# Low Incidence of Structural Valve Degeneration With the Trifecta Aortic Valve Bioprosthesis.

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# Abstract

### Objectives:

An ideal bioprosthetic heart valve would have excellent haemodynamic performance and a low rate of Structural Valve Degeneration (SVD). The objective of this study was to investigate the haemodynamic performance and incidence of reintervention due to SVD of the Trifecta aortic valve.

### Methods:

Between 2012 to 2019, 2934 valve surgeries were performed in which 2185 were biological valves. Out of 2185 patients, only 399 patients had undergone Trifecta biological Aortic Valve Replacement (AVR). Three surgeons performed all aortic Trifecta valve surgeries. Operative mortality, incidence of reintervention and overall survival figures was calculated.

### Results:

A total of 399 patients were included of which 260 (65.2%) were male. The mean (± SD) age was 73.4 ± 8.0 with 41 patients (10.3%) aged under 65 with 222 patients (55.6%) had isolated AVR and 176 (44.1%) had AVR combined with coronary artery bypass grafting and a single patient underwent aortic and mitral valve replacement. The mean (±SD) logistic EuroSCORE was 7.4 (±2.7).

The median valve size used was 23mm. A total of 21 patients (5.3%) required a permanent pacemaker to be implanted. The 30-day mortality rate was 2.8% (n=11). The rate of structural valve degeneration was 0.3% and median follow-up was 782 days. Neither peak nor mean valve gradients were significantly different between year 1 vs. year 3 (peak gradient: 18.3±8.0 vs. 17.1±8.5, p=0.34; mean gradient: 9.8±4.6 vs. 8.7±4.6, p=0.16).

### Conclusions:

Mid-term echocardiographic data showed a low rate of significant regurgitation and excellent gradients. Larger multicentre studies are required to validate these findings.


# Introduction:

Valvular heart disease has been found to affect over 10% of patients aged 65 and over(1). Valve repair or replacement is recommended for patients with severe valve disease associated with symptoms or signs of imminent clinical deterioration(2). It is estimated that globally over 200,000 valve replacements are performed each year and that this number is likely to increase significantly over the next 30 years as a result of an ageing population, improved diagnostic availability and the introduction of transcatheter treatment options(3).

The most common interventions for valvular heart disease in developed countries are valve replacements for aortic stenosis(4). Valve replacement can either be performed with a Mechanical Heart Valve (MHV) or Biological Heart Valve (BHV). Over recent years there has been a worldwide shift from the use of MHVs to BHVs in the treatment of aortic stenosis(5). In the United Kingdom (UK), bioprosthetic valves have been more commonly used than mechanical valves since 1999, and in 2012 approximately 86% of all aortic valve replacements were performed with a biological valve(6). A similar trend has also been demonstrated in the USA(7).

No prosthetic heart valve is perfect and both MHVs and BHVs have advantages and disadvantages. MHVs are durable but require life-long anti-coagulation. Although, BHVs do not require treatment with anticoagulation, they are at risk of structural valve degeneration (SVD). The use of BHVs has been shown to be associated with a better safety profile and sustained lifestyle quality(8, 9). There are numerous BHVs commercially available and long-term clinical outcomes have been shown to vary between devices(6).

The Trifecta GT with anti-calcification (Abbott™, Illinosis, USA) is a BHV designed for supra-annular placement in the aortic position. Previously published small scale and large-scale single centre studies have demonstrated excellent long-term durability of this Trifecta valve(10–14). On July 2020, the Medicines and Health Regulatory Authority (MHRA) issued a Medical Device Alert regarding cases of structural valve degeneration on all Trifecta series of valve patients to be followed up(15). The objective of this study was to present our centres experience and results obtained with this prosthesis with follow-up over 7 years.

# Methods:

All patients who underwent aortic valve replacement with Trifecta and Trifecta Glide Technology (St. Jude Medical™ and Abbott™, USA) aortic valves between 2012 and 2019 at a single UK centre were included. The decision about whether to implant a BHV or MHV was made by each individual patient in conjunction with the operating surgeon taking into consideration the management of valvular heart disease guidelines of the European Society of Cardiology and the European Association for Cardiothoracic surgery (2). The choice about which specific device was implanted was made by the operating surgeon. All preoperative, intraoperative, and postoperative clinical data were collected from a prospectively maintained clinical database. All echocardiographic data were obtained from intra-operative transoesophageal echo (TOE) or valve surveillance databases. Survival status was determined from the National Health Service (NHS) Patient Administration Lorenzo survival database.

