Featured Article

Implanted size and structural valve deterioration in the Edwards Magna bioprosthesis

Douglas R. Johnston[1,2], Christopher Mehta[1,2], S. Christopher Malaisrie[1,2], Abigail S. Baldridge[3], Duc T. Pham[1,2], Benjamin Bryner[1], Melissa G. Medina[1], Stephen Chiu[1], Kevin E. Hodges[1], Patrick M. McCarthy[1]

[1]Division of Cardiac Surgery, Northwestern Medicine and Bluhm Cardiovascular Institute, Northwestern Memorial Hospital, Chicago, IL, USA; [2]Center for Aorta Care, Northwestern Medicine and Bluhm Cardiovascular Institute, Chicago, IL, USA; [3]Clinical Trials Unit, Northwestern University, Chicago, IL, USA

Correspondence to: Douglas R. Johnston, MD. Division of Cardiac Surgery, Northwestern Medicine and Bluhm Cardiovascular Institute, Northwestern Memorial Hospital, 676 N St Clair St, Suite 730, Chicago, IL 60611, USA; Center for Aorta Care, Northwestern Medicine and Bluhm Cardiovascular Institute, Chicago, IL, USA. Email: doug.johnston@nm.org.

Background: The desire of patients to avoid anticoagulation, together with the potential of valve-in-valve (VIV) transcatheter aortic valve replacement (TAVR), have resulted in the increasing use of bioprosthetic valves for aortic valve replacement (AVR). While patient-prosthesis mismatch (PPM) is known to be an adverse risk after AVR, few studies have addressed the effect of PPM on valve durability. This study evaluates the role of valve size and hemodynamics on long term durability after AVR with a Magna bioprosthesis.

Methods: We performed a retrospective, single-center evaluation of patients who underwent a surgical AVR procedure between June 2004 through December 2022 using the Magna bioprosthesis. Perioperative information and long-term follow-up data were sourced from the institution's Society for Thoracic Surgeons Adult Cardiac Surgery Registry and outcomes database. Cumulative incidence of freedom from reintervention were estimated accounting for competing events. Group comparisons used Gray's test.

Results: Among 2,100 patients, the mean patient age was 69 years (range, 22–95 years), of whom 98% had native aortic valve disease, 32.5% had concomitant coronary bypass grafting, and 19% had mitral valve surgery. Median follow-up was 5.8 (1.9–9.4) years, during which 116 reinterventions were performed, including 74 explants and 42 VIV procedures. Nine hundred and twenty-eight patients died prior to reintervention. Incidence of all cause reintervention was 1.2%, 4.5%, and 11.7% at 5, 10, and 15 years, respectively. Smaller valve size was associated with worse survival (P<0.001), but not with reintervention. Higher mean gradient at implant was associated with increased late reintervention [sub-distribution hazard ratio: 1.016; 95% confidence interval (CI): 1.005 to 1.028; P=0.0047, n=1,661].

Conclusions: While reintervention rates are low for the Magna prosthesis at 15 years, the analysis is confounded by the competing risk of death. PPM, as reflected physiologically by elevated post-operative valve gradients, portends an increased risk of intervention. Further study is necessary to elucidate the mechanism of early stenosis in patients who progress to reintervention.

Keywords: Surgical aortic valve replacement (SAVR); transcatheter aortic valve replacement (TAVR); patient-prosthesis mismatch (PPM); valve durability

Submitted Apr 04, 2024. Accepted for publication May 05, 2024. Published online May 22, 2024.
doi: 10.21037/acs-2024-aae-26
View this article at: https://dx.doi.org/10.21037/acs-2024-aae-26

