# Durability and clinical experience using a bovine pericardial prosthetic aortic valve



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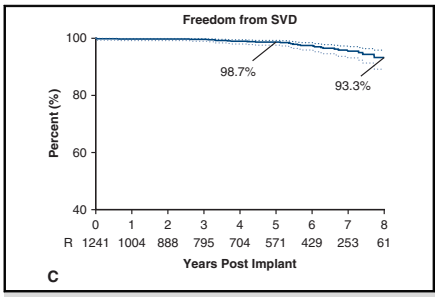
## ABSTRACT

**Objectives:** To report the implant experience and long-term outcomes from a large tertiary care referral center on surgical aortic valve replacement (SAVR) with a contemporary stented pericardial bioprosthesis with anticalcification treatment.

**Methods:** Patients underwent SAVR using the Trifecta valve at a single institution. Endpoints included procedural outcomes, adverse events, prosthesis–patient mismatch (PPM), long-term survival, and valve durability. Follow-up included 30-day, 6-month, and annual assessments. Treatment for structural valve deterioration (SVD) included surgical explant and valve-in-valve (V-in-V) transcatheter aortic valve implantation (TAVI).

**Results:** SAVR was performed in 1241 patients (median age, 73.5 ± 6.4 years; 54% male; median logistic EuroSCORE, 7.8) with concomitant procedures in 713 cases (57.5%). Intraprocedural mortality was 1.4%, and 30-day mortality was 6.0%. At hospital discharge, 68 patients (5.5%) had moderate PPM, and no patients had severe PPM. Adverse events included cardiac arrhythmias (44.7%, mostly atrial fibrillation), respiratory failure (22.9%), acute renal failure requiring temporary renal replacement therapy (12.9%), and low cardiac output syndrome (3.3%). Follow-up data were available over a total of 5469 patient-years (median duration of follow-up, 4.7 years). Freedom at 8 years from all-cause mortality, valve-related mortality, reoperation for SVD (redo SAVR or V-in-V TAVI), and endocarditis were 78.4%, 98.0%, 93.3%, and 96.5%, respectively. Of the 30 patients with SVD, 17 were treated by V-in-V TAVI and 13 underwent surgical explant.

**Conclusions:** Outcomes from this large single-center cohort at increased surgical risk demonstrate excellent long-term durability of the Trifecta valve for SAVR and feasibility of treating SVD by V-in-V TAVI. (J Thorac Cardiovasc Surg 2021;161:1742-9)




**Survival from structural valve deterioration.**

### CENTRAL MESSAGE

In a large high-risk cohort (median follow-up, 4.7 years; 5469 patient-years), the Trifecta aortic bioprosthesis achieved a low incidence of valve explant for structural valve deterioration and low valve-related mortality.

### PERSPECTIVE

Durability and low rates of valve-related complications are key objectives of surgical aortic valve replacement (SAVR). In the present study, SAVR with the Trifecta valve was associated with relatively low incidence of explantation for structural valve deterioration (SVD). Moreover, valve-in-valve transcatheter aortic valve implantation (TAVI) proved to be a safe and feasible treatment for SVD, avoiding surgical explant. These outcomes facilitate survival from valve-related mortality in high-risk patients.

See Commentaries on pages 1750 and 1751.

Surgical aortic valve replacement (SAVR) is an established therapy for the treatment of aortic stenosis or aortic regurgitation, using a variety of mechanical and bioprosthetic valves. The Trifecta bioprosthetic aortic valve (Abbott Structural Heart, St Paul, Minn) is a trileaflet stented valve designed for supra-annular placement during SAVR. The

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**Abbreviations and Acronyms**

CEP = Carpentier–Edwards Perimount
EOA = effective orifice area
IQR = interquartile range
PPM = prosthesis–patient mismatch
SAVR = surgical aortic valve replacement
SVD = structural valve deterioration
TAVI = transcatheter aortic valve implantation
V-in-V = valve-in-valve

Scanning this QR code will take you to the table of contents to access supplementary information.

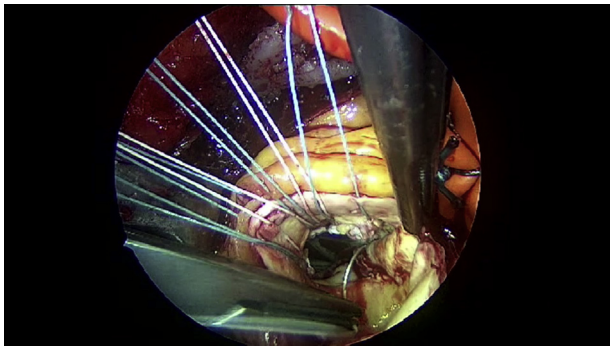
valve leaflets are manufactured from a single bovine pericardial tissue strip that is externally mounted onto the stent frame, with the objective of maximizing hemodynamic performance. The titanium alloy stent is covered with porcine pericardial tissue, allowing for only tissue-to-tissue contact during valve function. A next-generation Trifecta valve (Trifecta GT), introduced in 2016, has additional features intended to enhance durability and improve ease of implantation. The Trifecta valve is available in 6 sizes, ranging in annulus diameter from 19 to 29 mm.

