Full Title: Long-term Transcatheter Aortic Valve Durability: Data from the UK TAVI Registry

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Short Title: Long-term Transcatheter Aortic Valve Durability

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ABSTRACT

Background: Very little is known about long-term valve durability after trans-catheter aortic valve implantation (TAVI).

Objectives: To evaluate the incidence of structural valve degeneration 5 to 10 years post-procedure.

Methods:

Demographic, procedural, and in-hospital outcome data on patients who underwent TAVI from 2007-2011 were obtained from the UK TAVI Registry. Patients in whom echocardiographic data were available both at baseline and ≥5 years post-TAVI were included. Haemodynamic structural valve degeneration (SVD) was determined according to European task force committee guidelines.

Results:

241 patients (79.3±7.5 years; 46.4% female) with paired post-procedure and late echocardiographic follow-up (median 5.8 years, range 5 - 10 years) were included. 150 patients (64.1%) were treated with a CoreValve and 80 (34.2%) with an Edwards valve. Peak aortic valve gradient at follow-up was lower than post-procedure (17.2 vs 19.4 mmHg, p=0.003). More patients had none/trivial aortic regurgitation (AR) at follow-up (47.4% vs 32.9%, p=0.055), and fewer had mild AR (41.7% vs 57.7%, p=0.02). There was 1 case (0.4%) of severe SVD 5.3 years after implantation (new severe AR). There were 21 cases (8.7%) of moderate SVD (mean 6.1 years post-implantation; range 4.9- 8.6 years). 12 of these (57%) were due to new AR and 9 (43%) to restenosis.

Conclusions:

Long-term transcatheter aortic valve function is excellent. In our study, 91% of patients remained free of structural valve deterioration between 5 and 10 years post-implantation. The incidence of severe structural valve degeneration was less than 1%. Moderate structural valve degeneration occurred in one in twelve patients.

CONDENSED ABSTRACT

This study evaluated long-term valve function and the incidence of structural valve degeneration (SVD) 5 to 10 years post-procedure using data from the UK TAVI Registry. 241 patients were included; 150 treated with a CoreValve and 80 with an Edwards valve. Long-term valve function was excellent, with no significant increase in average peak gradient or the incidence of moderate or worse aortic regurgitation. There was only 1 case of severe SVD (new severe AR), and moderate SVD was seen in one in twelve patients (21 cases (8.7%), 12 new AR; 9 stenosis).

INTRODUCTION

Trans-catheter aortic valve implantation (TAVI) has emerged as an alternative to surgical aortic valve replacement (SAVR) for the treatment of severe aortic stenosis. However, there are very few data regarding long-term valve durability. Assessments of valve function in the early randomised trial cohorts and registries have consistently shown preserved valve function up to 5 years after TAVI [3-7]. However, it is well recognised that structural valve degeneration (SVD) with surgical aortic valve bioprostheses is usually not seen until 5-10 years post-procedure, and data in this time-frame following TAVI are very sparse. There is a pressing need for greater understanding of the long-term durability of TAVI valves, particularly as TAVI moves into lower-risk cohorts. The purpose of this study was to evaluate long-term valve function and to determine the incidence of haemodynamic structural valve degeneration between 5 and 10 years after TAVI using data from the UK TAVI Registry[1].

METHODS

Study population

The UK TAVI Registry is a prospective mandatory database that includes all patients undergoing TAVI in the United Kingdom. Data are managed by the National Institute for Cardiovascular Outcomes Research (NICOR). Detailed information about the nature of the database has been published previously[1]. For the purposes of this study anonymised demographic, procedural, and in-hospital outcome data on all patients who underwent TAVI in the UK from 2007-2011 were obtained from the UK TAVI registry database. Centres were asked to cross-reference their patients with the anonymised NICOR dataset using parameters such as date of procedure, age, gender, and serum creatinine, in order to allow access to clinical outcome and echocardiographic follow-up data not included in the UK TAVI registry.