### Isolated AVR technique (sternotomy):

A full median sternotomy is performed, the pericardium is incised and the patient is heparinised. The heart is cannulated and cardiopulmonary bypass commenced. Antegrade and retrograde cardioplegia cannulas are inserted. The aortic cross clamp is applied and cardioplegia administered. Once the heart is adequately protected and vented, the aortic valve is exposed, using either stay sutures or hand-held

retractors. Venting is performed either via the right superior pulmonary vein, directly via the aortic root or occasionally via the pulmonary artery. The native valve is excised and the annulus decalcified. The annulus is then measured and an appropriate prosthesis chosen. Multiple interrupted sutures are placed through the aortic annulus and then through the sewing ring of the valve. The sutures are then tied and cut. The aortotomy is closed as the patient is rewarmed. De-airing manoeuvres are performed and the cross-clamp removed. Ventricular and atrial epicardial pacing wires are attached prior to routine closure.

### Isolated AVR technique (minimal access):

All minimal access procedures were performed via an upper hemi-sternotomy. The sternum is divided in the midline below the level of the 3$^{rd}$ intercostal space and then laterally into each intercostal space. The visible pericardium is incised and aortic cannulation is performed as normal with cannulation of the right atrium performed either directly or via the superior vena cava depending on access.

Antegrade cardioplegia is given via the aortic root and subsequently directly using handheld cannulas into the coronary ostia. Venting is performed via the aortic root. Excision of the native valve and implantation of the prosthetic valve is performed as described for full sternotomy. Routine minimally invasive closure techniques were performed.

### Outcomes:

The primary outcome for the study was re-intervention for structural valve degeneration. Echocardiographic outcomes included mean and peak postoperative gradient across the aortic valve. Other secondary outcomes were postoperative complications, length of hospital stay, 30-day mortality and overall 1-year and 3-year survival.

### Statistical analysis:

All statistical analysis were performed using Prism v7.01. Descriptive statistics were used to demonstrate patient demographics and are expressed as mean ± standard deviation unless otherwise specified. Chi-square tests were performed for categorical variables and Student T tests were performed to compare continuous variables. When there were 3 or more paired time points to be analysed then the repeated measures one-way ANOVA was used followed by Tukey's corrected multiple comparisons tests. Overall survival was evaluated by Kaplan-Meier survival curves. Right censoring of patients occurred when they survived to the end of the study. Survival analyses were performed for the total cohort and stratified by age (<75 years versus ≥75 years) or by valve size (≤23mm vs. ≥25mm). Group survival comparisons were performed with the Log-rank (Mantel-Cox) test. Statistical significance was accepted when $p \leq 0.05$.

# Results:

### Demographics and preoperative variables:

A total of 399 procedures met the inclusion criteria and these were performed in 399 individual patients. The majority of patients were male (260, 65.2%) and the overall mean age of the cohort was 73.4 ± 8.0 years. The majority of patients had good pre-operative left ventricular function (281, 70.4%). Surgery was predominantly performed on an elective basis although 112 (28.1%) procedures were non-elective. There were 22 patients (5.5%) who had undergone previous cardiac surgery. The mean (±SD) logistic EuroSCORE was 7.4 (±2.7). Full pre-operative patient characteristics for the cohort are displayed in Table 1.

### Intraoperative outcomes:

Over 90% of procedures were performed in patients with moderate or severe aortic stenosis and 16.3% of patients had moderate or severe aortic regurgitation. Most patients underwent either isolated AVR (50.6%) or in combination with Coronary Artery Bypass Grafting (CABG) (40.1%), CABG + valve + other procedures (4%) and valve replacement with other procedures (5.3%). Other procedures included concomitant aortic surgery, additional valve surgery or surgical treatment of atrial fibrillation. There were 14% procedures performed via a minimally invasive approach and all of these were isolated AVR. Cumulative bypass time mean was 134.0 ± 49.0 and cumulative cross clamp mean time was 104.4 ± 38.1. The most common valve size implanted was 23mm. Full intraoperative details are displayed in Table 2.