Durability outcomes of the Trifecta valve have been published from relatively large cohorts over follow-up periods of up to 6 years.[1-4] Mid-term follow-up of a large series of patients implanted with the Trifecta valve at our institution has been reported previously.[5] Here we report on more than 1200 patients receiving the Trifecta valve with follow-up of up to 10 years and a specific focus on procedural outcomes, safety, overall survival, and durability. In addition, we examined the feasibility of a transcatheter aortic valve implantation (TAVI) valve-in-valve (V-in-V) procedure for failed Trifecta bioprostheses.

## MATERIALS AND METHODS

This study includes procedural and follow-up data of consecutive patients who underwent SAVR with the Trifecta bioprosthetic valve at our institution. The Leipzig University Medical Center is a large-volume tertiary referral center where high-risk patients are frequently referred for surgical management. Throughout the study, consistent surgical implantation techniques were used, as described in our earlier report.[5] Patients were indicated for SAVR according to the European Society of Cardiology/European Association for Cardio-Thoracic Surgery guidelines for the management of valvular heart disease.[6] The Trifecta valve was selected on an individual patient basis following an evaluation of patient characteristics, surgical aspects, and the surgeon's expertise and preference.

Intraoperative access was obtained by complete or upper partial median sternotomy with central cannulation for extracorporeal circulation.



**VIDEO 1.** Aortic valve replacement with a Trifecta valve. Video available at: https://www.jtcvs.org/article/S0022-5223(19)33473-7/fulltext.

Myocardial protection consisted of antegrade or retrograde administration of blood cardioplegia with mild hypothermia or antegrade administration of crystalloid cardioplegia (Bretschneider; Dr Franz Köhler Chemie, Bensheim, Germany). After native valve excision and complete decalcification of the annulus, the annulus diameter was determined using standard metric Trifecta sizers. Valve implantation was performed using 2-0 Tevdek Teflon reinforced U-stitches in all patients. This horizontal mattress suturing technique led to a slightly supra-annular position of the bioprosthesis (Video 1). Concomitant cardiovascular surgery was performed during the same procedure, if indicated.

Multiplane transesophageal echocardiography was used intraoperatively in all patients. Postoperative evaluation with transthoracic echocardiography was performed before hospital discharge to evaluate for stenosis with mean and peak gradients, signs of intraprosthetic regurgitation, and appropriate effective orifice area (EOA) according to valve size. Postoperative medical treatment included warfarin for 3 months (target international normalized ratio, 2.0 to 3.0), continued thereafter as indicated for reasons other than SAVR, such as atrial fibrillation (AF) or thrombosis. Follow-up assessments were scheduled at 30 days and 6 months postimplantation and yearly thereafter. Follow-up involved either direct patient contact by our outpatient department or per telephone interview, via information obtained from a family physician if the patient was not reachable, or in the event of death, via information in the national registration database.

Primary endpoints included procedural outcomes, early and late adverse events (defined as events occurring $\leq$30 days and >30 days after SAVR, respectively), overall survival, and structural valve deterioration (SVD) at long-term follow-up. SVD was defined as severe bioprosthetic dysfunction (stenosis or insufficiency exclusive of infection, thrombosis or paravalvular leak) as determined by reoperation, transcatheter intervention, autopsy, or clinical investigation (including periodic echocardiographic surveillance).[7] Treatment for SVD included surgical explant of the valve prosthesis or reintervention by means of V-in-V TAVI. Suitability for V-in-V TAVI was based on the transvalvular gradient and indexed EOA after initial valve implantation.

Prosthesis–patient mismatch (PPM) was determined at hospital discharge and based on the EOA,[8] with severe and moderate PPM defined as an indexed EOA <0.65 $cm^2/m^2$ and between 0.65 and 0.85 $cm^2/m^2$, respectively.

