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Valve-in-Valve TAVR versus Redo Surgical Aortic Valve Replacement: Early Outcomes

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Abstract

Objective This study aimed to assess short-term outcomes of patients with failed aortic valve bioprosthesis undergoing valve-in-valve transcatheter aortic valve replacement (ViV-TAVR) or redo surgical aortic valve replacement (rSAVR).

Methods Between 2009 and 2019, 90 patients who underwent ViV-TAVR ($n = 73$) or rSAVR ($n = 17$) due to failed aortic valve bioprosthesis fulfilled the inclusion criteria. Groups were compared regarding clinical end points, including in-hospital all-cause mortality. Patients with endocarditis and in a need of combined cardiac surgery were excluded from the study.

Results ViV-TAVR patients were older (78.0 ± 7.4 vs. 62.1 ± 16.2 years, $p = 0.012$) and showed a higher prevalence of baseline comorbidities such as atrial fibrillation, diabetes mellitus, hyperlipidemia, and arterial hypertension. In-hospital all-cause mortality was higher for rSAVR than in the ViV-TAVR group (17.6 vs. 0%, $p < 0.001$), whereas intensive care unit stay was more often complicated by blood transfusions for rSAVR patients without differences in cerebrovascular events. The paravalvular leak was detected in 52.1% ViV-TAVR patients compared with 0% among rSAVR patients ($p < 0.001$).

Conclusion ViV-TAVR can be a safe and feasible alternative treatment option in patients with degenerated aortic valve bioprosthesis. The choice of treatment should include the patient's individual characteristics considering ViV-TAVR as a standard of care.

Keywords
- valve-in-valve
- redo surgery
- deteriorated aortic valve bioprosthesis
- cardiac surgery
- early outcomes

Introduction

Redo surgical aortic valve replacement (rSAVR) is associated with incremental operative risk compared with primary SAVR. Data derived from the Society of Thoracic Surgeons (STS) National Database of patients with previous aortic valve surgery undergoing rSAVR indicates a twofold increase of short-term mortality (4.6%) compared with first-time SAVR (2.3%).[1] Valve-in-valve transcatheter aortic valve replacement (ViV-TAVR) for failed bioprosthesis is a less invasive procedure compared with rSAVR, and it is likewise

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linked to good short-term outcomes.[2] Nevertheless, the Valve-in-Valve International Data (VIVID) Registry showed a 7.6% 30-day mortality in an intermediate to high surgical risk population (STS predicted risk of mortality of 9.8%).[3] ViV-TAVR has been associated with procedure-specific complications such as coronary obstruction, high postoperative transvalvular gradients, and cerebrovascular events.[4]

Balancing procedure-specific risks of ViV-TAVR against potential complications associated with rSAVR, ViV-TAVR has increasingly become a valuable alternative to redo surgery. The minimally invasive transcatheter technique offers shorter operation time and less surgical trauma, as well as the avoidance of cardiopulmonary bypass (CPB).[5] Otherwise, redo surgery is still necessary for patients with endocarditis and offers a reasonable treatment option for patients with unfavorable vascular access routes or risks for patient-prosthesis mismatch (PPM). The goal of this study was to compare postoperative outcomes, including in-hospital all-cause mortality of patients with failed aortic valve bioprosthesis undergoing ViV-TAVR or rSAVR at our institution.

Materials and Methods

All patients enrolled in this retrospective, single-center data-analysis had previous surgical aortic valve replacement with degeneration of the aortic valve bioprosthesis and the need for reintervention between 2009 and 2019. Stratification to either ViV-TAVR or rSAVR procedure was based on the patient evaluation by the interdisciplinary Heart Team. Patients were identified using the institutional database with the retrospective extraction of relevant data such as preoperative baseline characteristics, procedural data, postoperative complications, and mortality. The main inclusion criteria was a previous surgical aortic valve replacement using a bioprosthesis with the need for reintervention due to stenosis or the insufficiency of the aortic valve bioprosthesis. Patients presenting with bioprosthetic valve endocarditis and in need of combined surgeries were excluded from the study. Finally, 90 patients were selected, of which 73 (81.1%) patients underwent ViV-TAVR, and 17 (18.9%) patients underwent rSAVR. The Ethics Committee of the Medical Faculty of the University of Cologne approved this project.

