of the second THV might obstruct the splayed leaflet after BASILICA. Khan et al. do not recommend "BASILICA TAVR-in-TAVR roulette," because, despite an adequate leaflet splay, it might not help to reaccess the coronary arteries, especially when the predicted mechanism of obstruction is narrow sinuses of Valsalva.[37] In addition, poor commissural alignment makes the leaflet modification technique ineffective. Finally, when performing BASILICA in a nitinol frame, there is a theoretical risk of

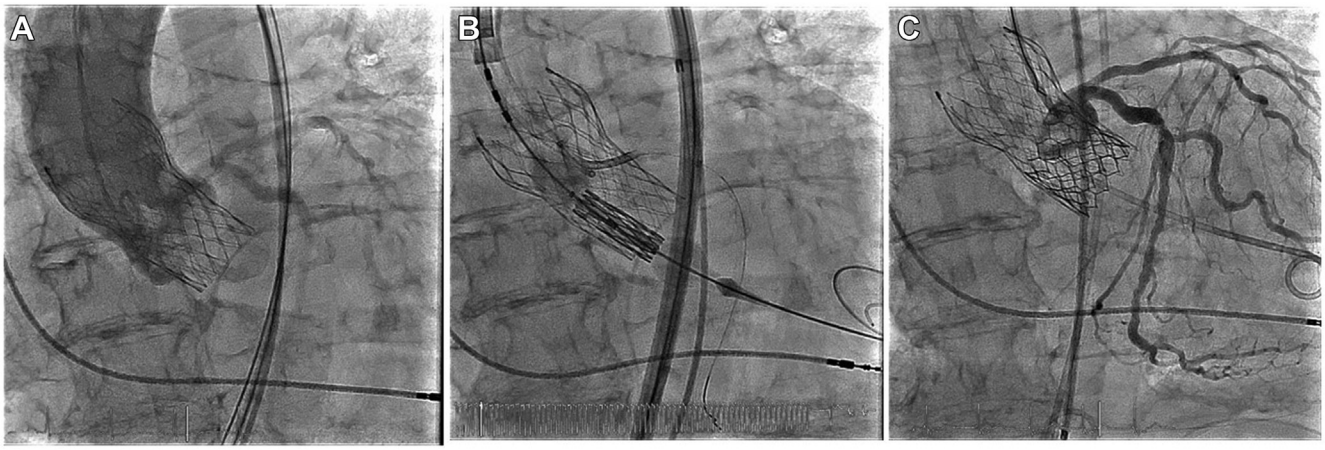

Figure 4. Fluoroscopic images of the redo-TAVR planned in Figure 3. A 23 mm Edwards Sapien S3 is deployed in the 26 mm degenerated Evolut R transcatheter heart valve.

electrical conduction from the nitinol alloy to the aortic annulus (potentially more important with the Evolut R, considering the single and inner layer of tissue), which may result in damage at the annulus level. This question should be answered with the use of bench testing.

Data From the Bench Test Studies

In *EuroIntervention*, Sathananthan et al. reported in 2021 the safety and feasibility of different combinations of valve type, size, and positioning.[38] Indeed, in a Sapien XT and an Evolut R, the implantation of different THVs (Sapien 3, Evolut Pro, Acurate neo, Allegra, and Portico) was tested *ex vivo* using different sizes. The results showed that in a 29 mm Sapien XT, the 27 mm Allegra THV had an insufficient anchoring and the 29 mm Portico embolised in all the different depths of implantation tested. When a 20 mm Sapien 3 was implanted in a 23 mm Evolut R or when a 23 mm Sapien 3 was implanted in a 26/29 mm Evolut R at nominal volume, dislodgement of the Sapien 3 was noted in cases of high implantation. On the other hand, when the Sapien 3 was implanted high in an Evolut R but overexpanded by increasing the volume in the balloon to simulate a larger valve (limited sizes of the different valves were available to perform the study), there was no dislodgement or embolisation. Postprocedure gradients were favourable. In conclusion, the majority of combinations were stable in the first THV, and the different valves implanted in a Sapien XT or an Evolut R were associated with favourable hydrodynamic performances.