### Statistical Analysis

Continuous and categorical variables are presented as mean $\pm$ standard deviation and number (percentage), respectively. Kaplan-Meier (KM) estimates were determined to characterize survival. A competing-risk analysis was implemented by considering 4 mutually exclusive time-related outcomes: alive without SVD or endocarditis (event-free survival), death without SVD or endocarditis, SVD, and endocarditis. The rates of late

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**TABLE 1. Patient demographics and baseline characteristics (n = 1241)**

| Characteristic | Value |
|---|---|
| Age, y, mean ± SD | 73.5 ± 6.4 |
| Male, sex, n (%) | 672 (54.1) |
| Body mass index, kg/m$^2$, mean ± SD | 28.3 ± 4.8 |
| Body surface area, m$^2$, mean ± SD | 1.9 ± 0.2 |
| Left ventricular ejection fraction, %, mean ± SD | 55.4 ± 12.3 |
| Left ventricular ejection fraction <35%, n (%) | 78 (6.3) |
| Primary indication, n (%) | |
| Aortic valve stenosis | 867 (69.9) |
| Aortic valve insufficiency | 374 (30.1) |
| Logistic EuroSCORE, % | |
| Median | 7.8 |
| IQR | 4.9–15.1 |
| Dialysis, n (%) | 37 (3.0) |
| Creatinine, mg/dL, mean ± SD | 1.15 ± 0.69 |
| Arterial hypertension, n (%) | 1120 (90.2) |
| Pulmonary hypertension >60 mm Hg, n (%) | 382 (30.8) |
| Smoker, n (%) | 323 (26.0) |
| Chronic obstructive pulmonary disease, n (%) | 51 (5.6) |
| Diabetes mellitus, n (%) | 451 (36.3) |
| Hyperlipidemia, n (%) | 810 (65.3) |
| Previous cerebrovascular accident, n (%) | 92 (7.4) |
| Peripheral vascular disease, n (%) | 267 (21.5) |
| New York Heart Association class, n (%) | |
| I | 95 (7.7) |
| II | 439 (35.4) |
| III | 614 (49.5) |
| IV | 92 (7.4) |
| Coronary artery disease, n (%) | |
| None | 692 (55.8) |
| 1-vessel disease | 184 (14.8) |
| 2-vessel disease | 162 (13.1) |
| 3-vessel disease | 202 (16.3) |
| Previous percutaneous coronary intervention, n (%) | 131 (10.6) |
| Previous myocardial infarction, n (%) | 125 (10.1) |
| Previous cardiac surgery, n (%) | 73 (5.9) |
| Active endocarditis, n (%) | 89 (7.2) |
| Type A aortic dissection, n (%) | 3 (0.2) |
| Cardiogenic shock, n (%)* | 113 (9.1) |

*SD*, Standard deviation; *IQR*, interquartile range. *Cardiogenic shock was assessed by clinical criteria (systolic blood pressure <90 mm Hg for at least 30 minutes or the need for supportive measures to maintain a systolic blood pressure ≥90 mm Hg and end-organ hypoperfusion) and hemodynamic criteria (cardiac index <2.2 L/minute/m$^2$ of body surface area, pulmonary capillary wedge pressure ≥15 mm Hg).

**TABLE 2. Procedural Characteristics**

| Characteristic | Value |
|---|---|
| Timing of surgical aortic valve replacement, n (%) | |
| Elective | 909 (73.2) |
| Urgent/emergency | 332 (26.8) |
| Implanted valve, n (%) | |
| First-generation Trifecta | 1018 (82.0) |
| Trifecta GT | 223 (18.0) |
| Valve size, n (%) | |
| 19 mm | 30 (2.4) |
| 21 mm | 404 (32.6) |
| 23 mm | 479 (38.6) |
| 25 mm | 248 (20.0) |
| 27 mm | 70 (5.6) |
| 29 mm | 10 (0.8) |
| Procedure duration, min, mean ± SD | 188 ± 68 |
| Bypass time, min, mean ± SD | 102 ± 42 |
| Cross-clamp time, min, mean ± SD | 74 ± 30 |
| Concomitant procedures, n (%) | 713 (57.5) |

*SD*, Standard deviation.

safety outcomes (except for death) were estimated using a cumulative incidence function accounting for death as a competing risk. Statistical analyses were performed using SPSS version 22 (IBM, Armonk, NY), SAS version 9.4 (SAS Institute, Cary, NC) and R version 3.5.1 (R Project for Statistical Computing, Vienna, Austria).

## RESULTS

### Patients

Between November 2007 and September 2018, 1241 patients (mean age, 73.5 ± 6.4 years; 54% male) underwent SAVR. Demographic data and baseline status of the cohort are presented in Table 1. While being an all-comers cohort, the study population was considered at increased surgical risk, as indicated by the logistic EuroSCORE (median, 7.8; interquartile range [IQR], 4.9-15.1) which reflects the presence of 1 or more comorbidities in the majority of patients, the high prevalence of endocarditis and cardiogenic shock, and the relatively high percentage of emergency procedures. Twenty-four patients (1.9%) underwent SAVR within 48 hours after experiencing myocardial infarction.

