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ORIGINAL RESEARCH

Long-term structural valve deterioration after TAVI: insights from the EORP ESC Valve Durability TAVI Registry

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ABSTRACT

BACKGROUND: Valve durability is a key consideration as the patient population eligible for transcatheter aortic valve implantation (TAVI) expands to include lower-risk and younger individuals who are expected to live many years after the procedure.

AIMS: This registry aimed to assess the incidence of long-term structural valve deterioration (SVD) beyond 5 years post-TAVI.

METHODS: Consecutive living patients who underwent TAVI up until 2014 using any commercially available transcatheter heart valve (THV) at 22 participant centres were enrolled in the European Valve Durability TAVI Registry. All patients underwent comprehensive echocardiographic assessments (61% were evaluated independently by a central core laboratory) within 6 months of enrolment and at least 5 years post-TAVI; SVD was defined according to Valve Academic Research Consortium 3 definitions.

RESULTS: A total of 597 patients (aged 79.6±7.1 years at the time of TAVI; 47.2% male, mean Society of Thoracic Surgeons score 5.0%) were included. At a median of 6.1 years of follow-up (interquartile range 5.2-7.3 years), the crude incidence of moderate/severe SVD was 9.5% (n=57; moderate: 6.2%, n=37; severe: 3.4%, n=20). Predictors of SVD identified by Cox regression analysis were use of an intra-annular THV (hazard ratio [HR] 38.44, 95% confidence interval [CI]: 10.8-136.3; p<0.001), a small THV size (HR 4.82, 95% CI: 2.42-9.60; p<0.001) and moderate/severe postprocedural paravalvular leak (HR 3.64, 95% CI: 1.59-8.32; p=0.002).

CONCLUSIONS: The incidence of moderate/severe SVD during long-term follow-up after TAVI is low, with severe SVD being even rarer than moderate SVD. SVD occurs more frequently in patients treated with older-generation intra-annular valves and in those with small-sized THVs.

KEYWORDS: structural valve deterioration; transcatheter aortic valve implantation; valve durability

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Valve durability is a critical concern as the population eligible for transcatheter aortic valve implantation (TAVI) expands to younger, lower-risk individuals with longer life expectancies[1-4]. As the number of younger patients undergoing TAVI increases, it becomes essential to have reliable, long-term durability data for various types of transcatheter heart valves (THVs) to guide lifetime management decisions effectively.

While studies show preserved valve function up to 5 years after TAVI[5-10], limited data exist on long-term durability beyond this period, primarily because of the competing risk of death[11-13] and the generally elderly patient population in earlier studies[14]. Inconsistent definitions of structural valve deterioration (SVD) in past trials have created uncertainty about its true incidence, and retrospective analyses often lacked crucial evaluations.

The European Valve Durability TAVI Registry was established to address these issues, with the primary aim of prospectively assessing SVD prevalence in a living patient cohort who had undergone TAVI at least 5 years previously. The registry incorporated the findings of echocardiography performed at the time of enrolment to ensure accurate and comprehensive assessment of THV function and detailed characterisation of SVD.

Impact on daily practice

The European Valve Durability TAVI Registry highlights the long-term performance of transcatheter aortic valve implantation (TAVI), which is crucial as its use expands to younger and lower-risk populations. The low incidence of moderate to severe structural valve deterioration (SVD) beyond five years post-TAVI indicates that first-generation transcatheter heart valves (THVs) demonstrate promising durability for extended use. However, caution is advised when using intra-annular valves or small THVs, as these are associated with a higher risk of SVD.

Methods

STUDY POPULATION

The European Valve Durability TAVI Registry was an international, longitudinal, multicentre, observational study conducted in European countries with the aim of collecting long-term data on the durability of TAVI from all high-volume centres in Europe that started TAVI procedures before 2014 (utilising devices available at that time). The focus of the study was on patients who had undergone TAVI at least 5 years before the launch of the registry. Inclusion was limited to those still alive at the time of enrolment, allowing a representative real-time snapshot of the TAVI population with prospective assessment of long-term echocardiographic valve function **(Figure 1)**. These selection criteria enabled contemporary evaluation of THV performance via clinical evaluation and echocardiographic assessment during the 6-month period following enrolment of individual centres in the registry. Patients with a prior history of aortic valve intervention were excluded from the analysis.

DATA COLLECTION

All data were managed by the EURObservational Research Programme (EORP), which is overseen by the European Society of Cardiology (ESC). Demographic, procedural, and in-hospital outcome data were extracted from the European Valve Durability TAVI Registry database, and baseline echocardiographic data were acquired from the initial transthoracic study conducted within 1 month after the index TAVI procedure. All contributing centres were then invited to contact patients by phone to arrange a clinical visit and updated follow-up echocardiogram within 6 months of enrolment. Subsequent assessment of both baseline and follow-up echocardiograms by a central core laboratory (Rennes University Hospital Centre, France) ensured consistent reporting and allowed a more comprehensive evaluation of THV function.

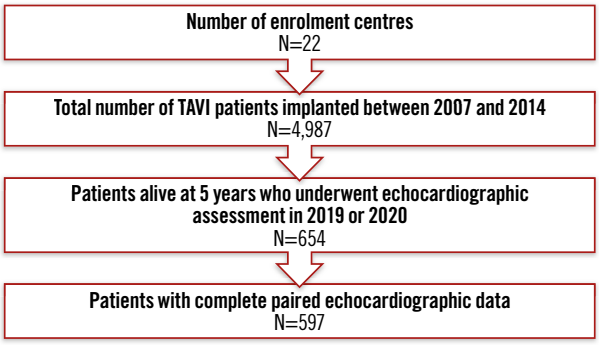


Figure 1. *Flowchart of the study population. TAVI: transcatheter aortic valve implantation*

DEFINITIONS

The joint ESC/European Association of Percutaneous Cardiovascular Interventions/European Association for Cardio-Thoracic Surgery (EAPCI/EACTS) definitions of SVD were the most widely used at the time of study design but were subsequently replaced by Valve Academic Research Consortium (VARC)-3 definitions that incorporate the ESC/EAPCI/EACTS principles and introduce additional criteria for more effective differentiation between SVD, non-structural valve deterioration (NSVD), and prosthesis-patient mismatch (PPM)[14,15]. VARC-3 definitions were therefore used for the primary analysis, with secondary comparison and sensitivity

Abbreviations

EOA	effective orifice area	**PPM**	prosthesis-patient mismatch	**TAVI**	transcatheter aortic valve implantation
EORP	EURObservational Research Programme	**PVL**	paravalvular leak	**THV**	transcatheter heart valve
MR	mitral regurgitation	**SAVR**	surgical aortic valve replacement	**VARC**	Valve Academic Research Consortium
NSVD	non-structural valve deterioration	**SVD**	structural valve deterioration		

analyses carried out using the original ESC/EAPCI/EACTS definitions.

The original, complete VARC-3 definition of SVD includes a concomitant decrease in Doppler velocity index. However, velocity indices were not systematically calculated in our study, and we therefore employed the modified "haemodynamic" definition, as previously applied in the NOTION trial[12]. The description of annular calcification on computed tomography prior to TAVI was site reported as none, mild, moderate or severe based upon the circumferential extent and the depth and thickness of calcification projecting into the left ventricular outflow tract[16]. Small device sizes were characterised according to THV type: SAPIEN/XT ≤23 mm (Edwards Lifesciences), CoreValve/Evolut R ≤26 mm (Medtronic), Portico ≤25 mm (Abbott), Lotus ≤23 mm (Boston Scientific), Direct Flow ≤25 mm (Direct Flow Medical)[17].

STATISTICAL ANALYSIS

Univariable analysis was applied to both continuous and categorical variables, with continuous variables reported as mean±standard deviation (SD) or median with interquartile range (IQR), and categorical variables as counts and percentages. Group comparisons used the Kruskal-Wallis test, chi^2 test, or Fisher's exact test for expected cell counts <5. Monte-Carlo estimates of exact p-values were used where necessary. For echocardiography comparisons between timepoints or investigator and core lab data, McNemar's, Bowker's, or the signed-rank test were applied. Cumulative incidence of SVD and 95% confidence intervals (CI) were calculated with the Kaplan-Meier method. Univariate Cox analysis of demographic, clinical, and procedural variables preceded the multivariable Cox model for SVD occurrence. Multicollinearity was checked before proceeding with the multivariable model; variables with multicollinearity issues were excluded. A backward Cox regression identified SVD predictors (p<0.05). Analysis was carried out for all devices and separately for those currently available. Model fit was assessed using concordance, the goodness-of-fit test, and Schoenfeld residuals[18]. SAS software version 9.4 (SAS Institute) was used.

Results

STUDY POPULATION

Living patients who had undergone TAVI in 2014 or earlier at 1 of 22 participating centres using any commercially available THV were included in this multicentre European registry between February 2019 and February 2020. Those who were unable to attend the reference centre for comprehensive follow-up echocardiography within 6 months of enrolment were excluded **(Figure 1)**. The final study population with echocardiographic data extending at least 5 years after TAVI consisted of 597 patients (mean age 79.6±7.1 years at the time of the procedure; mean age 86.1±7.1 years at enrolment; 47.2% male; mean Society of Thoracic Surgeons score 5.0±3.9%). Baseline characteristics at the time of TAVI are presented in **Table 1**.

PROCEDURAL DATA AND IN-HOSPITAL OUTCOMES

TAVI was performed via the transfemoral approach in 90.3% of cases, with THV distribution as follows: CoreValve (n=305, 51.2%), SAPIEN/XT (n=238, 39.9%), Lotus (n=30, 5.0%), Direct Flow (n=16, 2.7%), Portico (n=4, 0.7%), and Evolut R (n=3, 0.5%) **(Table 2, Supplementary Table 1)**. In-hospital major stroke or transient ischaemic attack (TIA) occurred in 1.5%, major vascular complications in 3.7%, major or life-threatening bleeding in 5.5%, stage 2/3 acute kidney injury in 1.3%, and new pacemaker implantation in 11.3% **(Supplementary Table 2)**.

POSTPROCEDURAL VERSUS LONG-TERM FOLLOW-UP ECHOCARDIOGRAPHY IN THE OVERALL POPULATION

The median echocardiographic follow-up was at 6.1 years (IQR 5.2-7.3 years) and extended to ≥7, 8, 9 or 10 years after the TAVI procedure in 189 (31.7%), 102 (17.1%), 48 (8.0%) and 23 (3.9%) patients, respectively. Compared to postprocedural assessment, the proportion of patients with no or trivial paravalvular leak (PVL) at long-term follow-up increased (50.9% vs 59.4%; p<0.001), while the percentage with mild PVL fell (43.2% vs 34.9%; p=0.05) **(Supplementary Table 3)**. The incidence of moderate or severe PVL remained unchanged (5.9% vs 5.7%; p=0.88), whereas the incidence of moderate or severe valvular aortic regurgitation (AR) increased over time (1.3% vs 3.4%; p=0.03), accompanied by a fall in valve area (1.8±0.5 cm^2 vs 1.6±0.5 cm^2; p<0.001), increased frequency of moderate to severe mitral regurgitation (11.5% vs 18.2%; p<0.001), and elevated estimated systolic pulmonary artery pressure (37.5 mmHg vs 39.9 mmHg; p=0.02).

POSTPROCEDURAL VERSUS LONG-TERM FOLLOW-UP ECHOCARDIOGRAPHY ACCORDING TO THV TYPE

Our second analysis focused exclusively on previous generations of currently available THVs, specifically comparing intra-annular (SAPIEN/XT or Portico) with supra-annular (CoreValve or Evolut R) devices, and excluded valve systems that are no longer commercially available (Lotus and Direct Flow). Regarding baseline characteristics, patients treated with supra-annular devices presented with a greater burden of comorbidities, including a higher incidence of coronary artery disease (48.4% vs 38.3%; p=0.019) and a history of myocardial infarction (17.5% vs 10.4%; p=0.02). They also experienced more cerebrovascular events (7.8% vs 3.7%; p=0.05) and had smaller native annuli as measured by computed tomography (perimeter: 75.2 mm vs 78.1 mm; p=0.006; area: 407.8 mm^2 vs 454.7 mm^2; p<0.001). However, severe renal impairment was more prevalent in patients with intra-annular devices (14.7% vs 7.4%; p=0.006) **(Supplementary Table 4)**.