In 2022, Akodad et al. published an important *in vitro* study to evaluate the optimal position of a Sapien 3 in an Evolut R, taking into account the expansion of the THV, changes in the height of the neoskirt, overhang of the leaflets, and hydrodynamic performance.[31,39] *In vitro* testing was performed under physiologic testing conditions in collaboration with the Cardiovascular Translational Laboratory (Vancouver, BC and Medtronic (Santa Ana, CA). They implanted the Sapien 3 THV at different depths at nodes 4, 5, and 6 of the Evolut R. Because the Sapien 3 shortens on the "inflow" side (ventricular side), they concluded that it was more predictable to align the Sapien 3 using the outflow (aortic side).

In all the configurations tested, the leaflet function of the Sapien 3 was preserved and the degree of leaflet overhang did not have a significant impact on the hydrodynamic performances of the Sapien 3. In addition, low implantation of a Sapien 3 in an Evolut R may facilitate future coronary access after redo-TAVR.

Meier et al. reported the effect of pre- and postdilation on final THV expansion when *ex vivo* redo-TAVR was performed using a Sapien 3 in a Sapien XT or a Sapien 3.[27] Without pre- or postdilation, the Sapien S3 was underexpanded, particularly in its mid-portion, for all combinations. To obtain nominal expansion with a Sapien S3 in a Sapien S3, the authors concluded that pre- and postdilatation should be performed. When implanting a Sapien S3 in a Sapien XT, the Sapien S3

Table 1. Systematic step-by-step approach to assess the feasibility and plan redo-TAVR

Assess the pre−index TAVR CT scan:
• valve morphology: native bicuspid or tricuspid valve
• native aortic annulus/LVOT and aortic root dimensions
• coronary artery height
• calcium distribution
Confirm the index THV type and size and look at:
• design of stent/struts, skirt and leaflets, supra- or intra-annular
• frame dimensions (height, waist diameter, inflow and outflow diameter)
• skirt and commissure (neoskirt) heights
Determine the mechanism of THV failure:
• stenosis vs regurgitation
• patient prosthesis mismatch
• paravalvular leak
• endocarditis
• thrombosis
Assess the post−index TAVR CT scan
• implantation depth of the TAVR
• appropriate expansion and sizing
• frame dimensions (height, waist diameter, inflow and outflow diameter)
• commissural post alignment
• coronary ostia height and different distances (VTC, VTSTJ, VTA)

Adapted from Tarantini et al.[30]

CT, computed tomography; LVOT, left ventricular outflow tract; TAVR, transcatheter atrial valve replacement; THV, transcatheter heart valve; VTA, valve-to-aorta distance at the neoskirt plane; VTC, valve-to-coronary distance at the midpoint plane; VTSTJ, valve-to-sinotubular junction distance at the sinotubular junction plane.

