Hemodynamic Comparison between the Avalus and the Perimount Magna Ease Aortic Bioprosthesis up to 5 Years

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Abstract

Background We aimed to compare hemodynamic performance of the Avalus (Medtronic) and the Perimount Magna Ease (PME, Edwards Lifesciences) bioprosthesis up to 5 years by serial echocardiographic examinations.

Methods In patients undergoing aortic valve replacement, 58 received PME prostheses between October 2007 and October 2008, and another 60 received Avalus prostheses between October 2014 and November 2015. To ensure similar baseline characteristics, we performed a propensity score matching based on left ventricular ejection fraction, age, body surface area, and aortic annulus diameter measured by intraoperative transesophageal echocardiography. Thereafter, 48 patients remained in each group. Mean age at operation was 67 ± 6 years and mean EuroSCORE-II was 1.7 ± 1.1. Both values did not differ significantly between the two groups.

Results At 1 year the mean pressure gradient (MPG) was 15.4 ± 4.3 mm Hg in the PME group and 14.7 ± 5.1 mm Hg in the Avalus group ($p = 0.32$). The effective orifice area (EOA) was $1.65 \pm 0.45\,cm^2$ in the PME group and $1.62 \pm 0.45\,cm^2$ in the Avalus group ($p = 0.79$). At 5 years the MPG was 16.6 ± 5.1 mm Hg in the PME group and 14.7 ± 7.1 mm Hg in the Avalus group ($p = 0.20$). The EOA was $1.60 \pm 0.49\,cm^2$ in the PME group and $1.51 \pm 0.40\,cm^2$ in the Avalus group ($p = 0.38$). Five-year survival was 88% in the PME group and 91% in the Avalus group ($p = 0.5$). In the PME group, there were no reoperations on the aortic valve, whereas in the Avalus group three patients required a reoperation due to endocarditis.

Conclusion Both bioprostheses exhibit similar hemodynamic performance during a 5-year follow-up.

Keywords
- aortic valve
- heart valve
- echocardiography

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Introduction

The enhanced long-term durability of biologic heart valves and new transcatheter techniques for the treatment of degenerated bioprostheses have contributed to a steady increase in the use of biological heart valves during the past 20 years.[1–3] Ideally, biologic heart valves should display good hemodynamic performance, long-term durability, and ease of implantation.[4]

The Avalus (Medtronic, Minneapolis, Minnesota, United States) and the Perimount Magna Ease (PME, Edwards Lifesciences, Irvine, California, United States) are both bovine pericardial bioprostheses. The Avalus bioprosthesis was introduced in 2014[5] and the PME bioprosthesis in 2006. Both prostheses are supra annular, stented, low-profile valves with a flexible cuff and internally mounted leaflets. Good long-term results up to 10 years have already been reported for the PME.[6] In contrast, only mid-term results have been reported for the Avalus valve yet.[7] The aim of this study was to compare hemodynamic performance of these two bioprostheses during 5 years follow-up, based on annually obtained transthoracic echocardiographic studies.

Methods

In this retrospective single center study, we compared a cohort of 58 patients in whom an aortic valve replacement was performed using a PME (implantation date: 10/2007–10/2008) with a cohort of 60 patients, who received an Avalus prosthesis (implantation date: 10/2014–11/2015). Both cohorts accomplished a complete annual echocardiographic follow-up over 5 years. None of the patients had undergone previous cardiac surgery, and none of them had been referred for endocarditis.

To adjust for cofounders and to achieve uniformity in baseline characteristics, we performed a 1:1 propensity-score matching on ejection fraction, age, body surface area, and baseline aortic annulus diameter. The propensity-score matching resulted in two equally sized groups of 48 patients each. Baseline demographic and clinical characteristics after propensity score matching are shown in ►**Table 1**. The Institutional Review Board of the Technical University approved the study (approval reference number: 518/21 S-NP). Due to the retrospective study design, the necessity for individual patient consent was waived.