Introduction

The desire of patients to avoid anticoagulation, along with the growth and increasing sophistication of transcatheter aortic valve replacement (TAVR), have resulted in the increased utilization of bioprosthetic aortic valves in progressively younger patients. Planning for lifetime management of the aortic valve requires an understanding of (I) the durability of an implanted prosthesis and (II) the procedures performed to treat structural valve deterioration (SVD) when it occurs. Multiple studies have demonstrated excellent long-term durability of different bioprostheses in the aortic position (1-3), however, less is known about the results of reintervention whether with redo-surgical aortic valve replacement (SAVR) or valve-in-valve (VIV) in this population (4). Of particular interest in this thought process are patients with smaller aortic roots. The effect of patient-prosthesis mismatch (PPM) on long term survival and left ventricular (LV) remodeling is well known (5,6). Recently, some surgeons have advocated for aggressive root enlargement procedures in all patients in order to maximize implanted valve size, with the goal of facilitating future VIV therapy (7). The primary mode of failure of bovine pericardial valves is calcific SVD, manifested by progressive stenosis and increasing valve gradients, much like in the case of native valve aortic stenosis (8). In a large study of the Carpentier Edwards Perimount prosthesis, valve gradient after implantation, rather than valve size, correlated with an increased risk of SVD and a more rapid increase in gradient over time (9). It might be expected that newer, more hemodynamically efficient valve designs, are less susceptible to accelerated SVD related to PPM, however, differences in leaflet orientation and anti-calcification treatment make generalization between valve models complex (10). The purpose of this study was to identify potential correlates of valve size and gradient at implantation as surrogates of PPM on patient outcomes and long-term valve durability following aortic valve replacement (AVR) with a Magna bioprosthesis.

Methods

Patients, interventions, and study design

We conducted a retrospective single-center study of patients within a large university based cardiac surgery program between June 2004 through December 2022. We included patients for whom the surgical procedure included an AVR with Magna bioprosthesis model 3000 or 3000TFX at Northwestern Memorial Hospital. Reoperations wherein the index valve was explanted, and a replacement was implanted were excluded, and considered as outcomes. Procedures included all consecutive surgical AVRs including concomitant procedures using the standard technique of aortic clamping, arrested heart with cardioplegia, valve excision, and prosthesis implant. Operative approach (full sternotomy, upper hemisternotomy J-incision, or right mini-thoracotomy) was at the discretion of the surgeon. Prosthesis choice was also at the discretion of the implanting surgeon. During the time period of the study, Edwards Magna valves represented the majority of aortic valve implants.

Data collection

Perioperative information for all patients were retrieved from the prospective Northwestern Memorial Hospital Society for Thoracic Surgeons (STS) Adult Cardiac Surgery Registry. Clinical information collected on patients from the STS registry included demographics, medical history, operative and implant details. STS database definitions were used for all perioperative variables. This study was approved by the Institutional Review Board at Northwestern University (STU00012288, approved through January 25, 2025).

Long term follow-up data were obtained from the institutional Cardiovascular Research Database (CARD), maintained in REDCap (11,12). Clinical follow-up, including obtainment of outside records, was conducted annually. Vital status for patients lost to follow-up were supplemented through query of the National Death Index in July 2022. Long-term outcomes included the first instance of any censoring event [aortic valve explant, aortic VIV surgery, ventricular assist device (VAD) implantation, heart transplant, or death]. Postoperative transthoracic echocardiographic reports were obtained from CARD, including outside reports, and from the Northwestern Medicine Electronic Data Warehouse (EDW).

Echocardiographic reports were used to assess intermediate and long-term changes in echocardiographic variables, specifically aortic regurgitation, aortic valve mean and peak gradients. Aortic regurgitation severity was categorized as none/trivial, mild, moderate, and severe. Intermediate grading ("mild-to-moderate") was classified as the higher grade ("moderate"). Echocardiograms were obtained routinely before discharge and periodically thereafter at the discretion of referring physicians. All

available follow-up data through December 2023 were utilized.

Statistical analysis

Data were summarized as means with standard deviation, medians with interquartile range (IQR), or as counts with percentages. Continuous variables were compared using the analysis of variance (ANOVA) test if normally distributed, or the Kruskal-Wallis test if skewed, and categorical variables were compared using Pearson's chi-squared test. Cumulative incidence of freedom from reintervention (combined aortic valve explant or aortic VIV surgery) were estimated accounting for competing events of VAD implantation, heart transplant, and death. Durability and mortality outcomes were compared by valve implant size, and group comparisons used Gray's test. Aortic valve mean and peak gradients during follow up were visualized by outcome (death, reintervention, or none) using the average gradient within each respective group at a given year post-surgery. Statistical significance for all analyses was declared at two-sided 5% alpha level, with no adjustments for multiplicity. All statistical analyses were performed using SAS v 9.4 (SAS Institute, Inc.).