### Post-operative in-hospital outcomes:

Post-operative outcomes are displayed in Table 3. Permanent pacemaker was implanted in 21 patients (5.3%). Overall, 1.3% had re-exploration for bleeding, 2.5% had dialysis/filtration, 1.3% had septicaemia, 1% had tracheostomy, 0.5% had re-intubation, 0.3% had ischemic bowel and 12% had atrial fibrillation complications. The median length of hospital stay was 7 days [interquartile range: 6 – 13 days]. A total of 386 (96.7%) patients were alive at discharge from the hospital.

### Reintervention and survival:

The majority (93.5%) of patients have not required any type of repeat surgery and one patient (0.3%) required re-intervention for structural valve degeneration. Survival to 30 days was 97.2% with 11 patients having died during this time. The Kaplan Meier plot for overall survival is displayed in Figure 1. Of the patients who had their surgery at least one year prior to the end of the study (n=308), 287 survived to 1 year (94.1%). Of the patients whose surgery occurred at least 3 years before the end of the study (n=162), there are 129 survivors (79.6%). When stratified by age, mortality up to 5 years follow-up was not significantly different between the groups (<75 years vs. ≥75 years, p=0.11, figure 2). Furthermore, no differences are observed in survival when stratified for valve size (valves ≤23mm vs. valves ≥25mm, p=0.67, figure 3)

### Valve gradients:

As shown in table 4, there was no incidence of severe paravalvular or transvalvular regurgitation in patients who have undergone echocardiographic surveillance at either 1-year (n=235) or 3 years (n=56).

One patient had moderate paravalvular regurgitation at 1-year follow-up. At 3-years, 27.8% of patients had developed mild transvalvular regurgitation and one patient had developed moderate transvalvular regurgitation. There were 12.5% of patients with mild paravalvular regurgitation at 3-years follow-up. Peak and mean valve gradients were compared for all patients with 1 and 3-year echocardiographic data available ( Figure 2). Neither peak nor mean valve gradients were significantly different between these years (year 1 vs. year 3; peak gradient: 18.3±8.0 vs. 17.1±8.5, p=0.34; mean gradient: 9.8±4.6 vs. 8.7±4.6, p=0.16).

# Discussion:

This single centre retrospective analysis of Trifecta valve utilisation demonstrates post-operative complication rates in line with other series(9, 16, 17). The incidence of aortic valve reoperation due to structural valve degeneration was low, with only a single patient requiring repeat aortic valve replacement at 3 years post-surgery for transvalvular leak due to a non-calcific leaflet tear. This was a 34-year-old man who had a previous AVR 10 years earlier with another BHV and wanted to avoid anticoagulation due to his lifestyle preferred to have another BHV. There are a range of BHVs available, but it can be either stented or stentless. Stentless BHVs were developed in an attempt to minimise the transvalvular gradient and improve the effective orifice area(11, 17). However, recent studies have suggested that stentless porcine valves have reduced durability(11) and an increased rate of SVD requiring re-intervention(18). Most BHVs used in contemporary practice are now stented and various bovine pericardial valve prosthesis have demonstrated initially better long-term durability and excellent haemodynamic performance(19). However, few studies have demonstrated that there is a high chance of SVD on trifecta(10, 12, 16) and pericardial mitral flow(19, 20) aortic prosthetic valve post-surgery.

The Trifecta valve is a stented pericardial bovine heart valve designed for supra-annular placement. It was first introduced for patient use in 2007. The valve leaflets are externally mounted on the stent which allows cylindrical opening during systolic contraction to provide an enhanced effective valve orifice area and optimised transvalvular gradients. Several literature reports identified that first-generation Trifecta aortic valve was at risk of cusp tears or leaflet calcification(21–24). The latest generation Trifecta GT valve was introduced in 2016 to provide added handling protection for the stent and leaflets (14). Modifications included a streamlined and enhanced holder, a softer sewing ring, an additional titanium band in the stent base, optimised leaflet suturing techniques and collagen alignment.

