Long-Term Functional and Structural Durability of Bioprosthetic Valves Placed in the Aortic Valve Position via Percutaneous Rout in Israel

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There is limited organized "real life" data regarding the long-term structural and functional durability of transcatheter aortic valve implants, a topic of major importance. We assessed the 5-year structural and functional integrity outcomes following trans-catheter aortic valve implantation (TAVI) with both self-expandable and balloon-expandable prosthetic valve devices.

This study included 450 consecutive patients who underwent TAVI for severe symptomatic aortic stenosis (AS) between September 2008 and December 2011. Data were acquired from a multicenter Israeli registry and the median follow up time was 5.6 years. In 184 patients (40.9%) who survived 5 years, prostheses displayed sustained hemodynamic performance, with average peak and mean aortic valve gradients of 16.2 ± 8.9 and 9.2 ± 6.6 mm Hg, respectively. Late structural valve deterioration was found in 22 (12.3%) patients. Of these, 16 (8.9%) experienced valve deterioration and 6 (3.3%) experienced valve failure. Among the 6 patients with bioprosthetic valve failure, only 3 underwent re-interventions. Bioprosthetic valve dysfunction occurred more frequently in patients with small valves (23 mm) and high peak and mean transvalvular gradients at baseline. In conclusion, a relatively low rate of valve deterioration or failure was noted in our long-term follow-up study after TAVI procedures with both the catheter-based self-expandable and balloon-expandable prosthetic valves. **(Am J Cardiol 2019;124:1748−1756)**

Long-term data on TAVI devices are limited, mostly due to the fact that few studies have performed systematic long-term valve durability assessments. In addition, many elderly patients with co-morbidities will not outlive their valves. Initial studies on the long-term (≥5 years) durability of TAVI devices from the PARTNER 1A trial and the pivotal CoreValve trial reported reassuring results.[1,2] They demonstrated a transvalvular gradient and a valve dysfunction rate similar to those of surgical valves. However, those studies mostly described early-generation devices and they had relatively short follow ups. Similarly, large registries have demonstrated that valve gradients remained stable for 5 years and valve dysfunction occurred at relatively low rates (3% to 4%).[3–7] Again, only a limited number of dedicated studies compared long-term hemodynamic performances of self-expandable CoreValves (CV) and balloon-expandable Edwards SAPIEN (ES) valves.[8] Therefore, the present study aimed to investigate long-term valve durability in patients that underwent TAVI, with either CV or ES, based on data from an "all comers" multicenter Israeli registry.

Methods

This Long-term Israeli TAVI durABILITY (LIABILITY) study included consecutive patients that underwent TAVI between April 2008 and December 2011, at 3 Israeli centers (Rabin Medical center, in Petach Tikva, Sheba Medical Center, in Ramat Gan, and Hadassah Medical Center, in Jerusalem, Israel). Eligible patients had follow-up data for 5 years or longer after TAVI procedures.

At the time of intervention, all patients had symptomatic severe AS. AS was defined, based on echocardiography, valve area ≤ 1 cm^2 with a transvalvular mean gradient ≥40 mm Hg and/or jet velocity >4.0 m/s, or alternatively, a low gradient in the presence of low flow stenosis. Candidates for TAVI were evaluated by each institution's heart team and included a thorough clinical, anatomic, geriatric, comprehensive, and image-based assessment. Surgical risk was calculated based on the EuroSCORE II and Society for Thoracic Surgeons Predicted Risk of Mortality scores.[9,10]

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The heart team operators selected the type of transcatheter valve prosthesis. Three types were used, including the self-expandable CV (Medtronic CoreValve, Medtronic, Minneapolis, MN); the balloon-expandable ES valve (Edwards LifeSciences, Irvine, CA); and later, the ES XT valve (Edwards LifeSciences). At all centers, transfemoral access was the default approach, unless there were anatomic limitations that required selection of an alternative approach. Patients were discharged with dual antiplatelet therapy (aspirin 75 to 100 mg and clopidogrel 75 mg) which was continued for 3 to 6 months after the procedure. For those who required oral anticoagulation, a single antiplatelet therapy was added. Procedural outcomes and follow-up events were classified according to Valve Academic Research Consortium 2 definitions.[11] Data were pooled in a dedicated multicenter database. Follow-up was conducted through clinical visits or telephone interviews with patients, or their general practitioner, the first month following the procedure and yearly thereafter.