Data collection

Demographic, procedural, and in-hospital outcome data were generated from the UK TAVI registry database. Vital status was determined using the NHS Spine mortality database. Baseline echocardiographic data were obtained from the first transthoracic echocardiogram (TTE) performed after the TAVI procedure, no more than 6 months after valve implantation. Follow-up echocardiographic data were derived from the most recent TTE, no less than 4 years 6 months post-TAVI.

Definitions

The definition of haemodynamic SVD was adapted from the European task force committee guidelines[2] to include peak velocity to define SVD where mean gradient was not recorded, reflecting common practice in the UK. Definitions were as follows: Severe SVD: (i) mean gradient ≥40 mmHg and/or ≥20 mmHg increase from baseline AND/OR (ii) peak velocity ≥4m/s and/or ≥2m/s increase from baseline AND/OR (iii) severe new or worsening intra-prosthetic aortic regurgitation. Moderate SVD: (i) mean gradient ≥20 and <40 mmHg and/or ≥10 and <20 mmHg increase from baseline AND/OR (ii) peak velocity ≥3 and <4 m/s and/or ≥1.5 and <2 m/s increase from baseline AND/OR (iii) moderate new or worsening intra-prosthetic aortic regurgitation.

Statistical analyses

Data were analysed using the statistical package Intercooled Stata version 14.2 (StataCorp, College Station, TX, USA). Data are expressed as mean (95% CI), mean (SD), median (range), or percentage where relevant. We used the χ^2 test or Fisher's exact test to compare categorical variables, and *t* tests or ANOVA for comparing continuous variables.

Ethics

Data were collected as part of a mandatory UK national cardiac audit and all patient-identifiable fields were removed prior to analysis. Ethical approval for the study was obtained from the UK Health Research Authority (HRA).

RESULTS

Study Population

Of the 22 centres that had undertaken TAVI procedures between 2007 and 2011, 15 centres agreed to participate in the study. Paired echocardiographic data both at baseline and ≥4.5 years post-TAVI were available in 241 patients – these patients formed the study population. 130 (53.6%) were male; mean age was 79.3±7.5 years. Mean Logistic Euro SCORE (LES) was 19.9% (95% CI: 18.4 - 21.6). Baseline characteristics are summarized in Table 1.

Procedural characteristics and outcomes

Procedural characteristics and in-hospital outcomes are shown in Tables 2 and 3. TAVI was undertaken for treatment of pure aortic stenosis in 91.4% of patients, and for degeneration of a surgical valve in 6.8%. 150 patients (64.1%) were treated with the CoreValve system (Medtronic, Minneapolis, MN), 80 (34.2%) with an Edwards valve (SAPIEN/SAPIEN XT (Edwards Lifesciences, Irvine, CA)), 4 (1.7%) with Portico (Abbott Vascular, Minneapolis, MN) and in 8 patients the valve type was not recorded. The access route was transfemoral in the majority (80.4%); the remaining 19.6% were performed via the subclavian, transaortic, or transapical route. 73.6% of the procedures were done under general anaesthesia (Table 2). Valve deployment was successful in 97.4% of cases.

Echocardiographic data

Median echocardiographic follow-up was 5.8 years (IQR: 5.3 – 7.7 years). Follow-up extended to 6 years (n=168; 69%); 7 years (n=68; 28%); 8 years (n=30; 12%), 9 years (n=9; 4%) and 10

years (n=2; 1%). Echocardiographic data at baseline and long-term follow-up are shown in Table 4. All 241 patients had baseline studies <6 months post-TAVI and at follow-up at least 4½ years post-TAVI. Peak gradient was lower at follow-up compared to baseline (17.2 vs 19.4 mmHg, *p*=0.003). More patients had none/trivial aortic regurgitation (AR) at follow-up (47.8% vs 32.9%, p=0.055), and fewer had mild AR (41.7% vs 57.7%, p=0.02) compared to baseline. There was no change in the incidence of moderate AR. One patient (0.4%) developed new severe AR at follow-up.