The rate of SVD in our study is lower than other previously published studies that have demonstrated a 1% incidence of repeat operation with Trifecta valve for SVD at 5 years(10), and 3.3% at 7 years(16). Studies have also reported that younger patients have a higher incidence of SVD (3 years: 2.4%, 5 years: 4.2% and at 7 years: 27.9%)(22). This was the case in our study with our single patient who is 34 years old, exhibiting SVD. Previous studies of the trifecta valve have reported the incidence of device related stroke, systemic embolism of 2.7–6.0%(12). In our cohort we observed a post-operative stroke rate of 0.8% in a patient who underwent combined AVR + CABG with no systemic embolic complications.

Valve performance in our cohort was good and in 3 year follow up data, there was no patient who exhibited severe paravalvular regurgitation and only one patient who had developed a moderate paravalvular regurgitation. The survival rate at hospital discharge was 96.7%, at 30 days was 97.2%, at 1 year 94.1% and at 3 years was 79.6%. Irrespective of having an older population in our cohort of patients, the survival rate was better than other studies who had survival rates ranging from 70–88.7% (11, 14, 16). The incidence of a mild paravalvular leak at one year was 2.6% (n = 287 patients at risk) and minimal transvalvular leak was 21.7%. Haemodynamic performance was very favourable in the case series with mean valve gradients at one year of 9.5 ± 4.1 mmHg compared to ranges from 10.1 to 20mmHg in the published literature (10, 11, 14).

Our experience demonstrates that the use of the Trifecta valve is safe and achieves good clinical outcomes. However, like any bioprosthetic valve it has its own advantages and disadvantages. In our experience avoiding over-sizing of the valve, careful knot tying and valve handling to avoid inadvertent damage to the leaflets are the key elements to achieving good results. We suggest that unnecessary handling of leaflets at the time of the implant may be a significant contributing factor to the early structural valve deterioration that has been reported in other studies(16, 22). We believe that proctoring and adequate training when a surgeon first uses the valve are vital to ensuring good results. We will also urge surgeons new to the use of this valve to exercise caution if they implant the valve with the Cor-Knot® system to avoid deploying the Cor-Knot® in such a way that it may be in contact with the valve leaflet and initiate SVD. In our practice, we try to avoid using Cor-knot especially if we are implanting the Trifecta valve.

### Limitations:

There are a number of limitations of this study. Firstly, it is a retrospective analysis of prospectively collected data with a small sample size from a single centre and as such the generalisability of these results to other centres is unknown. A further limitation is that echocardiographic follow-up was not available for all patients at either one or three year. This is due to the retrospective nature of the study and variations in regional surveillance programmes. 1-year echocardiographic data was available for two thirds of the original cohort and as such the results at this time are likely to be robust. However, 3-year follow-up echocardiographic information was only available for 13.5% of the original cohort. Despite this however it is encouraging that there has been no significant change in the gradients across the valves in these patients. Development of mild transvalvular regurgitation in around one quarter of patients between one and three years is potentially concerning, and these patients should continue to be followed up on a long-term basis. It should be noted that this study includes data from two versions of the Trifecta valve. Although the Trifecta GT contains a number of modifications the fundamental design of the valve is the same and as such no comparisons have been made between the two valve types. Another limitation is that this study represents a heterogeneous group of procedures. Although the key message regarding the safety profile of the Trifecta valve is not affected by this issue, it does mean that direct comparisons of the results from this study with other more homogenous groups should be undertaken with caution.

Long-term multicentre data is required to ensure the on-going safety issues of any implantable medical device. Unfortunately, the UK Heart Valve Registry was defunded and as such prospective and retrospective systematic monitoring of heart valve performance is not currently possible in UK. Ideally, as is the case with other devices such as hip replacements, prospective national registries with serial echocardiographic data for all biological valves implanted should be established and would provide an invaluable resource. Establishing such registries to facilitate long-term performance monitoring is now even more important given the rapid expansion in utilisation of transcatheter aortic valve implantation.

# Conclusion:

This study of patients who have received a Trifecta bioprosthetic aortic valve demonstrates good short and mid-term outcomes out to 3 -years with a low rate of structural valve degeneration requiring re-intervention.

# Abbreviations:

AVR: Aortic Valve Replacement, BHV: Biological Heart Valve, CABG: Coronary artery bypass grafting, GT: Glide Technology, MHV: Mechanical Heart Valve, NHS: National Health Service, SD: Standard Deviation, SVD: Structural Valve Degeneration, TOE: Transoesophageal echo, UK: United Kingdom, USA: United States America.