Patients undergoing ViV-TAVR had a preoperative CT angiography to assess annular and aortic root morphology as well as the vascular access route.

In the ViV-TAVR group, the new prosthesis was implanted into the degenerated aortic bioprosthesis using a transfemoral, transaortic, or transapical approach. In the rSAVR group, the degenerated aortic bioprosthesis was replaced through a median sternotomy followed by cardioplegic cardiac arrest and CPB.

Definitions

All data on perioperative and postinterventional complications were documented and listed according to the Valve Academic Research Consortium-2 consensus (VARC-2).[6] According to the Acute Kidney Injury Network, acute kidney injury was defined based on RIFLE classification.[7,8] Heart Team is considered collaboration and dedication across medical specialties to offer optimal patient-centered care, with a requirement that the cardiovascular surgeon and interventional cardiologist jointly participate during the procedure.[9]

Statistics

Statistical analyses were performed using IBM SPSS Statistics version 26 (IBM Corp, Armonk, New York, United States). Descriptive data for categorical variables of groups were compared using Fisher's exact test, expressed as percentages. Continuous variables indicated with mean ± standard deviation were compared using the unpaired *t*-test for parametric or the Mann-Whitney U test for non-parametric variables. All reported *p*-values are two-sided, and *p*-values of <0.05 were considered statistically significant.

Results

Baseline Parameters

Patients included in the study ($n = 90$) were stratified into two groups depending on the selected procedure: ViV-TAVR ($n = 73$, 81.1%) and rSAVR group ($n = 17$, 18.9%). All baseline characteristics are presented in ►**Table 1**. Patients in the ViV-TAVR group were older (78.0 ± 7.4 vs. 62.1 ± 16.2 years, $p = 0.012$). ViV-TAVR patients showed a higher prevalence of comorbidities such as atrial fibrillation, diabetes mellitus, hyperlipidemia, and arterial hypertension compared with the rSAVR group. ViV-TAVR patients had significantly more impaired preoperative renal function (53.4 vs. 23.5%, $p = 0.032$) than the rSAVR patients. The STS risk score showed no significant differences between the two groups (6.4 ± 3.1 vs. 6.4 ± 3.2, $p = 0.392$). Other clinical baseline characteristics did not differ significantly.

The most common indication for reintervention was stenotic degeneration of the previously implanted bioprosthesis in ViV-TAVR and rSAVR groups.

Surgical and Interventional Parameters

Group-specific interventional and surgical data are presented in ►**Table 2**. The mean duration of ViV-TAVR procedures was shorter compared with rSAVR operations (90.8 ± 35.0 vs. 220.7 ± 47.2 minutes, $p = 0.043$).

In the ViV-TAVR group, the most common vascular access route was femoral (84.9%), followed by transapical (9.6%) and transaortic (5.5%) access. Balloon-expandable valves were implanted in 25 cases (34.2%) (Edwards Lifesciences, Irvine, California, United States: Sapien 3 and XT), whereas self-expandable prostheses were implanted in a total of 48 cases (65.8%) (Medtronic, Minneapolis, United States: CoreValve Evolut; Symetis SA, Ecublens, Switzerland/Boston Scientific, Marlborough, Massachusetts: Acurate neo). The median radiation exposure time was 16 minutes, and contrast media applicated was 101.7 ± 72 mL. Endotracheal intubation was implemented in 33 patients (45.2%) for the ViV-TAVR procedure. ViV-TAVR procedures were complicated by cardiopulmonary resuscitation in four patients (5.5%). No other

Table 1 Demographic and preoperative data of patients undergoing ViV-TAVR and rSAVR ($n = 90$)