At least 3 comprehensive two-dimensional (2-D) transthoracic echocardiography studies were performed to evaluate prosthesis performance. These were systematically performed at baseline, during the index hospitalization after TAVI, and at the 5-year follow-up time point according to a designated shared protocol. Some patients were also evaluated at additional follow-up time points. Prosthesis

Table 1
Baseline characteristics*

Variable	Total (n = 450)	Long term follow-up (n = 179)	Drop-out group (n = 271)	p Value
Men	196 (43.5%)	72 (40.2%)	124 (45.8%)	0.29
Age (years)	82.2±6.3	81.2±5.7	82.8 ± 6.6	0.007
Diabetes mellitus	145 (32.2)	49 (27.7%)	96 (35.7%)	0.096
Hypertension[y]	387 (86%)	159 (89.8%)	228 (84.8%)	0.16
Coronary artery disease	233 (51.8%)	87 (50%)	146 (53.9%)	0.48
Coronary bypass	112 (24.9%)	42 (23.9%)	70 (25.9%)	0.70
Stroke (cerebrovascular accident/transient ischemic attack)	63 (14.0%)	25 (14.2%)	38 (14.2%)	1.0
Estimated glomerular filtration rate (ml/min/1.73 m^2)	49.4±21.4	49.3±18.3	49.35 ±23.8	0.98
Estimated glomerular filtration rate < 30	65 (14.4%)	22 (12.3%)	43 (15.9)	0.36
Hemoglobin (gr/dl)	11.9±1.5	11.9±1.5	11.8±1.5	0.54
Chronic obstructive pulmonary disease	107 (23.8%)	31 (17.7%)	76 (28.3%)	0.015
Peripheral vascular disease	80 (17.8%)	20 (11.4%)	60 (22.4%)	0.005
Society of Thoracic Surgeons Predicted Risk of Mortality (%)	7.25±4.8	6.2±4.1	7.9±4.9	0.001
Logistic - European System for Cardiac Operative Evaluation II (%)	6.3±5.9	5.5±5.7	6.6±5.9	0.102
Functional class -NYHA III, IV	350 (77.8%)	133 (74.3%)	217 (80.1%)	0.37
Left ventricular ejection fraction (%)	55.6±10.8	55.7±10.9	55.3±10.8	0.68
Peak aortic valve gradient (mm Hg)	76.5±24.1	78.9±24.9	75.0±23.9	0.10
Mean aortic valve gradient (mm Hg)	50.6±15.9	50.1±17	46.4±15.4	0.02
Aortic valve area (cm^2)	0.65±0.18	0.66±0.19	0.65±0.17	0.79
Left ventricular outflow tract diameter (mm)	20.6±2.2	20.6±3.3	20.55±1.9	0.94
Implanted valve type				
Core valve Medtronic	310 (68.9%)	125 (69.8%)	185 (68.3%)	0.81
SAPIEN Edwards/XT	140 (31.1%)	54 (30.2%)	86 (31.7%)	
Access site				
Transfemoral	356 (79.1%)	150 (83.8%)	206 (76.0%)	0.016
Transaxillary	28 (6.2%)	10 (5.6%)	18 (6.6%)	
Direct aortic	5 (1.1%)	4 (2.2%)	1 (0.4%)	
Transapical	61 (13.6%)	15 (8.4%)	46 (17.0)	
Implanted valve size (mm)				
23	80 (17.8%)	42 (23.5%)	38 (14.0%)	0.044
26	216 (48.0%)	77 (43.0%)	139 (51.3%)	
29	145 (32.2%)	58 (32.4%)	87 (32.1%)	
31	9 (2.0%)	2 (1.1%)	7 (2.6%)	
Preimplantation balloon valvuloplasty	369 (82.0%)	151 (87.8%)	218 (87.2%)	0.97
Post-implantation balloon valvuloplasty	44 (9.8%)	21 (12.7%)	23 (9.7%)	0.30
Valve migration	10 (2.2%)	3 (1.8%)	7 (2.6%)	0.83
Valve malposition /Need for 2nd valve	14 (3.1%)	10 (5.6%)	4 (2.2%)	0.56
Paravalvular leak				0.86
Mild-Moderate	39 (8.7%)	15 (8.4%)	24 (8.8%)	
Moderate	12 (2.7%)	4 (2.2%)	8 (2.9%)	
Moderate-Severe	4 (0.9%)	2 (1.1%)	2 (0.7%)	
Aortic valve gradient (peak)-In-hospital (mm Hg)	16.6 ±9.0	16.7 ±10.2	16.3±7.9	0.65
Aortic valve gradient (mean)-In-hospital (mm Hg)	9.3±5.7	9.6±6.5	9.0±4.9	0.36

* Values are presented as number (%) or mean ± standard deviation.

