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ORIGINAL RESEARCH

Impact of transcatheter heart valve type on outcomes of surgical explantation after failed transcatheter aortic valve replacement: the EXPLANT-TAVR international registry

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ABSTRACT

BACKGROUND: There are limited data on the impact of transcatheter heart valve (THV) type on the outcomes of surgical explantation after THV failure.

AIMS: We sought to determine the outcomes of transcatheter aortic valve replacement (TAVR) explantation for failed balloon-expandable valves (BEV) versus self-expanding valves (SEV).

METHODS: From November 2009 to February 2022, 401 patients across 42 centres in the EXPLANT-TAVR registry underwent TAVR explantation during a separate admission from the initial TAVR. Mechanically expandable valves (N=10, 2.5%) were excluded. The outcomes of TAVR explantation were compared for 202 (51.7%) failed BEV and 189 (48.3%) failed SEV.

RESULTS: Among 391 patients analysed (mean age: 73.0±9.8 years; 33.8% female), the median time from index TAVR to TAVR explantation was 13.3 months (interquartile range 5.1-34.8), with no differences between groups. Indications for TAVR explantation included endocarditis (36.0% failed SEV vs 55.4% failed BEV; p<0.001), paravalvular leak (21.2% vs 11.9%; p=0.014), structural valve deterioration (30.2% vs 21.8%; p=0.065) and prosthesis-patient mismatch (8.5% vs 10.4%; p=0.61). The SEV group trended fewer urgent/emergency surgeries (52.0% vs 62.3%; p=0.057) and more root replacement (15.3% vs 7.4%; p=0.016). Concomitant cardiac procedures were performed in 57.8% of patients, including coronary artery bypass graft (24.8%), and mitral (38.9%) and tricuspid (14.6%) valve surgery, with no differences between groups. In-hospital, 30-day, and 1-year mortality and stroke rates were similar between groups (all p>0.05), with no differences in cumulative mortality at 3 years (log-rank p=0.95). On multivariable analysis, concomitant mitral surgery was an independent predictor of 1-year mortality after BEV explant (hazard ratio [HR] 2.00, 95% confidence interval [CI]: 1.07-3.72) and SEV explant (HR 2.00, 95% CI: 1.08-3.69).

CONCLUSIONS: In the EXPLANT-TAVR global registry, BEV and SEV groups had different indications for surgical explantation, with more root replacements in SEV failure, but no differences in midterm mortality and morbidities. Further refinement of TAVR explantation techniques are important to improving outcomes.

KEYWORDS: aortic stenosis, degenerative valve, TAVI

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The expansion of transcatheter aortic valve replacement (TAVR) to younger, lower-risk patients with longer life expectancies will likely see an increase in future valve reintervention[1,2]. While redo-TAVR (transcatheter aortic valve [TAV]-in-TAV) remains an attractive option for transcatheter heart valve (THV) failure in carefully selected patients, not all patients will be eligible, due to indication or unfavourable anatomy[3-5]. On the other hand, surgical explantation of the THV (TAVR explant) can be offered to most patients who are surgical candidates, in addition to those presenting with endocarditis or concomitant pathologies that need to be addressed with open surgery. However, the reported mortality and morbidities associated with TAVR explant are not negligible, as evidenced by a recent analysis of the Society of Thoracic Surgeons (STS) database[6] and our prior study from the EXPLANT-TAVR registry[7]. TAVR explant is also technically more challenging, unlike first-time or even redo-surgical aortic valve replacement (SAVR), with respect to lacking a clean tissue plane for TAVR removal and often involving surrounding structures which may be influenced by the type of THV explanted. The clinical impact of the THV type (balloon-expandable valve [BEV] versus self-expanding valve [SEV]) after TAVR explant remains unknown. We therefore performed an in-depth evaluation comparing patients undergoing TAVR explant for failed BEV versus failed SEV.

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Impact on daily practice

In light of the significant mortality and morbidity associated with TAVR explant for THV failure, the clinical impact of THV type (BEV vs SEV) after TAVR explant remains unknown. In our study using the EXPLANT-TAVR global registry, compared to patients with failed BEV, those with failed SEV had fewer cases of endocarditis and more PVL as primary indications for TAVR explant, with no differences in SVD and PPM between groups. Mortality after TAVR explant was high (16% at 30 days; 33% at 1 year) but was not associated with the type of THV explanted after adjusting for baseline differences and performing subgroup analysis, despite more frequent aortic root replacement and fewer urgent/emergency cases in SEV explant.

Patients and methods

DATA SOURCE

The EXPLANT-TAVR registry is a multicentre, international registry with data compiled from 42 centres worldwide and includes patients who underwent surgical explantation of a THV after TAVR during a separate hospital admission. Our study design has been previously described[7]. Since all participating institutions contributed cases after obtaining local institutional review board approvals, the requirement to obtain patient consent was waived. The 30-day and longer-term follow-up of all subjects in this registry were adjudicated separately by each individual institution.

PATIENT POPULATION

We retrospectively analysed data from adult patients who underwent TAVR explant between November 2009 and February 2022. Mechanisms of TAVR failure included structural valve deterioration (SVD), prosthesis-patient mismatch (PPM), endocarditis, paravalvular leak (PVL), and valve migration. The primary indication for TAVR explant and primary reasons for exclusion from redo-TAVR were systematically determined by the multidisciplinary Heart Team at each respective institution. Patients undergoing concomitant coronary artery bypass graft (CABG) or valvular procedures were included. All TAVR explants performed during the same admission as the initial TAVR procedure were excluded as well as operations for mechanically expandable valve failure (N=10, 2.5%) **(Figure 1)**. The final study cohort was stratified into patients undergoing TAVR explant for failed BEV and failed SEV.

OUTCOMES OF INTEREST AND DEFINITIONS

The primary outcomes of interest were intraoperative, in-hospital, 30-day, and 1-year mortality, and cumulative mortality at 3 years. The secondary outcomes of interest included the median interval from the index TAVR procedure to TAVR explant, in-hospital rates of complications, the median intensive care unit (ICU) and hospital length of stay, 30-day readmission rates and stroke rates at 30 days and 1 year. All indications for TAVR explant and clinical endpoints, including SVD, and PVL severity, were reported according to the Valve Academic Research Consortium-3 criteria[8]. The timing of TAVR explant was classified, based on the time interval between the diagnosis of needing surgery and undergoing the surgical explantation, as previously described[7]. The interval from index TAVR to TAVR explant was calculated, in months, as the time between the dates of the two procedures. Survival was reported in months from the date of TAVR explant to mortality date or the date of last follow-up if the patient was still alive.