	ViV-TAVR group ($n = 73$, 81.1%)	rSAVR group ($n = 17$, 18.9%)	*p*-Value
Age (years)	78.0 ± 7.4	62.1 ± 16.2	**0.012**
Male gender no. (%)	32 (43.8%)	11 (64.7%)	0.121
BSA (m^2)	1.89 ± 0.21	1.88 ± 0.19	0.434
BMI (kg/m^2)	27.0 ± 5.0	25.9 ± 5.0	0.434
Coronary artery disease—no. (%)	34 (46.6%)	6 (35.3%)	0.399
LVEF (%)	51.4 ± 12	51.1 ± 12	0.224
Previous MI no. (%)	17 (23.3%)	9 (52.7%)	**0.015**
Pacer implantation no. (%)	9 (12.3%)	3 (17.6%)	0.561
Atrial fibrillation no. (%)	34 (46.6%)	2 (11.8%)	**0.008**
Diabetes mellitus type II no. (%)	31 (42.5%)	2 (11.8%)	**0.018**
Hyperlipidemia no. (%)	48 (65.8%)	5 (29.4%)	**0.006**
Arterial hypertension no. (%)	70 (95.9%)	9 (52.7%)	**<0.001**
Pulmonary hypertension no. (%)	31 (42.5%)	3 (17.6%)	**0.057**
PAD no. (%)	13 (17.8%)	2 (11.8%)	0.547
COPD no. (%)	20 (27.4%)	1 (5.9%)	0.059
Current tobacco use no. (%)	7 (9.6%)	4 (23.5%)	0.114
TIA no. (%)	5 (6.8%)	0 (0%)	0.267
Stroke no. (%)	9 (12.3%)	0 (0%)	0.127
CKD no. (%)	39 (53.4%)	4 (23.5%)	**0.032**
Stage I	12 (16.4%)	0 (0%)	
Stage II	16 (21.2%)	3 (17.6%)	
Stage III	8 (11%)	1 (5.9%)	
Stadium IV	3 (4.1%)	0 (0%)	
STS score	6.4 ± 3.1	6.4 ± 3.2	0.392

Abbreviations: BSA, body surface area; BMI, body mass index; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; LVEF, left ventricular ejection fraction; MI, myocardial infarction; PCI, percutaneous coronary intervention; PAD, peripheral arterial disease; rSAVR, redo surgical aortic valve replacement; TIA, transient ischemic attack; ViV-TAVR, valve-in-valve transcatheter aortic valve replacement.

Table 2 Intraoperative and interventional data of patients undergoing ViV-TAVR and rSAVR ($n = 90$)

	ViV-TAVR group ($n = 73$, 81.1%)	rSAVR group ($n = 17$, 18.9%)	*p*-Value
Indication for surgery no. (%)			
• Primary AV stenosis	51 (69.9%)	11 (64.7%)	0.679
• Primary AV regurgitation	22 (30.1%)	6 (35.3%)	0.679
Duration (minutes)	90.8 ± 35.0	220.7 ± 47.2	**0.043**
CPB time (minutes)	–	118.2 ± 36.0	
Cross clamp time (minutes)	–	71.8 ± 18.1	
Access route no. (%)		–	
• Transfemoral	62 (84.9%)	–	
• Transapical	7 (9.6%)	–	
• Transaortic	4 (5.5%)	–	

Table 2 (*Continued*)

	ViV-TAVR group ($n = 73$, 81.1%)	rSAVR group ($n = 17$, 18.9%)	*p*-Value
Implanted prosthesis no. (%)		–	
• Edwards Sapien XT	10 (13.7%)	–	
• Edwards Sapien 3	15 (20.5%)	–	
• CoreValve Evolut	47 (64.4%)	–	
• Symetis Accurate Neo	1 (1.4%)	–	
General anesthesia with intubation	33 (45.2%)	–	
Radiation exposure time (minute)	16 [4;53]	–	
Contrast media (mL)	101.7 ± 72	–	
Cardiopulmonary resuscitation no. (%)	4 (5.5%)	–	

Abbreviations: AV, aortic valve; CPB, cardiopulmonary bypass; rSAVR, redo surgical aortic valve replacement; ViV-TAVR, valve-in-valve transcatheter aortic valve replacement.

periinterventional complications were observed according to VARC-2 criteria, such as conversion to open-heart surgery, unplanned use of CPB, coronary obstruction, valve malposition, ventricular septal perforation, mitral valve damage, or cardiac tamponade.