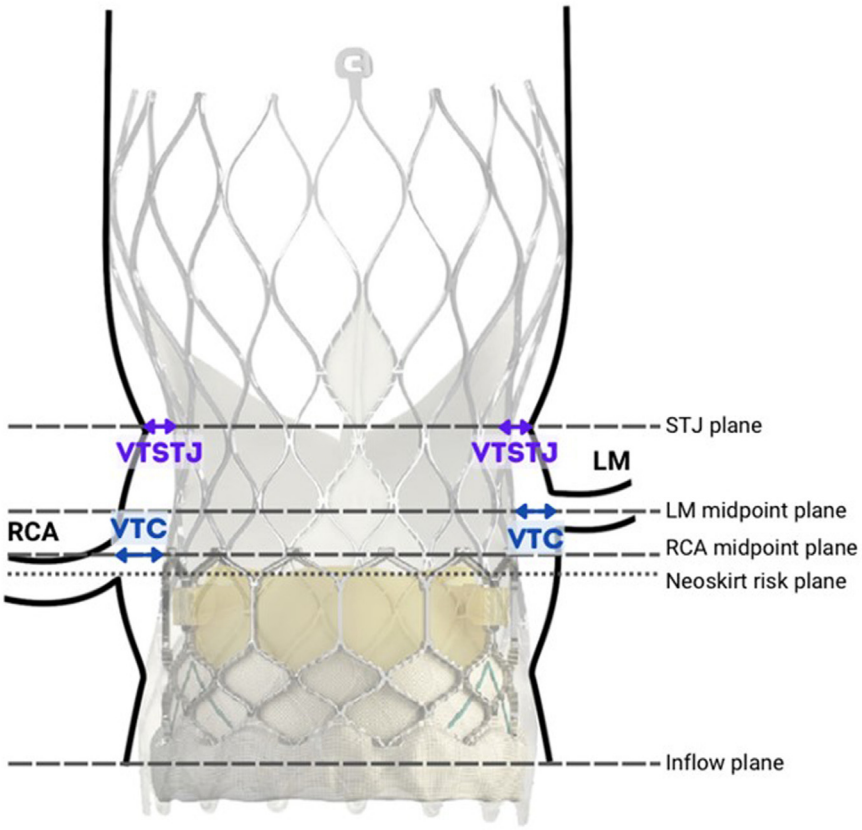

Figure 5. The different measurements to perform on computed tomographic scan when assessing redo-TAVR with a Sapien S3 in an Evolut transcatheter heart valve. LM, left main; RCA, right coronary artery; TAVR, transcatheter atrial valve replacement; VTC, valve-to-coronary distance at the midpoint plane; VTSTJ, valve-to-sinotubular junction distance at the sinotubular junction plane.

remained underexpanded despite pre- and postdilatation. All combinations had acceptable hydrodynamic performance, but the underexpanded samples had worse leaflet pinwheeling. Underexpansion of the Sapien S3 is known to be associated with an increased risk of HALT. When a Sapien S3 was implanted in a Sapien XT, because the Sapien S3 is 20% taller than the Sapien XT it was positioned 20% above the outflow of the Sapien XT to reduce the mean gradient and the transvalvular leak.

Importantly, bench-test studies may not fully reflect how a THV would perform in a degenerated THV implanted in a patient's native annulus.

Worldwide Clinical Experience

Redo-TAVR data are limited. The international Redo-TAVR registry analysed 212 redo-TAVR procedures from 37 centres out of a total of 63,876 TAVRs, corresponding to an incidence of 0.33%.[40] The procedures were performed during the first year after the initial TAVR in 35%, and 65% took place beyond 1 year. The cases treated during the first year are potentially more linked to a procedural failure rather than true SVD. The median time between TAVR and redo-TAVR was 5 years (IQR 3-6 years) when considering the 138 patients with more than 12 months between the initial procedure and redo-TAVR. The majority of cases with BVF during the first year (73%) presented with aortic regurgitation, whereas beyond the first year, the presentation was aortic stenosis (37%), a combination of stenosis and regurgitation (33%), and isolated aortic regurgitation (30%). Redo-TAVR was successful in 85% of cases with a high residual gradient as the primary cause of failure. The mean gradient found at 30 days (12.6 $\pm$ 7.5 mm Hg) remained stable at 12 months (12.9 $\pm$ 9.0 mm Hg). There was no mortality related to the procedure, and patients significantly improved their quality of life. The 30-day and 1-year survival rates were, respectively, 94.6% and 83.6% for cases treated within 1 year after TAVR and 98.5% and 88.3% for those treated more than 1 year after TAVR. The rate of 30-day complications after redo-TAVR was low (mortality 2.9%, stroke 1.4%, coronary occlusion 0.9%). However, the population was selected, and we do not know how many patients were initially evaluated but ultimately refused for a redo-TAVR owing to unfavourable anatomy (ie, risk of coronary obstruction).