STATISTICAL ANALYSIS

Continuous variables are reported as means with standard deviation or median with interquartile range (IQR), depending on the distribution of data. Normal distribution was examined using the Kolmogorov-Smirnov test. Categorical variables are reported as percentages. Depending on the distribution of data, differences between the failed BEV and failed SEV groups were detected using the Student's 2-sample t-test or Mann-Whitney U test for the continuous variables and the chi-squared or Fisher's exact test for the

Abbreviations

BEV	balloon-expandable valve	**SAVR**	surgical aortic valve replacement	**TAVR**	transcatheter aortic valve replacement
CPB	cardiopulmonary bypass	**SEV**	self-expanding valve	**THV**	transcatheter heart valve
PPM	patient-prosthesis mismatch	**STS**	Society of Thoracic Surgeons		
PVL	paravalvular leak	**SVD**	structural valve deterioration		

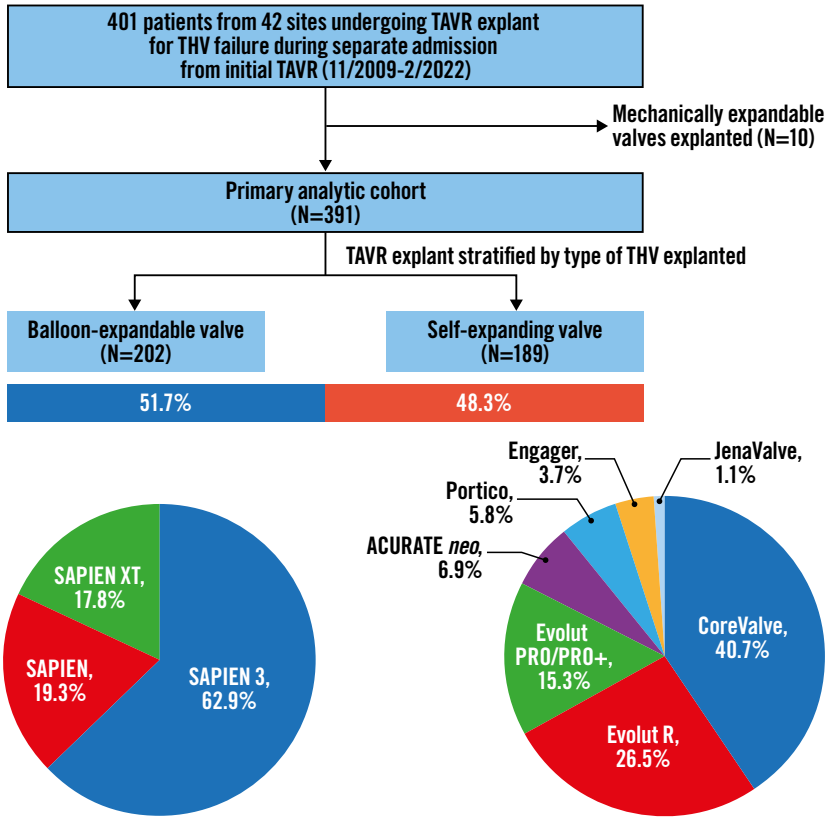


Figure 1. *Study population. From November 2009 to February 2022, 401 patients from 42 sites in the international EXPLANT-TAVR registry underwent TAVR explant for transcatheter valve failure during a separate admission from the initial TAVR. All TAVR explants for mechanically expandable valves (N=10, 2.5%) were excluded. Outcomes of 202 (51.7%) BEV were compared with 189 (48.3%) SEV. BEV: balloon-expandable valve; SEV: self-expanding valve; TAVR: transcatheter aortic valve replacement; THV: transcatheter heart valve*

categorical variables. Kaplan-Meier survival analysis was used to assess actuarial freedom from all-cause mortality, separately for the overall cohort, and stratified by THV type at TAVR explant.

An exploratory analysis to identify independent predictors of all-cause mortality after TAVR explant within each THV group was performed. Since model building was limited by the relatively low number of mortality events, only forward, stepwise, multivariable Cox regression models were developed. All variables with p<0.10 from univariable analysis, in addition to clinically relevant variables chosen *a priori* (including age and STS-Predicted Risk of Mortality [PROM] at index TAVR) and deemed to influence the outcomes of interest, were considered in multivariable Cox regression analysis, and only those with p<0.05 were included in the final model. Subgroup analysis was performed to determine the impact of THV type on all-cause mortality in various prespecified subgroups of interest. All statistical tests were 2-tailed, with p<0.05 considered significant. Statistical analyses were performed using SPSS version 24.0 (IBM).

Results

BASELINE CLINICAL CHARACTERISTICS AT INDEX TAVR

A total of 391 patients underwent TAVR explant for failed BEV (N=202, 51.7%) or failed SEV (N=189, 48.3%), as per the inclusion criteria. Baseline clinical characteristics are summarised in **Table 1**. The mean age was 73.0±9.8 years, and 33.8% were women, with no differences between groups. There were also no differences in the prevalence of comorbidities between the two groups, with the exception of more hostile mediastinum (10.9% vs 4.1%; p=0.017) and previous cardiac surgery (45.7% vs 31.7%; p=0.006) in the failed-SEV group. At index TAVR, 24.1% of patients were deemed low surgical risk by the local Heart Team. While there were no differences in surgical risk at index TAVR or TAVR explant between the two groups, the median STS risk score for SAVR increased significantly from the time of index TAVR to TAVR explant in both the failed-BEV (2.8% [IQR 1.9-5.0] to 5.1% [IQR 2.9-8.9]; p<0.001) and failed-SEV (3.3% [IQR 2.2-5.5] to 5.0% [IQR 3.0-8.5]; p<0.001) groups. The temporal trends of annual TAVR explant from 2009 to 2022 for failed BEV and failed SEV are illustrated in **Supplementary Figure 1**.

PROCEDURAL CHARACTERISTICS AT TAVR EXPLANT

The most frequent indications for TAVR explant were endocarditis (36.0% failed SEV vs 55.4% failed BEV; p<0.001), SVD (30.2% vs 21.8%; p=0.065), PVL (21.2% vs 11.9%; p=0.014) and PPM (8.5% vs 10.4%; p=0.61) **(Table 2, Supplementary Figure 2)**. After excluding the endocarditis

Table 1. Patient characteristics at the time of index TAVR.

Variables	BEV (N=202)	SEV (N=189)	*p*-value
Age, years	73.4 [9.2]	72.1 [10.3]	0.21
Female	68 (33.7)	64 (33.9)	1.00
Frailty	69 (36.3)	54 (31.6)	0.37
Coronary artery disease	115 (58.4)	98 (53.0)	0.30
Stroke	36 (18.3)	28 (15.1)	0.41
Cerebrovascular disease	64 (32.5)	45 (24.2)	0.089
Peripheral vascular disease	47 (23.9)	31 (16.7)	0.099
Diabetes	69 (35)	70 (37.4)	0.67
Atrial fibrillation	77 (39.1)	84 (44.9)	0.26
Pulmonary hypertension	57 (29.7)	55 (30.6)	0.91
Chronic kidney disease	77 (40.1)	74 (40.4)	1.00
Dialysis-dependent	9 (4.6)	10 (5.4)	0.82
Chronic obstructive pulmonary disease	59 (29.9)	47 (25.3)	0.36
Hostile chest or chest deformity	8 (4.1)	20 (10.9)	0.017
Porcelain aorta	13 (6.7)	8 (4.4)	0.38
Left ventricular ejection fraction, %	52.3 [12.4]	50.9 [13.4]	0.29
Prior permanent pacemaker/ICD	40 (20.2)	47 (25.3)	0.27
Prior percutaneous coronary intervention	60 (30.2)	48 (25.8)	0.37
Body surface area, m^2	2 [0.3]	2 [0.3]	0.10
New York Heart Association Class			
1	10 (5.7)	11 (6.4)	0.83
2	50 (28.7)	43 (24.9)	0.47
3	92 (52.9)	85 (49.1)	0.52
4	22 (12.6)	34 (19.7)	0.082
Previous cardiac surgery	63 (31.7)	85 (45.7)	0.006
Society of Thoracic Surgeons Predicted Risk of Mortality, %	2.8 [1.9-5.0]	3.3 [2.2-5.5]	0.10
EuroSCORE II	4.7 [2.7-9.2]	5.1 [2.6-10.0]	0.24
Heart Team risk stratification			
Low	32 (23.7)	36 (24.5)	0.89
Intermediate	60 (44.4)	52 (35.4)	0.14
High	36 (26.7)	49 (33.3)	0.24
Extreme	7 (5.2)	10 (6.8)	0.62