Compared to postprocedural measurements, the peak gradient at long-term follow-up was slightly lower in patients treated with a supra-annular THV (15.6 mmHg vs 15.0 mmHg; p=0.02), while not significantly different in those with an intra-annular device (20.6 mmHg vs 23.6 mmHg; p=0.65). Consistent with these findings, the effective orifice area (EOA) remained stable in patients who received a supra-annular THV (p=0.20) but fell significantly in those with an intra-annular THV (1.9±0.5 cm^2 vs 1.6±0.5 cm^2; p<0.001). There was a significant increase in the frequency of moderate or severe valvular AR (p=0.03) in patients treated with an intra-annular THV that was not observed in those with a supra-annular valve (p=0.66).

Table 1. Baseline characteristics of the overall population and of patients with or without moderate or severe (stage 2-3) SVD.

Baseline characteristics	Total (n=597)	SVD (n=57)	No SVD (n=540)
Age, yrs	79.6±7.1	79.2±6.6	79.6±7.1
Male	282 (47.2)	21 (36.8)	261 (48.3)
Logistic EuroSCORE, %			
Mean±SD	15.14±10.71	16.27±10.47	15.03±10.74
Median [IQR]	12.0 [8.0-18.7]	12.0 [9.0-19.5]	12.0 [8.0-18.7]
STS-PROM score, %			
Mean±SD	4.98±3.89	5.63±4.82	4.90±3.74
Median [IQR]	4.0 [2.7-6.0]	4.3 [2.6-6.9]	4.0 [2.7-5.8]
EuroSCORE II, %			
Mean±SD	5.17±4.62	4.69±4.26	5.21±4.65
Median [IQR]	3.7 [2.3-6.0]	2.9 [2.1-4.9]	3.7 [2.4-6.0]
Concomitant diseases at the time of TAVI			
Diabetes mellitus	157 (26.3)	17 (29.8)	140 (25.9)
Hypertension	468 (78.5)	49 (86.0)	419 (77.7)
Dyslipidaemia	350 (59.5)	35 (62.5)	315 (59.2)
Hyperparathyroidism	9 (1.7)	0 (0)	9 (1.9)
GFR <30 ml/min/1.73 m^2	57 (9.9)	8 (15.1)	49 (9.4)
Kidney failure requiring dialysis	2 (0.3)	1 (1.8)	1 (0.2)
Chronic pulmonary disease	94 (16.0)	6 (10.5)	88 (16.5)
Peripheral artery disease	91 (15.4)	9 (15.8)	82 (15.3)
Coronary artery disease	264 (44.5)	24 (42.1)	240 (44.8)
Patient history			
Prior MI	88 (15.2)	6 (11.1)	82 (15.6)
Prior TIA	16 (2.7)	1 (1.8)	15 (2.8)
Prior stroke	36 (6.0)	4 (7.0)	32 (5.9)
Prior TIA+stroke	51 (8.6)	4 (7.0)	47 (8.7)
Prior pacemaker	67 (11.2)	6 (10.5)	61 (11.3)
Prior atrial fibrillation	120 (20.4)	8 (14.0)	112 (21.1)
NYHA Class III-IV	346 (66.7)	38 (70.4)	308 (66.2)
Previous intervention before TAVI			
Prior CABG	106 (17.8)	10 (17.5)	96 (17.8)
Prior other cardiac surgery	26 (4.4)	3 (5.3)	23 (4.3)
Prior PCI	160 (27.3)	10 (17.5)	150 (28.3)
Pre-TAVI CT scan	417 (71.0)	41 (71.9)	376 (70.9)
Mean annulus diameter, mm	23.45±2.33	22.30±1.69	23.57±2.36
Annulus perimeter, mm	76.5±13.1	72.7±17.7	76.8±12.6
Annulus area, mm^2	435.2±99.2	444.1±156.4	434.4±92.7
Severe aortic valve calcification	76 (32.2)	13 (50.0)	63 (30.0)
Eccentric valve calcification	24 (21.1)	0 (0)	24 (24.0)

Data are presented as n (%) or mean±SD unless otherwise indicated. CABG: coronary artery bypass graft; CT: computed tomography; EuroSCORE: European System for Cardiac Operative Risk Evaluation; GFR: glomerular filtration rate; IQR: interquartile range; MI: myocardial infarction; NYHA: New York Heart Association; PCI: percutaneous coronary intervention; SD: standard deviation; STS-PROM: Society of Thoracic Surgeons Predicted Risk of Mortality; SVD: structural valve deterioration; TAVI: transcatheter aortic valve implantation; TIA: transient ischaemic attack

The frequency of mild PVL fell over time in patients with a supra-annular THV (54.2% vs 39.6%; p<0.001), accompanied by an increase in the incidence of no or trivial PVL (39.6% vs 54.6%; p<0.001), while PVL severity remained unchanged in those with an intra-annular THV (p=0.66). Finally, systolic pulmonary artery pressure increased significantly in patients with a supra-annular THV (37 mmHg vs 41 mmHg; p=0.019), while the frequency of accompanying moderate to severe mitral regurgitation (MR) increased significantly with both valve types (9.5% vs 15.2%; p=0.03, and 12.5% vs 22.5%; p<0.001, for intra-annular and supra-annular THVs, respectively) **(Table 3)**.

MODERATE OR SEVERE SVD IN THE OVERALL POPULATION

The crude incidence of moderate or severe SVD was 9.5% (n=57; moderate: 6.2%, n=37; severe: 3.4%, n=20).

The cumulative incidence of moderate or severe SVD after TAVI was as follows: 2.4% (95% CI: 1.0-3.8) at

Table 2. Procedural characteristics of the overall population and of patients with or without moderate or severe (stage 2-3) SVD.

Procedural characteristics	Total (n=597)	SVD (n=57)	No SVD (n=540)
Valve type			
SAPIEN/XT[a]	238 (39.9)	35 (61.4)	203 (37.7)
CoreValve[b]	305 (51.2)	16 (28.1)	289 (53.6)
Lotus[c]	30 (5.0)	4 (7.0)	26 (4.8)
Portico[d]	4 (0.7)	0 (0)	4 (0.7)
Direct Flow[e]	16 (2.7)	2 (3.5)	14 (2.6)
Evolut R[b]	3 (0.5)	0 (0)	3 (0.6)
Size of the device			
≥26 mm	466 (78.2)	27 (47.4)	439 (81.4)
Small	233 (39.1)	36 (63.2)	197 (36.5)
Large	363 (60.9)	21 (36.8)	342 (63.5)
Intra-annular prosthesis	288 (48.3)	41 (71.9)	247 (45.8)
Access			
Femoral	537 (90.3)	49 (86.0)	488 (90.7)
Transapical	23 (3.9)	4 (7.0)	19 (3.5)
Other	35 (5.9)	4 (7.0)	31 (5.8)
General anaesthesia	266 (48.0)	30 (52.6)	236 (47.5)
Predilatation	429 (73.5)	47 (85.5)	382 (72.2)
Post-dilatation	119 (21.0)	11 (20.4)	108 (21.0)
Valve malpositioning	7 (1.2)	0 (0)	7 (1.3)
Final angiographic implantation depth, mm	5.27±3.17	8.50±0.71	5.21±3.17
Final angiographic AR			
≥Moderate	30 (6.1)	5 (10.0)	25 (5.6)
Postprocedural echocardiographic data			
Peak gradient, mmHg	18.48±8.46	20.81±7.52	18.26±8.52
Mean gradient, mmHg	9.82±4.26	11.07±4.21	9.69±4.25
Effective orifice area, cm²	1.74±0.50	1.74±0.48	1.74±0.50
PVL			
None-trivial	248 (49.9)	22 (45.8)	226 (50.3)
Mild	218 (43.9)	19 (39.6)	199 (44.3)
Moderate	30 (6.0)	6 (12.5)	24(5.3)
Severe	1 (0.2)	1 (2.1)	0 (0)
Moderate or severe PVL	31 (6.2)	7 (14.6)	24 (5.3)
Type of hospital			
University	410 (68.7)	43 (75.4)	367 (68.0)
Community or district	187 (31.3)	14 (24.6)	173 (32.0)

Data are presented as n (%) or mean±SD. [a]By Edwards Lifesciences; [b]by Medtronic; [c]by Boston Scientific; [d]by Abbott; [e]by Direct Flow Medical. AR: aortic regurgitation; PVL: paravalvular leak; SD: standard deviation; SVD: structural valve deterioration

6 years, 5.4% (95% CI: 3.0-7.7) at 7 years, 13.2% (95% CI: 8.5-17.6) at 8 years, 25.9% (95% CI: 18.2-32.9) at 9 years and 33.2% (95% CI: 23.6-41.6) at 10 years **(Central illustration, Supplementary Table 5)**. The corresponding incidence of moderate or severe SVD according to ESC/EAPCI/EACTS definitions was 12.1% (n=72; moderate: 8.7%, n=52; severe 3.4%, n=20) **(Supplementary Table 6)**. Baseline clinical variables associated with moderate or severe SVD included older age at the time of TAVI (per 10-year increase: hazard ratio [HR] 1.48, 95% CI: 0.99-2.20; p=0.058), no prior percutaneous coronary revascularisation (28.3% vs 17.5%; HR 0.47, 95% CI: 0.24-0.94; p=0.034), and a small annulus dimension (mean annulus diameter 22.30±1.69 mm vs 23.57±2.36 mm; HR 0.74, 95% CI: 0.59-0.93; p=0.009) **(Table 1, Supplementary Table 7)**.

Procedural factors included a small THV size (52.6% vs 18.6%; p<0.001), use of an intra-annular prosthesis (71.9% vs 45.8%; p<0.001) and the presence of moderate or severe PVL (14.6% vs 5.3%; p=0.008) after THV implantation **(Table 2, Supplementary Table 7)**.

Cox regression analysis identified the use of an intra-annular THV as a strong predictor of SVD (HR 38.44, 95% CI: 10.84-136.30; p<0.001), along with the presence of moderate or severe PVL (HR 3.47, 95% CI: 1.52-7.90; p=0.003) and a small device size (HR 1.90, 95% CI: 1.04-3.49; p=0.038) **(Supplementary Table 8)**. When comparing

Table 3. Postprocedural and long-term follow-up echocardiography according to THV type (intra-annular vs supra-annular) in patients with both evaluations.