# Declarations:


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### Authors' contribution:

BK: Concept, study design, data collection, writing and review; WRC: Data analysis and curation; ND: Data collection, RVV: study concept and supervision, SWG, IK, JB and all authors: Review of the manuscript, read and approved the final manuscript.


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### Availability of data and materials:

Please contact corresponding author for data request.

### Ethical approval and participant consent:

This retrospective study complied with the Helsinki Declaration (2000) and approval to perform this analysis was given by the local ethical governance committee (registration no: 9711), based on retrospective data retrieval. For this reason, the ethical committee waived the need for written patients' informed consent.

### Consent for publication:

Yes, we have permission to publish this article and results of this study. All authors read and given permission to publish this article.

### Competing interests:

All authors declare no conflict on interest with respect to research, authorship, and publication of the article.

### Conflict of Interest:

None to declare for all authors.

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# Tables:

**Table 1:** Patient preoperative characteristics and operative variables

| Pre-operative details | N (%/SD) |
|---|---|
| Age (mean ± SD) | 73.4 ± 8.0 |
| Male | 260 (65.2%) |
| Hyperlipidaemia | 263 (65.9%) |
| Hypertension | 295 (73.9%) |
| Smoking history | 228 ( 57.1%) |
| *Data missing* | 13 (3.2%) |
| Diabetes | 88 (22.1%) |
| Urgency | |
| *Elective* | 287 (71.9%) |
| *Urgent* | 108 (27.1%) |
| *Emergency* | 4 (1.0%) |
| CCS grade | |
| *No angina* | 209 (52.4%) |
| *Angina with strenuous exertion* | 53 (13.3%) |
| *Angina with moderate exertion* | 90 (22.6%) |
| *Angina with mild exertion* | 44 (11.0%) |
| *Angina at rest* | 3 (0.7%) |
| NYHA grade | |
| *Data missing* | 3 (0.75%) |
| *No limitation of physical activity* | 49 (12.3%) |
| *Slight limitation of physical activity* | 180 (45.1%) |
| *Marked limitation of physical activity* | 148 (37.1%) |
| *Unable to carry out any physical activity without discomfort* | 19 (4.3%) |
| LVEF category | |
| *Good LV function >50%* | 281 (70.4%) |
| *Moderate LV function 31-50%* | 93 (23.3%) |
| *Poor LV function 21-30%* | 24 (6.0%) |
| *Very poor LV function <21%* | 1 (0.3%) |

| | |
|---|---|
| Previous cardiac surgery | |
| *None* | 377 (94.5%) |
| *CABG* | 7 (1.8%) |
| *Valve* | 8 (2.0%) |
| *CABG and valve* | 4 (1.0%) |
| *Congenital cardiac* | 1 (0.3%) |
| *Other* | 2 (0.4%) |
| Peripheral vascular disease | 50 (12.5%) |
| Gastrointestinal disease | 55 (13.8%) |
| Pulmonary hypertension | 26 (6.5%) |
| Renal disease | 7(1.8%) |
| History of pulmonary disease | 69 (17.3%) |
| History of neurological dysfunction | 12 (3.0%) |
| Extra-cardiac arteriopathy | 46 (11.5%) |

**Table 2:** This table illustrates the intraoperative variables.

| Intra-operative details | N ( % / SD) |
|---|---|
| Moderate/severe aortic stenosis | 371 (93.0%) |
| Moderate/severe aortic regurgitation | 65 (16.3%) |
| Isolated Valve replacement | 202 (50.6%) |
| CABG and valve replacement | 160 (40.1%) |
| CABG, valve replacement and other procedure | 16 (4.0%) |
| Valve replacement and other procedure | 21 (5.3%) |
| Concomitant Carotid surgery | 4 (1.0%) |
| Previous Aortic valve replacement | 10 (2.5%) |
| Minimally invasive aortic valve replacement | 56 (14.0%) |
| Cumulative bypass time (mins, mean ± SD) | 134.0 ± 49.0 |
| Cumulative cross clamp time (mins, mean ± SD) | 104.4 ± 38.1 |
| Logistic EuroSCORE | 10.0 ± 10.9 |
| Valve size | |
| *19* | 19 (4.8%) |
| *21* | 123 (30.8%) |
| *23* | 147 (36.8%) |
| *25* | 92 (23.1%) |
| *27* | 16 (4.0%) |
| *29* | 2 (0.5%) |
| Type of valve | |
| *Trifecta* | 120 |
| *Trifecta GT* | 279 |
| Occurrence | |
| *First procedure* | 389 (97.5%) |
| *First re-implant* | 10 (2.5%) |