All variables are expressed as mean [standard deviation], median [interquartile range] or N (%). *p*-values in red: $p<0.05$; p-values in blue: $p>0.05$ & <0.10 (to indicate trend). BEV: balloon-expandable valve; EuroSCORE: European System for Cardiac Operative Risk Evaluation; ICD: implantable cardioverter defibrillator; SEV: self-expanding valve; TAVR: transcatheter aortic valve replacement

cohort, there were no differences in the primary reasons for exclusion from redo-TAVR between groups; these included unfavourable anatomy for redo-TAVR (20.9% in BEV vs 19.5% in SEV; p=0.73) and prior valve-in-valve replacement (7.1% vs 8.5%; p=0.58). The median time from index TAVR to TAVR explant was 12.7 months (IQR 5.4-28.9) after BEV TAVR and 15.0 months (IQR 4.0-38.5) after SEV TAVR, with no differences between groups overall (p=0.63) or when stratified by indication for surgery **(Figure 2)**. The most common THV device explanted within each group was the SAPIEN 3 THV (Edwards Lifesciences; 62.9%) in the BEV group and the CoreValve (Medtronic; 40.7%) in the SEV group.

Emergency and urgent cases compromised 3.8% and 53.6% of all cases, respectively, with the SEV group having fewer urgent/emergency cases than the BEV group (52.0% vs 62.3%; p=0.057). Aortic root replacement was more frequently performed in the SEV group (15.3% vs 7.4%; p=0.016). Surgical bioprostheses were implanted in 85.4%

Table 2. Procedural characteristics in patients who underwent TAVR explant.

Variables	BEV (N=202)	SEV (N=189)	*p*-value
Primary clinical indications for AVR			
Prosthetic valve endocarditis	112 (55.4)	68 (36)	**<0.001**
Structural valve deterioration	44 (21.8)	57 (30.2)	**0.065**
Paravalvular leak	24 (11.9)	40 (21.2)	**0.014**
Prosthesis-patient mismatch	21 (10.4)	16 (8.5)	0.61
Prosthetic valve migration	4 (2)	6 (3.2)	0.53
Other	13 (6.4)	19 (10.1)	0.20
Society of Thoracic Surgeons Predicted Risk of Mortality, %	5.1 [2.9-8.9]	5.0 [3.0-8.5]	0.52
Timing of operation			
Elective	73 (37.8)	83 (48)	**0.057**
Urgent	111 (57.5)	85 (49.1)	0.12
Emergent	9 (4.7)	5 (2.9)	0.43
Explanted valve size, mm	26 [23-26]	29 [26-29]	
Time from TAVR to explant, months	12.7 [5.4-28.9]	15.0 [4.0-38.5]	0.27
Cardiopulmonary bypass time, mins	129 [103-174]	141 [100-194]	0.54
Aortic cross-clamp time, mins	95 [73-127]	97 [68-153]	0.57
Implanted valve size, mm	23 [21-25]	23 [23-25]	
Aortic valve replacement	187 (92.6)	160 (84.7)	**0.016**
Mechanical	28 (15.0)	25 (15.6)	0.88
Tissue	159 (85.0)	135 (84.4)	
Root replacement	15 (7.4)	29 (15.3)	**0.016**
Mechanical	2 (13.3)	2 (6.9)	0.60
Tissue	13 (86.7)	27 (93.1)	
Concomitant procedure(s)	117 (57.9)	109 (57.7)	1.00
Ascending aortic replacement	9 (7.7)	10 (9.2)	0.81
Coronary artery bypass graft	33 (28.2)	23 (21.1)	0.22
Root repair	7 (6)	4 (3.7)	0.54
Mitral valve surgery	42 (35.9)	46 (42.2)	0.34
Tricuspid valve surgery	11 (9.4)	22 (20.2)	0.024
Mitral or tricuspid valve surgery	47 (40.2)	54 (49.5)	0.18
Root enlargement	22 (10.9)	26 (13.8)	0.44

All variables are expressed as mean [standard deviation], median [interquartile range] or N (%). *p*-values in red: p<0.05; *p*-values in blue: *p*>0.05 & <0.10 (to indicate trend). AVR: aortic valve replacement; BEV: balloon-expandable valve; SEV: self-expanding valve; TAVR: transcatheter aortic valve replacement

of cases, with no differences between groups. The median cardiopulmonary bypass time (132 minutes [IQR 103-186]) and aortic cross-clamp time (95 minutes [IQR 70-136]) were also similar between groups. Among 57.8% of patients undergoing concomitant cardiac procedures during TAVR explant, CABG (24.8%), and mitral (38.9%) and tricuspid (14.6%) valve surgery were the most frequent concurrent procedures performed. There were no differences in concomitant non-aortic procedures between groups, with the exception of more frequent tricuspid valve surgery during SEV explantation (20.2% vs 9.4%; p=0.024).

POSTPROCEDURAL AND MIDTERM CLINICAL OUTCOMES

The overall rates of intraoperative and in-hospital mortalities were 0.8% and 13.0%, respectively, with no significant differences between groups. There were also no differences between the two groups in the duration of mechanical ventilation, ICU stay, hospital stay, new pacemaker implantation, in-hospital stroke, vascular complications, or major or life-threatening bleeding events **(Table 3)**. At 30 days, there were no significant differences in mortality (15.1% vs 17.3%; p=0.57), stroke (4.4% vs 7.1%; p=0.36) or readmission rates (13.9% vs 8.9%; p=0.17) between the BEV and SEV groups, respectively; both