Echocardiographic Assessment

Annulus diameters were measured by intraoperative transesophageal echocardiography (TEE). Echocardiographic indices of valvular function were assessed by transthoracic echocardiography done preoperatively, at discharge, and once annually during the 5 years of follow-up. LV ejection fraction was evaluated in biplane images, using the Simpson method. Mean pressure gradient (MPG) as well as trans- or paraprosthetic regurgitation was determined by Doppler echocardiography. Effective orifice area (EOA) was determined using the continuity equation. Patient-prosthesis mismatch (PPM) was calculated using the indexed EOA at discharge (iEOA) (12). PPM was graduated as moderate (iEOA $= 0.85–0.65\ cm^2/m^2$) or severe (iEOA $< 0.65\ cm^2/m^2$) for non-obese patients and moderate (iEOA $= 0.70–0.55\ cm^2/m^2$) or severe (iEOA $< 0.55\ cm^2/m^2$) for obese (body mass index >30) patients.[8]

Implantation Technique

Valve sizes were determined using the valve sizer provided by the manufacturer. We used pledged, interrupted, non-everting mattress sutures for supra-annular implantation.

Anticoagulation Management

All patients received phenprocoumon as anticoagulant for the first three postoperative months. Unless otherwise indicated, this regimen was then terminated.

Statistics

Descriptive statistics were expressed as frequencies and percentages for categorical variables. Continuous variables were reported as mean ± standard deviation or as numbers and percentage as appropriate. Propensity score matching of ejection fraction, age, body surface area, and aortic annulus diameter measured by intraoperative transesophageal echocardiography was conducted with nearest neighbor matching using a caliper of 0.2. For group comparisons, Student's *t*-test, Mann-Whitney U-test, or Fisher's exact test were engaged as applicable. Kaplan-Meier analysis was applied to calculate estimated survival. Statistical significance was set

Table 1 Baseline characteristics before and after matching

	Entire cohort			Matched cohort		
	Avalus	Perimount Magna Ease	*p*-Value	Avalus	Perimount Magna Ease	*p*-Value
n	60	58		48	48	
Age (years)	70 ± 6	63 ± 9	<0.001	68 ± 6	66 ± 7	0.105
Body surface area (m^2)	2.04 ± 0.21	1.96 ± 0.22	0.050	2.04 ± 0.22	2.00 ± 0.20	0.351
Aortic annulus diam. (mm)	23.3 ± 2.4	23.8 ± 2.0	0.249	23.6 ± 2.3	23.7 ± 2.0	0.868
LV-ejection fraction (%)	58 ± 9	63 ± 10	0.012	61 ± 5	61 ± 9	0.946
Male gender *n* (%)	45 (75%)	42 (72%)	0.835	36 (75%)	38 (79%)	0.809

Table 2 Patient characteristics

	All	Avalus	Perimount Magna Ease	*p*-Value
N	96	48	48	
Age (years)	67 ± 6	68 ± 6	66 ± 7	0.105
Male gender *n* (%)	74 (77%)	36 (75%)	38 (79%)	0.809
Body surface area (m^2)	2.02 ± 0.21	2.04 ± 0.22	2.00 ± 0.20	0.351
Hypertension *n* (%)	74 (77.1%)	40 (83.3%)	34 (70.8%)	0.224
Dyslipidemia *n* (%)	63 (65.6%)	27 (56.2%)	36 (75.0%)	0.085
Diabetes *n* (%)	16 (16.7%)	8 (16.7%)	8 (16.7%)	1.000
Coronary artery disease *n* (%)	50 (52.1%)	21 (43.8%)	29 (60.4%)	0.215
Previous stroke *n* (%)	3 (3.1%)	3 (6.2%)	0 (0.0%)	0.242
Creatinin (mg/dL)	0.97 ± 0.19	1.00 ± 0.18	0.94 ± 0.20	0.134
Atrial fibrillation *n* (%)	6 (6.2%)	4 (8.3%)	2 (4.2%)	0.677
EuroSCORE II (%)	1.65 ± 1.08	1.58 ± 1.08	1.72 ± 1.09	0.530
Aortic annulus diameter (mm)	23.7 ± 2.1	23.6 ± 2.3	23.7 ± 2.0	0.868
LV ejection fraction (%)	61 ± 8	61 ± 5	61 ± 9	0.946
Mean pressure gradient (mm Hg)	50.5 ± 16.0	47.2 ± 12.9	58.8 ± 20.0	0.028
Effective orifice area (cm^2)	0.8 ± 0.4	0.8 ± 0.5	0.8 ± 0.2	0.594
Aortic regurgitation > mild *n* (%)	2 (2.1%)	2 (4.2%)	0 (0.0%)	0.495