Echocardiographic data according to valve type

Baseline and follow-up data according to valve type are shown in Table 5 and Figures 1-2. Amongst patients treated with the CoreValve prosthesis, peak gradient at follow-up was significantly lower than at baseline (15.2 vs 19.3 mmHg, p<0.0001), while there was no difference for the Edwards valve (19.8 vs 21.5 mmHg, p=0.29). CoreValve patients also demonstrated a significant reduction in the frequency of mild AR at follow-up (44.3% vs 69.9%, p=0.001) and a corresponding increase in none/trivial AR (46.3% vs 22.1%, p=0.02) For the Edwards valve there was no change in the proportion of patients with mild AR over time (33.3% vs 32.6%, p=0.98). The frequency of moderate AR was unchanged from baseline to follow-up with both valve types.

Structural valve degeneration

Severe SVD

One patient who was treated with a 26mm CoreValve developed severe SVD with severe valvular aortic regurgitation 5 years and 4 months post-implantation. Her baseline echocardiogram showed mild paravalvular AR only. There were no features to suggest aortic endocarditis and she was not considered fit for further intervention.

Moderate SVD

There were 21 cases (8.7%) of moderate SVD. 12 of these were due to new moderate aortic regurgitation, and 9 were due to an increased transvalvular gradient. Deterioration of the valve was noted at a median duration of 6 years 1 month (range 4 years 11 months to 8 years 7 months) 13 (62%) of these patients were treated with the CoreValve, and 8 (38%) with an Edwards valve.

No SVD

In the substantial majority of patients (n=220; 90.9%) there was no structural valve deterioration of note. The Kaplan-Meier curves for survival free of severe and moderate SVD is shown in Figure 3.

DISCUSSION

The principal findings of this study are as follows: 1) Overall long-term function of trans-catheter aortic heart valves was excellent, with no increase in average peak gradient, and a reduction in aortic regurgitation at long-term follow-up. 2) Structural valve degeneration was very rare, with only 1 case of severe haemodynamic SVD (0.4%), and 21 cases of moderate SVD (8.7%). 3) The CoreValve prosthesis was associated with a fall in peak gradient from baseline to follow-up, and a change in the degree of AR from mild to none/trivial.

Existing Data on TAVI Valve Durability

Medium-term (≤ 5 years)

There is now a significant body of randomised and registry data indicating good overall function of trans-catheter aortic valves up to 5 years, with a very low incidence of SVD. The Placement of Aortic Trans-catheter Valves (PARTNER) 1 trial randomised 699 patients with severe AS to either TAVI with the balloon-expandable SAPIEN valve or SAVR. No patients in either arm

demonstrated any evidence of SVD at 5 years follow up[8]. In a pooled analysis of 3 European trials: REVIVE II, TRAVERCE, and PARTNER EU, 410 patients were treated with the SAPIEN valve and no cases of SVD were identified[9] .In the CoreValve Advance study, 996 patients had TAVI using the CoreValve prosthesis. Echocardiographic data were available on 860 patients with a mean follow up of 36.0 ± 21.1 months, with 267 patients having follow-up through 5 years. SVD was noted in 0.2% at 1 year, and 0.9% of patients at 5 years[10]. A recent review of nearly 14,000 cases using multiple valve types found survival at 5 years to be 48% and at 7 years 28%[11], and another review of 8914 patients with a median follow-up between 1.6 and 5 years, reported an incidence of SVD post-TAVI up to 1.34 per 100 patient years. The pooled incidence of SVD in both studies was 28.08 per 10 000 patients/year (95% CI 2.46 - 73.4 per 100 patient years), and 12% of these patients underwent valve re-intervention[12].In the Nordic aortic valve intervention (NOTION) trial, which compared TAVI vs. SAVR in 280 low risk patients (STS SCORE < 4%) with severe AS, the incidence of SVD at 5 years in patients treated with TAVI was significantly lower than patients treated surgically (3.9 vs. 26.1%, p<0.0001)[13].

Long-term durability (> 5 years)

Data from surgical bioprostheses have consistently shown that structural valve degeneration is rare in the first 5 years after surgery, but that failure occurs increasingly thereafter. Currently very few data exist describing TAVI valve function beyond 5 years. To our knowledge we have described the largest cohort of patients with echocardiographic assessment of valve function between 5 and 10 years, with data on 242 patients at 5 years, 168 at 6 years, 68 at 7 years, and 30 at 8 years. We found an incidence of severe SVD of less than 0.5% at a median follow-up of 5.8 years, with moderate SVD in 8.7%.