	Intra-annular			Supra-annular		
	Post-procedure (n=242)	Follow-up (n=242)	*p*-value	Post-procedure (n=308)	Follow-up (n=308)	*p*-value
Peak gradient, mmHg	20.6±7.0	23.6±15.8	0.65	15.6±7.3	15.0±9.8	0.021
Mean gradient, mmHg	11.3±4.0	13.2±9.2	0.35	8.0±3.6	8.1±6.5	0.089
Effective orifice area, cm²	1.9±0.5	1.6±0.5	<0.001	1.7±0.4	1.7±0.5	0.20
PVL						
None-trivial	129 (62.0)	128 (61.5)	0.66	95 (39.6)	131 (54.6)	0.009
Mild	68 (32.7)	68 (32.7)		130 (54.2)	95 (39.6)	
Moderate	10 (4.8)	12 (5.8)		15 (6.3)	13 (5.4)	
Severe	1 (0.5)	0 (0)		0 (0)	1 (0.4)	
Moderate or severe PVL	11 (5.3)	12 (5.8)	0.78	15 (6.3)	14 (5.8)	0.85
Intraprosthetic AR						
None-trivial	189 (92.2)	171 (83.4)	0.046	219 (91.6)	230 (96.2)	0.10
Mild	12 (5.9)	21 (10.2)		18 (7.5)	6 (2.5)	
Moderate	3 (1.5)	10 (4.9)		2 (0.8)	3 (1.3)	
Severe	1 (0.5)	3 (1.5)		0 (0)	0 (0)	
Moderate or severe intraprosthetic AR	4 (2.0)	13 (6.3)	0.029	2 (0.8)	3 (1.3)	0.66
PPM	2 (0.9)	6 (2.7)	0.10	1 (0.4)	2 (0.8)	0.32
Severe PPM	1 (50)	0 (0)		0 (0)	0 (0)	
Late embolisation	0 (0)	0 (0)		0 (0)	0 (0)	
LV ejection fraction, %	57±12	57±10	0.19	56±11	54±11	0.08
LV ejection fraction <30%	6 (2.9)	2 (1.0)	0.16	5 (2.5)	8 (3.9)	0.37
End-diastolic volume, ml	96±34	97±40	0.83	101±36	91±35	0.013
End-diastolic diameter, mm	49±8	50±9	0.22	49±8	47±7	0.007
End-systolic volume, ml	43±25	44±24	0.71	48±35	41±28	0.11
End-systolic diameter, mm	35±14	34±10	0.89	33±7	35±10	0.16
MR						
None-trivial	107 (50.7)	81 (38.4)	0.012	83 (34.6)	80 (33.3)	0.039
Mild	84 (39.8)	98 (46.4)		127 (52.9)	106 (44.2)	
Moderate	17 (8.1)	30 (14.2)		28 (11.7)	48 (20.0)	
Severe	3 (1.4)	2 (0.9)		2 (0.8)	6 (2.5)	
Moderate or severe MR	20 (9.5)	32 (15.2)	0.028	30 (12.5)	54 (22.5)	<0.001
sPAP, mmHg*	38±14	39±14	0.41	37±10	41±13	0.019

Data are presented as n (%), n/N (%) or mean±SD. *n=90 for intra-annular THV; n=106 for supra-annular THV. AR: aortic regurgitation; LV: left ventricular; MR: mitral regurgitation; PPM: prosthesis-patient mismatch; PVL: paravalvular leak; SD: standard deviation; sPAP: systolic pulmonary artery pressure; THV: transcatheter heart valve

currently available THVs, specifically intra-annular (SAPIEN/XT or Portico) versus supra-annular (CoreValve or Evolut R) devices, the analysis confirmed intra-annular THV use as a significant predictor of SVD (HR 4.82, 95% CI: 2.42-9.60; p<0.001), accompanied by moderate or severe PVL (HR 3.64, 95% CI: 1.59-8.32; p=0.002) **(Supplementary Table 9, Supplementary Table 10)**.

In terms of clinical outcomes after TAVI, patients who developed moderate or severe SVD had a higher rate of hospitalisation for heart failure compared to those without SVD (15.8% vs 7.1%; p=0.034). No differences were found for other major cardiovascular events, such as stroke and myocardial infarction **(Supplementary Table 2)**.

MODERATE OR SEVERE SVD ACCORDING TO THV TYPE AND SIZE

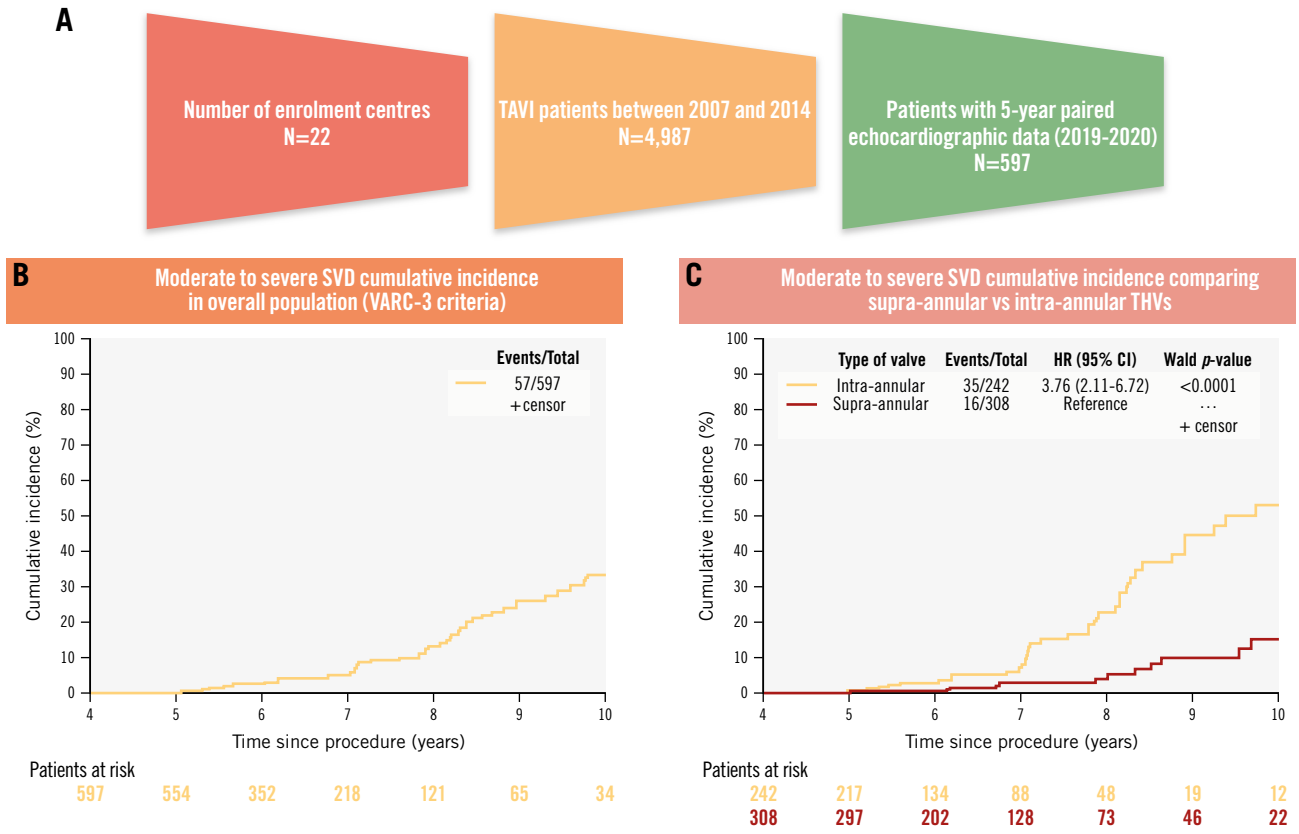
Our next analysis compared intra-annular (SAPIEN/XT, Portico) with supra-annular (CoreValve, Evolut R) devices. The proportion of patients with moderate or severe SVD was significantly higher in those with an intra-annular THV compared to those with a supra-annular valve (14.4% vs 5.2%; HR 3.76; p<0.0001) **(Central illustration)**. This difference was confined to patients who received a small valve (SAPIEN/XT ≤23 mm [n=92] or Portico ≤25 mm [n=4] vs CoreValve/Evolut R ≤26 mm [n=119: 25.0% vs 5.0%; p<0.001]), and was not observed in patients with larger valves (SAPIEN/XT ≥26 mm [n=146], Portico ≥27 mm [n=0] vs CoreValve/Evolut R ≥29 mm [n=189]: 7.5% vs 5.3%; p=0.40) **(Table 4, Figure 2, Supplementary Table 11)**.

OTHER MECHANISMS OF THV DYSFUNCTION

The crude incidences of thrombosis and PPM were 0.2% and 1.5%, respectively. There were no patients with infective endocarditis, cusp entrapment by pannus, aortic root dilatation, prosthesis erosion or embolism.

EuroIntervention — Central **Illustration**

Cumulative incidence of moderate or severe SVD over 10-year follow-up.



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A) Study population. B) Cumulative incidence of moderate or severe SVD over 10-year follow-up for the entire cohort. Over a median follow-up of 6.1 years, the overall incidence of moderate to severe SVD was 9.5% (moderate: 6.2%; severe: 3.4%). C) Cumulative incidence of moderate or severe SVD over 10-year follow-up according to transcatheter heart valve design (supra-annular vs intra-annular). Moderate to severe SVD was more frequent with intra-annular than with supra-annular THVs. P-value is based on Cox regression. CI: confidence interval; HR: hazard ratio; SVD: structural valve deterioration; TAVI: transcatheter aortic valve implantation; THV: transcatheter heart valve; VARC: Valve Academic Research Consortium

CORE LAB ANALYSIS

Independent echocardiographic analysis undertaken at the central core laboratory in a subset of 364/597 patients (61.0% of the original cohort) demonstrated a high rate of concordance (94.8%) with investigator-derived data **(Supplementary Table 12)**.

Discussion

The durability of THVs has become a significant focus as TAVI indications extend to younger patients with extended life expectancies. The present study provides novel findings concerning the long-term durability of first- and second-generation THVs over a follow-up period of more than 5 years, based upon data from 603 patients enrolled in the European Valve Durability TAVI Registry.

The main findings of this study, based on living patients assessed at least 5 years after TAVI (with a median echocardiographic follow-up of 6.1 years [IQR 5.2-7.3 years]), are as follows:

(1) The overall long-term performance of THVs was excellent, as highlighted by the absence of a significant increase in the average peak and mean gradients, and an overall reduction in PVL. However, there was an increase in the incidence of moderate or severe AR.

(2) The crude incidence of moderate or severe SVD was relatively low (9.5%) and severe SVD was even rarer (3.4%).

(3) Moderate or severe SVD was more common in patients treated with intra-annular THVs and small device sizes, as well as those with postprocedural moderate or severe PVL.

(4) The higher incidence of SVD observed with intra-annular THVs was most notable in those patients with a small valve (with no significant difference in those with a larger device).

Table 4. Echocardiography at long-term follow-up by THV size (large vs small) and type (supra-annular vs intra-annular).