### Procedural Data

Procedural characteristics are summarized in Table 2. No aortic root enlargement procedures were performed, whereas concomitant procedures were performed in 713 patients (57.5%). In 1 isolated case, the implanted Trifecta valve showed acute grade II aortic insufficiency. This valve was successfully replaced by another Trifecta valve. No structural failure or other issues were identified on analysis of the explanted valve by the manufacturer. Intraprocedural mortality was 1.4% (n = 17 patients). Paravalvular leakage was observed postprocedure in 1 patient and was treated by reoperation.

**TABLE 3. Early and late safety outcomes**

| Adverse event | Early events, n (%) (N = 1241) | Late events, n | Cumulative incidence, %* (95% CI) | | |
|---|---|---|---|---|---|
| | | | 1 year | 5 years | 8 years |
| Mortality | 75 (6.0) | 151 | 13.0 (11.3-15.0) | 17.9 (15.7-20.2) | 23.0 (19.5-26.9) |
| Cardiac arrhythmias | 554 (44.7) | 0 | — | — | — |
| Respiratory failure requiring prolonged respiratory support | 279 (22.5) | 5 | 0 | 0.4 (0.1-1.0) | 1.0 (0.3-2.3) |
| Acute renal failure requiring dialysis | 160 (12.9) | 0 | — | — | — |
| Gastro-intestinal complications | 134 (10.8) | 3 | 0 | 0.2 (0.05-0.8) | 0.8 (0.1-2.6) |
| Low cardiac output syndrome | 41 (3.3) | 0 | — | — | — |
| Intra-aortic balloon pump | 40 (3.2) | 0 | — | — | — |
| Extracorporeal membrane oxygenation | 19 (1.5) | 0 | — | — | — |
| Major stroke | 38 (3.1) | 4 | 0 | 0 | 0.7 (0.1-2.8) |
| Myocardial infarction | 5 (0.4) | 2 | 0 | 0.2 (0.04-0.7) | 0.2 (0.04-0.7) |
| Sepsis | 43 (3.5) | 4 | 0 | 0.4 (0.1-1.0) | 0.4 (0.1-1.0) |
| Deep sternal wound infection | 7 (0.6) | 2 | 0.2 (0.04-0.6) | 0.2 (0.04-0.6) | 0.2 (0.04-0.6) |
| Cardiopulmonary resuscitation | 57 (4.6) | 5 | 0.09 (0.0-0.5) | 0.4 (0.1-1.1) | 0.7 (0.2-1.6) |
| Pacemaker or ICD implantation | 85 (2.4) | 0 | — | — | — |
| Reexploration for bleeding | 92 (7.4) | 0 | — | — | — |
| Reoperation | 3 (0.2) | 55 | 1.6 (1.0-2.4) | 3.5 (2.5-4.8) | 8.6 (5.9-1.2) |
| Explant for structural valve deterioration | 1 (0.1) | 12 | 0.2 (0.03-0.7) | 0.8 (0.4-1.5) | 1.4 (0.7-2.5) |
| Valve-in-valve TAVI for structural valve deterioration | 0 (0.0) | 17 | 0 | 0.3 (0.1-0.9) | 4 .1 (2.1-7.2) |
| Endocarditis | 0 (0.0) | 26 | 1.2 (0.7-2.0) | 2.2 (1.4-3.2) | 3.0 (1.7-4.9) |
| Pericardial effusion | 2 (0.2) | 0 | — | — | — |

*CI*, Cardiac index; *ICD*, implantable cardiac defibrillator; *TAVI*, transcatheter aortic valve implantation. *Cumulative incidence of each event in which mortality is a competing risk.

Re-exploration for bleeding was performed in 92 patients (7.4%). During the index hospitalization, 24 patients (1.9%) underwent additional surgery not related to the aortic valve or to the SAVR procedure. At hospital discharge, moderate PPM was present in 68 patients (5.5%), and no cases of severe PPM were observed.

## Safety Outcomes

Early and late safety outcomes are presented in Table 3. Frequent complications restricted to the early postoperative period included cardiac arrhythmias (n = 554; 44.7%), mostly atrial fibrillation, respiratory failure (n = 284; 22.9%), and acute renal failure necessitating dialysis (n = 160; 12.9%). Of the 38 early major strokes, 29 (2.3% of all patients) occurred within 72 hours post-SAVR. A new permanent pacemaker or an implantable cardioverter defibrillator was implanted in 80 patients (6.4%) and 5 patients (0.4%), respectively.