Interestingly, similar THV types were used in 59% of cases of redo-TAVR. In the case of a degenerated Medtronic self-expanding THV, redo-TAVR was performed using a similar supra-annular Medtronic THV (off-label) in 55 cases (58% of the redo-TAVRs in Medtronic THVs).[40]

Propensity score matching was applied using the Redo-TAVR registry data, and 165 redo-TAVRs were matched with 165 TAVs-in-SAV.[41] Procedural success was higher in the redo-TAVR group, owing to a lower residual mean aortic

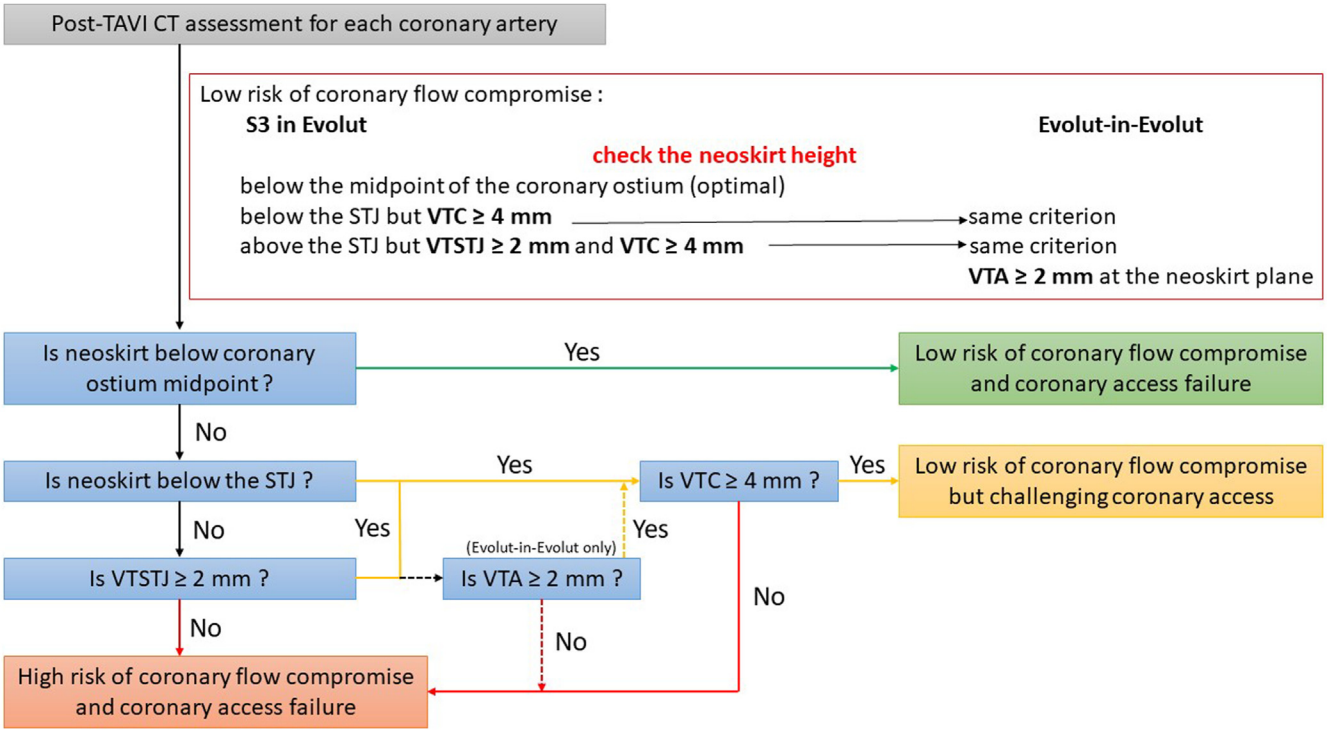

Figure 6. Stratification of the risk of coronary flow compromise with redo-TAVR. CT, computed tomography; STJ, sinotubular junction; TAVR, transcatheter atrial valve; VTA, valve to aorta distance at the neoskirt plane; VTC, valreplacementve-to-coronary distance at the midpoint plane; VTSTJ, valve-to-sinotubular junction distance at the sinotubular junction plane. Adapted from Grubb et al.[32]

gradient, but there was no difference in early safety and mortality up to 1 year. However, the frequency and degree of aortic regurgitation were higher after redo-TAVR than after TAV-in-SAV.