	Large			Small		
	Supra-annular (n=189)	Intra-annular (n=146)	*p*-value	Supra-annular (n=119)	Intra-annular (n=96)	*p*-value
Peak gradient, mmHg	15.42±10.80	20.10±12.75	<0.001	15.43±11.48	28.90±17.46	<0.001
Mean gradient, mmHg	7.97±6.34	11.02±7.41	<0.001	8.69±8.18	16.27±10.30	<0.001
Effective orifice area, cm²	1.69±0.51	1.74±0.49	0.38	1.71±0.48	1.31±0.39	<0.001
PVL						
None-trivial	110 (59.5)	95 (68.8)	0.22	59 (51.3)	44 (51.2)	0.71
Mild	64 (34.6)	35 (25.4)		50 (43.5)	35 (40.7)	
Moderate	10 (5.4)	8 (5.8)		6 (5.2)	7 (8.1)	
Severe	1 (0.5)	0 (0)		0 (0)	0 (0)	
Moderate or severe PVL	11 (5.9)	8 (5.8)	0.95	6 (5.2)	7 (8.1)	0.40
Intraprosthetic AR						
None-trivial	175 (95.6)	127 (90.7)	0.024	109 (94.8)	61 (71.8)	<0.0001
Mild	4 (2.2)	11 (7.9)		5 (4.3)	11 (12.9)	
Moderate	4 (2.2)	1 (0.7)		1 (0.9)	11 (12.9)	
Severe	0 (0)	1 (0.7)		0 (0)	2 (2.4)	
Moderate or severe intraprosthetic AR	4 (2.2)	2 (1.4)	0.70	1 (0.9)	13 (15.3)	<0.001
PPM	2 (1.1)	1 (0.7)	>0.99	1 (0.8)	5 (5.4)	0.089
Severe PPM	0 (0)	0 (0)		0 (0)	1 (20.0)	
LV ejection fraction, %	52.6±11.3	55.4±10.1	0.034	56.6±8.9	58.3±9.8	0.14
LV ejection fraction <30%	10 (5.6)	2 (1.4)	0.054	1 (0.9)	1 (1.1)	
End-diastolic volume, ml	93.9±34.8	106.1±41.3	0.032	80.5±29.7	82.4±29.2	0.61
End-diastolic diameter, mm	47.8±8.1	49.7±7.8	0.057	45.4±6.5	47.4±10.3	0.39
End-systolic volume, ml	42.4±22.9	50.6±25.8	0.036	37.2±21.9	36.7±20.5	0.69
End-systolic diameter, mm	34.1±8.5	34.0±8.6	0.97	32.6±7.8	31.8±11.6	0.22
MR						
None-trivial	63 (34.1)	61 (43.3)	0.062	40 (34.5)	28 (31.8)	0.87
Mild	78 (42.2)	62 (44.0)		52 (44.8)	43 (48.9)	
Moderate	41 (22.2)	17 (12.1)		21 (18.1)	16 (18.2)	
Severe	3 (1.6)	1 (0.7)		3 (2.6)	1 (1.1)	
Moderate or severe MR	44 (23.8)	18 (12.8)	0.012	24 (20.7)	17 (19.3)	0.81
sPAP, mmHg	38.6±12.0	36.2±13.5	0.061	39.8±15.1	41.2±15.8	0.71
Crude incidence of moderate or severe SVD	10 (5.3)	11 (7.5)	0.40	6 (5.0)	24 (25.0)	<0.001

Data are presented as n (%) or mean±SD. AR: aortic regurgitation; LV: left ventricular; MR: mitral regurgitation; PPM: prosthesis-patient mismatch; PVL: paravalvular leak; SD: standard deviation; sPAP: systolic pulmonary artery pressure; SVD: structural valve deterioration; THV: transcatheter heart valve

COMPARATIVE DATA

In recent years, data from various randomised studies and registries have consistently shown low rates of SVD after TAVI within a 5-year time frame. For instance, the PARTNER 1 trial assessed the first generation of balloon-expandable (intra-annular) THVs and revealed no evidence of SVD at 5-year follow-up[6]. The FRANCE-2 Registry (the largest midterm TAVI durability registry including over 4,000 patients with both supra-annular and intra-annular THVs) reported severe SVD in 2.5% and moderate or severe SVD in 13.3% (VARC-2 criteria) of surviving patients at 5 years[19]. Similarly, rates of irreversible severe SVD (according to VARC-3 definitions) were comparable at the 5-year follow-up in both treatment arms of the PARTNER 3 trial (balloon-expandable [intra-annular]: TAVI 1.1%; surgery: 1.0%)[10].

Although the studies used varying definitions of SVD, its low incidence suggests that durability concerns may arise later, highlighting the need for long-term data to fully understand the implications of THV use.

However, data on THV function beyond 5 years after TAVI are very scarce, especially beyond 10 years[20]. Most available data come from relatively small registries and involve first-generation THVs, which report an incidence of severe SVD ranging from 2.4% to 5.9% (according to ESC/EAPCI/EACTS definitions)[5,13,21-23]. Specifically, the UK TAVI registry reported long-term outcomes in 221 patients (median echocardiographic follow-up of 7.0 years [IQR 5-13 years]; >10 years in 43 patients

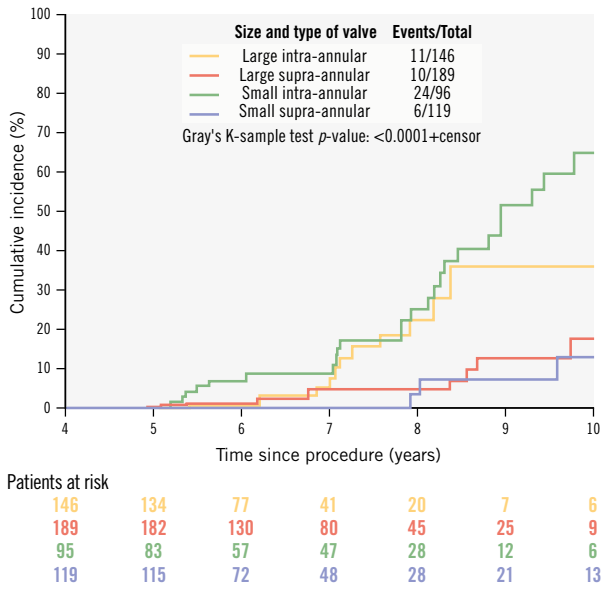

Figure 2. *Cumulative incidence of moderate or severe structural valve deterioration according to transcatheter heart valve design (supra-annular vs intra-annular) and size (large vs small).*

[19.5%]) with severe SVD identified in 13 (5.9%) of them at a median of 7.8 years after TAVI[13]. The NOTION trial included 145 patients who underwent TAVI with self-expanding (supra-annular) THVs between 2010 and 2013 and has thus far been the only randomised controlled study to provide follow-up data beyond 5 years. In this trial, the incidence of severe SVD (according to ESC/EAPCI/EACTS definitions) was lower after TAVI compared with surgical aortic valve replacement (SAVR; 13.9% vs 28.3%; p=0.0017) at 8-year follow-up with no significant difference in the incidence of bioprosthetic valve failure (BVF; 8.7% vs 10.5%; p=0.61)[11]. These findings remained consistent at a recently reported 10-year follow-up after application of the VARC-3 definitions, with a lower incidence of severe SVD after TAVI compared with SAVR (1.5% vs 10%; HR 0.2, 95% CI: 0.04-0.70; p=0.02) and an equivalent incidence of BVF in both treatment arms (9.7% vs 13.8%; HR 0.7, 95% CI: 0.4-1.5; p=0.4)[12].

The reported incidence of SVD varies significantly across different studies despite the widespread adoption of the ESC/EAPCI/EACTS definitions. This may be due to the frequent absence of an external echocardiographic core laboratory, which increases the risk of interobserver variability, or the lack of systematic echocardiographic follow-up. These limitations potentially compromise the precise characterisation of THV dysfunction, particularly if evaluation relies upon the retrospective assessment of echocardiograms by a single individual. Furthermore, the limited number of patients available for long-term follow-up in these studies is largely due to the competing risk of death among the elderly and frail population that underwent TAVI during the early pivotal trials. This reduction in the at-risk cohort over time can bias the long-term durability data, as fewer individuals are available to assess the true longevity of the valves.

Given these considerations, our registry is unique in exclusively enrolling living patients who underwent TAVI at least 5 years previously and employing comprehensive echocardiographic evaluation to assess THV performance using VARC-3 criteria, thereby ensuring an accurate and real-time representation of SVD incidence in the TAVI population[15]. Furthermore, use of a centralised echocardiographic core laboratory (which analysed 61% of the studies and demonstrated a concordance rate of 95% with investigator data in defining SVD) substantially bolsters the reliability and validity of our findings.

INCIDENCE OF SVD ACCORDING TO TYPE AND SIZE OF THV

The incidence of moderate or severe SVD in our registry was significantly higher in patients treated with an intra-annular rather than a supra-annular THV (14.4% vs 5.2%; p<0.001). One potential explanation for this difference may be the inherent design features of the two valve systems. Supra-annular THVs generally have a greater EOA and reduced transvalvular gradients compared to intra-annular devices, with potential implications for sustained durability.

Our findings are consistent with those of the previously mentioned French registry, which demonstrated rates of moderate and severe SVD of 8.9% and 0%, respectively, at 5-year follow-up for self-expanding (supra-annular) THVs, compared with 13.8% and 4.1%, respectively, for balloon-expandable (intra-annular) devices[19]. In a single-centre German registry, at 7 years, the overall crude cumulative incidence of moderate or severe SVD, according to the ESC definition, was even higher at 14.9%. However, it was once again more frequent in balloon-expandable THVs compared to self-expanding THVs (22.6% vs 11.8%, respectively)[23].

Similarly, in the head-to-head CHOICE trial, moderate or severe SVD was observed more frequently in patients with balloon-expandable (intra-annular) valves at 5-year follow-up (6.6% vs 0%; p=0.018)[24]. Finally, severe SVD was more frequent in patients with intra-annular THVs (SAPIEN/SAPIEN XT) compared with supra-annular devices (CoreValve) at a median follow-up of 7.0 years in the UK TAVI registry (11.9% vs 3.5%; p=0.02)[13].

However, these observations unveil several unresolved questions regarding potential underlying mechanisms. The size of the aortic annulus is a crucial anatomical feature that significantly influences valve haemodynamics and clinical outcomes after both TAVI and SAVR, and previous research has shown that the risk of PPM is significantly higher after SAVR in patients with small annuli (and associated with adverse midterm clinical outcomes)[25]. Several studies have confirmed that TAVI offers an advantage in this setting, particularly when performed with a supra-annular THV[26-28]. In our analysis, the significantly higher incidence of moderate/severe SVD affecting intra-annular THVs (SAPIEN/XT and Portico) compared to supra-annular devices (CoreValve/Evolut R) was restricted to patients treated with smaller valves (25.0% vs 5.0%; p<0.001), with no significant difference in those receiving larger devices. These observations are consistent with findings in the UK TAVI registry (severe SVD with small SAPIEN/XT 28.6% vs small CoreValve 3.6%). The recently published SMART trial randomised patients

with small annuli to TAVI using either the Evolut PRO/PRO+/FX or SAPIEN 3/3 Ultra THVs and demonstrated superior haemodynamics at 1 year in those who received a supra-annular Evolut device (EOA 1.99 cm^2 vs 1.50 cm^2; p<0.001), suggesting an important association between haemodynamic performance and long-term durability[13,17].

Several other factors warrant consideration, including the impact of oversizing, which can lead to underexpansion, pinwheeling, and increased bending stress on the valve leaflets. Balloon post-dilation may also cause leaflet injury, potentially accelerating SVD. Additionally, THV design plays a critical role, as the outflow orifice of the prosthetic valve leaflets may be the primary determinant of haemodynamics, rather than the intra-annular or supra-annular positioning[27,29].

Accurate device sizing, increasing operator expertise and advances in THV design (including novel biomimetic platforms, improved skirt technology, anticalcification treatments and acellular leaflets) may address these concerns but will also require rigorous evaluation in future randomised trials and registries.

Limitations

Our study has several limitations. Firstly, long-term echocardiographic data were available for only a limited proportion of the total patients who underwent TAVI in participating centres between 2007 and 2014 (654/4,987; 13%). The patient population during this period was primarily elderly with various comorbidities, and many did not survive beyond 5 years post-procedure. The cause of death was unknown for most cases, so we cannot exclude the possibility that some succumbed to SVD-related complications. Thus, our registry lacks crucial data on 5-year survival after TAVI. Secondly, our inclusion criteria required patients to be alive at enrolment, preventing us from determining the incidence of BVF (according to VARC-3 definitions) without data on valve-related deaths. Thirdly, all TAVI procedures occurred before 2015, making our findings specific to first- and second-generation THVs. Finally, the COVID-19 pandemic hindered many patients from travelling to their TAVI centre for follow-up echocardiography, complicating enrolment and leading to the decision to halt recruitment at 654 subjects.

Conclusions

The European Valve Durability TAVI Registry assessed nearly 600 patients at least 5 years post-TAVI, demonstrating that the haemodynamic function of first-generation THVs remains stable up to 10 years. The incidence of moderate or severe SVD was relatively low (9.5%) at a median 6.1-year follow-up, with severe SVD even rarer (3.4%). However, rates were higher in patients with older-generation intra-annular THVs and smaller-sized devices.