**Table 3:** Postoperative outcomes

| Postoperative details | |
|---|---|
| *Reoperation for bleeding/tamponade* | 5 (1.3%) |
| *Permanent Stroke* | 3 (0.8%) |
| *Infective complications* | 11 (2.8%) |
| *Postoperative dialysis/haemofiltration* | 10 (2.5%) |

**Table 4:** This table illustrates the preoperative and post-surgery valve gradients.

| **Valve gradient variables (pre-operative)** | |
|---|---|
| AV area (cm2, mean ± SD) | 0.76 ± 0.30 |
| AV peak gradient (mmHg, mean ± SD) | 67.3 ± 26.2 |
| AV mean gradient (mmHg, mean ± SD) | 39.3 ± 17.0 |
| Stenosis | |
| *None* | 18 (4.5%) |
| *Mild* | 10 (2.5%) |
| *Moderate* | 53 (13.3%) |
| *Severe* | 318 (79.7%) |
| Regurgitation | |
| *None* | 140 (35.1%) |
| *Mild* | 194 (48.6%) |
| *Moderate* | 44 (11.0%) |
| *Severe* | 21 (5.3%) |
| **Valve gradient variables (post-operative – 1 year, n=235)** | |
| AV peak gradient (mmHg, mean ± SD) | 18.1 ± 7.1 |
| AV mean gradient (mmHg, mean ± SD) | 9.5 ± 4.1 |
| Transvalvular regurgitation | |
| *None* | 186 (78.3%) |
| *Minimal* | 49 (20.9%) |
| *Moderate* | 0 (0.0%) |
| *Severe* | 0 (0.0%) |
| Paravalvular leak | |
| *None* | 228 (97.0%) |
| *Minimal* | 6 (2.6%) |
| *Moderate* | 1 (0.4%) |
| *Severe* | 0 (0.0%) |
| Valve ratio (mean ± SD) | 0.5 ± 0.1 |
| **Valve gradient variables (post-operative – 3 year, n=54)** | |

| | |
|---|---|
| AV peak gradient (mmHg, mean ± SD) | 17.1 ± 8.5 |
| AV mean gradient (mmHg, mean ± SD) | 8.7 ± 4.6 |
| Transvalvular regurgitation | |
| *None* | 38 (70.4%) |
| *Mild* | 15 (27.8%) |
| *Moderate* | 1 (1.9%) |
| *Severe* | 0 (0.0%) |
| Paravalvular leak | |
| *None* | 35 (87.5%) |
| *Mild* | 5 (12.5%) |
| *Moderate* | 0 (0.0%) |
| *Severe* | 0 (0.0%) |
| Valve ratio (mean ± SD) | 0.5 ± 0.1 |