In the rSAVR group, the average CPB time was 118.2 ± 36.0 minutes, and the average aortic clamp time was 71.8 ± 18.1 minutes.

Postoperative Parameters

Outcome data regarding the postoperative course of patients are displayed in ►**Table 3**. The postoperative course of rSAVR patients was complicated by rethoracotomy ($n = 2$, 11.8%), use of intra-aortic balloon pump (IABP) ($n = 1$, 5.9%), and extracorporeal membrane oxygenation (ECMO) ($n = 2$, 11.8%) with no corresponding events in the ViV-TAVR group. Patients in the rSAVR group needed more blood transfusions than the ViV-TAVR patients (4.1 ± 8.2 vs. 0.7 ± 1.5 units, $p = 0.001$). Five patients (6.8%) in the ViV-TAVR group and one patient (5.9%) in the rSAVR group developed a new 3rd degree atrioventricular (AV) block with subsequent implantation of a permanent pacemaker ($p = 0.886$).

Twelve ViV-TAVR patients (16.4%) developed vascular complications postinverventionally according to VARC-2 criteria. Among them, nine patients (12.3%) developed an inguinal hematoma at the vascular access site. A pseudoaneurysm of the femoral access artery was observed in three patients (4.1%). Five patients (6.9%) underwent a local surgical revision due to persistent bleeding from the transfemoral vascular access site. The incidence of gastrointestinal bleeding showed no significant difference between ViV-TAVR and rSAVR group (1.4 vs. 5.9%, $p = 0.256$).

The rate of acute kidney injury (AKI) was similarly distributed among both groups (34.7 vs. 29.4%, $p = 0.677$), with no significant difference in the rate of new dialysis (5.5 vs. 5.9%, $p = 0.948$). Patients in the rSAVR group had a longer in-hospital stay than ViV-TAVR patients (12.3 ± 7.3 vs. 10.6 ± 9.2 days, $p = 0.316$). In-hospital all-cause mortality was significantly lower for ViV-TAVR patients than in rSAVR patients (0 vs. 17.6%, $p < 0.001$). Two patients died due to fulminant cardiogenic shock, and one patient died due to multiorgan failure because of septic shock.

Echocardiographic Characteristics

The preoperative left ventricular ejection fraction did not differ significantly between the two groups. Postinterventionally, a mild paravalvular leak (PVL) was present in 32 patients (47.8%) and a moderate PVL in six patients (9%) in the ViV-TAVR group, whereas no PVL occurred in the rSAVR group ($p < 0.001$). The mean and maximal transvalvular gradients, as well as the maximal velocity, did not show a significant difference between the two groups; however, the effective orifice area was larger in rSAVR patients compared with ViV-TAVR patients (1.8 ± 0.7 vs. $1.28 \pm 0.4\,cm^2$, $p = 0.716$).

Discussion

The presented dataset's scope was to analyze short-term outcomes in patients treated for bioprosthetic aortic valve degeneration. Patients with endocarditis or failed mechanical prostheses were excluded from the analysis. All 90 included patients received either ViV-TAVR or redo-surgery, respectively. Both groups include patients with high procedure-specific risks for adverse events and incorporate characteristic differences since ViV-TAVR patients were older than rSAVR patients. The presented results indicate higher in-hospital mortality for rSAVR patients. As rSAVR patients more often had relevant postoperative complications, including higher short-term mortality, ViV-TAVR was linked to the presence of a postinterventional paravalvular leak and slightly higher transvalvular gradients.

The need for strict anticoagulation therapy after mechanical aortic valve replacement combined with the possibility of a ViV-TAVR procedure favors bioprostheses' implantation even in middle-aged patients. Thus, implantation rates of aortic valve bioprostheses currently increase, and consequently, evaluation of the different treatment options for patients with failed aortic valve bioprostheses gains an important role.[10] As long as randomized controlled trials

Table 3 Postoperative data of patients undergoing ViV-TAVR and rSAVR ($n = 90$)