Further research is needed to address the mechanisms behind accelerated SVD, and larger ongoing studies with newer THV designs will enhance generalisation. Our findings underscore the importance of imaging-guided and anatomically tailored device selection in clinical practice. However, due to potential confounding factors, future randomised trials are necessary to compare the durability of current intra-annular and supra-annular valves, especially in younger patients with long life expectancies.

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All investigators are listed in **Supplementary Appendix 1**.

Guest Editor

This paper was guest edited by Franz-Josef Neumann, MD, PhD; *Department of Cardiology and Angiology, University Heart Center Freiburg - Bad Krozingen, Bad Krozingen, Germany.*

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References

1. Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S, Bauersachs J, Capodanno D, Conradi L, De Bonis M, De Paulis R, Delgado V, Freemantle N, Haugaa KH, Jeppsson A, Jüni P, Pierard L, Prendergast BD, Sádaba JR, Tribouilloy C, Wojakowski W. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. *EuroIntervention.* 2022;17:e1126-96.

2. Popma JJ, Deeb GM, Yakubov SJ, Mumtaz M, Gada H, O'Hair D, Bajwa T, Heiser JC, Merhi W, Kleiman NS, Askew J, Sorajja P, Rovin J, Chetcuti SJ, Adams DH, Teirstein PS, Zorn GL 3rd, Forrest JK, Tchétché D, Resar J, Walton A, Piazza N, Ramlawi B, Robinson N, Petrossian G, Gleason TG, Oh JK, Boulware MJ, Qiao H, Mugglin AS, Reardon MJ; Evolut Low Risk Trial Investigators. Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients. *N Engl J Med.* 2019;380:1706-15.

3. Thyregod HG, Steinbrüchel DA, Ihlemann N, Nissen H, Kjeldsen BJ, Petursson P, Chang Y, Franzen OW, Engstrøm T, Clemmensen P, Hansen PB, Andersen LW, Olsen PS, Søndergaard L. Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Severe Aortic Valve Stenosis: 1-Year Results From the All-Comers NOTION Randomized Clinical Trial. *J Am Coll Cardiol.* 2015;65:2184-94.

4. Mack MJ, Leon MB, Thourani VH, Makkar R, Kodali SK, Russo M, Kapadia SR, Malaisrie SC, Cohen DJ, Pibarot P, Leipsic J, Hahn RT, Blanke P, Williams MR, McCabe JM, Brown DL, Babaliaros V, Goldman S, Szeto WY, Genereux P, Pershad A, Pocock SJ, Alu MC, Webb JG, Smith CR; PARTNER 3 Investigators. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. *N Engl J Med.* 2019;380:1695-705.

5. Barbanti M, Petronio AS, Ettori F, Latib A, Bedogni F, De Marco F, Poli A, Boschetti C, De Carlo M, Fiorina C, Colombo A, Brambilla N, Bruschi G, Martina P, Pandolfi C, Giannini C, Curello S, Sgroi C, Gulino S, Patanè M, Ohno Y, Tamburino C, Attizzani GF, Immè S, Gentili A, Tamburino C. 5-Year Outcomes After Transcatheter Aortic Valve Implantation With CoreValve Prosthesis. *JACC Cardiovasc Interv.* 2015;8:1084-91.

6. Mack MJ, Leon MB, Smith CR, Miller DC, Moses JW, Tuzcu EM, Webb JG, Douglas PS, Anderson WN, Blackstone EH, Kodali SK, Makkar RR, Fontana GP, Kapadia S, Bavaria J, Hahn RT, Thourani VH, Babaliaros V, Pichard A, Herrmann HC, Brown DL, Williams M, Akin J, Davidson MJ, Svensson LG; PARTNER 1 trial investigators. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial. *Lancet.* 2015;385:2477-84.

7. Kapadia SR, Leon MB, Makkar RR, Tuzcu EM, Svensson LG, Kodali S, Webb JG, Mack MJ, Douglas PS, Thourani VH, Babaliaros VC, Herrmann HC, Szeto WY, Pichard AD, Williams MR, Fontana GP, Miller DC, Anderson WN, Akin JJ, Davidson MJ, Smith CR; PARTNER trial investigators. 5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial. *Lancet*. 2015;385:2485-91.

8. Toggweiler S, Humphries KH, Lee M, Binder RK, Moss RR, Freeman M, Ye J, Cheung A, Wood DA, Webb JG. 5-year outcome after transcatheter aortic valve implantation. *J Am Coll Cardiol*. 2013;61:413-9.

9. Forrest JK, Deeb GM, Yakubov SJ, Gada H, Mumtaz MA, Ramlawi B, Bajwa T, Teirstein PS, DeFrain M, Muppala M, Rutkin BJ, Chawla A, Jenson B, Chetcuti SJ, Stoler RC, Poulin MF, Khabbaz K, Levack M, Goel K, Tchétché D, Lam KY, Tonino PAL, Ito S, Oh JK, Huang J, Popma JJ, Kleiman N, Reardon MJ; Low Risk Trial Investigators. 3-Year Outcomes After Transcatheter or Surgical Aortic Valve Replacement in Low-Risk Patients With Aortic Stenosis. *J Am Coll Cardiol*. 2023;81:1663-74.

10. Mack MJ, Leon MB, Thourani VH, Pibarot P, Hahn RT, Genereux P, Kodali SK, Kapadia SR, Cohen DJ, Pocock SJ, Lu M, White R, Szerlip M, Ternacle J, Malaisrie SC, Herrmann HC, Szeto WY, Russo MJ, Babaliaros V, Smith CR, Blanke P, Webb JG, Makkar R; PARTNER 3 Investigators. Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years. *N Engl J Med*. 2023;389:1949-60.

11. Jørgensen TH, Thyregod HGH, Ihlemann N, Nissen H, Petursson P, Kjeldsen BJ, Steinbrüchel DA, Olsen PS, Søndergaard L. Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. surgical aortic valve replacement. *Eur Heart J*. 2021;42:2912-9.

12. Thyregod HGH, Jørgensen TH, Ihlemann N, Steinbrüchel DA, Nissen H, Kjeldsen BJ, Petursson P, De Backer O, Olsen PS, Søndergaard L. Transcatheter or surgical aortic valve implantation: 10-year outcomes of the NOTION trial. *Eur Heart J*. 2024;45:1116-24.

13. Ali N, Hildick-Smith D, Parker J, Malkin CJ, Cunnington MS, Gurung S, Mailey J, MacCarthy PA, Bharucha A, Brecker SJ, Hoole SP, Dorman S, Doshi SN, Wiper A, Buch MH, Banning AP, Spence MS, Blackman DJ. Long-term durability of self-expanding and balloon-expandable transcatheter aortic valve prostheses: UK TAVI registry. *Catheter Cardiovasc Interv*. 2023;101:932-42.

14. Capodanno D, Petronio AS, Prendergast B, Eltchaninoff H, Vahanian A, Modine T, Lancellotti P, Sondergaard L, Ludman PF, Tamburino C, Piazza N, Hancock J, Mehilli J, Byrne RA, Baumbach A, Kappetein AP, Windecker S, Bax J, Haude M. Standardized definitions of structural deterioration and valve failure in assessing long-term durability of transcatheter and surgical aortic bioprosthetic valves: a consensus statement from the European Association of Percutaneous Cardiovascular Interventions (EAPCI) endorsed by the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). *Eur J Cardiothorac Surg*. 2017;52:408-17.

15. VARC-3 WRITING COMMITTEE; Généreux P, Piazza N, Alu MC, Nazif T, Hahn RT, Pibarot P, Bax JJ, Leipsic JA, Blanke P, Blackstone EH, Finn MT, Kapadia S, Linke A, Mack MJ, Makkar R, Mehran R, Popma JJ, Reardon M, Rodes-Cabau J, Van Mieghem NM, Webb JG, Cohen DJ, Leon MB. Valve Academic Research Consortium 3: updated endpoint definitions for aortic valve clinical research. *Eur Heart J*. 2021;42:1825-57.

16. Blanke P, Weir-McCall JR, Achenbach S, Delgado V, Hausleiter J, Jilaihawi H, Marwan M, Nørgaard BL, Piazza N, Schoenhagen P, Leipsic JA. Computed Tomography Imaging in the Context of Transcatheter Aortic Valve Implantation (TAVI)/Transcatheter Aortic Valve Replacement (TAVR): An Expert Consensus Document of the Society of Cardiovascular Computed Tomography. *JACC Cardiovasc Imaging*. 2019;12:1-24.

17. Herrmann HC, Mehran R, Blackman DJ, Bailey S, Möllmann H, Abdel-Wahab M, Ben Ali W, Mahoney PD, Ruge H, Wood DA, Bleiziffer S, Ramlawi B, Gada H, Petronio AS, Resor CD, Merhi W, Garcia Del Blanco B, Attizzani GF, Batchelor WB, Gillam LD, Guerrero M, Rogers T, Rovin JD, Szerlip M, Whisenant B, Deeb GM, Grubb KJ, Padang R, Fan MT, Althouse AD, Tchétché D; SMART Trial Investigators. Self-Expanding or Balloon-Expandable TAVR in Patients with a Small Aortic Annulus. *N Engl J Med*. 2024;390:1959-71.

18. Hosmer DW, Hosmer T, Le Cessie S, Lemeshow S. A comparison of goodness-of-fit tests for the logistic regression model. *Stat Med*. 1997;16: 965-80.

19. Didier R, Eltchaninoff H, Donzeau-Gouge P, Chevreul K, Fajadet J, Leprince P, Leguerrier A, Lièvre M, Prat A, Teiger E, Lefevre T, Tchetché D, Carrié D, Himbert D, Albat B, Cribier A, Sudre A, Blanchard D, Rioufol G, Collet F, Houel R, Dos Santos P, Meneveau N, Ghostine S, Manigold T, Guyon P, Cuisset T, Le Breton H, Delepine S, Favereau X, Souteyrand G, Ohlmann P, Doisy V, Lognoné T, Gommeaux A, Claudel JP, Bourlon F, Bertrand B, Iung B, Gilard M. Five-Year Clinical Outcome and Valve Durability After Transcatheter Aortic Valve Replacement in High-Risk Patients. *Circulation*. 2018;138:2597-607.

20. Ternacle J, Hecht S, Eltchaninoff H, Salaun E, Clavel MA, Côté N, Pibarot P. Durability of transcatheter aortic valve implantation. *EuroIntervention*. 2024;20:e845-64.

21. Sathananthan J, Lauck S, Polderman J, Yu M, Stephenson A, Sathananthan G, Moss R, Cheung A, Ye J, Blanke P, Leipsic J, Wood DA, Webb JG. Ten year follow-up of high-risk patients treated during the early experience with transcatheter aortic valve replacement. *Catheter Cardiovasc Interv*. 2021;97: E431-7.

22. Panico RA, Giannini C, De Carlo M, Angelillis M, Spontoni P, Pieroni A, Costa G, Bertini P, Guarracino F, Petronio AS. Long-term results and durability of the CoreValve transcatheter aortic bioprosthesis: outcomes beyond five years. *EuroIntervention*. 2019;14:1639-47.

23. Deutsch MA, Erlebach M, Burri M, Hapfelmeier A, Witt OG, Ziegelmueller JA, Wottke M, Ruge H, Krane M, Piazza N, Bleiziffer S, Lange R. Beyond the five-year horizon: long-term outcome of high-risk and inoperable patients undergoing TAVR with first-generation devices. *EuroIntervention*. 2018;14:41-9.

24. Abdel-Wahab M, Landt M, Neumann FJ, Massberg S, Frerker C, Kurz T, Kaur J, Toelg R, Sachse S, Jochheim D, Schäfer U, El-Mawardy M, Robinson DR, Richardt G; CHOICE Investigators. 5-Year Outcomes After TAVR With Balloon-Expandable Versus Self-Expanding Valves: Results From the CHOICE Randomized Clinical Trial. *JACC Cardiovasc Interv*. 2020;13:1071-82.