## Follow-Up

Follow-up, either by direct patient contact or by information obtained from a family physician or the national registration database, was complete in all patients, resulting in a total follow-up experience of 5469 patient-years (mean follow-up, 4.6 ± 2.9 years; median, 4.7 years) and with follow-up in 18 patients extending up to 10 years. Freedom from all-cause and valve-related mortality, SVD, and endocarditis are shown in Figure 1. A total of 226 patients died during follow-up, including 23 valve-related deaths. Survival from all-cause and valve-related death at 8 years post-SAVR was 78.4% and 98.0%, respectively. SVD was observed in 30 patients (2.4%) who were treated for this condition (median time to treatment, 5.5 years; IQR, 3.6-6.7 years) by either surgical explant (n = 13) or V-in-V TAVI (n = 17) (Table 4). Patients with SVD had no significant PPM after the index procedure, except for 2 patients with moderate PPM, including 1 patient who underwent TAVI and 1 who underwent surgical valve replacement. For the 17 patients treated with V-in-V TAVI, the original bioprosthetic valve sizes were 21 mm (n = 5), 23 mm (n = 7), 25 mm (n = 3), and 27 mm (n = 2). The median indexed EOA after initial SAVR in these 17 patients was 0.98 $cm^2/m^2$ (IQR, 0.92-1.06 $cm^2/m^2$). At 8 years after SAVR, the actuarial freedom from treatment for SVD was