The international TRANSIT (Transcatheter Aortic Valve Replacement for Degenerated Transcatheter Aortic Valves) registry, involving 28 centres and 40,000 TAVRs, also reported a very low redo-TAVR rate of 0.4%, corresponding to 172 patients.[42] In 33% of cases (n = 57), the cause of BVF was stenosis, in 56% of cases (n = 97) regurgitation, and in 11% of cases (n = 18) a combination of both. All patients had a first TAVR that met the success criteria (gradient < 20 mm Hg or paravalvular leak ≤ grade 1). Only 3.5% of the patients underwent redo-TAVR during the first year after TAVR. The EuroSCORE II and the STS score were 8.8 ± 3.4% and 6.1 ± 5.7%, respectively. The success rate of redo-TAVR was 79%, and procedural failure was secondary to a significant residual mean gradient in 14% of cases and an aortic regurgitation in 7%. The second valve was a self-expanding valve in 61%. Similarly to the redo-TAVR registry, more than one-half of the degenerated CoreValve THVs (63%; n = 53) had an Evolut THV implanted, whereas 29% (n = 25) had an Edwards THV. For degenerated Edwards THVs, a second Edwards THV was implanted in 55% of cases (n = 33), whereas an Evolut THV was implanted in 35% (n = 21). The all-cause mortality and in-hospital stroke rates were 4.1% and 3.5%, respectively. At 30 days, all-cause mortality was 7.0%, with no new cases of cardiovascular mortality after hospital discharge. The 30-day rehospitalisation rate was 3.6%. Valves treated for stenosis had a higher mean post–redo-TAVR gradient, and valves treated for regurgitation had a higher rate of postintervention aortic regurgitation. At 12 months, all-cause mortality reached 10% and cardiovascular mortality 5.8%, whereas in the international redo-TAVR registry all-cause mortality was 11.7%. No cases of valve thrombosis were reported and < 1% of coronary occlusion. The very low rate of coronary occlusion was certainly linked to a rigourous selection of cases with the use of CT scans.

The results of these 2 multicentric registries are promising, but follow-up beyond 12 months is lacking and the cases are selected and performed in centres recognised for their expertise. Furthermore, we do not know how many patients with BVF were turned down and what happened to them.

Recently, the international registry EXPLANTORREDO-TAVR included, over 13 years, 396 patients from 29 centres performing both surgical (46.4%; n = 181) and transcatheter (54.3%; n = 215) reintervention for BVF in an admission separate from the index TAVR.[43] Among the 66,760 TAVR patients treated in the participating centres from May 2009 to February 2022, 0.59% (with a rising trend during the study period) required a reintervention for BVF, which is 3 times more than in TAVR-EXPLANT,[20] twice more than in the international Redo-TAVR registry,[40] and one-third more than in TRANSIT.[42] In this registry, TAVR explantation compared with redo-TAVR had a shorter median time from the initial procedure to reintervention (17.6 vs 45.7 months; $P < 0.001$), less SVD (51.9% vs 63.7%; $P = 0.023$), and more prosthesis-patient mismatch (17.1% vs 0.5%; $P < 0.001$) and emergency procedures (38.6% vs 20.8%; $P < 0.001$). In the cohort of TAVR explantation, aortic root

replacement was performed in 10.7% and a concomitant procedure in 55.8% (ie, mitral valve surgery 20.4%, tricuspid valve surgery 2.8%, coronary artery bypass grafting 17.7%, and ascending aorta replacement 6.1%). The decision to perform one or the other approach was made by the local heart teams. There were no differences in the reintervention approach for balloon-expandable valves (54.7% of redo-TAVR vs 45.3% of TAVR explantation; $P = 0.92$) or self-expandable or mechanical valves (54.0% of redo-TAVR vs 46.0% of TAVR explantation; $P = 0.92$). Independent risk factors for mortality after TAVR explantation were dialysis, pulmonary hypertension, and concomitant mitral valve surgery. The 30-day and 1-year mortalities were higher after TAVR explantation (13.6% vs 3.4% [$P < 0.001$] and 32.4% vs 15.4% [$P = 0.001$], respectively), but when surviving the first 30 days after TAVR explantation, the survival was similar to redo-TAVR, with a mortality rate around 30% at 4 years.