at $p < 0.05$. All computations were done using R (v3.5.2; R Foundation for Statistical Computing, Vienna, Austria).

Results

Preoperative characteristics of the 96 matched patients are shown in ►**Table 2**. Mean age was 67 ± 6 years with male patients accounting for 77%. Mean EuroSCORE II was 1.7 ± 1.1. Perioperative data are summarized in ►**Table 3**. Concomitant procedures included coronary artery bypass grafting (35%), supracoronary ascending aorta replacement (5.2%), and aortic root replacement (3%).

There was one in-hospital death (2%) in each group. In the PME group, five patients (10%) died during follow-up, two of

Table 3 Procedural details

	All	Avalus	Perimount Magna Ease	*p*-Value
N	96	48	48	
Partial sternotomy *n* (%)	50 (52.1%)	21 (43.8%)	29 (60.4%)	0.152
Cardioplumonary bypass time (min)	97.8 ± 26.0	101.4 ± 30.3	94.2 ± 20.7	0.179
Aortic cross-clamp time (min)	70.7 ± 21.9	73.8 ± 26.1	67.6 ± 16.6	0.170
Valve size				
– 19 *n* (%)	2 (2.1%)	0 (0.0%)	2 (4.2%)	0.495
– 21 *n* (%)	15 (15.6%)	9 (18.8%)	6 (12.5%)	0.575
– 23 *n* (%)	32 (33.3%)	19 (39.6%)	13 (27.1%)	0.279
– 25 *n* (%)	37 (38.5%)	14 (29.2%)	23 (47.9%)	0.093
– 27 *n* (%)	10 (10.4%)	6 (12.5%)	4 (8.3%)	0.740
Isolated aortic valve replacement *n* (%)	55 (57.3%)	25 (52.1%)	30 (62.5%)	0.409
CABG *n* (%)	34 (35.4%)	16 (33.3%)	18 (37.5%)	0.831
Supracoronary aortic replacement *n* (%)	5 (5.2%)	4 (8.3%)	1 (2.1%)	0.362
Aortic root replacement *n* (%)	3 (3.1%)	3 (6.2%)	0 (0.0%)	0.242

Abbreviation: CABG, coronary artery bypass graft.