Webb et al reported data on 236 patients who underwent TAVI between 5 and 10 years previously, and demonstrated severe structural valve degeneration, classified as severe stenosis, regurgitation, or re-intervention for SVD, in only 5 patients (1.9%)[14]. However, only 68 patients were alive at 4 years, 41 at 6 years, and 8 at 8 years post-TAVI. Eltchaninoff described

findings in 242 patients treated more than 5, and up to 14 years previously[15]. 1 patient required re-intervention for severe SVD, while 4 in total had moderate or severe SVD. Again, numbers at risk beyond 5 years were small - only 17 at 6 years and 1 at 8 years. Testa et al[16] presented data on 2343 patients who underwent TAVI at 13 Italian centres between June 2007 and December 2016. All patients received the Core Valve or Evolut R system. Mean duration of follow up was 22 months, with a very small number of patients having follow up to 9 years. The total number of cases of severe SVD was extremely low, seen in only 3 patients at 26, 72 and 89 months respectively.

Surgical Valve Durability

Understanding of surgical valve durability has been hampered by the absence of standardized definitions of structural valve degeneration. Most studies have reported SVD in terms of the need for re-operation. Puri and colleagues reported that SVD in surgical bioprostheses tends to be seen about 8 years post-surgery, and rapidly increases in frequency after 10 years[17]. Current data suggest an incidence of SVD (defined as death, re-operation or clinical reinvestigation due to suspected SVD) of less than 1% before 5 years, increasing to 10% at 10 years for patents >65 years age[18]. However, the incidence and timing of SVD is highly dependent on the type of prosthesis used, with time to SVD being reported as early as 3.8+/- 1.4 years for the Sorin Mitroflow prosthesis[19]; and as late as 19 years for the Carpentier-Edwards Perimount (Edwards Lifesciences) valve[20]. Freedom from SVD has been reported to be 95% for the Trifecta valve (St Jude) [21] at 6 years, and 95% for the Hancock II valve (Medtronic) at 10 years[22]. Pibarot reported overall freedom from re-intervention or death in surgical valves of 95% at 5 years, 70-90% at 10 years and 50-80% at 15 years[23].

A number of factors may influence the relative durability of surgical and trans-catheter valves. Valve tissue damage during loading, lack of routine anti-calcification treatment in first-generation devices, and incomplete and eccentric frame expansion might all potentially lead to worse long-

term durability for trans-catheter valves[24]. In contrast, the increased effective orifice area of the TAVI valve, particularly with supra-annular prostheses, and reduced incidence of patient prosthesis mismatch may confer a significant advantage with respect to durability.[25] Current data suggest trans-catheter valve durability is comparable to surgical valve durability in the short to medium term, but long term data are lacking.

Comparison of CoreValve and Edwards prostheses

We found excellent overall long-term durability with both the CoreValve and Edwards prostheses, with only 1 case of severe SVD with CoreValve and none with Edwards, and no difference in the incidence of moderate SVD. However, the CoreValve device was associated with a reduction in peak gradient over time. In addition, there appeared to be an improvement in paravalvular AR with

Corevalve, with a significant increase in the number of patients with none or trivial leak. Both of these findings may be explained by long-term continued expansion of the self-expanding nitinol frame of the CoreValve. Nonetheless, these data are not randomized, involve a relatively small number of patients, and should be considered hypothesis-generating only.

STUDY LIMITATIONS

Echocardiographic follow up data were only available in those patients who were still alive and/or in whom late echocardiographic follow-up data were available before death, and this was only 15.8% of all patients who underwent TAVI in the contributing centres between 2007-2011. A significant proportion of those patients without long-term echo data were dead, with the cause of death being uncertain in the majority of patients. We cannot exclude death due to SVD in some of these patients.