Results

Demographic data

From June 2004 to December 2022, 2,100 patients underwent AVR using Magna bioprosthesis models 3000 or 3000TFX at Northwestern Memorial Hospital. Mean age of the cohort was 69 years (range, 22–95 years) and 38% were female (*Table 1*). In 2,062 patients (98%), the native aortic valve was replaced, and this was predominantly for aortic stenosis (n=1,683; 82%). Prosthesis label size was 19 or 21 mm in 565 (27%). In 1,117 patients (53%), AVR with this prosthesis was an isolated procedure; in 983 (47%), it was combined with concomitant procedures, such as coronary artery bypass grafting (32.5%), and mitral valve surgery (18.7%). Surgical approach was a less invasive partial sternotomy or thoracotomy in 22%.

Median clinical follow-up was 5.8 (1.9–9.4) years, and 12,707 patient-years of follow-up data were available for analysis. A total of 8,029 echocardiographic records were available for 1,647 patients. Median (IQR) echocardiographic follow-up time was 5.9 (2.7–9.5) years, with 22% of patients followed up for 10 or more years and 3% more than 15 years.

Overall risk of prosthesis reintervention

A total of 116 prostheses were reintervened during follow-up, including 74 explants and 42 VIV procedures. A total of 928 patients died before valve explant. Risk of death before reintervention dominated risks of reintervention. Overall cumulative incidence (in the presence of death, VAD, and heart transplant) of reintervention for any cause were 1.2% at 5-year, 4.5% at 10-year, and 11.7% at 15-year (*Figure 1*).

Table 1 Characteristics of 2,100 patients undergoing AVR with an Edwards Magna valve

Characteristics	Overall (n=2,100)	Outcome[†]				P value[‡]
		None (n=1,050)	Valve explant (n=74)	Valve in valve (n=42)	Death (n=928)	
Age (years), mean ± SD (n=2,100)	69±13	66±12	53±14	59±13	74±10	<0.001
Female, n (%) (n=2,100)	790 (37.6)	376 (35.8)	32 (43.2)	16 (38.1)	365 (39.3)	0.31
LV ejection fraction (%), mean ± SD (n=2,074)	56.8±12.5	58.8±10.7	58.0±11.8	59.1±9.1	54.5±13.8	<0.001
NYHA class, n (%) (n=1,044)						<0.001
I	57 (5.5)	22 (5.8)	5 (12.5)	3 (11.5)	26 (4.4)	
II	376 (36.0)	141 (37.4)	23 (57.5)	15 (57.7)	197 (33.1)	
III	458 (43.9)	154 (40.8)	7 (17.5)	7 (26.9)	288 (48.3)	
IV	126 (12.1)	39 (10.3)	5 (12.5)	1 (3.8)	79 (13.3)	
Not documented	27 (2.6)	21 (5.6)	0 (0)	0 (0)	6 (1.0)	

Table 1 (*continued*)