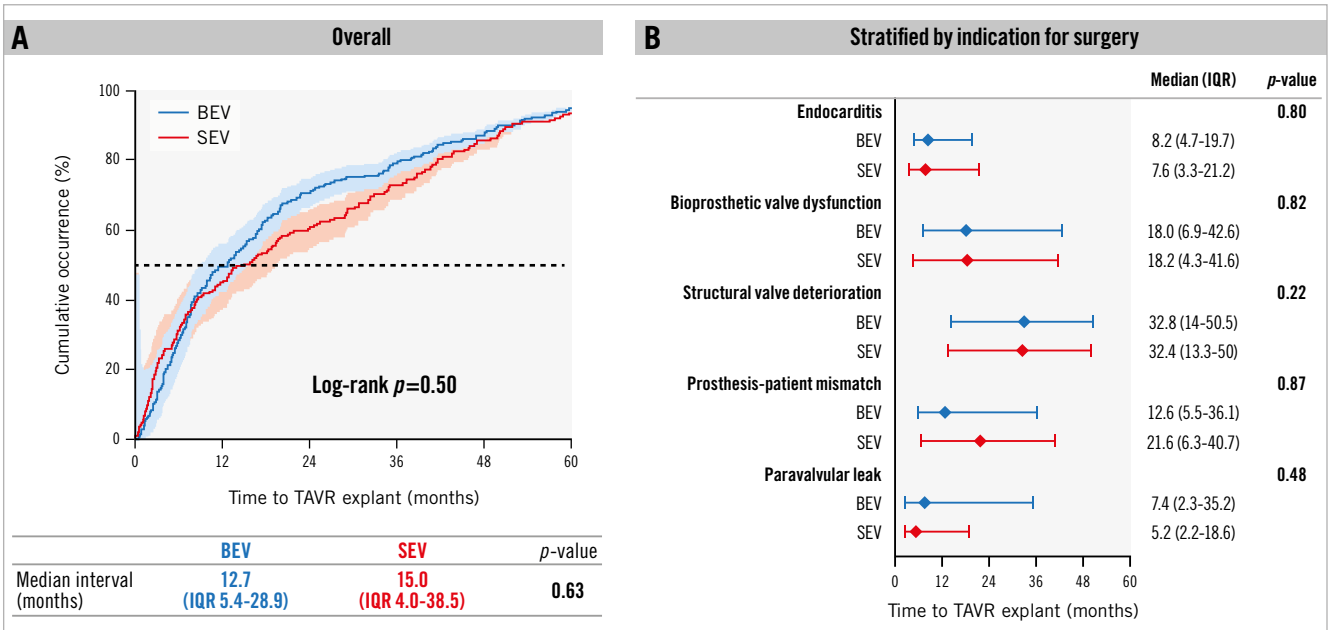


Figure 2. *Timing of TAVR explant. There were no significant differences in the median interval from index TAVR to TAVR explant between the BEV and SEV groups overall (A) or by indication for TAVR explant (B). BEV: balloon-expandable valve; IQR: interquartile range; SEV: self-expanding valve; TAVR: transcatheter aortic valve replacement*

groups demonstrated similar mean aortic valve gradients (12.3±11.7 vs 9.9±4.4 mmHg; p=0.11). Among 247 patients who completed 1-year follow-up, mortality was 32.8%, with no differences between groups (31.8% BEV vs 33.9% SEV). The overall median follow-up (including all mortality) was 30.4 months (IQR 14.4-51.1) from the index TAVR and 6.6 months (IQR 1.0-18.8) after TAVR explant. There were no differences in actuarial estimates of cumulative mortality at 3 years between groups (log-rank p=0.95) **(Central illustration)**.

PREDICTORS OF ALL-CAUSE MORTALITY AFTER TAVR EXPLANT

On univariate analysis, chronic kidney disease (CKD), New York Heart Association (NYHA) Class, longer cardiopulmonary bypass (CPB) and cross-clamp times were associated with mortality after BEV explant **(Figure 3A)**. After multivariable logistic regression, peripheral vascular disease (hazard ratio [HR] 1.95, 95% confidence interval [CI]:1.08-3.50), dialysis (HR 4.68, 95% CI:1.95-11.25), emergency surgery (HR 4.66, 95% CI: 1.94-11.22) and concomitant mitral surgery (HR 2.00, 95% CI: 1.07-3.72) were found to be independent predictors of all-cause mortality. Similarly, pulmonary hypertension was associated with mortality after SEV explant, while diabetes (HR 1.94, 95% CI: 1.07-3.54), cirrhosis (HR 2.42, 95% CI: 1.07-5.50), longer CPB time (HR 1.22 per hour, 95% CI: 1.001-1.49) and concomitant mitral surgery (HR 2.00, 95% CI: 1.08-3.69) were independent predictors of all-cause mortality **(Figure 3B)**.

Neither surgical risk, determined by the STS risk score or the local Heart Team during index TAVR, nor indication for TAVR explant were associated with mortality after TAVR explant in either the BEV or SEV group. After adjusting for baseline differences in a multivariable Cox regression model with THV type as a covariate, the THV type had no significant impact on all-cause mortality after TAVR explant (unadjusted HR 0.99, 95% CI: 0.67-1.45; adjusted HR 1.15, 95% CI: 0.76-1.75) **(Supplementary Table 1)**. THV type also had no significant impact on mortality after TAVR explant in subgroup analyses stratifying patients based on various prespecified cohorts of interest, including age >75 years, sex, prior cardiac surgery, CKD, time to TAVR explant, TAVR explant generation, indication and timing of surgery, in addition to concomitant cardiac/mitral surgery and root replacement during TAVR explant (all p<0.05) **(Central illustration)**. Cumulative mortality at 2 years was similar between the BEV and SEV groups (32.7% vs 28.4% respectively; p=0.49) even after excluding all TAVR explants for endocarditis **(Supplementary Figure 3)**.

Discussion

This study, a subgroup analysis of the international EXPLANT-TAVR registry, compared the characteristics and outcomes of patients undergoing TAVR explant for failed BEV versus failed SEV. Our key findings are as follows: 1) The failed SEV group had fewer cases of endocarditis and more PVL as primary indications for TAVR explant, with no differences in SVD or PPM between groups. 2) SEV explant was associated with more frequent aortic root replacement and trended fewer urgent/emergency cases. 3) Mortality after TAVR explant was high (16% at 30 days; 33% at 1 year) but was not associated with the type of THV explanted, despite adjusting for baseline differences and in subgroup analyses. 4) In a significant proportion of TAVR explants requiring concomitant cardiac procedures (58%), mitral surgery was the most common combined procedure and was an independent predictor of mortality in both groups.

DIFFERENT INDICATIONS FOR TAVR EXPLANT IN PATIENTS WITH FAILED BEV VERSUS FAILED SEV

Endocarditis (46%) was the predominant mode of THV failure in our study, followed by SVD (26%) and significant

Table 3. Outcomes after TAVR explant.

Variables	BEV (N=202)	SEV (N=189)	*p*-value
Intraoperative mortality	2 (1)	1 (0.5)	1.00
In-hospital mortality	24 (11.9)	27 (14.3)	0.55
Ventilator hours	16 [8-37]	19 [10-37]	0.70
ICU length of stay, hours	75 [38-168]	72 [32-161]	0.75
Hospital length of stay, days	12 [8-21]	13 [8-19]	0.50
New permanent pacemaker*	29/158 (18.4)	24/137 (17.5)	0.88
In-hospital stroke	7 (3.6)	11 (6)	0.34
In-hospital vascular complication	9 (4.6)	2 (1.1)	0.064
In-hospital life-threatening bleed	14 (7.1)	11 (6)	0.84
In-hospital major bleed	23 (11.7)	24 (13.2)	0.76
30-day			
Mortality	28/186 (15.1)	30/173 (17.3)	0.57
Stroke	8 (4.4)	12 (7.1)	0.36
Readmission	23 (13.9)	14 (8.9)	0.17
Mean aortic gradient, mmHg	12.3 [11.7]	9.9 [4.4]	0.11
1-year			
Mortality	42/132 (31.8)	39/115 (33.9)	0.79
Stroke	11 (8.3)	15 (12.8)	0.30

All variables are expressed as mean [standard deviation], median [interquartile range], N (%) or n/N (%). *p*-values in blue: *p*>0.05 & <0.10 (to indicate trend). *Patients with prior pacemaker or implantable cardioverter defibrillator were excluded. BEV: balloon-expandable valve; ICU: intensive care unit; SEV: self-expanding valve; TAVR: transcatheter aortic valve replacement

