The new St Jude Trifecta versus Carpentier-Edwards Perimount Magna and Magna Ease aortic bioprosthesis: Is there a hemodynamic superiority?

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Objectives: The Trifecta valve (St Jude Medical, St Paul, Minn) is a new bioprosthetic heart valve designed for supra-annular aortic valve replacement. We compared the hemodynamic performance of the Trifecta against the Perimount-Magna and Magna-Ease valve prostheses (Edwards Lifesciences, Irvine, Calif) in a nonrandomized, observational, single-center study.

Methods: A total of 346 consecutive patients with aortic valve disease underwent aortic valve replacement between January 2003 and November 2011, with implantation of the Trifecta (group 1, n = 121), the Perimount-Magna (group 2, n = 126), or the Magna Ease bioprosthesis (group 3, n = 99). Clinical and hemodynamic data were prospectively recorded and compared. Hemodynamic performance was evaluated by transthoracic echocardiography, including mean pressure gradient (MPG) and aortic valve area (AVA) at baseline, discharge, and 6-month follow-up. A multivariate model of covariance analysis was constructed to further compare the primary study end points of MPG and AVA at 6-month follow-up.

Results: For all valve sizes, unadjusted MPGs did not differ ($P = .08$), but AVAs differed ($P < .001$) between groups at 6-month follow-up. After final adjustment by a multivariate model of covariance analysis, neither the MPGs ($P = .16$) nor the AVAs ($P = .92$) at 6 months postoperatively were influenced by the type of prosthesis used.

Conclusions: The present observational study is the first to compare the new Trifecta valve with well-established supra-annular aortic valve bioprostheses from a hemodynamic perspective. Although mean pressure gradients and aortic valve areas seem to be advantageous at 6-month follow-up with the new Trifecta valve, after multivariate covariance analysis, no influence of prosthesis type on mean pressure gradient or aortic valve area could be demonstrated. (J Thorac Cardiovasc Surg 2014;147:1553-60)

Many commercially available aortic valve substitutes have undergone design modifications over the years, including the supra-annular Carpentier-Edwards Perimount Magna and Perimount Magna Ease (Edwards Lifesciences, Irvine, Calif) bioprostheses, which represent further development of the original Carpentier-Edwards Perimount bioprosthetic heart valve.^{1,2} In several previous studies, the hemodynamic performance and clinical results of the Perimount valve have been excellent.³⁻⁷ Recently, a novel supra-annular aortic valve bioprosthesis, the Trifecta (St Jude Medical, St

Paul, Minn) valve, has been launched. Great emphasis has been placed on various determinants of prosthetic valve performance, including aortic valve area, pressure gradients, and durability. Detailed hemodynamic data on the Trifecta aortic valve bioprosthesis have been released by the manufacturer, but it has not yet been investigated extensively or independently.⁸

This study aims to compare the hemodynamic performance of these next-generation supra-annular aortic valve bioprostheses in a single-center observational study.

METHODS

Study Design

This study was an observational, single-center, cohort study of 346 consecutive patients who underwent surgical aortic valve replacement at the West-German Heart Center Essen between January 2003 and November 2011. Patients received the Trifecta (group 1, n = 121), the Carpentier-Edwards Perimount Magna (group 2, n = 126), or the Carpentier-Edwards Perimount Magna Ease (group 3, n = 99) bioprostheses, depending on surgeon and patient preference. After sizing the annulus with the relevant commercial sizer, the prosthesis size was carefully chosen according to the prosthesis-patient mismatch (PPM) chart provided by the manufacturer. According to our institutional policy, an implanted prosthesis should provide an effective orifice area index (EOAI) of at least more than $0.85 \text{ cm}^2/\text{m}^2$ to prevent potential PPM.⁹ Surgical aortic valve replacement was routinely performed, as previously described, in all

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Abbreviations and Acronyms

ANOVA	= analysis of variance
AVA	= aortic valve area
CABG	= coronary artery bypass grafting
CPB	= cardiopulmonary bypass
EOAI	= effective orifice area index
EuroSCORE	= European System for Cardiac Operative Risk Evaluation
MPG	= mean pressure gradient
STS	= Society of Thoracic Surgeons

patients using median sternotomy, a standard cardiopulmonary bypass (CPB) technique with ascending aortic and venous cannulation, mild hypothermia ($>32^{\circ}\text{C}$), and cold crystalloid cardioplegic arrest.¹⁰ Echocardiographic examinations were performed preoperatively, at discharge, and at 6-month follow-up.