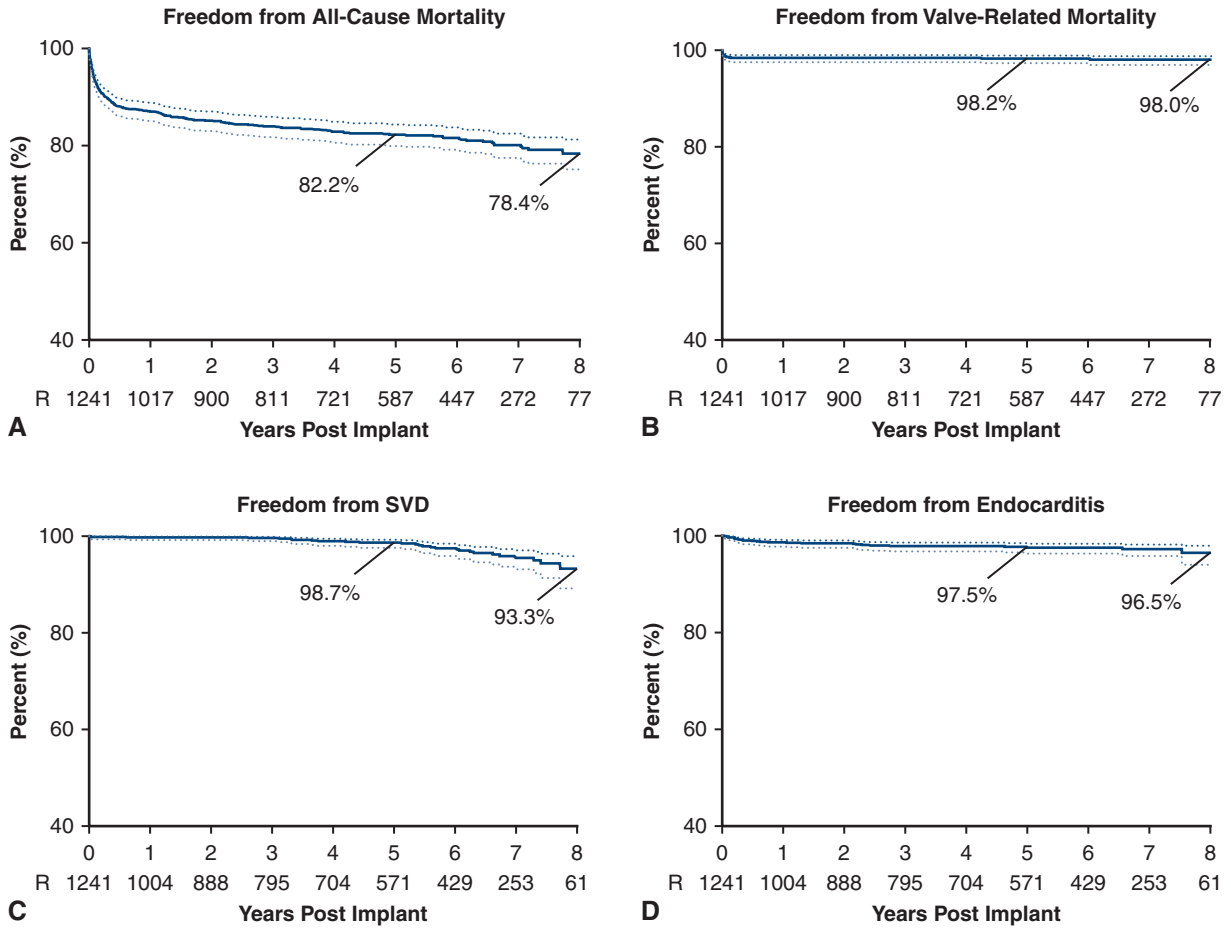


**FIGURE 1.** Kaplan-Meier survival curves for freedom from all-cause mortality (A), valve-related mortality (B), structural valve deterioration (C), and endocarditis (D). *Dotted lines* represent 95% confidence bounds. *R*, Patients at risk; *SVD*, structural valve deterioration.

93.3%, with similar rates for patients age <65 years and ≥65 years (89.8 ± 4.8% and 93.8 ± 1.8%, respectively; $P = .155$). During follow-up, 3 patients who had been treated for SVD by V-in-V TAVI (all implanted with the CoreValve; Medtronic; Minneapolis, Minn) died from causes unrelated to the aortic valve and with no evidence of coronary obstruction observed on computed tomography scan.

**TABLE 4. Details of patients with structural valve deterioration (n = 30)**

| Parameter | Surgical explant (n = 13) | V-in-V TAVI (n = 17) |
|---|---|---|
| Left ventricular ejection fraction, %, mean ± SD | 60.7 ± 7.5 | 51.2 ± 13.6 |
| Mean aortic transvalvular gradient, mm Hg, mean ± SD | 42.6 ± 13.1 | 38.8 ± 14.8 |
| Aortic regurgitation, n | 3 | 6 |
| Aortic stenosis, n | 7 | 5 |
| Both, n | 3 | 6 |
| Time to treatment, y, mean ± SD | 4.1 ± 2.8 | 6.0 ± 1.6 |

*V-in-V*, Valve-in-valve; *TAVI*, transcatheter aortic valve implantation; *SD*, standard deviation.

In addition to the 13 patients undergoing surgical valve explant for SVD, surgical valve explant was performed due to endocarditis in 26 patients. There was no intraoperative mortality associated with treatment for SVD or endocarditis. In 2 other patients, pericardial effusion was resolved surgically. The 8-year freedom from all-cause reoperation (including TAVI V-in-V procedures) was 90.0 ± 2.0%.

A competing-risk analysis, accounting for 4 mutually exclusive outcomes, showed an 8-year actuarial event-free survival for 71.1% of the patients (Figure 2). Events in the remaining patients included death without intervention for SVD or endocarditis (20.5%), SVD (5.4%; all cases treated by surgical valve explant or V-in-V TAVI), and endocarditis (3.0%). All patients with endocarditis underwent surgical valve explant and thus were no longer at risk for SVD.

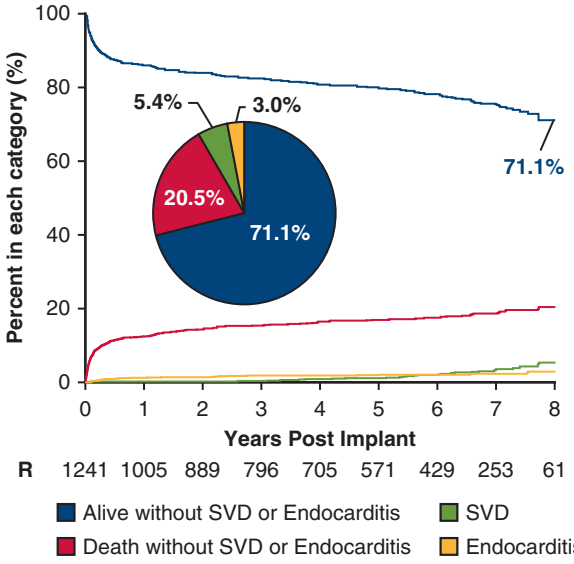


**FIGURE 2.** Competing-risk analysis results accounting for 4 mutually exclusive outcomes, including structural valve deterioration (*SVD*), endocarditis, death without SVD or endocarditis, and alive without SVD or endocarditis. All patients diagnosed with SVD underwent either surgical valve explant or valve-in-valve transcatheter aortic valve implantation. All patients with endocarditis underwent surgical valve explant and thus were no longer at risk for SVD. *R*, Patients at risk.