[y] Hypertension was defined as systolic blood pressure above 140 mm Hg and/or diastolic above 90 mm Hg.

performance parameters included the transprosthetic gradient, the effective orifice area, and the presence of aortic regurgitation (AR) − either intravalvular or paravavular leak (PVL). Global morphology and function were also measured. The severity of AR and PVL were graded as mild, moderate, or severe, according to quantitative and semiquantitative parameters, as recommended in guidelines.[12]

Echocardiographic studies were performed by experienced sonographers, and the results were reviewed by cardiologists that specialized in echocardiography. Some patients underwent echocardiographic assessments at centers other than the implantation treatment center. In these cases, we located the transthoracic echocardiogram images and transferred them to the implantation center for further analysis. We also took into consideration that some patients with a poor functional and/or cognitive state were unable or unwilling to travel to the medical center for an elective echocardiography follow-up exam. This situation might have introduced a selection bias and underrepresentation of patients in the worst general health condition. Therefore, we designed an outreach program, where a special team of cardiologists with a mobile echocardiography unit travelled to the home or nursing-facility to perform the examination.

Patients were excluded from the study analysis when they did not have at least one follow-up echocardiography at 5 years after the TAVI, or when echocardiography data were missing. We also excluded few patients with very poor quality images.

This study complied with the Declaration of Helsinki and was approved by the local Institutional review boards. All patients provided informed written consent before the procedure.

The definitions of structural deterioration and valve failure were based on current definitions established by the transcatheter aortic bioprosthetic valve failure consensus statement.[13] Bioprosthetic valve dysfunction (BVD) was defined as moderate or severe structural valve deterioration (SVD). SVD was defined as a mean gradient ≥20 mm Hg, or a mean gradient ≥10 mm Hg above the baseline gradient, or moderate/severe intraprosthetic AR (new or worse than baseline AR). Bioprosthetic valve failure (BVF) was defined as one or more of the following: Valve-related death, aortic valve reintervention, or severe hemodynamic SVD. Severe hemodynamic SVD was defined as a mean gradient ≥40 mm Hg, or a mean gradient ≥20 mm Hg above the baseline gradient, or moderate/severe new intraprosthetic AR.

Statistical analysis-continuous, normally-distributed variables are presented as means ± standard deviations (SD), and means were compared between groups with the Student's t test. Ordinal and/or non-normally-distributed continuous variables are presented as the median and interquartile range (IQR), and medians were compared between groups with the Wilcoxon rank sum test. Normality was assessed by visual inspection of quantile-quantile (QQ) plots. Categorical variables were compared between groups with the chi square test.

For the multivariable model, we chose variables based on previous knowledge. Considering the rule-of-thumb of 10 events per variable, we were restricted to 2 independent variables under 1:10 events per variable. To evaluate the time to dysfunction, we used the Kaplan Meier method.

Analyses were performed with R (a language and environment for statistical computing, Vienna, Austria, 2018).

Results

A total of 450 patients underwent TAVI due to severe symptomatic AS in the participating centers. Baseline demographic, clinical, and echocardiographic characteristics are summarized in Table 1. The mean age was 82.2 ± 6.3 years; the mean logistic EuroSCORE II and STS were 6.3% and 7.25%, respectively; and most patients (77.8%) were categorized as NYHA functional class III or IV at baseline. Procedural characteristics are shown in Table 1. Self-expandable CVs were used in the majority of patients (n = 310, 68.9%); balloon-expandable ESs were used in 140 (31.1%) patients (10% ES and 90% ES-XT).