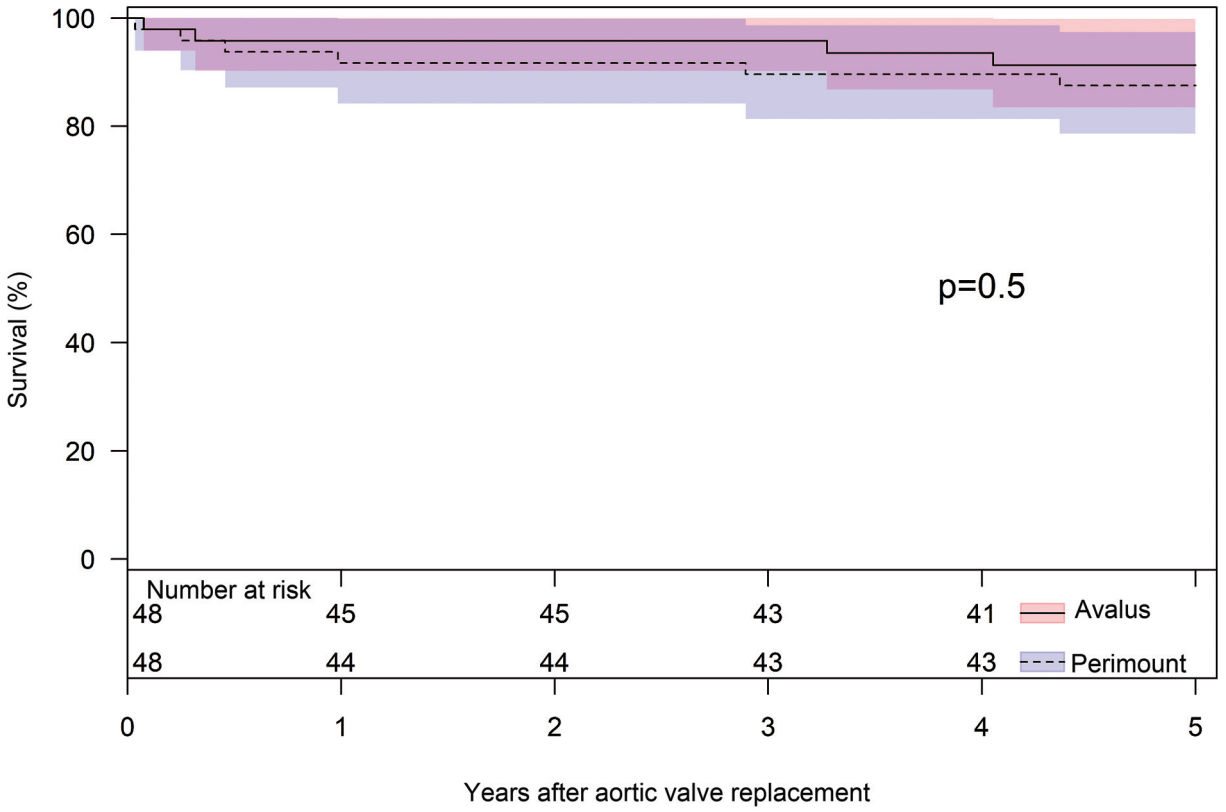

Fig. 1 Survival.

them from cardiac causes. In the Avalus group, three patients (6%) died during the follow-up, one of them from cardiac causes. Three patients with an Avalus valve underwent reoperation for endocarditis; there were no reoperations on the prosthetic valve due to other reasons within the first 5 years. One patient of the Avalus group had a severely increased mean transprosthetic gradient of 43 mm Hg at the 5-year follow-up. ►**Fig. 1** depicts the Kaplan Meier Curves of both groups.

Postoperative echocardiography revealed comparable rates of PPM in the Avalus (moderate: 14/48, 29%; severe: 7/48, 15%) and the PME (moderate: 19/48, 40%; severe: 3/48, 6%) groups ($p = 0.91$). ►**Table 4** shows the rates of PPM for each valve size and type. Completeness of echocardiographic follow-up was >95% for each year, except for the fifth year (Avalus, 86%; PME, 93%). MPG and EOA of both prostheses during follow-up are depicted in ►**Fig. 2**. Follow-up MPG and EOA data are comprehensively listed in ►**Table 5**, allowing comparison by prosthetic group and according to annulus size (<23 mm, 23–24 mm, or >24 mm) at 1 and 5 years after implantation. For the most part, group differences were not significant. However, at smaller annulus sizes (<23 mm), 5-year MPG was significantly lower for the Avalus group (13.6 vs. 20.3 mm Hg; $p = 0.02$).

No perioperative strokes occurred in any of the groups. There was one ischemic stroke 11 months after the procedure and three ischemic strokes beyond one year after the procedure in the Avalus group and there was one cerebral bleeding beyond 1 year after the procedure in the PME group.

In the Avalus group, five patients (10%) required a pacemaker implantation due to atrioventricular block ($n = 4$) and sick-sinus-syndrome ($n = 1$) before hospital discharge. An additional two patients (4%) required pacemaker implantation due to atrioventricular block beyond 1 year of follow-up.