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Characteristics	Overall (n=2,100)	Outcome†				P value‡
		None (n=1,050)	Valve explant (n=74)	Valve in valve (n=42)	Death (n=928)	
STS PROM, median (IQR) (n=1,258)	2.2 (1.3–4.0)	1.5 (0.9–2.7)	1.3 (0.9–1.9)	1.6 (1.3–2.3)	3.9 (2.3–6.2)	<0.001
Medical history, n (%)						
Paroxysmal or persistent atrial fibrillation (n=2,100)	504 (24.0)	183 (17.4)	12 (16.2)	3 (7.1)	304 (32.8)	<0.001
Endocarditis (n=2,100)	124 (5.9)	62 (5.9)	11 (14.9)	2 (4.8)	49 (5.3)	0.010
Dialysis (n=2,100)	46 (2.2)	7 (0.7)	4 (5.4)	1 (2.4)	34 (3.7)	<0.001
Procedure, n (%)						
Implant size, n (%) (n=2,091)						<0.001
19 mm	119 (5.7)	32 (3.1)	4 (5.4)	3 (7.1)	78 (8.4)	
21 mm	446 (21.3)	177 (17.0)	17 (23.0)	10 (23.8)	242 (26.1)	
23 mm	638 (30.5)	307 (29.4)	21 (28.4)	10 (23.8)	300 (32.4)	
25 mm	550 (26.3)	299 (28.7)	19 (25.7)	13 (31.0)	218 (23.5)	
27 mm	246 (11.8)	159 (15.2)	10 (13.5)	4 (9.5)	73 (7.9)	
29 mm	92 (4.4)	69 (6.6)	3 (4.1)	2 (4.8)	15 (1.6)	
Status, n (%) (n=2,100)						0.001
Elective	1,788 (85.1)	924 (88.0)	67 (90.5)	38 (90.5)	755 (81.4)	
Emergent	21 (1.0)	13 (1.2)	0 (0)	1 (2.4)	7 (0.8)	
Emergent salvage	1 (0)	1 (0.1)	0 (0)	0 (0)	0 (0)	
Urgent	290 (13.8)	112 (10.7)	7 (9.5)	3 (7.1)	166 (17.9)	
Incidence, n (%) (n=2,098)						<0.001
First CV surgery	1,731 (82.5)	914 (87.0)	65 (87.8)	37 (88.1)	710 (76.6)	
First reop CV surgery	325 (15.5)	119 (11.3)	9 (12.2)	4 (9.5)	193 (20.8)	
Second reop CV surgery	38 (1.8)	15 (1.4)	0 (0)	1 (2.4)	22 (2.4)	
Third reop CV surgery	3 (0.1)	1 (0.1)	0 (0)	0 (0)	2 (0.2)	
Fourth or more reop CV surgery	1 (0)	1 (0.1)	0 (0)	0 (0)	0 (0)	
Mitral valve surgery, n (%) (n=2,100)	392 (18.7)	156 (14.9)	7 (9.5)	7 (16.7)	219 (23.6)	<0.001
Tricuspid valve surgery, n (%) (n=2,100)	155 (7.4)	41 (3.9)	2 (2.7)	1 (2.4)	109 (11.7)	<0.001
Coronary artery bypass grafting, n (%) (n=2,100)	683 (32.5)	268 (25.5)	11 (14.9)	7 (16.7)	397 (42.8)	<0.001
Atrial fibrillation procedure, n (%) (n=2,100)	388 (18.5)	154 (14.7)	10 (13.5)	4 (9.5)	219 (23.6)	<0.001

†, N=4 patients had a VAD and N=2 patients had a heart transplant and were censored from further analysis at the time of procedure. These six patients were not included in group comparisons due to small group sample sizes; ‡, continuous variables were compared using the ANOVA test if normally distributed or the Kruskal-Wallis test if skewed, and categorical variables were compared using Pearson's chi-squared test. AVR, aortic valve replacement; SD, standard deviation; LV, left ventricular; NYHA, New York Heart Association; STS PROM, Society of Thoracic Surgeons predicted risk of mortality; IQR, interquartile range; CV, cardiovascular; reop, reoperation; VAD, ventricular assist device; ANOVA, analysis of variance.