All patients who underwent isolated aortic valve replacement were included in the present study. Patients requiring redo aortic valve replacement or concomitant surgical procedures, such as (1) myectomy, (2) aortic root enlargement, (3) surgery of the ascending aorta and/or coronary artery bypass grafting, and/or (4) additional valve surgery (mitral valve repair/replacement or tricuspid valve repair/replacement), were also included.

Ethics approval was granted by the Institutional Review Board, according to the Declaration of Helsinki. All of the patients had previously granted permission for use of their medical records for research purposes.

The primary study end points were mean pressure gradients and aortic valve area at 6-month follow-up. The secondary end point was the influence of prosthesis type on mean pressure gradients and aortic valve area at 6 months after adjustment by a multivariate model of covariance analysis.

Data Collection and Follow-up

Patient demographics and operative data were recorded in a prospective institutional database and retrospectively extracted and evaluated. Perioperative deaths (30-day mortality) were tracked from the institutional database or by active follow-up. All surviving patients were contacted on a routine basis and underwent a comprehensive echocardiographic examination 6 months postoperatively at the West-German Heart Center Essen. Discharge echo-data could be obtained in 51 patients of group 1, 39 patients of group 2, and 69 patients of group 3. The 6-month echo-data were available in 79 patients of group 1, 82 patients of group 2, and 56 patients of group 3.

Echocardiography

Transthoracic 2-dimensional echocardiographic standard views were obtained in a left lateral supine position using a standard ultrasound system with a 3.5-MHz (S5-1) probe (iE33; Philips Medical Systems, Andover, Mass). Left ventricular dimensions were measured according to the recommendations of the American Society of Echocardiography. Doppler flow data were acquired from the left ventricular outflow tract region in the pulsed-wave mode, and from the aortic valve in the continuous-wave mode in the apical 5-chamber view. The modified Bernoulli equation was used to calculate peak and mean pressure gradients (MPGs) across the prosthetic valve.

Statistics

Descriptive statistics are summarized for categorical variables as frequencies and percentages. Continuous variables are reported as mean $\pm$ SD. New York Heart Association class is presented as a median. Groups were compared using Pearson χ^2 tests for categorical variables and 1-way analysis of variance (ANOVA) for continuous variables. Mean pressure

gradients and aortic valve areas were compared using 1-way ANOVA and, in addition, pairwise comparisons were performed using the Student *t*-test if a significance of .05 was observed with the ANOVA. A multivariate model of covariance analysis was constructed to further compare the primary study end points of MPG and aortic valve area (AVA) at 6-month follow-up. The following preoperative variables were used for the regression analysis: group membership (model of the implanted valve type), sex, age, body height and body weight, body surface area, serum creatinine level, the Society of Thoracic Surgeons (STS) score, European System for Cardiac Operative Risk Evaluation (EuroSCORE), EOAI, concomitant coronary artery bypass grafting (CABG) surgery, concomitant valve surgery, left ventricular ejection fraction, and New York Heart Association functional class. Those variables identified by the univariate analysis with $P < .1$ were added to the multivariable model, in addition to the model of implanted prosthesis. In general, $P < .05$ indicated statistical significance. All statistical analyses were performed using SAS, version 9.2 (SAS Inc, Cary, NC). The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agreed to the article as written.

RESULTS

Preoperative characteristics of the 3 groups are summarized in Table 1. The groups differed for all listed variables, except for age, body mass index, chronic obstructive pulmonary disease, renal disease, diabetes, existing coronary artery disease, and previous cardiac surgery. Preoperative MPGs were higher in group 1 than in groups 2 and 3 (48.7 ± 17.0 vs 43.8 ± 19.3 vs 45.1 ± 20.8 mm Hg; $P < .001$). Preoperative risk assessment, as measured by logistic EuroSCORE and STS score, indicated a lower level of risk for patients in group 1 than for the other groups (logistic EuroSCORE: $15.8\% \pm 13.5\%$ vs $19.8\% \pm 15.1\%$ vs $19.6\% \pm 10.7\%$ [$P = .005$]; and STS score: $4.7\% \pm 5.8\%$ vs $9.2\% \pm 7.5\%$ vs $13.2\% \pm 12.0\%$ [$P < .001$]).