Follow-up echo data were obtained from standard clinical follow-up scans rather than dedicated research studies, and as a consequence complete dataset were not available in all cases, Hence, some analysis may have been affected by missing variables.

Median follow-up was only 5.8 years, with fewer than 15% having follow up beyond 8 years. Longer-term data are needed for more robust analysis; we plan to continue follow-up of this study cohort and report annually on valve durability.

Finally, only first-generation of TAVI valves were used during the study period, and operator experience was limited.

CONCLUSIONS

Long-term TAVI valve function after TAVI was excellent, with no increase in gradient or regurgitation at a median follow-up of 5.8 years, up to a maximum of 10 years, and severe structural valve degeneration in less than 0.5% of patients.

PERSEPECTIVES

COMPETENCY IN PATIENT CARE AND PROCEDURAL SKILLS: Severe Structural valve degeneration is uncommon in patients undergoing TAVI, with excellent long term outcomes.

TRANSLATIONAL OUTLOOK: Further research should be directed toward understanding the mechanisms of structural valve degeneration, and its relationship to long term outcomes in patients undergoing TAVI.

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Figure Legends

Figure 1: Severity of aortic regurgitation at baseline and follow up according to valve type

Figure 2: Boxplot of peak gradient at baseline and follow-up by valve type

Figure 3: Kaplan-Meier curve demonstrating freedom from structural valve degeneration over time

Table 1: Baseline characteristics of study population

Male (n/N, %)	126/235 (54%)
Age (mean ± SD)	79.3±7.47
Logistic Euroscore (mean ±SD)	19.7±12.3
Prior cardiac surgery	93/224 (41.5%)
Pulmonary disease	60/163 (26.9%)
Previous stroke/TIA	43/181 (19.2%)
Peripheral vascular disease	60/235 (25.5%)
Creatinine > 200 µmol/l	11/224 (4.9%)
Atrial fibrillation	55/220 (25.0%)
Previous MI	60/235 (25.5%)
Diabetes mellitus	52/224 (23.2%)
Peak gradient (mean±SD)	80.6±26.2
Aortic valve area (mean±SD)	0.69±0.3
Left ventricular function	
• Normal (LVEF ≥50%)	163/235 (69.4%)
• Moderately impaired (30-49%)	52/235 (22.1%)
• Severely impaired (<30%)	20/235 (8.5%)
PA pressure >60mmHg	39/235 (16.6%)
Annulus diameter (mean ±SD; mm)	23.4, (22.7±2.3)

Data are presented as n/total number (percent). Denominators vary due to some missing data.

Table 2: Procedural Data

General Anaesthesia, %	173/235 (73.6%)
Access, %	
• Trans-femoral	180/224 (80.36%)
• Trans-apical	31/224 (13.8%)
• Subclavian	8/224 (3.6%)
• Transaortic	5/224 (2.2%)
Valve Type	
SAPIEN	45/234 (19.2%)
SAPIEN XT	35/234 (15%)
Core Valve	150/234 (64.1%)
Portico	4/234 (1.7%)
Pre-dilatation (BAV)	214/235 (91.1%)

Table 3: In hospital outcomes

Successful valve deployment	229/235 (97.4%)
AR grade (echo or fluoro)	
None/Mild	193/213 (90.6%)
Moderate	20/213 (9.4%)
Severe	0/213 (0%)
Major vascular complications	4/234 (1.7%)
Stroke	5/234 (2.1)%
New permanent pacemaker	39/222 (17.6%)

Table 4: Baseline vs Follow-up Echocardiographic Data for all valves

	Baseline	**Follow up**	**P**
Peak gradient*	19.4 (18.1 – 20.6)	17.2 (15.8– 18.6)	0.003
Aortic regurgitation			
None/Trivial	70/213 (32.9%)	110/230 (47.8%)	0.055
Mild	123/213 (57.7%)	96/230 (41.7%)	0.01
Moderate	20/213 (9.4%)	23/230 (10%)	0.95
Severe	0/213 (0%)	1/230 (0.45%)	-
LV function			
Normal	186/218 (85.3%)	187/221 (84.6%)	0.83
Moderately impaired	20/218 (9.2%)	22/221 (10%)	0.94
Severely impaired	12/218 (5.5%)	12/221 (5.4%)	0.99