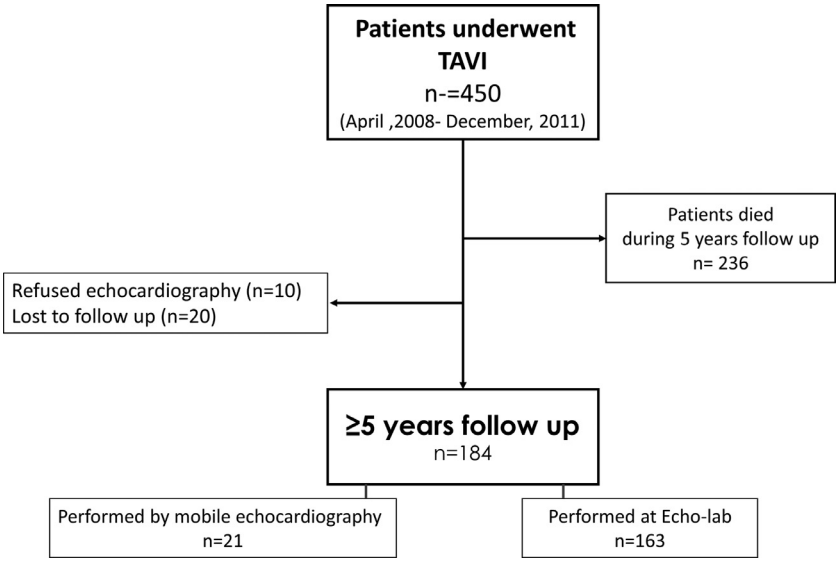

Figure 1. Flow chart of study cohort.

Preimplantation balloon valvuloplasty was performed in 369 (82.0%) patients, and postimplantation balloon valvuloplasty was performed in only 44 (9.8%) patients. Valve hemodynamic and device success were high (Table 1).

A 5-year follow-up was completed in 184 (40.9%) patients (flow chart presented in Figure 1). This squat number was mostly due to the low 5-year survival rate. During the study period, 236 (52.4%) patients died. The median follow-up time was 5.6 years (IQR 5.2 to 6.4). The longest follow-up was 8.1 years. Mobile echocardiography studies were performed for 21 patients at their home or nursing facility.

We compared baseline demographic and procedural characteristics between the 5-year follow-up group and the group that did not complete a 5-year follow-up (drop-out group; Table 1). Largely, the follow-up group was younger, had fewer comorbid diseases, and had lower estimated STS scores than the drop-out group. Considering the procedural characteristics and outcome, a small valve size (23 mm) was used more often in the follow-up group, and the transapical approach was used less frequently, compared with the drop-out group. Other than those features, there were no significant differences between the groups.

The long-term echocardiographic characteristics are presented in Table 2. The hemodynamic performance of prostheses was sustained during follow-up, with average mean and peak aortic valve gradients that were not significantly different from baseline values (Figure 2, $p = 0.85$ and $p = 0.63$ respectively). Mean aortic valve pressure gradient values above 20 mm Hg were observed in 15 (8.4%) patients. Mean transvalvular gradient changes >10 mm Hg above baseline were observed in 10 (5.6%) patients; of these, 3 exhibited gradients >20 mm Hg above baseline (Table 2). The PVL was worse than moderate in 5.6% of patients after 5 years, compared with 3.6% at baseline. According to the definition, SVDs were identified in 22 (12.3%) patients; of these, 16 (8.9%) were defined as BVD and 6 (3.3%) were defined as BVF (Table 2). Among the 6 patients that met the criteria for BVF, only 3 patients underwent valve reinterventions. The annualized incidence rate of BVF or BVD was 2.2% (BVF, 0.6 % and BVD, 1.8 %).

Bioprosthetic valve dysfunction occurred most frequently in patients with small valves (23 mm) and high peak and mean transvalvular gradients at baseline (Table 3). The univariate analysis indicated that ES valves had higher rates of BVD (11 of 54, 20%) than CV valves (11 of 125, 9%, $p = 0.05$); however, ES valves were used more frequently in patients treated with small valves ($p < 0.001$). The multivariate regression analysis indicated that, after adjusting for valve type and postprocedure transvalvular gradients, the smaller valve (23 mm) was associated with a high BVD incidence (Table 4). In contrast, the valve type was not significantly associated with BVD incidence. The SVD-free times, according to valve size, are presented in Figures 3 and 4, for the entire cohort.