25. Pibarot P, Dumesnil JG. Hemodynamic and clinical impact of prosthesis-patient mismatch in the aortic valve position and its prevention. *J Am Coll Cardiol*. 2000;36:1131-41.

26. Rodés-Cabau J, Pibarot P, Suri RM, Kodali S, Thourani VH, Szeto WY, Svensson LG, Dumont E, Xu K, Hahn RT, Leon MB. Impact of aortic annulus size on valve hemodynamics and clinical outcomes after transcatheter and surgical aortic valve replacement: insights from the PARTNER Trial. *Circ Cardiovasc Interv*. 2014;7:701-11.

27. Abdelghani M, Mankerious N, Allali A, Landt M, Kaur J, Sulimov DS, Merten C, Sachse S, Mehilli J, Neumann FJ, Frerker C, Kurz T, El-Mawardy M, Richardt G, Abdel-Wahab M. Bioprosthetic Valve Performance After Transcatheter Aortic Valve Replacement With Self-Expanding Versus Balloon-Expandable Valves in Large Versus Small Aortic Valve Annuli: Insights From the CHOICE Trial and the CHOICE-Extend Registry. *JACC Cardiovasc Interv*. 2018;11:2507-18.

28. Mauri V, Kim WK, Abumayyaleh M, Walther T, Moellmann H, Schaefer U, Conradi L, Hengstenberg C, Hilker M, Wahlers T, Baldus S, Rudolph V, Madershahian N, Rudolph TK. Short-Term Outcome and Hemodynamic Performance of Next-Generation Self-Expanding Versus Balloon-Expandable Transcatheter Aortic Valves in Patients With Small Aortic Annulus: A Multicenter Propensity-Matched Comparison. *Circ Cardiovasc Interv*. 2017;10:e005013.

29. Brown JA, Yousef S, Toma C, Kliner D, Serna-Gallegos D, Makani A, West D, Wang Y, Thoma F, Pompeu Sá M, Sultan I. Self-Expanding Transcatheter Aortic Valves Optimize Transvalvular Hemodynamics Independent of Intra- Versus Supra-Annular Design. *Am J Cardiol*. 2023;207:48-53.

Supplementary data

Supplementary Appendix 1. EORP Oversight, Registry, and Executive Committees – Investigators List.

Supplementary Table 1. Classification of valve type and size in the overall population and in patients with or without moderate or severe (stage 2-3) SVD.

Supplementary Table 2. In-hospital outcomes and long-term clinical follow-up of the overall population and in patients with or without moderate or severe (stage 2-3) SVD.

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Supplementary Table 11. Cox regression model adjusted for covariates comparing all subgroups with small supra-annular valves.
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The supplementary data are published online at: https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-24-00662

Supplementary data

Supplementary Appendix 1. EORP Oversight, Registry, and Executive Committees – Investigators List.

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Supplementary Table 1. Classification of valve type and size in the overall population and in patients with or without moderate or severe (stage 2-3) SVD.

	Total (n = 597)	**SVD (n = 57)**	**no-SVD (n = 540)**	**p-value***
Sapien/XT (mm)				
N	238	35	203	
23	92 (38.7%)	24 (68.6%)	68 (33.5%)	<.001
26	114 (47.9%)	7 (20.0%)	107 (52.7%)	
29	32 (13.4%)	4 (11.4%)	28 (13.8%)	
Small	92 (38.7%)	24 (68.6%)	68 (33.5%)	
Large	146 (61.3%)	11 (31.4%)	135 (66.5%)	
CoreValve (mm)				
N	305	16	289	
23	9 (2.9%)	0	9 (3.1%)	1.0
26	109 (35.7%)	6 (37.5%)	103 (35.6%)	
29	157 (51.5%)	9 (56.3%)	148 (51.2%)	
31	30 (9.8%)	1 (6.3%)	29 (10.0%)	
Small	118 (38.7%)	6 (37.5%)	112 (38.8%)	
Large	187 (61.3%)	10 (62.5%)	177 (61.2%)	
Lotus (mm)				
N	30	4	26	
23	9 (30.0%)	4 (100.0%)	5 (19.2%)	0.008
25	6 (20.0%)	0	6 (23.1%)	
27	15 (50.0%)	0	15 (57.7%)	
Small	9 (30.0%)	4 (100.0%)	5 (19.2%)	
Large	21 (70.0%)	0	21 (80.8%)	
Portico (mm)				
N	4	0	4	
23	2 (50.0%)		2 (50.0%)	
25	2 (50.0%)		2 (50.0%)	
Small	4 (100.0%)		4 (100.0%)	
Direct Flow (mm)				
N	16	2	14	
25	9 (56.3%)	2 (100.0%)	7 (50.0%)	0.55
27	7 (43.7%)	0	7 (50.0%)	
Small	9 (56.3%)	2 (100.0%)	7 (50.0%)	
Large	7 (43.8%)	0	7 (50.0%)	
Evolut R (mm)				
N	3	0	3	
23	1 (33.3%)		1 (33.3%)	
29	2 (66.7%)		2 (66.7%)	

SVD= structural valve deterioration.

Supplementary Table 2. In-hospital outcomes and long-term clinical follow-up of the overall population and in patients with or without moderate or severe (stage 2-3) SVD.

	Total (n = 597)	**SVD (n = 57)**	**no-SVD (n = 540)**	**p-value**
In-hospital outcomes				
AKI stage 2 or 3	8 (1.3%)	0	8 (1.5%)	1.0
Conversion to open surgery	3 (0.5%)	0	3 (0.6%)	1.0
Minor vascular complication	52 (8.7%)	4 (7.0%)	48 (8.9%)	0.81
Major vascular complication	22 (3.7%)	4 (7.0%)	18 (3.3%)	0.15
Life-threatening bleeding	6 (1.0%)	1 (1.8%)	5 (0.9%)	0.45
Major bleeding	27 (4.5%)	3 (5.3%)	24 (4.4%)	0.74
Minor bleeding	107 (17.9%)	7 (12.3%)	100 (18.5%)	0.24
Myocardial infarction	4 (0.7%)	1 (1.8%)	3 (0.6%)	0.33
Stroke or TIA	9 (1.5%)	2 (3.5%)	7 (1.3%)	0.21
Permanent pacemaker implantation	67 (11.3%)	3 (5.3%)	64 (11.9%)	0.13
Long term clinical follow-up				
Stroke	20 (3.3%)	1 (1.8%)	19 (3.5%)	0.71
Time between stroke and TAVI (years)				
Median (IQR)	3.0 (2.5-3.7)	2.8 (2.8-2.8)	3.1 (2.5-4.0)	
Myocardial Infarction	15 (2.5%)	3 (5.3%)	12 (2.2%)	0.17
Time between MI and TAVI (years)				
Median (IQR)	3.0 (1.1-4.1)	3.1 (1.1-3.7)	2.8 (1.2-4.3)	
Re-hospitalisation with HF	47 (7.9%)	9 (15.8%)	38 (7.1%)	**0.034**
Time between HF and TAVI (years)				
Median (IQR)	3.9 (3.0-5.3)	5.5 (3.7-7.1)	3.9 (2.0-4.9)	

SVD= Structural valve deterioration; AKI= acute kidney injury; TIA= transient ischemic attack; TAVI= transcatheter aortic valve implantation; IQR= interquartile range; MI=Myocardial Infarction; HF=heart failure.

Supplementary Table 3. Postprocedural and long-term follow-up echocardiography in the overall population.

	Postprocedural (n = 597)	Follow-up (n = 597)	P-value
Peak gradient (mmHg)			
Mean ± SD	18.34 ±7.90	19.55 ±14.07	0.18
Mean gradient (mmHg)			
Mean ± SD	9.88 ±4.29	10.92 ±8.51	0.77
Aortic valve area (cm^2)			
Mean ± SD	1.77 ±0.49	1.62 ±0.51	<0.001
PVL			
None-trivial	242 (50.9%)	282 (59.4%)	0.047
Mild	205 (43.2%)	166 (34.9%)	
Moderate	27 (5.7%)	26 (5.5%)	
Severe	1 (0.2%)	1 (0.2%)	
Moderate or severe PVL	28 (5.9%)	27 (5.7%)	0.88
Intra-prosthetic AR			
None/trivial	435 (92.0%)	429 (90.7%)	0.58
Mild	32 (6.8%)	28 (5.9%)	
Moderate	5 (1.1%)	13 (2.7%)	
Severe	1 (0.2%)	3 (0.6%)	
Moderate or severe intra-prosthetic AR	6 (1.3%)	16 (3.4%)	0.033
PPM	3 (0.6%)	8 (1.6%)	0.059
Severe PPM	1 (25.0%)	0	0.317
LV ejection fraction (%)			
Mean ± SD	56.4 ±11.7	55.2 ±10.7	0.020
LV ejection fraction<30%	12 (2.7%)	10 (2.3%)	0.66
End-diastolic volume (ml)			
Mean ± SD	98.0 ±35.1	94.4 ±37.9	0.066
End-diastolic diameter (mm)			
Mean ± SD	48.8 ±7.6	48.5 ±8.3	0.378
End-systolic volume (ml)			
Mean ± SD	45.0 ±28.7	43.0 ±25.5	0.53
End-systolic diameter (mm)			
Mean ± SD	34.2 ±12.5	34.4 ±10.0	0.36
Moderate or severe MR	55 (11.5%)	87 (18.2%)	<0.001
PAPs (mmHg)			
Mean ± SD	37.5 ±11.6	39.9 ±13.5	0.019

AR=aortic regurgitation; TAVI= transcatheter aortic valve implantation; LV= left ventricle; MR= mitral regurgitation; PAPs= Systolic pulmonary artery pressure; PPM= prosthesis-patient mismatch.

Supplementary Table 4. Baseline characteristics according to THV type (intra-annular vs supra-annular) excluding Lotus and Direct Flow devices.

	Total (n = 550)	**Intra-annular (n = 242)**	**Supra-annular (n = 308)**	**p-value**
Age (yrs)				
Mean ± SD	79.5 ±7.1	80.2 ±6.7	79.0 ±7.3	0.078
Male	253 (46.0%)	112 (46.3%)	141 (45.8%)	0.91
Logistic Euroscore (%)				
Mean ± SD	15.53 ±10.80	15.16 ±10.58	15.80 ±10.98	
Median (IQR)	12.2 (8.4-18.8)	12.0 (8.9-18.4)	12.7 (8.0-19.6)	0.72
STS score mortality (%)				
Mean ± SD	5.07 ±4.02	5.26 ±4.11	4.95 ±3.96	
Median (IQR)	4.0 (2.7-6.1)	4.2 (2.8-6.6)	3.9 (2.6-5.8)	0.33
EuroSCORE II (%)				
Mean ± SD	5.42 ±4.73	6.18 ±5.93	5.14 ±4.19	
Median (IQR)	3.8 (2.6-6.3)	3.8 (2.6-6.9)	3.8 (2.6-6.1)	0.75
Concomitant diseases at time of TAVI				
Diabetes mellitus	146 (26.5%)	65 (26.9%)	81 (26.3%)	0.88
Hypertension	433 (78.9%)	186 (76.9%)	247 (80.5%)	0.31
Dyslipidaemia	322 (59.4%)	146 (60.3%)	176 (58.7%)	0.70
Hyperparathyroidism	9 (1.9%)	5 (2.2%)	4 (1.6%)	0.74
GFR<30 ml/min	56 (10.6%)	34 (14.7%)	22 (7.4%)	**0.006**
Dialysis	2 (0.4%)	1 (0.4%)	1 (0.3%)	1.0
Chronic pulmonary disease	86 (15.9%)	37 (15.3%)	49 (16.3%)	0.74
Peripheral artery disease	88 (16.1%)	42 (17.4%)	46 (15.1%)	0.47
Coronary artery disease	240 (44.0%)	92 (38.3%)	148 (48.4%)	**0.019**
Prior MI	77 (14.4%)	24 (10.4%)	53 (17.5%)	**0.020**
Prior TIA	14 (2.6%)	5 (2.1%)	9 (2.9%)	0.53
Prior stroke	33 (6.0%)	9 (3.7%)	24 (7.8%)	**0.047**
Prior TIA + stroke	46 (8.4%)	14 (5.8%)	32 (10.4%)	**0.055**
Prior pacemaker	58 (10.6%)	21 (8.7%)	37 (12.0%)	0.21
Prior atrial fibrillation	112 (20.6%)	55 (22.7%)	57 (18.9%)	0.27
NYHA class III-IV	321 (67.6%)	148 (69.5%)	173 (66.0%)	0.42
Previous intervention before TAVI				
Prior CABG	96 (17.5%)	48 (19.8%)	48 (15.6%)	0.19
Prior other cardiac surgery	23 (4.2%)	12 (5.0%)	11 (3.6%)	0.42
Prior PCI	143 (26.4%)	59 (24.4%)	84 (28.1%)	0.33
Mean annulus diameter (mm)				
Mean ± SD	23.42 ±2.34	23.68 ±2.34	23.25 ±2.33	0.49
Annulus perimeter (mm)				
Mean ± SD	76.1 ±13.7	78.1 ±18.8	75.2 ±10.3	**0.006**
Annulus area (mm^2)				
Mean ± SD	433.3 ±97.9	454.7 ±107.6	407.8 ±78.1	**<.001**
Severe aortic valve calcification	68 (31.5%)	41 (33.1%)	27 (29.3%)	0.56
Eccentric valve calcification	23 (20.9%)	14 (21.9%)	9 (19.6%)	0.77
Type of hospital				
University	384 (69.8%)	194 (80.2%)	190 (61.7%)	**<.001**
Community or district	166 (30.2%)	48 (19.8%)	118 (38.3%)	