*Data are mean (95% confidence interval); p values are from t-tests for continuous variables or from a two-sample test of proportions

Table 5: Baseline vs Follow-up Echocardiographic data according to valve type

	SAPIEN/XT Baseline	**SAPIEN/XT Follow-up**	**P**	**CoreValve Baseline**	**CoreValve Follow-up**	**P**
Peak gradient*	19.3 (17.2 – 21.3)	20.5 (17.6 – 23.3)	0.29	19.2 (17.7 – 20.8)	15.3 (13.9–16.8)	<0.0001
None/Trivial AR	37/68 (54.4%)	37/69 (53.6%)	0.84	30/136 (22.1%)	69/149 (46.3%)	0.02
Mild AR	22/68 (32.3%)	23/69 (33.3%)	0.97	95/136 (69.9%)	66/149 (44.3%)	0.001
Moderate AR	9/68 (13.2%)	9/69 (13.04%)	0.99	11/136 (8.1%)	13/149 (8.7%)	0.96
Severe AR	0/68 (0%)	0/69 (0%)	NS	0/136 (0%)	1/149 (0.7%)	NS

*Data are mean (95% confidence interval); p values are from t-tests for continuous variables or from a two-sample test of proportions

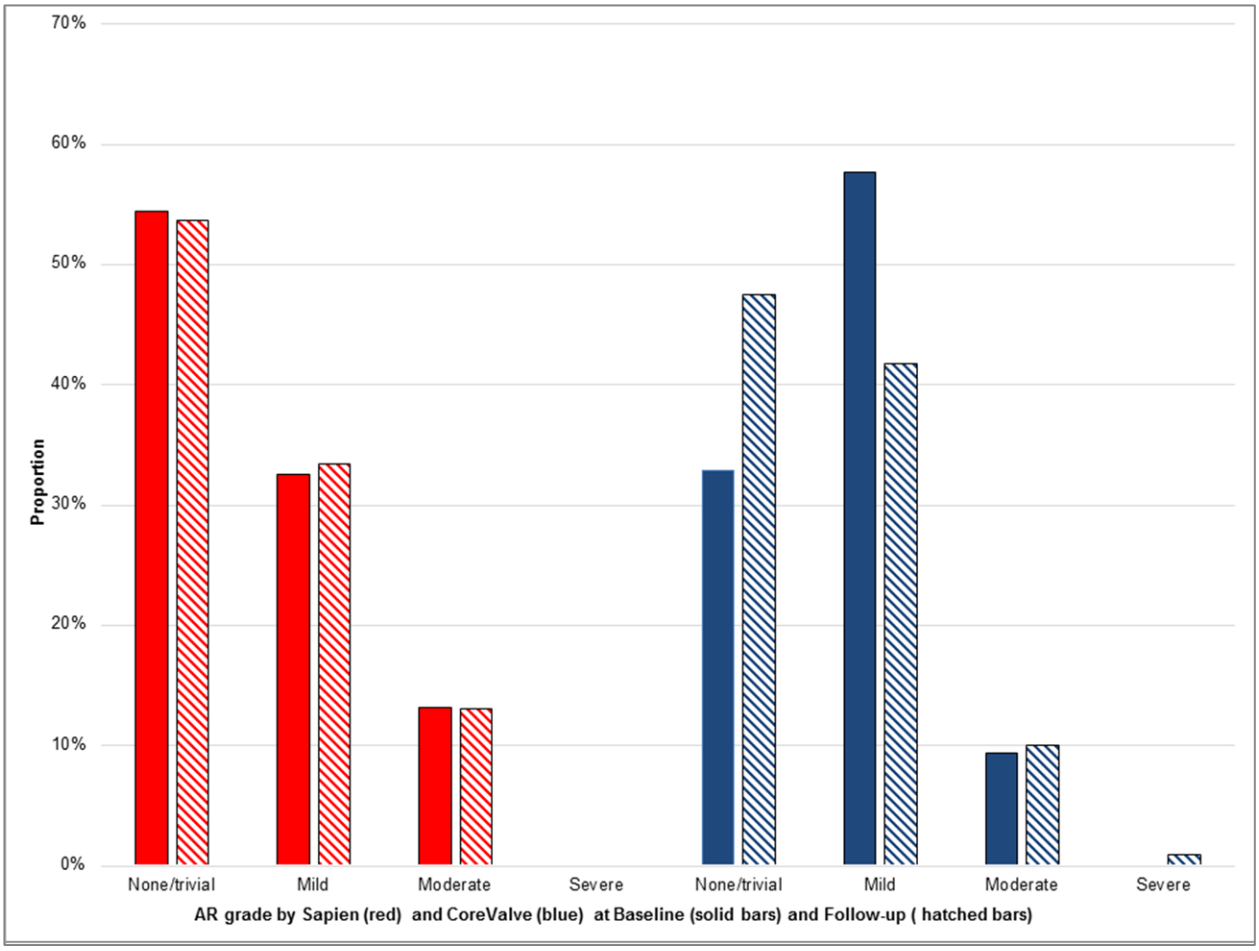

Figure 1

Severity of aortic regurgitation at baseline and follow up according to valve type