	ViV-TAVR group ($n = 73$, 81.1%)	rSAVR group ($n = 17$, 18.9%)	*p*-Value
Postoperative resuscitation no. (%)	2 (2.7%)	0 (0%)	0.490
Rethoracotomy no. (%)	–	2 (11.8%)	–
IABP no. (%)	0 (0%)	1 (5.9%)	**0.037**
ECMO no. (%)	0 (0%)	2 (11.8%)	**0.003**
Blood transfusion (units)	0.7 ± 1.5	4.1 ± 8.2	**0.001**
New 3rd degree AV block	5 (6.9%)	1 (5.9%)	0.886
New pacemaker implantation no. (%)	5 (6.9%)	1 (5.9%)	0.886
Tracheostomy no. (%)	0 (0%)	0 (0%)	–
Cerebrovascular events no. (%)	2 (2.7%)	0 (0%)	0.788
• TIA	1 (1.4%)	0 (0%)	0.627
• Stroke	1 (1.4%)	0 (0%)	0.627
Postoperative delirium no. (%)	17 (23.3%)	3 (17.6%)	0.614
GI bleeding no. (%)	1 (1.4%)	1 (5.9)	0.256
Vascular complications no. (%)			
• Inguinal hematoma	9 (12.3%)	–	
• Pseudoaneurysm	3 (4.1%)	–	
• Surgical revision of access site	5 (6.9%)	–	
• Intravascular stenting	1 (1.4%)	–	
Acute kidney injury no. (%)	25 (34.7%)	5 (29.4%)	0.677
• Stage I	5 (6.9%)	2 (11.8%)	0.496
• Stage II	13 (17.8%)	1 (5.9%)	0.222
• Stage III	7 (9.5%)	2 (11.8%)	0.788
New dialysis no. (%)	4 (5.5%)	1 (5.9%)	0.948
In-hospital stay (day)	10.6 ± 9.2	11.6 ± 7.3	**0.001**
ICU stay (day)	3.0 ± 4.0	3.4 ± 3.6	0.126
In-hospital mortality no. (%)	0 (0%)	3 (17.6%)	**<0.001**
Immediate mortality no. (%)	0 (0%)	1 (5.9%)	**0.037**
Postoperative echocardiography			
Ejection fraction (%)	51.9 ± 11.9	51.6 ± 13.0	0.870
Mean gradient (mm Hg)	17.2 ± 10.1	11.0 ± 6.6	0.503
Max gradient (mm Hg)	30.2 ± 17.4	19.7 ± 11.2	0.140
Max velocity (m/s)	2.7 ± 0.8	2.1 ± 0.6	0.828
Effective orifice area (cm^2)	1.28 ± 0.4	1.8 ± 0.7	0.716
Paravalvular leak no. (%)	38 (52.1%)	0 (0%)	**<0.001**
• Mild	32 (43.8%)	0 (0%)	**0.001**
• Moderate	6 (8.2%)	0 (0%)	0.221
Moderate PPM	6 (8.2)	5 (29.4)	**0.016**

Abbreviations: AV block, atrioventricular block; ECMO, extracorporeal membrane oxygenation; GI bleeding, gastrointestinal bleeding; IABP, intra-aortic balloon pump; Immediate mortality, mortality within 48 hours after the procedure; PPM, patient-prosthesis mismatch; rSAVR, redo surgical aortic valve replacement; TIA, transient ischemic attack; ViV-TAVR, valve-in-valve transcatheter aortic valve replacement.

do not address this issue, retrospective analyses have to guide decision-making.

In an overall comparable patient cohort, Erlebach et al. investigated short-term outcomes and 1-year survival in patients treated for failed surgical bioprosthetic valves by minimally invasive transcatheter technique or redo surgery. Analyzing 102 consecutive patients showed no relevant difference in 30-day all-cause mortality but a significantly

higher survival rate for redo surgery patients after 1 year. Incidence rates of myocardial infarction and stroke were equally distributed; however, post-procedural need for dialysis and the paravalvular leak was higher in ViV-TAVR patients. As the authors conclude that redo surgery should continue to stay the standard treatment option, they also state that the valve-in-valve technique may be reasonable for a specific subgroup of patients.[5] In the presented dataset, the mortality rate was in favor of valve-in-valve patients compared with three deaths in the redo surgery group. Thus, our results do not support the assumption of redo-surgery as a standard treatment option. The mortality rate (17.6%) for rSAVR patients in the presented dataset was higher than previously reported in the literature (2.6–5.7%).[5,11,12] This could be attributed to preoperative comorbidities (CKD, LVEF $< 35\%$) and postoperative complications that these patients developed (AKI, rethoracotomy, ECMO, and IABP implantation). The higher mortality rate could also be due to the small group size of 17 patients who underwent the rSAVR.