Finally, redo-TAVR is less invasive, but TAVR explantation is preferred in operable patients when the anatomy is not favourable for redo-TAVR or a suboptimal hemodynamic result is expected.

Perspective

Redo-TAVR is a desirable approach that is not always feasible, and some patients may benefit from a TAVR explantation with the implantation of a surgical bioprosthetic valve. Lifetime management of aortic stenosis requires anticipation of a second procedure, especially when discussing patients whose life expectancy exceeds valve durability. Indeed, these patients remain a subject of debate. Should we perform SAVR followed by TAV-in-SAV, or TAVR followed by THV explantation with implantation of a surgical bioprosthetic valve, or redo-TAVR?

Considering the lack of data after 12 months for redo-TAVR and the high mortality risk when performing TAVR explantation, a SAVR-first approach remains the safer option for patients who are expected to survive their first bioprosthetic valve.

Chatfield et al. proposed an algorithm for the lifetime management of aortic stenosis by which the choice between surgery and TAVR is made based on the patient's initial anatomy evaluated on a CT scan. They considered the width of the sinuses of Valsalva and the height of the coronary ostia as criteria to select the best initial approach.[44] In the case of first-line surgery, they recommend the implantation of a valve favourable to TAV-in-SAV. Of note, in the Cleveland Clinic series, hospital mortality associated with isolated reoperation after SAVR has declined from 3.4% in 1985 to 1.3% in 2011, which is similar to the mortality after primary isolated SAVR.[45] Therefore, the decision regarding reoperation after SAVR should be made on an individual basis, taking into account valve durability and the need for future reinterventions rather than solely focusing on avoiding reoperation.

In the case of initial TAVR, the lowest risk of coronary access failure is in the configuration of a Sapien THV in a Sapien THV, the intermediate risk occurs when combining a Sapien THV with an Evolut THV regardless of which one is implanted first. Finally, the highest risk is when 2 valves, such as the Evolut, whose frame goes up to the ascending aorta, have been implanted.

TAVR explantation will remain the treatment of choice in patients with endocarditis, patient-prosthesis mismatch, and anatomy unfavourable for a redo-TAVR. Given the growing experience of the surgical community with this potentially challenging procedure, the mortality rate after TAVR explantation has the potential to decrease as lower-risk and younger patients are treated by experienced surgeons. Nevertheless, research and development teams should design devices dedicated to redo-TAVR to secure and facilitate future access to the coronary arteries. Bench test and CT scan studies have shown that implanting a second supra-annular Medtronic THV in a first similar valve is not the optimal strategy to reduce the risk of coronary obstruction and coronary access failure.

Given the potential higher risk of valve thrombosis with 2 THVs, the strategy of anticoagulation or antiplatelet therapy should be evaluated. In addition, patients with a residual mean gradient after redo-TAVR should be closely monitored to detect early degeneration of the new valve. Conceptually, in a small intra-annular 20 mm Sapien THV, a TAVR explantation or a supra-annular self-expanding valve should be favoured to reduce the gradients, especially with an initial post-TAVR mismatch.

Conclusion

Patients often anticipate being able to benefit from a redo-TAVR in the event of BVF after TAVR, despite the lack of long-term data and the risk of unfavourable anatomy. Our understanding of the feasibility of redo-TAVR is constantly improving thanks to bench-test studies and growing worldwide experience. However, much remains unknown. One of the heart team's objectives is to anticipate the need to reaccess the coronary arteries and implant a second or even a third valve when life expectancy may exceed the durability of the bioprosthetic valve. CT scan assessment is crucial in assessing the risk of coronary access failure. At this stage, patients should be informed transparently, and members of the heart team should anticipate possible new procedures when making their initial choice of treatment.

Ethics Statement

This review article followed the relevant ethical guidelines.

Patient Consent

The authors confirm that patient consent does not apply to this article: This is a review article with a retrospective case report using de-identified data in Figure 3; therefore the institutional review board did not require consent from the patient, who had signed a consent to be included in our local and national TAVR registry.

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Disclosures

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