CABG= coronary artery bypass graft; CT= computed tomography; GFR= glomerular filtrate rate; IQR= interquartile range; MI= myocardial infarction; NYHA= New York Heart Association; PCI=

percutaneous coronary intervention; STS= Society of Thoracic Surgeons; TAVI= transcatheter aortic valve implantation; THV= transcatheter heart valve; TIA= transient ischaemic attack.

Supplementary Table 5. Cumulative incidence of the detection of moderate or severe (stage 2-3) SVD after TAVI.

Year	Cumulative incidence (95% CI) by Kaplan-Meier method Total
1	0.0 (0.0-0.0%)
2	0.0 (0.0-0.0%)
3	0.0 (0.0-0.0%)
4	0.0 (0.0-0.0%)
5	0.0 (0.0-0.0%)
6	2.4 (1.0-3.8%)
7	5.4 (3.0-7.7%)
8	13.2 (8.5-17.6%)
9	25.9 (18.2-32.9%)
10	33.2 (23.6-41.6%)

SVD= structural valve deterioration.

Supplementary Table 6. Moderate or severe SVD according to VARC-3 and ESC/EAPCI/EACTS definitions.

	(n = 597)
VARC-3	
Moderate SVD	37 / 597 (6.2%)
Severe SVD	20 / 597 (3.4%)
Moderate or severe SVD	57 / 597 (9.5%)
ESC/EAPCI/EACTS	
Moderate SVD	52 / 597 (8.7%)
Severe SVD	20 / 597 (3.4%)
Moderate or severe SVD	72 / 597 (12.1%)

SVD= structural valve deterioration;VARC=Valve Academic Research Consortium

Supplementary Table 7. Univariable Cox regression for moderate or severe (stage 2-3) SVD in the overall population.

	N Obs.	Hazard Ratio	95% CI	p Wald
Age at TAVI per 10 years	597/597 (100.0%)	1.48	[0.99-2.20]	**0.058**
Female	597/597 (100.0%)	1.51	[0.88-2.59]	0.13
Diabetes mellitus	597/597 (100.0%)	1.48	[0.83-2.63]	0.18
Hypertension	596/597 (99.8%)	1.63	[0.77-3.44]	0.20
Dyslipidemia	588/597 (98.5%)	1.00	[0.58-1.73]	0.99
Hemoglobin (g/dl)	568/597 (95.1%)	1.03	[0.87-1.21]	0.75
Creatinine (mg/dL)	573/597 (96.0%)	1.02	[0.93-1.11]	0.74
GFR<30 ml/min	573/597 (96.0%)	0.91	[0.42-1.96]	0.80
Dialysis	595/597 (99.7%)	4.36	[0.60-31.81]	0.15
Chronic Pulmonary Disease	589/597 (98.7%)	0.73	[0.31-1.70]	0.46
Peripheral vascular disease	592/597 (99.2%)	0.81	[0.40-1.66]	0.57
Coronary artery disease	593/597 (99.3%)	0.74	[0.43-1.25]	0.26
Prior Myocardial infarction	580/597 (97.2%)	0.63	[0.27-1.48]	0.29
Prior TIA + stroke	596/597 (99.8%)	0.77	[0.28-2.13]	0.61
Prior pacemaker	596/597 (99.8%)	1.18	[0.51-2.76]	0.70
Prior atrial fibrillation	589/597 (98.7%)	1.05	[0.49-2.22]	0.90
NYHA class >= 3	519/597 (86.9%)	1.22	[0.68-2.18]	0.51
Prior CABG	597/597 (100.0%)	0.73	[0.36-1.45]	0.37
Prior other cardiac surgery	597/597 (100.0%)	0.95	[0.30-3.04]	0.93
Prior PCI	587/597 (98.3%)	0.48	[0.24-0.94]	**0.034**
Pre-TAVI CT scan: Mean annulus diameter (mm)	**213/597 (35.7%)**	0.74	[0.59-0.93]	**0.009**
Pre-TAVI CT scan: Maximum annulus diameter (mm)	267/597 (44.7%)	0.96	[0.82-1.12]	0.60
Pre-TAVI CT scan: Minimum annulus diameter (mm)	**262/597 (43.9%)**	0.84	[0.70-1.01]	**0.066**
Pre-TAVI CT scan: Annulus perimeter (mm)	**211/597 (35.3%)**	0.97	[0.94-1.00]	**0.083**
Pre-TAVI CT scan: Annulus area (mm^2)	251/597 (42.0%)	1.00	[1.00-1.01]	0.46
Pre-TAVI CT scan: Severe Aortic valve calcification	236/597 (39.5%)	1.78	[0.82-3.85]	0.144
TAVI intra-annular (Lotus + Direct Flow)	596/597 (99.8%)	16.22	[5.83-45.14]	**<.001**
TAVI: Intra-annular (SAPIEN/XT + Portico)		3.75	[2.07-6.80]	**<.001**
TAVI: Small size of the device	596/597 (99.8%)	2.06	[1.20-3.54]	**0.009**
TAVI: Size of the device >= 26mm	596/597 (99.8%)	0.28	[0.16-0.46]	**<.001**
Pre-dilatation	584/597 (97.8%)	1.08	[0.51-2.32]	0.83
Post-dilatation	568/597 (95.1%)	1.11	[0.57-2.15]	0.75
In hospital outcomes	596/597 (99.8%)	1.01	[0.59-1.73]	0.98
Acute kidney injury: Stage 1	596/597 (99.8%)	0.47	[0.06-3.40]	0.90
Stage 2		NA	NA	.
Stage 3		NA	NA	.
Minor vascular complication	597/597 (100.0%)	0.95	[0.34-2.64]	0.92
Major vascular complication	597/597 (100.0%)	1.46	[0.53-4.06]	0.47
Life-threatening bleeding	597/597 (100.0%)	1.60	[0.22-11.69]	0.64
Major bleeding	597/597 (100.0%)	0.67	[0.21-2.15]	0.50
Minor bleeding	597/597 (100.0%)	0.81	[0.37-1.80]	0.61
Stroke or TIA	596/597 (99.8%)	1.12	[0.27-4.63]	0.88
Permanent pacemaker implantation	595/597 (99.7%)	0.42	[0.13-1.34]	0.14
Post-TAVI echo: Peak Gradient (mmHg)	496/597 (83.1%)	1.01	[0.98-1.05]	0.37
Post-TAVI echo: Mean Gradient (mmHg)	499/597 (83.6%)	1.06	[0.99-1.13]	**0.083**
Post-TAVI echo: Aortic valve area (cm^2)	351/597 (58.8%)	1.03	[0.53-2.01]	0.92
Post-TAVI echo: Moderate or severe paravalvular leak	497/597 (83.2%)	3.02	[1.34-6.79]	**0.008**
Post-TAVI echo: Moderate or severe Intra-prosthetic aortic regurgitation	496/597 (83.1%)	1.34	[0.18-9.74]	0.77
Post-TAVI echo: LV ejection fraction (%)	456/597 (76.4%)	1.01	[0.98-1.04]	0.50
Post-TAVI echo: LV ejection fraction<30%	456/597 (76.4%)	2.81	[0.68-11.66]	0.16
Post-TAVI echo: End-diastolic volume (ml)	224/597 (37.5%)	0.99	[0.98-1.01]	0.28
Post-TAVI echo: End-diastolic diameter (mm)	346/597 (58.0%)	1.00	[0.95-1.04]	0.89

	N Obs.	Hazard Ratio	95% CI	p Wald
Post-TAVI echo: End-systolic volume (ml)	176/597 (29.5%)	0.98	[0.96-1.01]	0.13
Post-TAVI echo: End-systolic diameter (mm)	204/597 (34.2%)	0.99	[0.94-1.05]	0.80
Post-TAVI echo: Moderate or severe mitral regurgitation	489/597 (81.9%)	0.43	[0.13-1.39]	0.16
Post-TAVI echo: Systolic pulmonary artery pressure (mmHg)	262/597 (43.9%)	1.00	[0.97-1.04]	0.93
University Hospital	597/597 (100.0%)	1.56	[0.86-2.86]	0.15

SVD= structural valve deterioration; TAVI= transcatheter aortic valve implantation; GFR= glomerular filtrate rate; TIA= transient ischaemic attack; NYHA= New York Heart Association; CABG= coronary artery bypass graft; PCI= percutaneous coronary intervention; CT= computed tomography.

For type of valve, the reference is Supra-annular (CoreValve/Evolut R); For acute kidney injury, the reference is No.
Significant variables ($p<0.10$) were then proposed in the multivariable model except data from pre-TAVI CT scan because the number of missing values is more than 50%.

Supplementary Table 8. Final Cox regression analysis for moderate or severe (stage 2-3) SVD according to VARC-3 definitions in the overall population.

	Hazard Ratio	95% CI	p Wald
Intra-annular vs. Supra-annular	38.44	[10.84-136.30]	<.001
Intra-annular vs Supra-annular	4.31	[2.15-8.65]	<.001
Small-size device	1.90	[1.04-3.49]	0.038
Post-TAVI echo: Moderate or Severe PVL	3.47	[1.52-7.90]	0.003

Cox analysis is performed with a backward procedure with SLSTAY=0.05.
Goodness of Fit test: p=0.12. Concordance= 0.77 – Global Schoenfeld residual test p=0.78
The reference for the type of valve is Supra-annular devices (CoreValve/Evolute R).
SVD= structural valve deterioration; TAVI=transcatheter aortic valve implantation; PVL=paravalvular leak.

Supplementary Table 9. Univariable Cox regression for moderate or severe (stage 2-3) SVD excluding Lotus and Direct Flow devices.