# Figures

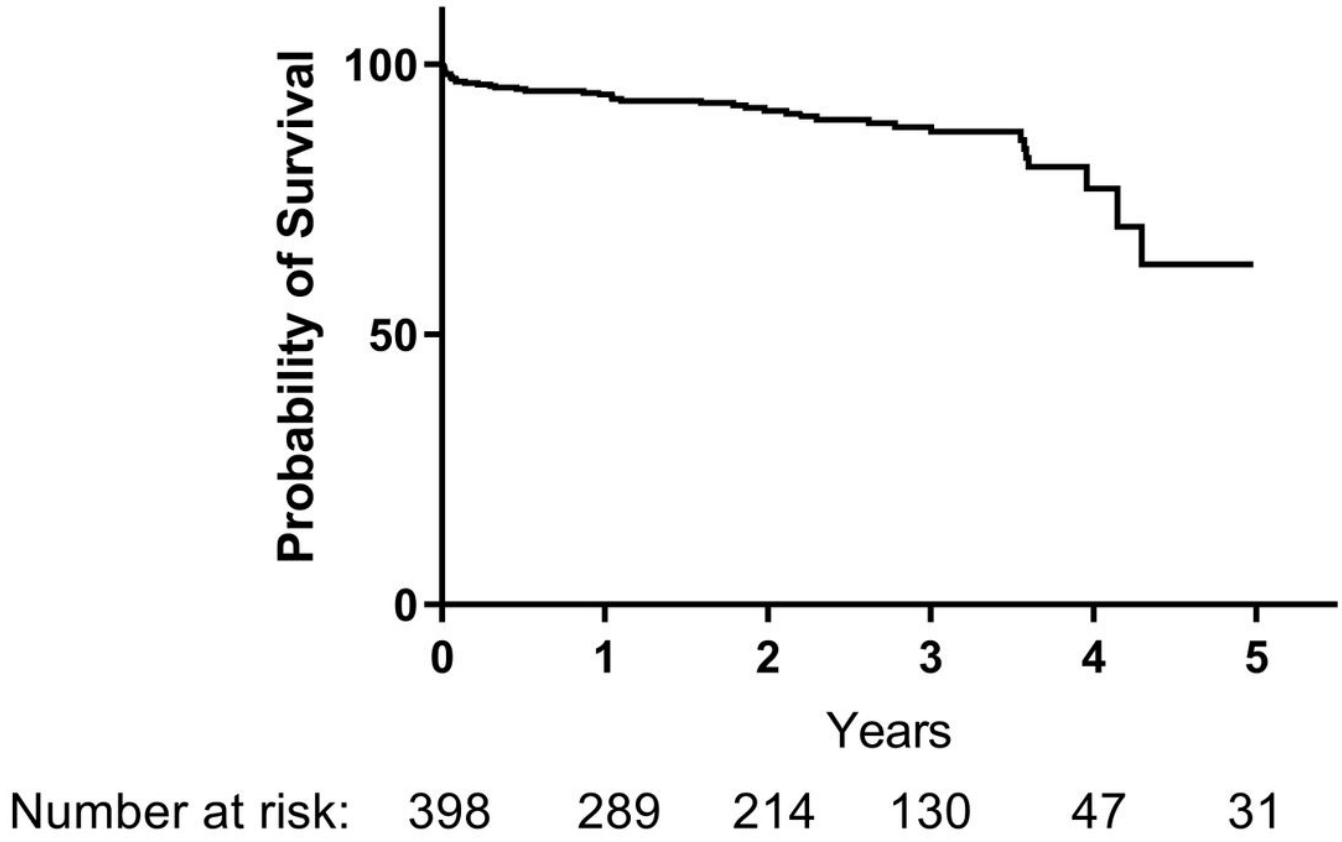
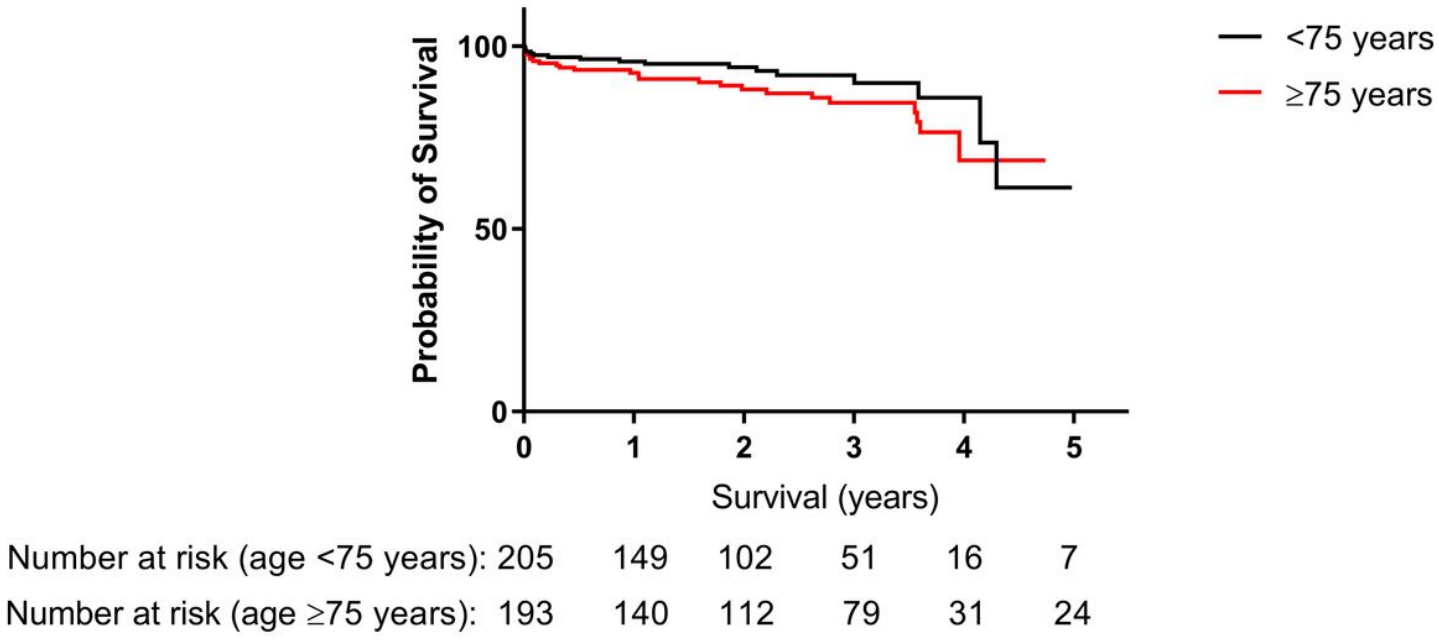