Table 4 Patient prosthesis mismatch at discharge

	Moderate or severe PPM	Severe PPM
Avalus		
#19	0/0 (0%)	0/0 (0%)
#21	3/9 (33%)	3/9 (33%)
#23	11/19 (58%)	3/19 (16%)
#25	7/14 (50%)	1/14 (7%)
#27	0/6 (0%)	0/6 (0%)
Perimount Magna Ease		
#19	2/2 (1%)	0/2 (0%)
#21	4/6 (67%)	1/6 (17%)
#23	4/13 (31%)	0/13 (0%)
#25	11/23 (48%)	2/23 (9%)
#27	1/4 (25%)	0/4 (0%)

Abbreviation: PPM, patient-prosthesis mismatch.
Note: PPM was graduated as moderate (iEOA = 0.85–0.65 cm^2/m^2) or severe (iEOA <0.65 cm^2/m^2) for non-obese patients and moderate (iEOA = 0.70–0.55 cm^2/m^2) or severe (iEOA <0.55 cm^2/m^2) for obese (body mass index >30) patients.

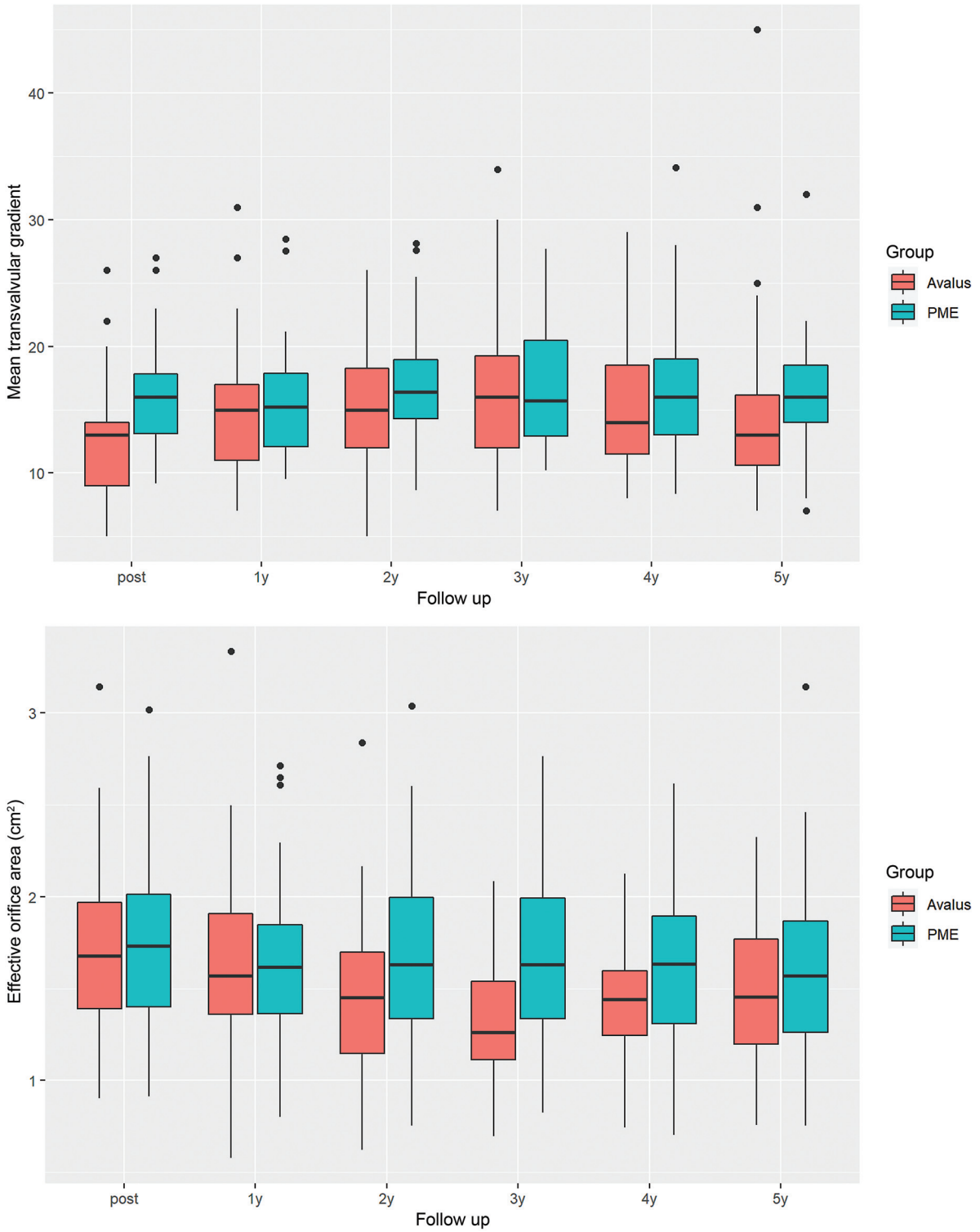

Fig. 2 Aortic mean pressure gradient and aortic effective orifice area over a 5-year follow-up. PME, Perimount Magna Ease.

In the PME group, two patients (4%) required pacemaker implantation before hospital discharge, one patient (2%) required pacemaker implantation 3 months after hospital discharge, and one (2%) 2 years after hospital discharge. The reason for pacemaker implantation was atrioventricular block in all four cases. There was no significant difference in group rates of pacemaker placement ($p = 0.32$).

Discussion

This is the first study reporting on mid-term results of the Avalus bioprosthesis and comparing those to the well-established PME. We found that the two valves displayed similar hemodynamic properties over a 5-year course, including comparable MPGs and EOAs. Furthermore, the occurrence of

Table 5 Hemodynamic results after 1 y and 5 y of follow-up

	Avalus	Valid echo (*n*)	Perimount Magna Ease	Valid echo (*n*)	*p*-Value
All					
MPG at 1 y (mm Hg)	14.73 ± 5.09	45	15.74 ± 4.31	43	0.32
MPG at 5 y (mm Hg)	14.73 ± 7.17	38	16.59 ± 5.08	39	0.20
EOA at 1 y (cm^2)	1.62 ± 0.45	44	1.65 ± 0.45	43	0.79