Table 2
Echocardiographic parameters at 5 years follow-up*

Echocardiographic parameters	N = 179
Systolic blood pressure (mm Hg)	141.0 ±21.2
Diastolic blood pressure (mm Hg)	69.3± 12.3
Heart rate (beat per minute)	71.1± 13.0
Left ventricular ejection fraction (%)	56.9± 10.6
Stroke volume (ml)	56.6 ± 17.4
V max (cm/s)	188.1± 61.9
Velocity time integral$_{LVOT}$ (cm)	21.6±6.1
Velocity time integral$_{AV}$ (cm)	42.45±37.7
Doppler velocity index (VTI_{LVOT}/VTI_{AV})	0.57 ±0.18
Acceleration time (ms)	88.3±21.2
Left ventricular ejection time (ms)	313.8±69.1
Acceleration time/Ejection time	0.29±0.07
Aortic valve area (cm^2)	1.7 ± 0.7
Peak aortic valve gradient (mm Hg)	16.2 ± 8.9
Mean aortic valve gradient (mm Hg)	9.2 ± 6.6
Mean aortic valve gradient >20mm Hg	14 (7.8%)
Mean aortic valve gradient >40mm Hg	1 (0.55%)
Mean gradient increase >10 mm Hg from baseline	7 (3.9%)
Mean gradient increase >20 mm Hg from baseline	3 (1.7%)
Paravalvular leak	
Mild	35 (21.2%)
Mild-Moderate	17 (9.5%)
Moderate	8 (4.5%)
Moderate-Severe	2 (1.1%)
Circumferential extent of paravalvular leak	
<10%	63 (35.2%)
10-29	28 (15.6%)
≥30	2 (1.1%)
Intravalvular leak	
Mild	9 (5.0%)
Mild-Moderate	3 (1.7%)
Moderate	3 (1.7%)
Moderate-Severe	2 (1.1%)
Diastolic flow reverse in descending aorta	9 (5.0%)
Thickened valve leaflet	10 (5.6%)
Raptured valve	2 (1.1%)
Mitral regurgitation	
Mild-Moderate	37 (20.7%)
Moderate	10 (5.6%)
Moderate-Severe	6 (3.3%)
Severe	2 (1.1%)
Pulmonary pressure (mm Hg)	40±17
Bioprosthetic valve dysfunction	16 (8.9%)
Bioprosthetic valve Failure	6 (3.3%)

AV = aortic valve; LVOT = left ventricular outflow tract; TVI = velocity time integral.

* Values are presented as number (%) or mean ± standard deviation.

Discussion

The main findings of the current study were: (1) Among patients that survived at least 5 years, the annualized incidence rate of BVF or BVD was only 2.2% (BVF, 0.6% and BVD, 1.8%).; (2) SVD was not associated with the prosthetic valve type; and (3) risk factors for BVD were a small valve size (23 mm) and elevated in-hospital transvalvular gradients.

The long-term durability of transcatheter valves has become a focus of concern, due to conflicting data and the relatively recent acceptance of TAVI for treating patients with longer life expectancies (e.g., those at lower risk and younger than the traditional target population). Limited data are available regarding the long-term durability of transcatheter valves, due to the low rate of follow-up echocardiography studies, the relatively low long-term survival, and the rapid turnover of device generations.[3–7]

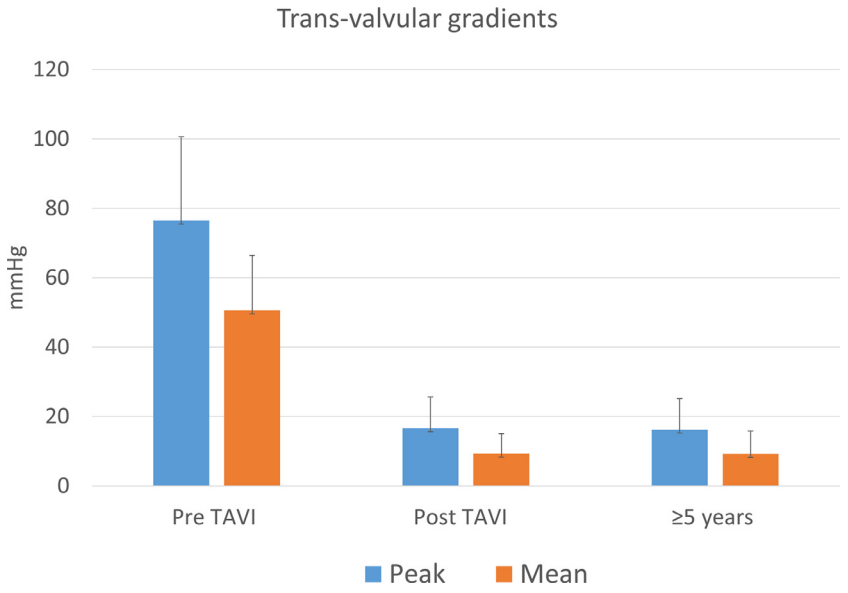

Figure 2. Transvalvular gradients change across follow-up time. The graph presents the average transvalvular gradients as peak and mean (mm Hg). TAVI = transcatheter aortic valve implantation.