In a larger cohort of 350 patients undergoing ViV-TAVR or redo-surgery due to failed stented aortic bioprosthesis, Sedeek et al. described similar operative mortality in both groups. In contrast, procedure-related complications occurred less frequently in the ViV-TAVR group.[12] However, the echocardiographic assessment revealed higher transvalvular gradients with higher rates of a severe PPM after ViV-TAVR compared with rSAVR, while aortic regurgitation was remarkably rare ($<1\%$) and was equally distributed between the two groups. We similarly detected favorable echocardiographic findings in patients who underwent redo-surgery with lower mean and maximal transvalvular gradients and no paravalvular leak than the ViV-TAVR cohort. However, we could not foresee the long-term effect of marginally higher gradients and an increased rate of paravalvular leaks in the ViV-TAVR group, given the higher short-term mortality in the operated cohort.[13]

Interestingly, the calculated PPM favored ViV-TAVR patients with six patients with a moderate PPM (8.2 vs. 29.4%, $p = 0.016$), which does not explain the postoperative echocardiographic parameters' hemodynamics. Moreover, Bleiziffer et al. showed that neither severe PPM nor elevated gradients were linked to adverse clinical events, including 1-year mortality in patients after ViV-TAVR.[14] These retrospective studies, including the presented dataset, do not include procedures implementing valve fracturing (cracking) to achieve more favorable postinterventional hemodynamic results.[15] This technique could reduce transvalvular gradients after ViV-TAVR and abolish the advantageous echocardiographic findings for rSAVR in future studies.

The five rSAVR patients (29.4%) who developed a moderate PPM postoperatively had a smaller new bioprosthesis than the old bioprosthesis. Fallon et al. reported that severe and moderate PPMs increase the mortality risk after a surgical aortic valve replacement.[16] Moderate PPM could be one of the reasons for the higher mortality in the reported rSAVR group.

Evaluating evidence from retrospective trials covering a total of 500 patients, Tam et al. reported favorable outcomes for ViV-TAVR patients compared with redo surgery patients with degenerated aortic bioprosthesis in a systematic review with meta-analysis.[11] The authors describe comparable mortality rates but, finally, a lower need for pacemaker implantation and dialysis after the ViV-TAVR. Most recently, a U.S.-nationwide study of matched high-risk patients detected superior outcomes for valve-in-valve technique compared with redo surgery regarding 30-day mortality and bleeding complications.[17]

Several reasons limit the interpretation of our results. The study is a retrospective data analysis simultaneously incorporating imbalances regarding preoperative baseline characteristics of both treatment groups. The patients undergoing ViV-TAVR were markedly older and presented with a higher prevalence of relevant comorbidities. Additionally, none of the ViV-TAVR patients underwent valve fracturing, ultimately resulting in higher postinterventional transvalvular gradients.

In conclusion, our results provide insights into current clinical outcomes for ViV-TAVR and rSAVR patients with higher mortality rates in the redo-group in a single-center setting. Patients presenting with degenerated aortic valve bioprostheses should be treated according to their individual risk profile. ViV-TAVR should become the standard of care for patients with isolated degenerated aortic valve bioprosthesis. rSAVR should be considered an option for patients with unfavorable vascular access or other contraindications for ViV-TAVR.

Authors' Contribution

Since our author list overcomes the limit of seven authors per manuscript, we would like to elaborate on the individual authors' contribution. A.C. and E.K. have contributed equally to the writing of the manuscript. K.E., C.W., and V.M. did the literature search as well as data extraction. P.B.R. and M.A. made the statistical interpretation of data. T.R., S.B., and T.W. were responsible for the critical revision of the manuscript.

Conflict of Interest

None declared.

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