## DISCUSSION

This report comprises a comprehensive 10-year follow-up of SAVR using the Trifecta valve in a large cohort from a tertiary care referral center. Our study cohort was at increased surgical risk, reflected by the mean age of 73.5 ± 6.4 years, a median EuroSCORE of 7.8, urgent or emergency SAVR in 26.8% including active endocarditis in 7.2% and cardiogenic shock in 9.1%, and concomitant procedures in 57.5% of the patients. Despite the high-risk profile, the reported outcomes from this large cohort show relatively low mortality and very good valve durability.

### Overall and Valve-Related Mortality

Survival from all-cause mortality in our cohort was 78.4% at 8 years after surgery. The initial decline in survival from all-cause mortality (Figure 1, *A*) most likely reflects the patients' overall health status, which was characterized by frequent comorbidities and urgent or emergent need for SAVR. At 1 year post-SAVR, overall survival decreased by an average of 1.2% per year. In particular, survival from valve-related mortality was 98.0% at 8 years after the index procedure. These survival rates are consistent with the outcomes observed in an earlier multicenter, long-term follow-up study on the Trifecta valve, reporting 6-year survival from all-cause and valve-related death of 87.9% and 98.3%, respectively.[2] Moreover, our outcomes compare favorably with those reported from the Carpentier-Edwards Perimount (CEP) valve (Edwards Lifesciences, Irvine, Calif), which, like the Trifecta valve, is a stented aortic bioprosthesis intended for supra-annular positioning. In the postapproval cohort implanted with the CEP valve from approximately 20 years ago, the 8-year survival rates from all-cause and valve-related mortality were 65.4% and 92.3%, respectively.[9] From the more recent



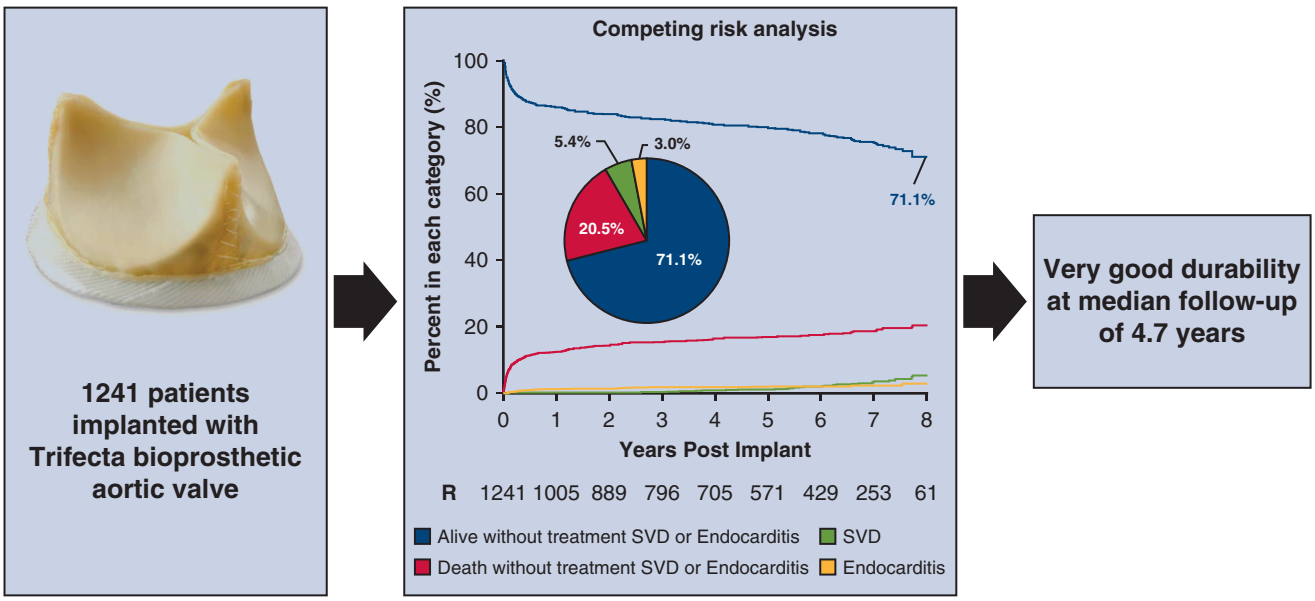


**FIGURE 3.** The Trifecta valve is associated with an extremely low degree of prosthesis–patient mismatch, relatively low rates of all-cause and valve-related mortality, and very good durability at median follow-up. *R*, Patients at risk; *SVD*, structural valve deterioration.

Magna Ease version of this device, 5-year survival rates from overall and valve-related mortality were 82.7% and 93.8%, respectively.[10] Based on these results, patients implanted with the Trifecta valve appear to have a comparable survival.