EOA at 5 y (cm^2)	1.51 ± 0.40	36	1.60 ± 0.49	39	0.38
Annulus diameter <23 mm					
MPG at 1 y (mm Hg)	15.42 ± 5.23	12	19.24 ± 4.27	8	0.09
MPG at 5 y (mm Hg)	13.56 ± 4.29	10	20.29 ± 5.62	7	0.02
EOA at 1 y (cm^2)	1.46 ± 0.38	12	1.31 ± 0.58	8	0.53
EOA at 5 y (cm^2)	1.49 ± 0.44	10	1.12 ± 0.51	7	0.15
Annulus diameter 23–24 mm					
MPG at 1 y (mm Hg)	13.76 ± 3.90	17	14.80 ± 3.23	11	0.45
MPG at 5 y (mm Hg)	13.78 ± 3.96	15	14.67 ± 3.50	9	0.57
EOA at 1 y (cm^2)	1.55 ± 0.34	17	1.57 ± 0.29	11	0.88
EOA at 5 y (cm^2)	1.40 ± 0.33	14	1.46 ± 0.30	9	0.69
Annulus diameter > 24 mm					
MPG at 1 y (mm Hg)	15.25 ± 6.16	16	15.01 ± 4.30	24	0.89
MPG at 5 y (mm Hg)	16.74 ± 10.94	13	16.22 ± 5.04	23	0.87
EOA at 1 y (cm^2)	1.84 ± 0.54	15	1.80 ± 0.41	24	0.82
EOA at 5 y (cm^2)	1.67 ± 0.41	12	1.81 ± 0.43	23	0.35

Abbreviations: EOA, effective orifice area; MPG, mean pressure gradient.

structural valve deterioration was low in both groups. Relative to earlier studies, the frequency of PPM we observed was lower for both Avalus[9] and PME[6] prostheses. This is perhaps attributed to the use of updated definition of PPM in our study.[8]

Despite their structural similarities as stented bovine pericardial valves, the Avalus and the PME are distinctive in terms of leaflet cutting, sewing methods, and anticalcification treatment. More importantly, the two differ in sewing cuff sizes: compared with the PME, the external sewing ring diameter of the Avalus is 3 mm larger at valve sizes 19 to 25 and 4 mm larger at sizes 27 and 29. This fact might lead to situations in which, despite the same label size of the Avalus and the PME, the surgeon would opt for different valve sizes depending on the chosen bioprosthesis. Thus to ensure a fair comparison, we matched the patients based on their annulus size measured by TEE, and not based on their labeled valve size.