PVL (16%). Prosthetic valve endocarditis is associated with significant mortality and morbidity, and has a reported incidence of 1.0%/person-year after TAVR[9]. While TAVR explant remains the mainstay of definitive therapy, redo-TAVR may be considered for treating sequelae such as severe aortic regurgitation after completion of antibiotic treatment and clearance of infection in select patients with no surgical option. However, the impact of THV device type on the development of endocarditis remains unclear, with conflicting data regarding differences in incidence between THV types. For example, while there were no differences in the 1-year frequency (1.25% vs 0.95%; p=0.33) or TAVR explant rates (13.8% vs 8.7%; p=0.21) between the BEV and SEV groups, respectively, in the Infectious Endocarditis After TAVR Registry[10], another study reporting outcomes after TAVR explant using the STS national database showed that patients with BEV prostheses more frequently had endocarditis than those with SEV (24% vs 13%; p=0.006)[11]. In our study, while the failed BEV group had more endocarditis, the failed SEV group had more PVL as the indication for TAVR explant, with no differences in SVD or PPM between groups. SEV patients in our study had a greater degree of PVL (>mild PVL: 43.0% SEV vs 23.5% BEV; p<0.001) after the index TAVR procedure, which is in line with a meta-analysis showing more significant PVL after SEV TAVR[12]. Furthermore, significant PVL may not be amenable to percutaneous closure, especially in SEV patients, given the difficulty in traversing the stent frame[13]. TAVR explant may be the only treatment option in these cases.

MORE AORTIC ROOT REPLACEMENT WITH FAILED SEV

THV design can present technical challenges during TAVR explant, as THV interaction with the surrounding structures is different for SEV, which are taller than BEV. A higher aortotomy may be necessary to extract the taller stent frame of SEV, where visualisation of the aortic annular complex is often challenging and can result in more root damage. On the other hand, surgical explantation of shorter BEV may be more familiar to the non-TAVR surgeon, as their stent profile is similar to surgical aortic valves. This may explain why aortic root replacements are more frequently performed during SEV explantation compared to BEV (15.3% vs 7.4%; p=0.016). However, there were no differences in ascending aortic replacement between THV groups. These findings are contrary to prior reports from the STS database, where Fukuhara et al reported similar rates of root replacement between THV groups (18.9% BEV vs 22.1% SEV; p=0.52) but higher rates of ascending aortic replacement with SEV (18.2% vs 8.2%; p=0.009)[14]. Patients in both studies, however, had similarly high 30-day mortality.

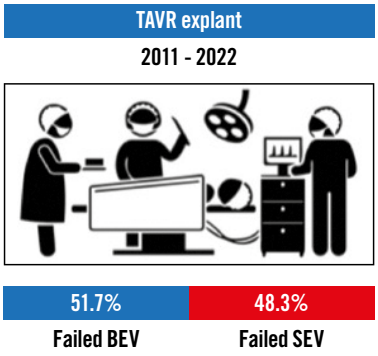
CONCOMITANT CARDIAC SURGERY IN TAVR EXPLANT WAS COMMON FOR BOTH THV TYPES

Patients undergoing TAVR often have concomitant valvular or coronary disease that may progress despite successful TAVR, and they may not be candidates for additional transcatheter therapies. When such patients undergo cardiac surgery, TAVR explant may be necessary if THV compression/deformity occurs. Conversely, any inadvertent injury to

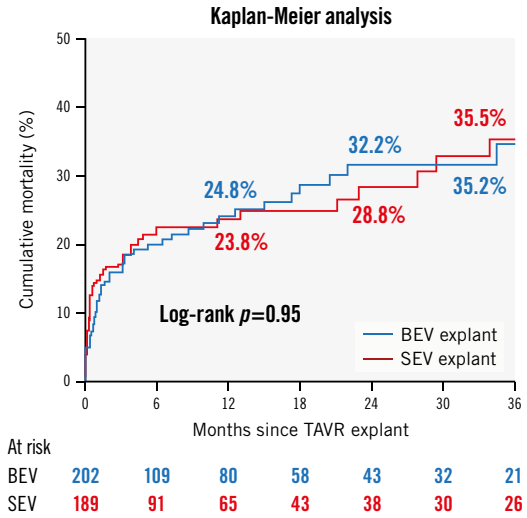
EuroIntervention — Central **Illustration**

Impact of THV type on mortality after TAVR explant.

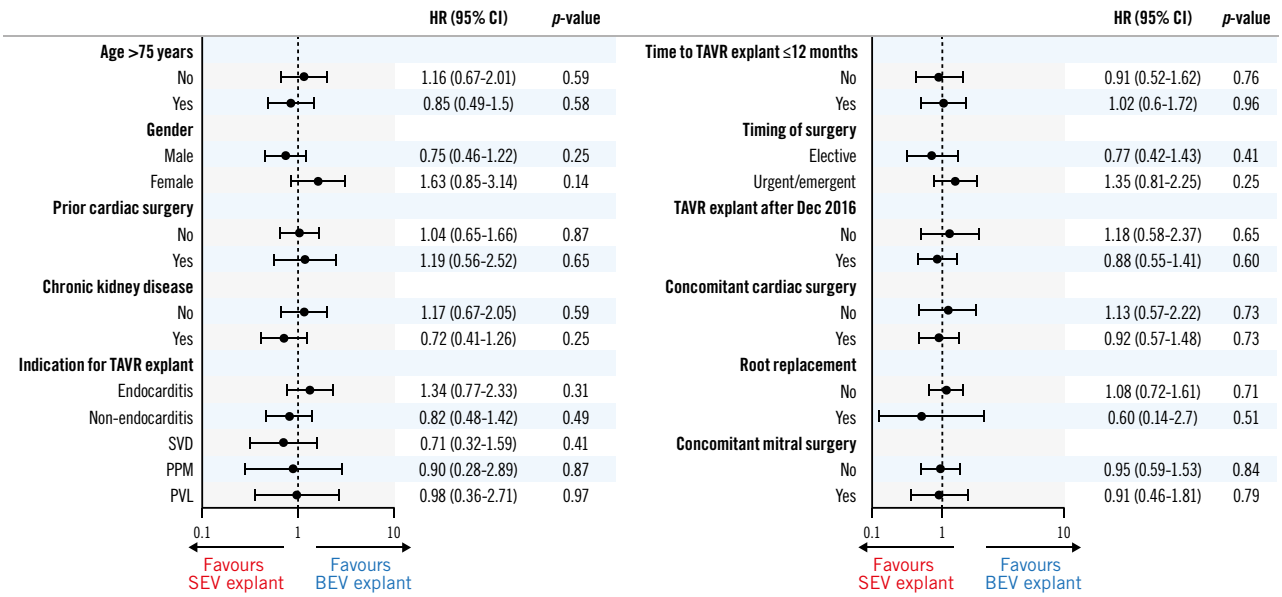
TAVR explant for failed balloon-expandable versus self-expanding valves: The EXPLANT-TAVR international registry (42 centres, 391 patients)



Median follow-up: 6.6 months (IQR 1.0-18.8)