The durability of transcatheter valves depends on multiple factors. Some factors are unique to the TAVI procedure. Some features that could impact long-term valve function include mechanical stress, incomplete valve expansion, prosthesis distortion due to a calcified native aortic valve, thin leaflet material, and valve crimping.[13] Therefore, in addition to the prosthetic valve design, long-term valve function could be influenced by the preparation of the valve, the implantation technique, and individual learning curves. The impact of these factors might vary, due to diverse operating practices in different centers and in different countries. Thus, it is important to collect long-term TAVI durability data from different institutions all over the world. In the present study, we encountered a relatively high rate of follow-up echocardiography studies (86%) among patients that survived at least 5 years. To the best of our knowledge, this study was the first to pursue allcomers patients that were unable or unwilling to visit the hospital for follow-up exams. This approach allowed us to achieve the lowest possible selection bias among our patients' cohort.

Earlier studies were criticized for using valve failure definitions that were not standardized, which resulted in heterogeneous definitions.[12,15–18] The present study was designed prospectively. Echocardiography studies were dedicated to determining transcatheter valve function. Function was categorized according to predefined parameters, based on the most recent standardized definitions established with the transcatheter aortic bioprosthetic valve failure-consensus document.[13] However, recently new proposed criteria for structural valve degeneration were proposed by Dvir et al[19] and Hahn et al,[20] suggesting several additional parameters to better differentiate between SVD versus normal valve function and in order to improve the quality of research in clinical trials. Thus, future studies are required to determine if different valvular outcomes might be predicted using these suggested criteria.

Furthermore, it might be that the criteria used in our study to define SVD[13] discriminate against 23 mm valves: if the early post-procedural mean transvalvular gradient is 10 to 20 mm Hg, a small rise of 10 mm Hg or even less might easily upgrade the gradient to more than 20 mm Hg. Therefore, if only mean gradient is required to define SVD, 23 mm valves can unjustifiably gain poor reputation. According to Hahn et al,[20] an increase in mean transvalvular gradient of >10 mm Hg is not enough: It should be accompanied by concomitant decrease in EOA >25% and/or DVI >20% of baseline echocardiographic assessment. It is likely that the use of such an integrated approach might have reduced the rate of SVD noted in smaller valves, this should be evaluated in future studies.

Consistent with previous studies which evaluated 5 years durability,[1,3–8,14] in the present study, the transcatheter aortic BVF rate was relatively low (3.3%); moreover, only half of the BVFs required reintervention. Thus, our results suggested that there is likely no basis for major concerns about the durability of transcatheter aortic bioprosthetics up to 5 years since implantation as they exhibited sustainable, low transvalvular gradients over time and a relatively low BVD rate.

We also attempted to evaluate risk factors for early valve degeneration. However, most probably due to a relatively small sample size, we could identify only one significant risk factor which is a small valve diameter. The association between a small valve size and higher gradients, which, in turn, predispose to earlier valve deterioration, might be an important concern. When young patients are considered eligible for both TAVI and surgical valve replacement, their inherently small annuli could lead to early valve dysfunction, which could require subsequent reinterventions.

It is important to emphasize that self-expandable and balloon-expandable valves were associated with similar rates of early BVD when matched for size. This observation was also consistent with previous trials.[6] Thus, risk factors

Table 3
Comparison of baseline characteristics of patients with bioprosthetic valve dysfunction to those with normal functioning valve at 5 years follow-up*