Intraoperative variables are listed in Table 2. Aortic cross-clamp time (85 ± 30 vs 97 ± 34 vs 88 ± 33 minutes; $P = .012$) and CPB times (127 ± 52 vs 142 ± 54 vs 131 ± 39 minutes; $P = .002$) differed significantly between the groups, with highest aortic cross-clamp and CPB times in group 2. Concomitant valve surgery, including additional surgery on the mitral and tricuspid valves, was more common in group 1 than groups 2 and 3 (32.2% vs 18.3% vs 16.1% ; $P = .005$). All groups had similar rates of concomitant CABG surgery ($P = .52$). Group 2 showed a significantly higher percentage of additional aortic root enlargement than groups 1 and 3 (25.4% vs 9.1% vs 12.1% ; $P = .002$). Patients in group 2 also had a higher rate of additional septal myectomy than those in groups 1 and 3 (59.5% vs 19.8% vs 35.4% ; $P < .001$). In 21% ($n = 19$) of the patients in group 1, in 23% ($n = 30$) of the patients in group 2, and in 1% ($n = 1$) of the patients in group 3 ($P < .01$), the choice of valve prosthesis resulted in moderate prosthesis-patient mismatch, as defined by an EOAI of 0.65 to $0.85 \text{ cm}^2/\text{m}^2$. Of those patients in the PPM category, the mean EOAI was $0.81 \pm 0.01 \text{ cm}^2/\text{m}^2$ (minimum, $0.74 \text{ cm}^2/\text{m}^2$) in group 1, $0.82 \pm 0.02 \text{ cm}^2/\text{m}^2$ (minimum, $0.80 \text{ cm}^2/\text{m}^2$) in group 2, and $0.79 \text{ cm}^2/\text{m}^2$

TABLE 1. Patient baseline characteristics

Variable	Group 1 (n = 121)	Group 2 (n = 126)	Group 3 (n = 99)	P value
Demographics				
Age, y	72.2 ± 6.7	75.2 ± 7.4	73.2 ± 7.3	.06
Female sex	36 (29.8)	43 (34.1)	48 (48.5)	.004
BMI, kg/m ²	26.9 ± 6.7	26.6 ± 4.4	27.8 ± 4.6	.31
BSA, m ²	1.9 ± 0.3	1.8 ± 0.2	1.8 ± 0.3	.02
Risk factors and comorbidities				
NYHA class, median (range)	III (II-IV)	III (II-IV)	III (II-IV)	—
Peripheral vascular disease	25 (20.7)	39 (31.0)	8 (8.1)	<.001
Systemic hypertension	92 (76.0)	118 (93.7)	92 (92.9)	.006
COPD	22 (18.2)	27 (21.4)	23 (23.2)	.47
Renal disease (serum creatinine >200 μmol/L)	11 (9.1)	21 (16.6)	18 (18.1)	.11
Diabetes mellitus	35 (28.9)	37 (29.4)	27 (27.3)	.09
Cardiac history				
LV-EF, %	50.5 ± 13.4	55.2 ± 12.9	51.1 ± 10.6	<.001
LV-EF <35%	12 (9.9)	9 (7.1)	4 (4.0)	<.001
Pulmonary hypertension	17 (14.0)	40 (31.7)	29 (29.3)	.003
Coronary artery disease	78 (64.5)	81 (64.3)	67 (67.7)	.59
Preoperative AVA, cm ²	0.86 ± 0.35	0.86 ± 0.37	0.76 ± 0.28	.016
Preoperative MPG, mm Hg	48.7 ± 17.0	43.8 ± 19.3	45.1 ± 20.8	<.001
Previous cardiac surgery	7 (5.8)	13 (10.3)	4 (4.0)	.65
Atrial fibrillation	21 (17.4)	14 (11.1)	13 (13.1)	.01
Risk scores				
STS score, %	4.7 ± 5.8	9.2 ± 7.5	13.2 ± 12.0	<.001
Logistic EuroSCORE, %	15.8 ± 13.4	19.8 ± 15.1	19.6 ± 10.7	.005

Data are presented as mean ± SD or number (%). BMI, Body mass index; BSA, body surface area; NYHA, New York Heart Association; COPD, chronic obstructive pulmonary disease; LV, left ventricle; EF, ejection fraction; AVA, aortic valve area; MPG, mean pressure gradient; STS, Society of Thoracic Surgeons; EuroSCORE, European System for Cardiac Operative Risk Evaluation.