Subgroup analysis



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Kaplan-Meier analysis showed no differences in actuarial estimates of 3-year cumulative mortality between groups (35.2% BEV vs 35.5% SEV; log-rank p=0.95) (A). THV type also had no significant impact on mortality after TAVR explant in various prespecified subgroups of interest (B). BEV: balloon-expandable valve; CI: confidence interval; HR: hazard ratio; IQR: interquartile range; PPM: prosthesis-patient mismatch; PVL: paravalvular leak; SEV: self-expanding valve; SVD: structural valve deterioration; TAVR: transcatheter aortic valve replacement; THV: transcatheter heart valve

the surrounding structures during TAVR explant may warrant a more complex procedure, not just an isolated SAVR. Deep valve implantation, particularly with earlier-generation THVs, may impinge on the aortomitral curtain and anterior mitral leaflet as well as the membranous septum. If these structures are injured during TAVR explant, repair of the ventricular septal defect or concomitant mitral surgery will be required. Although we are unable to differentiate between

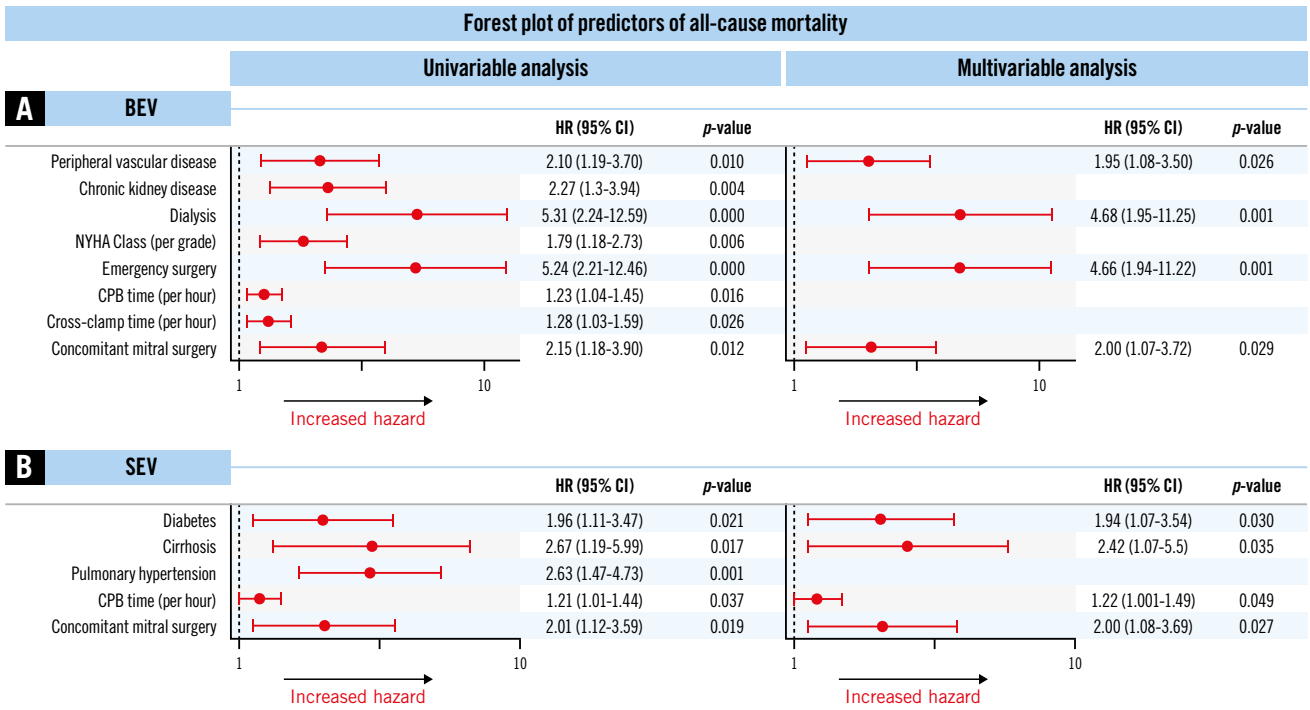

Figure 3. *Predictors of all-cause mortality after TAVR explant. Forest plot showing univariate and multivariable predictors of 1-year mortality after BEV explant (A) and SEV explant (B). BEV: balloon-expandable valve; CI: confidence interval; CPB: cardiopulmonary bypass; HR: hazard ratio; NYHA: New York Heart Association; SEV: self-expanding valve; TAVR: transcatheter aortic valve replacement*

valvular disease progression versus iatrogenic injury during TAVR explant as the primary indication for concomitant surgery, the burden of concomitant cardiac surgery during TAVR explant was significant (at nearly 60%) and similar to prior reported studies[11,14]. In our series, concomitant mitral (40%), coronary artery bypass (25%), and tricuspid valve surgery (15%) were the most frequent concurrent procedures performed. Interestingly, similar to the STS report by Fukuhara et al[11], there were no differences in concomitant non-aortic procedures performed between the BEV and SEV groups in our study, with the exception of more frequent tricuspid valve surgery during SEV explantation (20.2% vs 9.4%; p=0.024).

Mitral valve surgery was the most frequently performed concomitant procedure in our study and an independent predictor of mortality in both BEV and SEV groups. Although we could not determine from our registry whether patients undergoing concomitant mitral surgery met criteria for intervention at the time of the index TAVR procedure, these patients likely represented the highest-risk subgroup in our study, as evidenced by higher surgical risk at index TAVR and a more complex double valve operation with longer cross-clamp and CPB times at TAVR explant regardless of the THV type, which may explain the worse outcomes in this cohort. The elevated mortality and morbidity rates may simply reflect early surgical experience.

MORTALITY AFTER TAVR EXPLANT REMAINED HIGH IRRESPECTIVE OF THV TYPE

There is growing evidence suggesting that the mortality and morbidity associated with TAVR explant are not negligible; with an increased observed-to-expected mortality[5,6,10]. The results from our international multicentre registry further shed light on the impact of THV type on outcomes after TAVR explant. We found that mortality after TAVR explant was high (16% at 30 days; 33% at 1 year) but was not associated with the type of THV explanted, despite adjusting for baseline differences and performing subgroup analysis. Our findings are consistent with those reported by Fukuhara et al from the STS national database[11] and are not surprising considering there were no differences between the two groups in terms of surgical risk at index TAVR or subsequent TAVR explant procedure, with similar CPB and cross-clamp times. There were also no significant differences in postoperative or midterm outcomes between the BEV and SEV groups despite more frequent root replacement in patients with failed SEV. One potential explanation is that the threshold for performing aortic root replacement may be higher in patients with comorbidities, as shown in our prior subgroup analysis between patients with SAVR and root replacement after TAVR explant[15]. Nonetheless, our findings suggest that while THV design may pose technical challenges during TAVR explant, it does not significantly influence outcomes after surgery.

Limitations

Despite the strengths of our multicentre international registry-based study, it is a retrospective observational analysis with all the inherent limitations. First, we are limited by our overall sample size and the relatively low number of mortality events in demonstrating statistically significant differences in mortality between groups, and only forward, stepwise,

multivariable Cox regression models were developed. Second, the retrospective nature of this study and the long study period may have introduced time selection and learning curve biases. Third, the primary indication for TAVR explant and reasons for exclusion from redo-TAVR were assessed independently by the respective Heart Teams at each institution, which may have introduced patient selection biases. We were unable to account for qualifying patients that did not undergo or declined TAVR explant. Fourth, the volume of TAVR procedures performed outside participating centres that were referred to our participating sites for reintervention was not captured. Finally, we were unable to account for the potential impact of procedural volume and operator/centre-level variations in transcatheter and surgical techniques on clinical outcomes. The decision to perform root replacement and/or additional cardiac procedures was at the surgeon's discretion at the time of procedure.