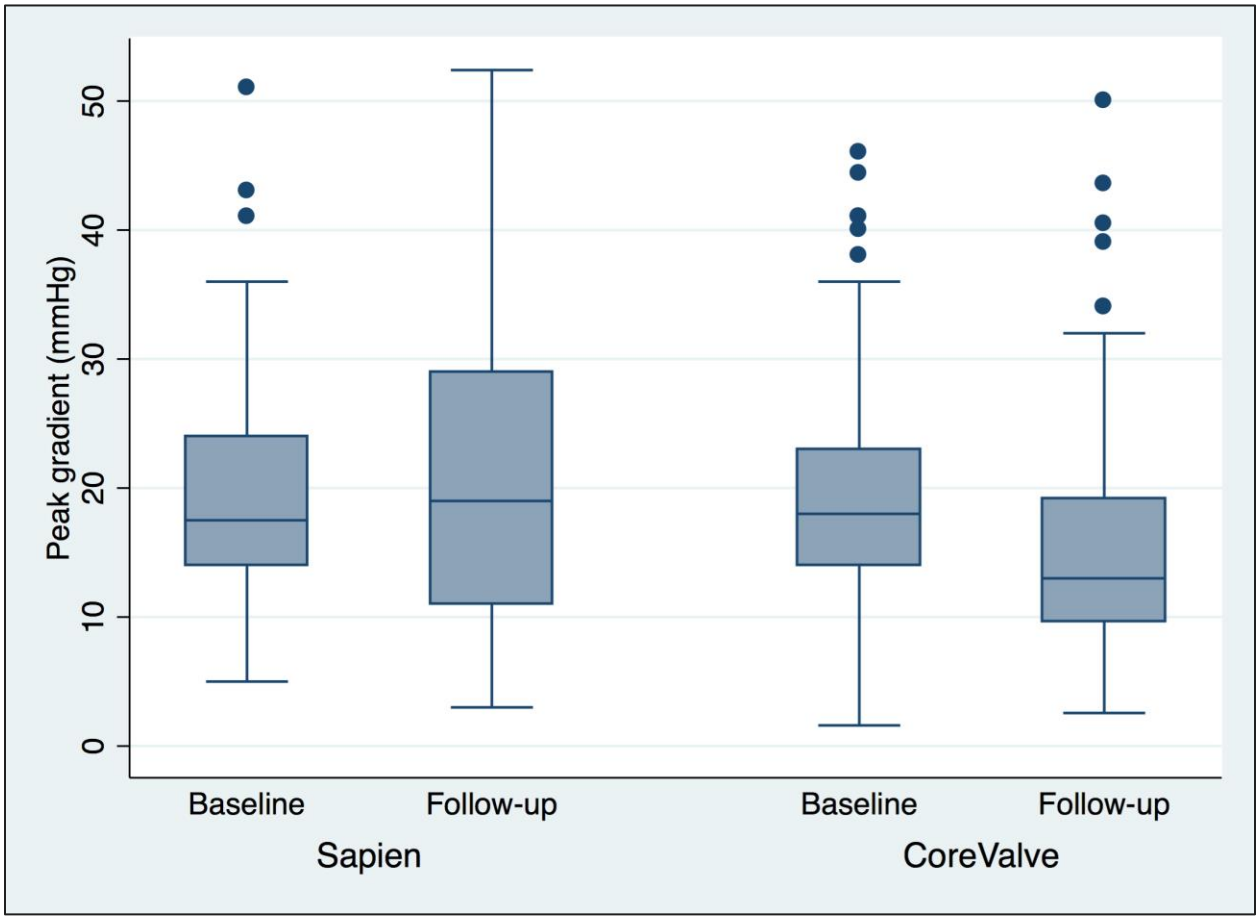

Figure 2

Box and whisker plot with its IQR divided by the median and Tukey-style whiskers which extend to a maximum of 1.5 × IQR beyond the box. The dots beyond the whiskers represent outliers. No difference in peak gradient (mmHg) in