Variable	Bioprosthetic valve dysfunction		p Value
	No (n = 157)	Yes (n = 22)	
Men	66 (42%)	6 (27.3%)	0.27
Age (years)	81.2±5.8	80 ±6	0.94
Body mass index (kg/m^2)	26.4±4.1	27±6	0.78
Diabetes mellitus	42 (27.1%)	7 (32%)	0.83
Hypertension[y]	140 (89.2%)	19 (86%)	0.84
Coronary artery disease	80 (50.9%)	7 (32%)	0.11
Coronary bypass	38 (24.7%)	4 (18%)	0.69
Stroke	23 (14.9%)	2 (9%)	0.68
Estimated glomerular filtration rate (ml/min/1.73 m^2)	48.4±16.9	56.3±26.3	0.07
Estimated glomerular filtration rate < 30	20 (12.7%)	2 (9%)	0.89
Chronic obstructive pulmonary disease	25 (16.3%)	6 (27%)	0.34
Peripheral vascular disease	17 (11.0)	3 (14%)	0.96
Society of Thoracic Surgeons Predicted Risk of Mortality (%)	6.1±4.1	7±4	0.35
Logistic - European System for Cardiac Operative Evaluation II (%)	5.3±5.7	7 ±6	0.42
Functional class - New-York heart association III, IV	114 (72.6%)	19 (86%)	0.50
Left ventricular ejection fraction (%)	55.6 ±11.6	58± 7	0.39
Core valve Medtronic	114 (72.6%)	11 (50%)	0.05
SAPIEN Edwards/XT	43 (27.4%)	11 (50%)	
Transfemoral	130 (82.8%)	20 (91%)	0.56
Transaxillary	10 (6.4%)	0	
Direct aortic	4 (2.5%)	0	
Transapical (mm)	13 (8.3%)	2[9]	
23	30 (18.2%)	12 (55%)	0.003
26	72 (45.9%)	5 (23%)	
29	53 (33.8%)	5 (23%)	
31	1 (0.6%)	0	
Preimplantation balloon valvuloplasty	133 (88.1%)	18 (86%)	0.99
Postimplantation balloon valvuloplasty	19 (13.0%)	2 (11%)	0.89
Valve migration	3 (2.1%)	0	1
Valve malposition/Need for 2nd valve	10 (12.5%)	0	0.63
In hospital perivalvular leak			0.81
Mild-Moderate	14 (9.9%)	1 (5%)	
Moderate	3 (2.1%)	1 (5%)	
Moderate-Severe	2 (1.4%)	0	
Aortic valve gradient (peak)-In hospital	16.0 ±9.1	24±15	<0.001
Aortic valve gradient (mean)-In hospital	9.1±5.9	14±9	0.003

* Values are presented as number (%) or mean ± standard deviation.
[y] Hypertension was defined as systolic blood pressure above 140 mm Hg and/or diastolic above 90 mm Hg.

for early degeneration should be evaluated further in larger trials.

The present study had several limitations. Although it was a multicenter study, the sample size was relatively small. Also, data were available only for the survival cohort, which comprised approximately 50% of patients that underwent TAVI. This issue might have biased our analysis although it is an inherent limitation of long-term follow-up trials.

There was no core laboratory for the echocardiographic studies. However, echocardiograms were carefully interpreted by dedicated and experienced cardiologists, thus minimizing the likelihood of measurement and interpretation error.

Table 4
Multivariate analysis*

	Odds ratio	95% CI	p Value
Valve type- Medtronic Core valve	1.32	0.21 – 8.27	0.769
Valve Size- 26mm	0.12	0.02 – 0.76	0.025
Valve Size- 29mm	0.17	0.02 – 1.34	0.093
Post TAVI mean gradient	0.99	0.92 – 1.07	0.846

TAVI = transcatheter aortic valve implantation.
* Regression analysis, after adjustment for valve type and postprocedure transvalvular gradients.