### PPM

The hemodynamic performance of the Trifecta valve and the low incidence of PPM, as reported earlier by our group[5] and others[1,3] may have contributed to these favorable survival outcomes. PPM has been shown to be associated with overall mortality both short-term and long-term, particularly in patients aged <70 years, those with BMI <30 kg/m$^2$ or with left ventricular dysfunction.[8,11,12] A multicenter study on 1014 patients implanted with the Trifecta valve[1] reported moderate and severe PPM in 22.8% and 2.0%, respectively. Similar rates have been reported from other valves,[10,13,14] whereas comparative studies showed superior PPM outcomes for the Trifecta valve.[15,16] In our cohort, only 5.5% of the patients showed moderate PPM, and no severe PPM was observed, despite the absence of any surgical measures for annular enlargement.

### Durability

In this study, the freedom from treatment for SVD was 98.7% at 5 years and 93.3% at 8 years post-SAVR. Similar outcomes were reported for the CEP valve (ie, 90.2% rate at 10 years,[17] although patients with untreated SVD were included in this cohort) and the new-generation CEP Magna Ease valve (99.1% at 5 years[10]). Along with the comparable risk of SVD overall, the Trifecta valve appears to be associated with a relatively low incidence of early failure, with 11 of the 30 SVD cases occurring within the first 5 years post-SAVR and a median time to SVD of 5.5 years after SAVR. Follow-up of the new-generation Trifecta GT valve, more recently implanted in 223 patients in our cohort, is limited to short-term outcomes only. Nevertheless, we believe that these outcomes reflect the minimum performance of this new-generation valve, and longer-term durability should be confirmed by future results from our cohort.

One aspect that may reduce the adverse consequences of SVD is the contemporary option to perform V-in-V TAVI as an alternative to surgical explant and redo valve replacement. However, earlier reported outcomes have raised the concern of coronary obstruction[18] during V-in-V for bioprostheses with externally mounted leaflets and without proper pre-procedure planning. In the present cohort, 17 out of 30 cases of SVD were treated by V-in-V TAVI with overall satisfactory outcomes, including no cases of coronary obstruction. In addition, V-in-V TAVI in these patients resulted in highly acceptable PPM outcomes. The option of V-in-V TAVI for SVD with low risk of coronary obstruction was also reported for other surgical valves in general,[19] and the feasibility of this procedure for the Trifecta valve was indicated by earlier clinical and in vitro reports.[20,21] As TAVI became a more common procedure and our confidence with the V-in-V technique grew during the study period, V-in-V TAVI was performed more frequently for failing Trifecta prostheses.

Our competing-risk analysis indicated that 71.1% of the patients experienced an 8-year event-free survival, while 20.5% of the patients died without reintervention for SVD or endocarditis. Similar analyses for the CEP valve showed an 8-year event-free survival of approximately 60% and mortality of approximately 36%.[22,23] However, these rates were reported from studies not yet using V-in-V TAVI as an option to treat SVD. Nevertheless, the event-free survival in our cohort (ie, alive with no reintervention for SVD or endocarditis) was markedly higher than in these studies, irrespective of the way SVD was treated. When examining only those cases from our cohort in whom surgical explant was performed, the freedom from surgical explant due to SVD at 8 years was 98.3% for the Trifecta valve.

### Limitations

This study was limited by the fact that it was a single-center study without an active control group. Observations may require confirmation in a randomized study or an appropriate propensity-matched study. Nevertheless, we consider our results representative of the real-world clinical practice and an all-comers population of patients requiring SAVR.

Another limitation was that routine follow-up echocardiography was not performed at our institution. Although this may have led to underestimation of SVD rates, we believe that this likelihood is small, given the fact that regular echocardiographic follow-up is routinely performed by referring physicians post-SAVR in Germany, and patients with symptomatic valvular problems are routinely referred back to tertiary centers for intervention.

## CONCLUSIONS

Continued follow-up of this large cohort confirms our earlier reported data[5] and shows that the Trifecta valve is associated with an extremely low degree of PPM, relatively low rates of all-cause and valve-related mortality, and very good longer-term durability (Figure 3). V-in-V TAVI appears to be a feasible option for treating structural deterioration of this valve, potentially reducing the adverse consequences associated with valve failure.

### Conflict of Interest Statement

Dr Borger discloses relationships with Abbott, Edwards Lifesciences, Medtronic, and CryoLife. All other authors have nothing to disclose with regard to commercial support.

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**Key Words:** Trifecta, structural valve deterioration, prosthesis-patient mismatch

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