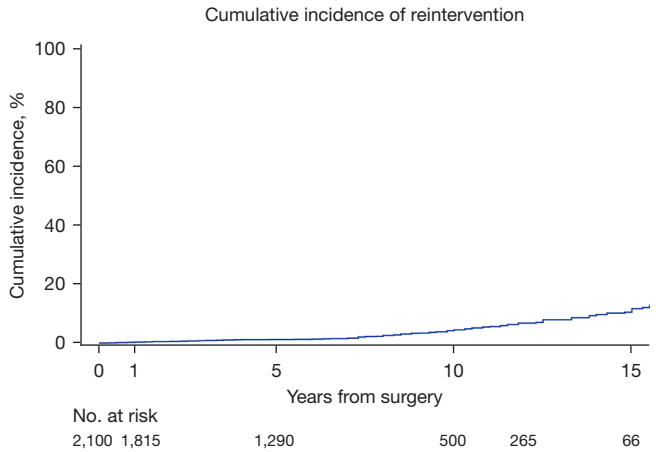

Figure 1 Cumulative incidence of aortic valve reintervention. Among 2,100 patients with a bioprosthetic Magna aortic valve implant, a total of 116 prostheses were reintervened during follow-up, including 74 explants and 42 valve-in-valve procedures. The overall cumulative incidence of reintervention for any cause, accounting for competing events of death, VAD, and HT, were 1.2% at 5-year, 4.5% at 10-year, and 11.7% at 15-year. VAD, ventricular assist device; HT, heart transplant.

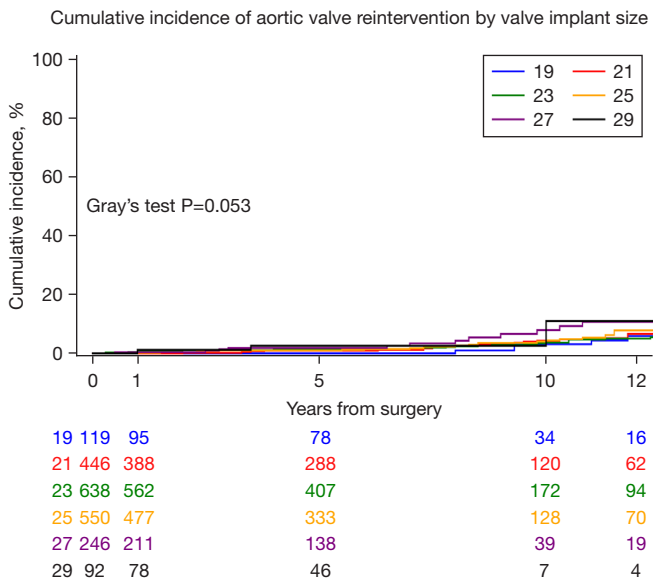

Figure 2 Cumulative incidence of aortic valve reintervention by index valve implant size. The overall cumulative incidence of reintervention for any cause, accounting for competing events of death, VAD, and HT, was not associated with the labeled valve size of the index Magna aortic valve implant. VAD, ventricular assist device; HT, heart transplant.

PPM and reintervention

Labeled valve size was not associated with long-term cumulative incidence of reintervention (P=0.053; *Figure 2*). In a Cox proportional hazards model accounting for competing risks of death, VAD, and heart transplant, valve implant size was not associated with risk of reintervention (P=0.32). Pre-operative mean aortic valve gradient was associated with risk of reintervention [sub-distribution hazard ratio: 1.016; 95% confidence interval (CI): 1.005 to 1.028; P=0.0047, n=1,661] but peak aortic valve gradient was not (P=0.76; n=1,461).

Temporal trend of echocardiographic findings

Patients who underwent reintervention developed earlier increases in peak and mean gradient than those who did not. Reintervention patients exhibited a trend of gradually increasing gradients beginning as soon as one year after implantation, whereas those who did not had relatively stable peak and mean gradients as long as 15 years after implantation. Patients who died before intervention exhibited similar trends (*Figure 3A*,*3B*).

Discussion

Principal findings

Overall risk of reintervention was low over the course of 15 years of follow-up, while the competing risk of death far exceeded risk of reintervention. Implanted valve size was not an independent risk factor for reintervention; however, smaller implanted valve size did correlate with late risk of death. Mean gradient at implantation did correlate with risk of reintervention. The trajectory of echocardiographic gradients differed for patients with no reintervention *vs.* those with reintervention, in that patients in the reintervention group had not only higher initial gradients but a steeper rate of gradient increase. Valve gradients were remarkably stable in the non-reintervention group.