Conclusions

In the EXPLANT-TAVR global registry, BEV and SEV groups had different indications for surgical explantation with more ascending/root replacements in patients with SEV failure, but no differences in short- and midterm mortality and morbidity. Further refinement of TAVR explant techniques will be important for the improvement of outcomes.

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Conflict of interest statement

G. Tang is a physician proctor and consultant for Medtronic; a consultant and physician advisory board member for Abbott Structural Heart; and a physician advisory board member for JenaValve. N.S. Kleiman has been involved in clinical trials for Edwards Lifesciences, Medtronic, and Boston Scientific; is involved in clinical education for Medtronic; and is on the steering committee for Boston Scientific. M. Szerlip is a physician proctor and consultant for Edwards Lifesciences; has received speaker honoraria for Boston Scientific; served as an advisory board member for Abbott; and is on the steering committee for Medtronic. M. Mack served as co-primary investigator for the PARTNER trial for Edwards Lifesciences and the COAPT trial for Abbott; and served as the study Chair for the APOLLO trial for Medtronic. T. Nazif has equity in Venus Medtech; and has received consulting fees or honoraria from Keystone Heart, Edwards Lifesciences, Medtronic, and Boston Scientific. A. 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Supplementary data

Supplementary Table 1. Multivariable Cox regression model showing impact of THV type on mortality after TAVR explant.

Supplementary Figure 1. Temporal trends in annual TAVR explant.

Supplementary Figure 2. Indications for surgery by type of THV explanted.

Supplementary Figure 3. Cumulative mortality stratified by surgical indication and THV type.

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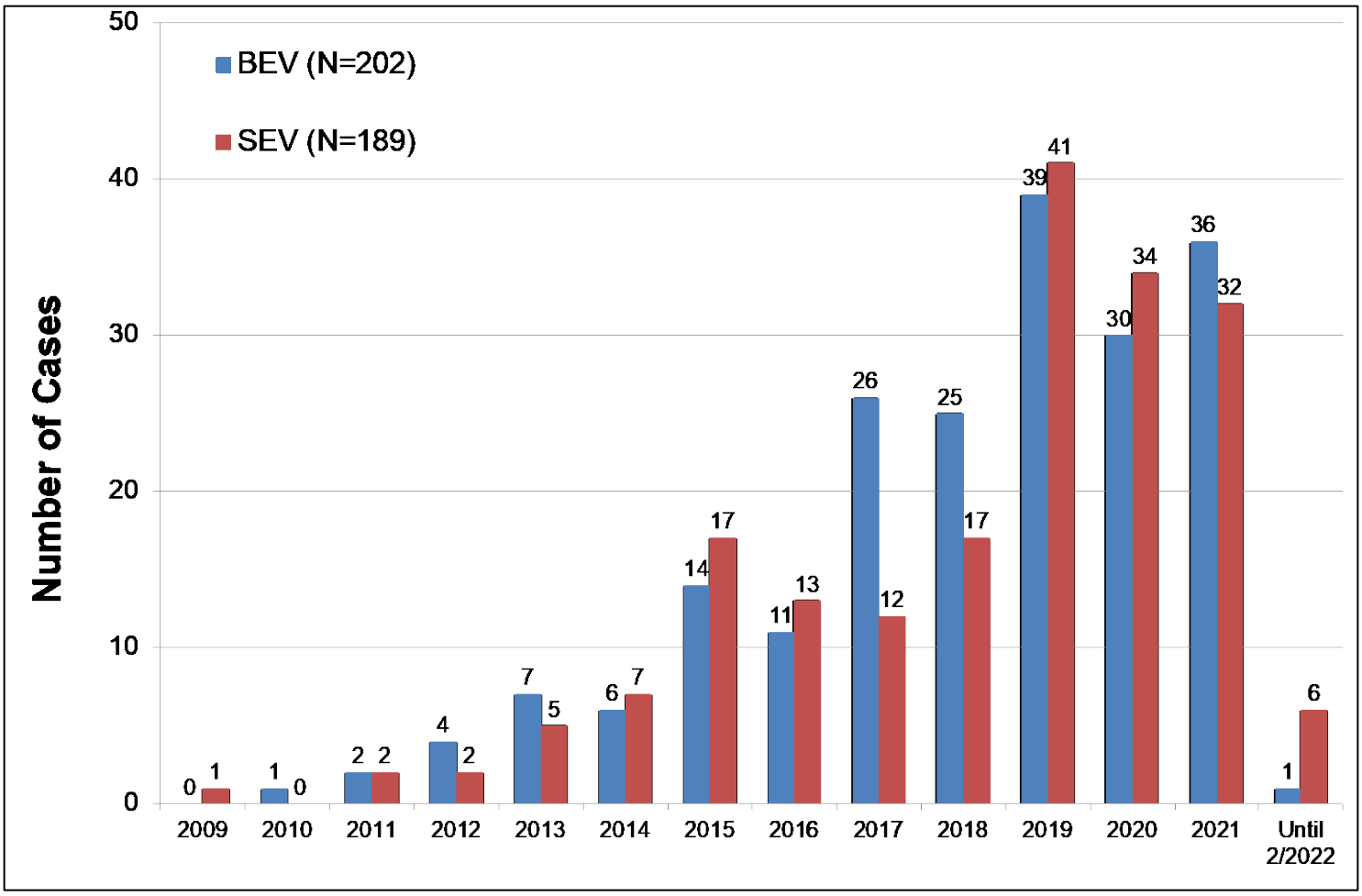
Supplementary data

Supplementary Table 1. Multivariable Cox regression model showing impact of THV type on mortality after TAVR explant.

Variables	Hazard Ratio	95% Confidence Interval		p-value
		Lower	Upper	
SEV (Reference - BEV)	1.15	0.76	1.75	0.51
Age (per year)	0.99	0.97	1.01	0.43
Female	1.05	0.68	1.62	0.83
Cerebrovascular Disease	1.00	0.63	1.58	0.99
Peripheral Vascular Disease	1.50	0.93	2.42	0.09
Hostile Chest or Chest Deformity	0.44	0.16	1.23	0.12
TAVR-Explant for Endocarditis	1.40	0.85	2.30	0.19
TAVR-Explant for Paravalvular leak	1.22	0.65	2.28	0.53
Urgent/Emergency Surgery	1.05	0.69	1.61	0.82
Root Replacement	0.56	0.26	1.23	0.15