SAPIEN/XT system over time (19.3 v 20.5, p=0.484). Significant changes in peak gradient for Core Valve/Evolut system 19.3 vs 15.2 mmHg, p<0.0001.

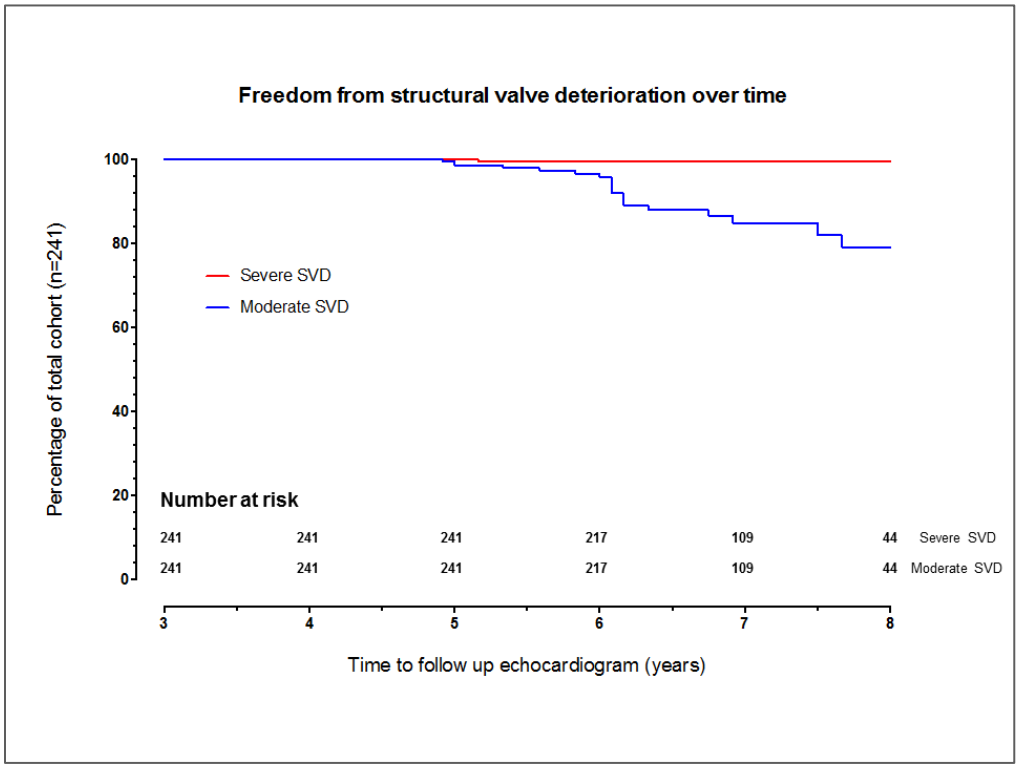

Figure 3

Kaplan-Meier curve demonstrating freedom from structural valve degeneration over time