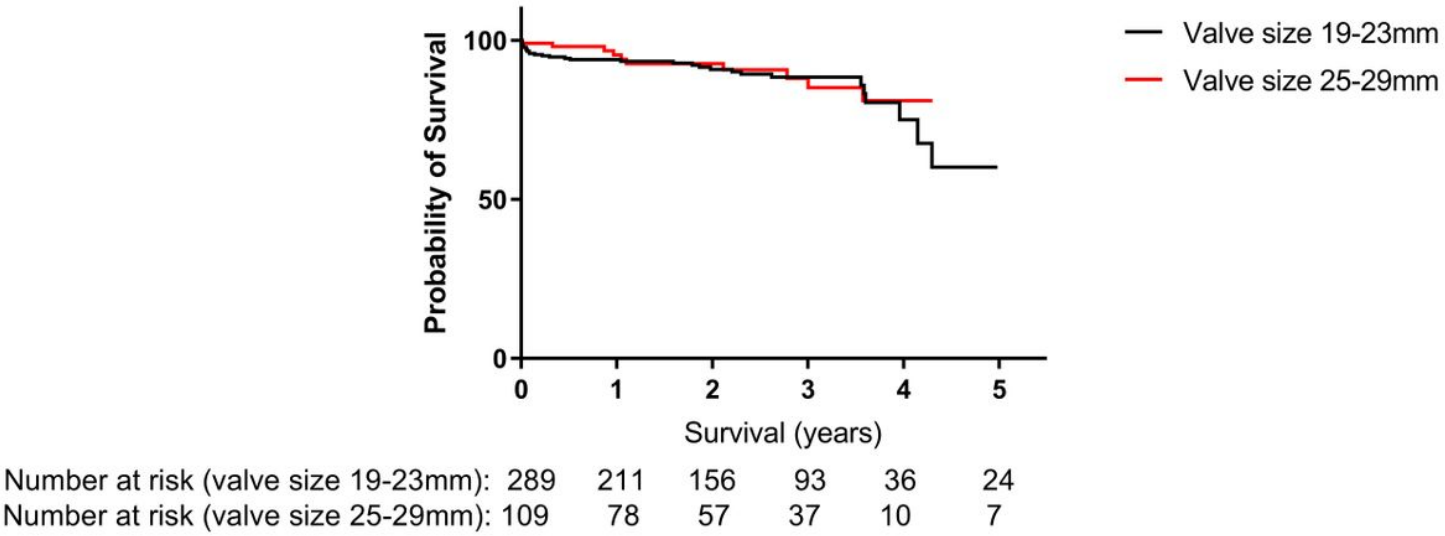

**Figure 1**

This figure illustrates the overall survival of the cohort to 3 years.



## Figure 2

This figure illustrates the peak and mean valve gradients at 1 and 3 years for all patients with 3-year follow-up data available (n=54).




## Figure 3

This figure illustrates the survival stratified by valve size.