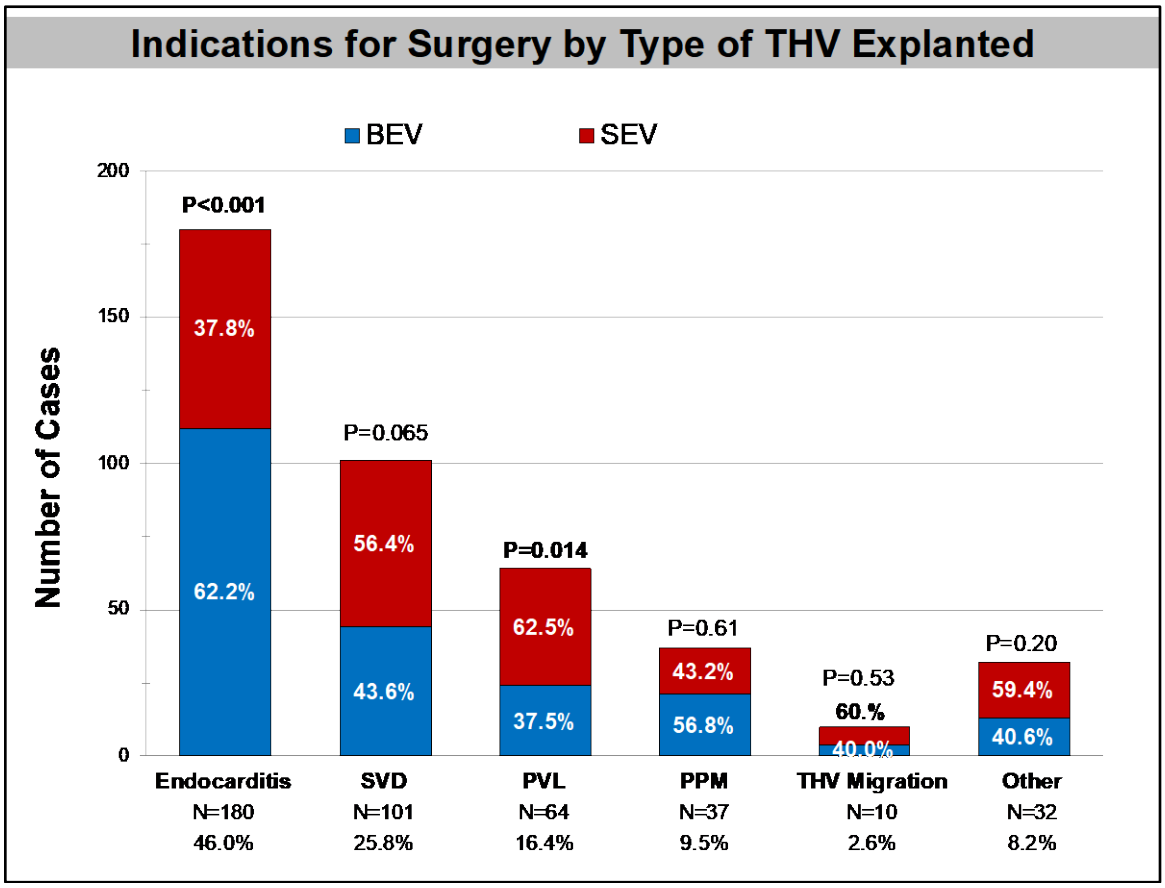


Supplementary Figure 1. Temporal trends in annual TAVR explant.

Trends in annual number of BEV and SEV between 2009 and 2022 among patients undergoing TAVR-explant in the EXPLANT-TAVR registry.

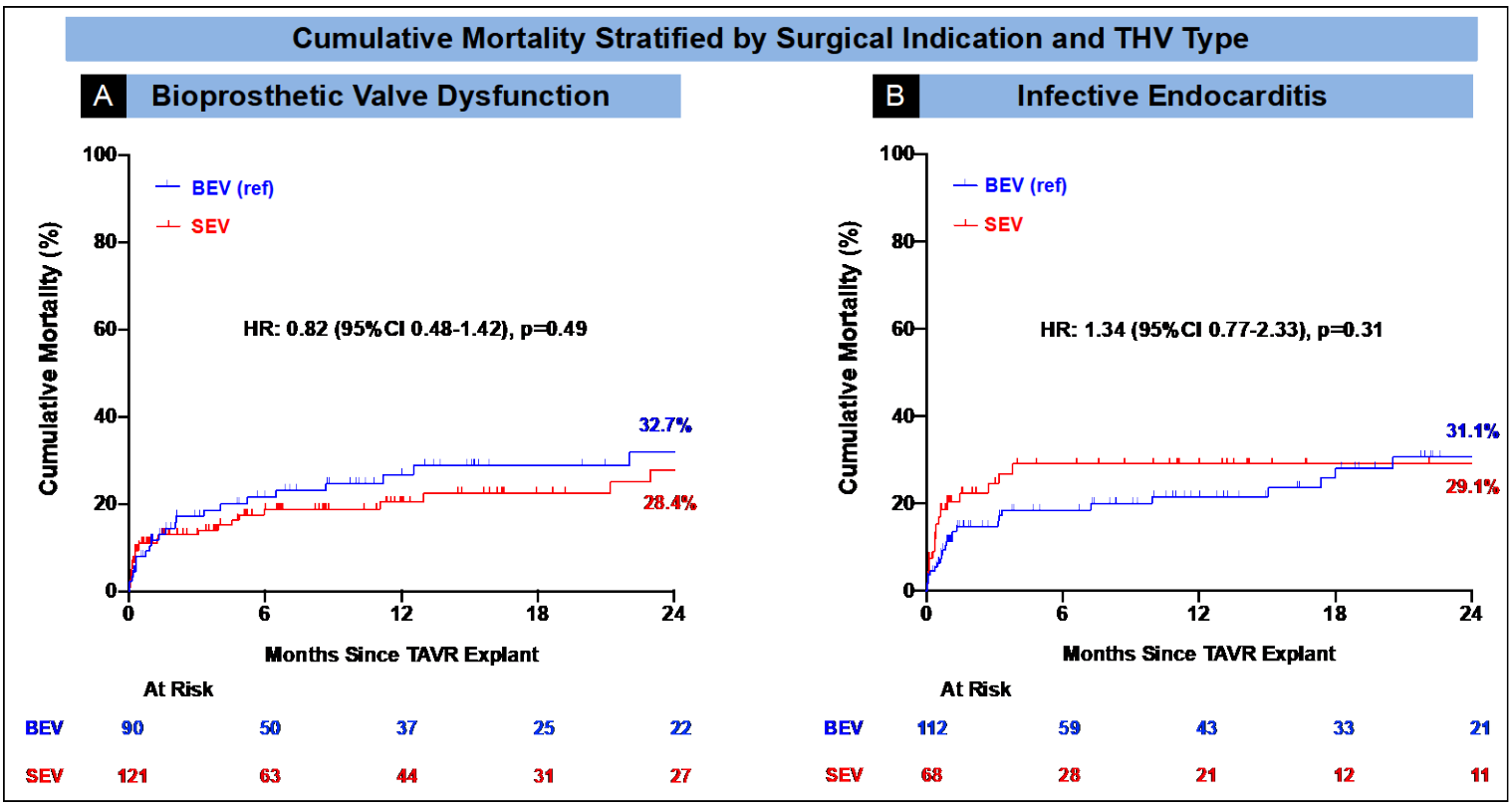
**Study period ended in first quarter of 2022.*

BEV=balloon-expandable valve; SEV=self-expanding valve; TAVR=transcatheter aortic valve replacement



Supplementary Figure 2. Indications for surgery by type of THV explanted.

BEV=balloon-expandable valve; PPM=prosthesis-patient mismatch, PVL=paravalvular leak, SEV=self-expanding valve; SVD=structural valve deterioration; TAVR=transcatheter aortic valve replacement; THV=transcatheter heart valve



Supplementary Figure 3. Cumulative mortality stratified by surgical indication and THV type.

There were no differences in cumulative mortality between the BEV and SEV groups in patients undergoing TAVR-explant for Bioprosthetic valve dysfunction (A) or Infective Endocarditis (B).

BEV=balloon-expandable valve; SEV=self-expanding valve; TAVR=transcatheter aortic valve replacement; THV=transcatheter heart valve