The PME has already demonstrated excellent long-term durability: MPG at 10 years was reported to be 16.6 ± 7.3 mm Hg, EOA 1.3 ± 0.4 cm^2, and freedom from severe SVD was reported to be 86%.[6] Previous models as the Perimount Magna valve have also conferred high levels of freedom from reoperation (10 years, 96%; 20 years, 67%).[10] The Avalus prosthesis, in contrast, has been introduced into the market in the middle of the last decade. The flexibility of the struts, decreasing stress on the leaflet tips, is design to improve long-term performance, however, data about the durability of the valve are sparse. On behalf of the PERIGON investigators Dagenais et al, Klautz et al, and Sabik et al reported a low rate of valve-related events up to 2 years after Avalus implantations.[4,5,9] Considering hemodynamic outcome, the longest follow-up of the Avalus prosthesis was reported by Kiaii et al. They showed that the reduction of MPG and improvement of EOA were maintained 5 years after Avalus implantation, measuring a MPG of 12.5 mm Hg and an EOA of 1.43 cm^2 in the overall cohort.[7] Recently, Tadokoro et al compared the Avalus and the PME prosthesis postoperatively and at 1 year. They did not match the patient cohort and they compared valve sizes as labeled. No differences were encountered in MPGs or EOAs across all valve sizes at 1 week or at 1 year, with exception of a lower MPG at 1 week for the size 23 Avalus valve.[11]

The Avalus and the PME are both pericardial valves with internally mounted leaflets. Other valves of similar design are the Soprano valve (Sorin group, Milan, Italy) or the Inspiris Resilia valve (Edwards Lifesciences, Irvine, California, United States). Pericardial bioprostheses with externally mounted leaflets, such as the Mitroflow (Sorin group, Milan, Italy) or the Trifecta bioprosthesis (Abbott, Plymouth, Minnesota, United States), have been marked by significantly lower transprosthetic gradients, larger EOAs, and thus less frequent PPM.[12] The clinical consequences of PPM are still discussed.[4,13,14] However, bioprosthetic valves with externally mounted leaflets have been shown to have higher rates of structural valve deterioration.[15] Recently, an experimental study has raised the issue of premature leaflet tear in externally mounted bovine pericardial bioprosthesis when

comparing the Trifecta (externally mounted leaflets) with the Perimount prosthesis.[16]

Furthermore, the Trifecta has been shown recently to exhibit significantly higher long-term reoperation rates compared with Perimount bioprosthesis.[17] Thus, we believe that internally mounted pericardial bioprosthesis will continue to be a popular choice for aortic valve replacement. Two of the latest generation of these bioprostheses, such as the PME and the Avalus show excellent equal mid-term results.

Limitations

The study is limited by its retrospective design. Also, propensity score matching ends up with small groups. Therefore, the evaluation of rare adverse valve-related events such as endocarditis, thromboembolism, pacemaker implantation, bleeding, stroke, or cardiac death is difficult.

Conclusion

In conclusion, the Avalus bioprosthetic valve exhibits similar clinical and hemodynamic results compared with the well-established Perimount Magna Ease valve over a period of 5 years.

Authors' Contribution

N.B. and M.B. performed data collection, analysis, and writing of the manuscript together, and thus contributed equally to the manuscript.

Conflict of Interest

R.L.: Lecture fees, royalties, and serving on an advisory board for Medtronic; lecture fees and serving on an advisory board for LivaNova; and lecture fees, shares, and serving on an advisory board for Highlife; V.K.: Serving on an advisory board for Medtronic.

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