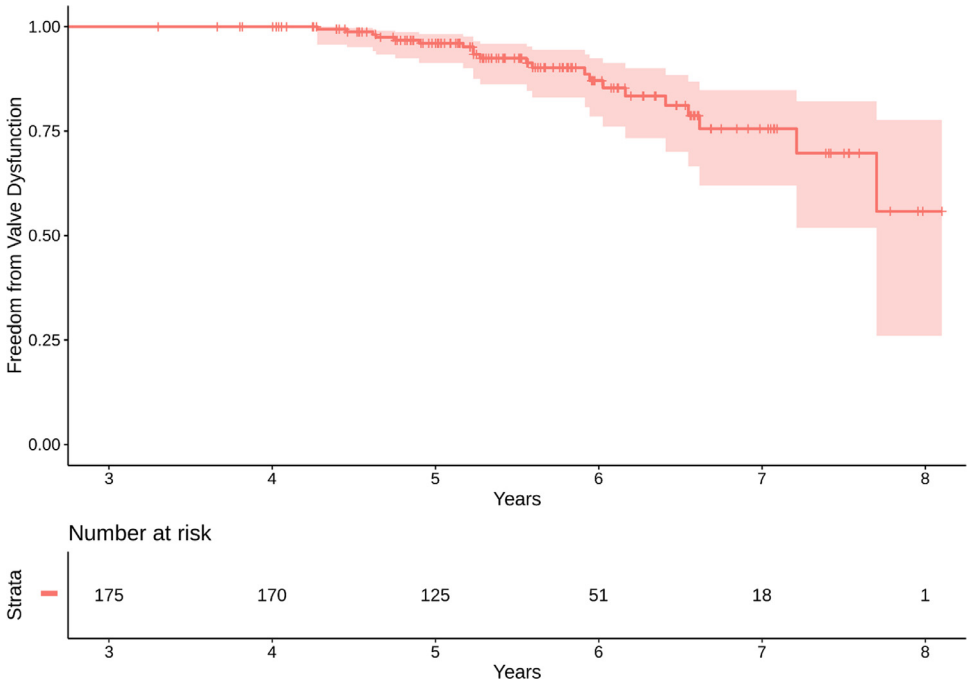

Figure 3. Kaplan Meier plot presenting freedom from valve dysfunction over follow up time.

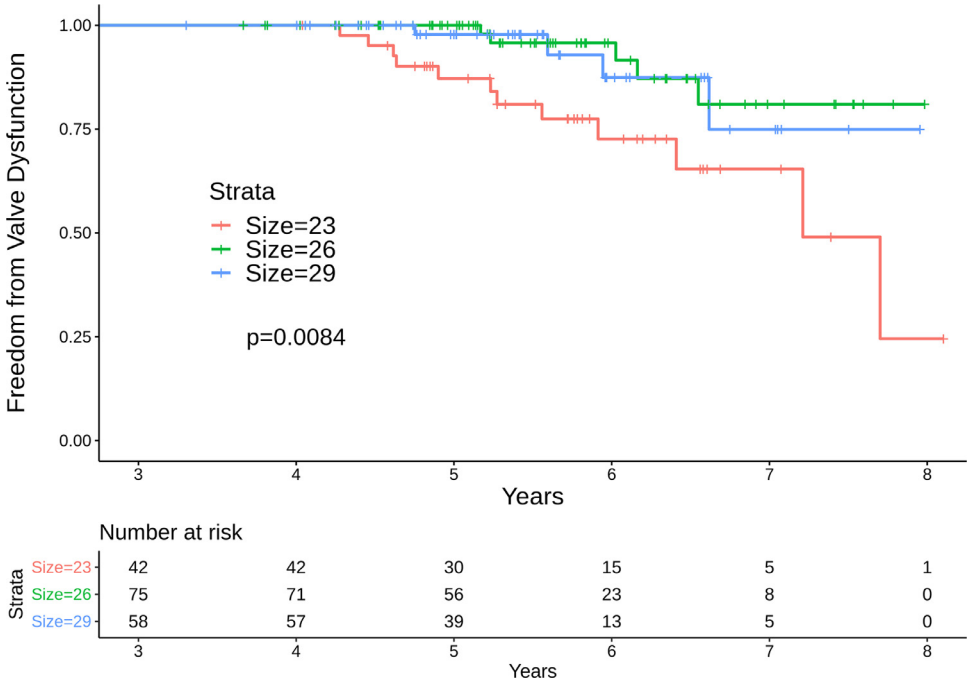

Figure 4. Kaplan Meier plot presenting freedom from valve dysfunction stratified according to valve size. Patients with smaller valve size had significantly shorter time to valve dysfunction.

Finally, comprehensive data were not available on valve thrombosis or endocarditis; therefore, these events were not included in the analyses of structural valve deterioration.

In conclusion, this study demonstrated favorable durability outcomes over the long term after successful TAVI in consecutive patients with severe AS who received either self-expandable or balloon-expandable prosthetic valves. The hemodynamic performance of the bioprostheses was sustained, and there was a low bioprosthetic failure rate.

Disclosures

The authors have no conflicts of interest to disclose.

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