Implanted valve size and survival

We observed a correlation between implanted valve size and long-term survival, with patients with 19 mm implants having the worst survival, and 29 mm implants having the best. While implanted size is a surrogate for PPM, it is also reflective of other potential risk factors in this

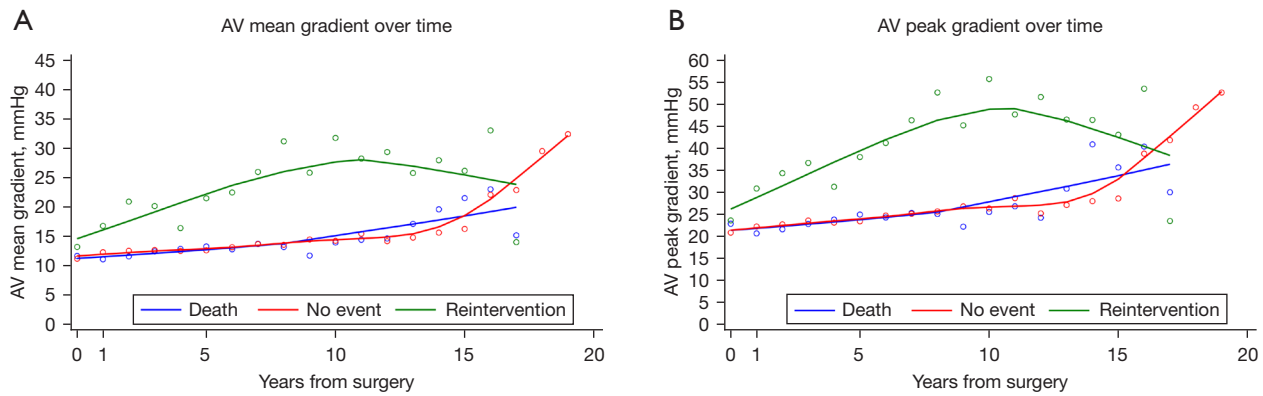

Figure 3 AV mean (A) and peak (B) gradients over time. Among patients with an index Magna AV implant, all available echo follow-up after surgery is shown with loess curves grouped by the occurrence of post-operative events. AV, aortic valve.

heterogeneous real world patient population; 23 mm was the most commonly implanted size, as has been the case in most series of Magna valve outcomes (13).

Pibarot *et al.* (14) and others (5) have demonstrated that the impact of PPM on survival is more pronounced in younger populations. Mihaljevic *et al.* demonstrated that PPM also impacts survival in patients with more severe left ventricular hypertrophy (LVH) and those with lower ejection fractions. In a cohort of patients implanted with the Perimount prosthesis with a mean age of 71 years, Johnston *et al.* demonstrated a 76% probability of death before explant (9). The current study in a similar age group reflects the same phenomenon, in that only a subset of patients with bioprosthetic aortic valves survive to the point where reintervention may be considered. Implantation of smaller aortic valves may reflect a variety of anatomic considerations, including small body size, challenging root anatomy, and the presence of other prostheses. It is beyond the scope of this analysis to evaluate whether root enlargement would have mitigated some of the effects of small prosthesis size on mortality.

PPM and valve reintervention

In a recent study of SAVR outcomes in the STS database, Fallon *et al.* found that severe PPM was associated with a 1.41 fold higher reintervention rate (15). While other studies have found a similar effect, variability in the definition of PPM [whether based on predicted effective orifice area indexed (EOAi) or echocardiographic measurements] have made generalizability of these findings difficult. In their evaluation of 12,569 Perimount valve implants, Johnston *et al.* found that gradient after implantation, rather than implanted valve size, predicted the risk of late explantation in the pre-valve in valve era (9). In this analysis of the Magna valve, we note a similar finding. Valve size alone did not predict late reintervention, however, a higher gradient at implantation did. Our understanding of the mechanism of SVD early after valve surgery is limited. While most bovine pericardial valves fail through slowly progressive leaflet calcification and stenosis, those factors other than age and renal insufficiency which lead to earlier failure are not well elucidated (8). That higher implant gradients presage a higher risk of late failure may implicate turbulence, mechanical wear, pannus, or thrombus as mechanisms. 4D computed tomography (CT) will likely augment our ability to measure the earlier phases of calcific SVD, as well as identify reduced leaflet motion in the absence of calcium which may be related to pannus, thrombus, or immune-mediated leaflet thickening. However, this data is not yet available at a large scale, or in a longitudinal fashion to allow for understanding of the individual progression of SVD (16).