	N Obs.	Hazard Ratio	95% CI	p Wald
Age at TAVI per 10 years	550/550 (100.0%)	1.43	[0.94-2.18]	**0.097**
Female	550/550 (100.0%)	1.46	[0.83-2.58]	0.19
Diabetes mellitus	550/550 (100.0%)	1.81	[1.00-3.27]	**0.048**
Hypertension	549/550 (99.8%)	1.67	[0.75-3.72]	0.21
Dyslipidemia	542/550 (98.5%)	1.06	[0.59-1.89]	0.86
Hemoglobin (g/dl)	524/550 (95.3%)	1.01	[0.85-1.20]	0.89
Creatinine (mg/dL)	530/550 (96.4%)	1.02	[0.93-1.12]	0.62
GFR<30 ml/min	530/550 (96.4%)	0.98	[0.45-2.14]	0.96
Dialysis	548/550 (99.6%)	4.88	[0.66-35.80]	0.12
Chronic Pulmonary Disease	542/550 (98.5%)	0.85	[0.36-1.99]	0.70
Peripheral vascular disease	545/550 (99.1%)	0.91	[0.44-1.87]	0.79
Coronary artery disease	546/550 (99.3%)	0.76	[0.44-1.33]	0.34
Prior Myocardial infarction	533/550 (96.9%)	0.58	[0.23-1.46]	0.25
Prior TIA + stroke	549/550 (99.8%)	0.85	[0.30-2.37]	0.75
Prior pacemaker	549/550 (99.8%)	1.15	[0.45-2.89]	0.77
Prior atrial fibrillation	544/550 (98.9%)	1.26	[0.59-2.68]	0.55
NYHA class >= 3	475/550 (86.4%)	1.03	[0.57-1.88]	0.92
Prior CABG	550/550 (100.0%)	0.82	[0.40-1.64]	0.57
Prior other cardiac surgery	550/550 (100.0%)	1.02	[0.32-3.30]	0.97
Prior PCI	541/550 (98.4%)	0.54	[0.27-1.08]	**0.083**
Pre-TAVI CT scan: Mean annulus diameter (mm)	201/550 **(36.5%)**	0.73	[0.56-0.96]	**0.022**
Pre-TAVI CT scan: Maximum annulus diameter (mm)	252/550 (45.8%)	0.97	[0.82-1.15]	0.76
Pre-TAVI CT scan: Minimum annulus diameter (mm)	247/550 (44.9%)	0.86	[0.71-1.04]	0.12
Pre-TAVI CT scan: Annulus perimeter (mm)	190/550 **(34.5%)**	0.97	[0.94-1.00]	**0.090**
Pre-TAVI CT scan: Annulus area (mm^2)	228/550 **(41.5%)**	1.00	[1.00-1.01]	**0.035**
Pre-TAVI CT scan: Severe aortic valve calcification	216/550 (39.3%)	1.60	[0.68-3.79]	0.283
TAVI: Intra-annular (SAPIEN/XT + Portico)	550/550 (100.0%)	3.76	[2.08-6.81]	**<.001**
TAVI: Small size of the device	550/550 (100.0%)	1.64	[0.94-2.88]	**0.084**
TAVI: Size of the device >= 26mm	550/550 (100.0%)	0.34	[0.20-0.60]	**<.001**
Pre-dilatation	540/550 (98.2%)	1.03	[0.46-2.33]	0.93
Post-dilatation	523/550 (95.1%)	1.14	[0.57-2.28]	0.72
In hospital outcomes	549/550 (99.8%)	0.88	[0.49-1.58]	0.67
Acute kidney injury: Stage 1	549/550 (99.8%)	0.50	[0.07-3.65]	0.93
Stage 2		NA	NA	
Stage 3		NA	NA	
Minor vascular complication	550/550 (100.0%)	1.09	[0.39-3.05]	0.86
Major vascular complication	550/550 (100.0%)	1.61	[0.58-4.49]	0.36
Life-threatening bleeding	550/550 (100.0%)	1.81	[0.25-13.23]	0.56
Major bleeding	550/550 (100.0%)	0.72	[0.22-2.33]	0.59
Minor bleeding	550/550 (100.0%)	0.66	[0.26-1.67]	0.38
Stroke or TIA	549/550 (99.8%)	0.59	[0.08-4.30]	0.60
Permanent pacemaker implantation	548/550 (99.6%)	0.30	[0.07-1.24]	**0.096**
Post-TAVI echo: Peak Gradient (mmHg)	466/550 (84.7%)	1.01	[0.98-1.05]	0.54
Post-TAVI echo: Mean Gradient (mmHg)	466/550 (84.7%)	1.05	[0.98-1.13]	0.19
Post-TAVI echo: Aortic valve area (cm^2)	329/550 (59.8%)	1.27	[0.64-2.52]	0.49
Post-TAVI echo: Moderate or Severe PVL	470/550 (85.5%)	3.37	[1.48-7.64]	**0.004**
Post-TAVI echo: Moderate or severe Intra-prosthetic aortic regurgitation	467/550 (84.9%)	1.45	[0.20-10.56]	0.72
Post-TAVI echo: LV ejection fraction (%)	426/550 (77.5%)	1.01	[0.98-1.05]	0.39
Post-TAVI echo: LV ejection fraction<30%	426/550 (77.5%)	1.59	[0.22-11.66]	0.65
Post-TAVI echo: End-diastolic volume (ml)	221/550 (40.2%)	0.99	[0.98-1.01]	0.25
Post-TAVI echo: End-diastolic diameter (mm)	338/550 (61.5%)	1.00	[0.96-1.05]	0.98
Post-TAVI echo: End-systolic volume (ml)	174/550 (31.6%)	0.98	[0.95-1.01]	0.12

	N Obs.	Hazard Ratio	95% CI	p Wald
Post-TAVI echo: End-systolic diameter (mm)	198/550 (36.0%)	1.00	[0.95-1.05]	0.98
Post-TAVI echo: Moderate or severe mitral regurgitation	461/550 (83.8%)	0.31	[0.07-1.29]	0.11
Post-TAVI echo: Systolic pulmonary artery pressure (mmHg)	251/550 (45.6%)	1.01	[0.97-1.05]	0.77
University Hospital	550/550 (100.0%)	1.49	[0.66-3.35]	0.34

SVD= structural valve deterioration; TAVI= transcatheter aortic valve implantation; GFR= glomerular filtrate rate; TIA= transient ischaemic attack; NYHA= New York Heart Association; CABG= coronary artery bypass graft; PCI= percutaneous coronary intervention; CT= computed tomography; PVL= paravalvular leak; LV= left ventricle.

For type of valve, the reference is Supra-annular (CoreValve/Evolut R); For acute kidney injury, the reference is No.
Significant variables ($p<0.10$) were then proposed in the multivariable model except data from pre-TAVI CT scan because the number of missing values is more than 50%.

Supplementary Table 10. Final Cox regression analysis for moderate or severe (stage 2-3) SVD according to VARC-3 definitions.

	Hazard Ratio	95% CI	p Wald
Intra-annular vs. Supra-annular	4.82	[2.42-9.60]	<.001
Post-TAVI echo: Moderate or Severe PVL	3.64	[1.59-8.32]	0.002

SVD= structural valve deterioration; TAVI=transcatheter aortic valve implantation; PVL=paravalvular leak.

Cox analysis is performed with a backward procedure with SLSTAY=0.05.
Goodness of Fit test: p=0.38. Concordance= 0.73 – Global Schoenfeld residual test p=0.42
Cox Regression Analysis considering only patients treated with the brand of devices currently available in the market, thus excluding Lotus and Direct Flow
When we add in this final model, the type of hospital, the type of device as moderate or severe paravalvular leak stay significant**.**

Supplementary Table 11. Cox regression model adjusted for covariates comparing all subgroups with small supra-annular valves.

	Event/Total	Median (95% CI)[1]	Hazard Ratio (95% CI)[2]	Covariate Level P-values	P-value
Size and type of valve					<0.0001[3]
Large intra-annular	11/146	NE (8.2-NE)	2.96 (1.14-7.66)	0.0255[4]	
Large supra-annular	10/189	NE (10.0-NE)	1.27 (0.50-3.22)	0.6153[4]	
Small intra-annular	24/96	9.0 (8.3-NE)	5.52 (2.44-12.48)	<0.0001[4]	
Small supra-annular	6/119	NE (10.3-NE)	Reference	--	

[1]Cumulative incidence method; [2]Cox model; [3]Gray's k-sample test for equality of cumulative incidence functions; [4]Wald Chi-Square test;

Supplementary Table 12. Echocardiography at study enrolment: investigator data versus core lab data – patients with both evaluations.

	Investigator data Study enrolment (n = 364)	CoreLab data Study enrolment (n = 364)	P-value*
Peak Gradient (mmHg)			
Mean ± SD	20.38 ±14.43	19.61 ±14.38	
Median (IQR)	17.0 (12.0-24.0)	16.0 (11.0-24.0)	0.002
Mean Gradient (mmHg)			
Mean ± SD	11.10 ±8.76	10.79 ±8.50	
Median (IQR)	9.0 (6.0-13.0)	9.0 (6.0-12.0)	0.12
Aortic valve area (cm^2)			
Mean ± SD	1.62 ±0.49	1.96 ±0.67	
Median (IQR)	1.6 (1.3-1.9)	1.9 (1.4-2.5)	<0.001
Paravalvular leak			
None-trivial	203 (58.7%)	210 (60.7%)	<0.001
Mild	120 (34.7%)	84 (24.3%)	
Moderate	22 (6.4%)	44 (12.7%)	
Severe	1 (0.3%)	8 (2.3%)	
Moderate or severe paravalvular leak	23 (6.6%)	52 (15.0%)	<0.001
Intra-prosthetic aortic regurgitation			
None-trivial	304 (88.1%)	318 (92.2%)	0.16
Mild	26 (7.5%)	20 (5.8%)	
Moderate	13 (3.8%)	6 (1.7%)	
Severe	2 (0.6%)	1 (0.3%)	
Moderate or severe Intra-prosthetic aortic regurgitation	15 (4.3%)	7 (2.0%)	0.02
Patient-prosthesis mismatch	8 (2.3%)	6 (1.8%)	0.56
Severe Patient-prosthesis mismatch	0	1 (100.0%)	
LV ejection fraction (%)			
Mean ± SD	55.1 ±10.4	59.4 ±10.8	
Median (IQR)	56 (50-62)	61 (55-67)	<0.001
LV ejection fraction<30%	7 (2.1%)	3 (0.9%)	0.10
End-diastolic volume (ml)			
Mean ± SD	92.8 ±33.8	98.4 ±37.7	
Median (IQR)	86 (70-110)	88 (73-114)	0.009
End-diastolic diameter (mm)			
Mean ± SD	47.6 ±7.9	47.9 ±7.2	
Median (IQR)	47 (42-53)	47 (43-53)	0.42
End-systolic volume (ml)			
Mean ± SD	41.1 ±21.4	40.7 ±23.2	
Median (IQR)	35 (26-49)	32 (26-54)	0.46
End-systolic diameter (mm)			
Mean ± SD	32.6 ±7.4	32.7 ±8.4	
Median (IQR)	32 (28-36)	32 (26-35)	0.84
Mitral regurgitation			
None-trivial	125 / 349 (35.8%)	169 / 349 (48.4%)	<0.001
Mild	159 / 349 (45.6%)	132 / 349 (37.8%)	
Moderate	62 / 349 (17.8%)	39 / 349 (11.2%)	
Severe	3 / 349 (0.9%)	9 / 349 (2.6%)	
Moderate or severe mitral regurgitation	65 / 349 (18.6%)	48 / 349 (13.8%)	0.035
Systolic pulmonary artery pressure (mmHg)			
Mean ± SD	36.6 ±11.2	37.4 ±12.5	
Median (IQR)	35 (29-42)	34 (28-45)	0.98
Thrombosis	1 (0.3%)	0	
Endocarditis	0	0	
Moderate or severe SVD	41 (11.3%)	38 (10.4%)	0.65

IQR= interquartile range; LV= Left ventricular; SD= Standard Deviation; TAVI= Transcatheter Aortic Valve Implantation.