At present, echocardiographic gradients present the best available physiologic data with which to evaluate progression of SVD. It is important to note that progression of valve gradients over time is not linear, such that a higher post-implant gradient necessarily predicts an earlier reintervention, rather higher post-implant gradients are a risk factor for earlier reintervention which may reflect increased turbulence, mechanical wear, pannus, etc.

Progression in mean gradient after implantation

Similar to what was observed with the predicate Perimount valve, patients undergoing early reintervention

on the Magna valve display a very different pattern of echocardiographic gradients over time. Those patients going on to early explant or VIV display not only higher post-implant gradients, but a steeper rate of increase prior to reintervention. In comparison, most valves exhibit remarkably stable gradients out to 10 or more years post implant, with a late increasing phase.

This finding has implication for prosthesis selection as well as decisions regarding adjunctive procedures such as root enlargement. It will be important to understand the mechanism for early increase in gradients in patients with reintervention, and 4D CT may be a useful adjunct to echocardiography in this group. Early leaflet calcification may implicate immune or metabolic phenomena which are unique in this population in comparison to those with stable gradients. Alternatively, non-calcific SVD related to thrombus or pannus formation may be related to implant technique, root size, and flow dynamics. Trusty and colleagues found that flow stasis was directly related to thrombus formation in TAVR valves (17). Such data do not yet exist to evaluate differences in flow dynamics for SAVR valves, in particular, in the setting of aggressive root enlargement where the implanted valve is "off of center" to the aortic outflow tract.

In this study, we were not able to identify novel risk factors which might help stratify patients into a "likely early failure" group, however, rising gradients in the first 5 years after implant should suggest early intervention is likely. An aggressive focus on the population with elevated gradients after implantation and/or early rising gradients may allow us to differentiate those who would benefit from different implants or operative strategy. Further study will be necessary to codify the difference in SVD progression in these groups.

Limitations

This is a relatively large, single-institution report with most procedures performed by a small number of surgeons. Intraoperative conduct and technical details such as valve choice and repair technique play a role in clinical decision-making and may affect outcomes. While the pattern of reintervention and survival was consistent across implant sizes, nearly 90% of the AVRs were performed with an implant between 21 to 27 mm. Our inferences are limited by effective sample size for major morbidity and mortality, which is proportional to number of events observed, not number of patients followed. These results may not be generalizable across institutions or geographic area, although they represent a valve practice with a national referral base.

Conclusions

The implanted valve size of the Magna bioprosthesis correlated with long-term survival, with larger implanted size having the best survival. Smaller size at implantation did not predict late valve reintervention, however, mean transvalvular gradients post-implant did, with a higher gradient at implant correlating with more valve reinterventions. Valve gradients in most patients were remarkably stable over time, in many cases for longer than 10 years before an increase was observable. In contrast, patients undergoing reintervention had an early and more rapid rise in mean gradient, suggesting an accelerated course of SVD. While implanting larger valves may result in improved durability in some cases, further work is necessary to understand which patients benefit from aggressive enlargement techniques, and whether these techniques impact SVD over time.

Acknowledgments

The authors thank Jane Kruse, BSN for her contributions to the manuscript.
Funding: None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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Cite this article as: Johnston DR, Mehta C, Malaisrie SC, Baldridge AS, Pham DT, Bryner B, Medina MG, Chiu S, Hodges KE, McCarthy PM. Implanted size and structural valve deterioration in the Edwards Magna bioprosthesis. Ann Cardiothorac Surg 2024;13(3):275-282. doi: 10.21037/acs-2024-aae-26