(minimum, 0.79 cm/m²) in group 3. EOIs calculated according to the PPM charts provided by manufacturers gave values of 1.0 ± 0.1cm²/m² for group 1, 0.9 ± 0.1cm²/m² for group 2, and 0.9 ± 0.1cm²/m² for group 3, for all valve sizes ($P = .001$). Only patients in group 1 received 19-mm (n = 6), 27-mm (n = 10), and 29-mm (n = 4) prostheses. Comparing the remaining valve sizes, the implantation of 21- and 23-mm valve prostheses was

more common in group 2 ($P < .03$ and $P < .001$, respectively), whereas the implantation of a 25-mm valve was more common in group 1 ($P < .001$).

Postoperative Outcomes

There was no difference in intraoperative mortality between the 3 groups. Only 1 patient died intraoperatively, in group 1. The 30-day mortality was 8.3% (10/121) in

TABLE 2. Intraoperative data

Variable	Group 1 (n = 121)	Group 2 (n = 126)	Group 3 (n = 99)	P value
ACC time, min	85 ± 30	97 ± 34	88 ± 25	.012
CPB time, min	127 ± 52	142 ± 54	131 ± 39	.002
Concomitant valve surgery*	39 (32.2)	23 (18.3)	16 (16.1)	.005
Concomitant CABG	65 (53.7)	76 (60.3)	60 (60.6)	.52
Aortic root enlargement	11 (9.1)	32 (25.4)	12 (12.1)	.002
Septal myectomy	24 (19.8)	75 (59.5)	35 (35.4)	<.001
Implanted valve size, mm				
19	6 (4.9)	—	—	—
21	26 (21.5)	43 (34.1)	30 (30.3)	.03
23	41 (33.9)	70 (55.6)	48 (48.5)	<.001
25	34 (28.1)	13 (10.3)	21 (21.2)	<.001
27	10 (8.3)	—	—	—
29	4 (3.3)	—	—	—
Theoretical EOAI of implanted valve according to manufacturer, cm ² /m ²	1.0 ± 0.1	0.9 ± 0.1	0.9 ± 0.1	.001

Data are presented as mean ± SD or number (%). ACC, Aortic cross-clamp time; CPB, cardiopulmonary bypass; CABG, coronary artery bypass grafting; EOAI, effective orifice area index. *Concomitant valve surgery includes concomitant tricuspid and mitral valve surgery.

FIGURE 1. Mean pressure gradients (MPGs) at discharge (A) and at the 6-month follow-up (B). Black bars, Group 1; white bars, group 3; gray bars, group 2.

group 1 compared with 15% (19/126) in group 2 and 7.1% (7/99) in group 3 ($P = .04$).

Hemodynamic Outcomes

Unadjusted mean pressure gradients for all valve sizes at discharge were 9.1 ± 3.9 mm Hg in group 1 compared with 11.2 ± 4.1 mm Hg in group 2 and 14.0 ± 5.0 mm Hg in group 3 ($P = .01$). At the 6-month follow-up, mean pressure gradients for all valve sizes were 8.9 ± 3.9 mm Hg in group 1 compared with 10.8 ± 4.7 mm Hg in group 2 and 11.4 ± 3.1 mm Hg in group 3 ($P = .08$). Because size distribution between the groups was different, not surprisingly, the overall aortic valve areas at discharge were 1.8 ± 0.4 cm² in group 1 compared with 1.6 ± 0.5 cm² in group 2 and 1.5 ± 0.3 cm² in group 3 ($P < .001$); at the 6-month follow-up, aortic valve areas were 2.1 ± 0.5 cm² in group 1 compared with 1.6 ± 0.5 cm² in group 2 and 1.7 ± 0.3 cm² in group 3 ($P = .004$). A detailed breakdown of MPGs and AVAs at discharge and 6-month follow-up for each valve size is presented in Figures 1 and 2 (19-, 27-, and 29-mm bioprostheses only implanted in group 1).

Regression Analysis

To further control for study bias, a multivariate model of covariance analysis was constructed based on 14 major risk factors, to evaluate possible factors influencing the primary study end points of MPG and AVA at the 6-month follow-up (Table 3). In the univariate model, the following variables

were strongly associated with MPGs at 6-month follow-up: sex, patient's height, EOAI, and, most notably, the implanted prosthesis type (Table 4). Within the univariate model, AVAs at 6 months were also influenced by the prosthesis type, sex, height, EOAI, and, in addition, weight, body surface area, STS score, concomitant CABG surgery, and left ventricular ejection fraction. At the 6-month follow-up, neither MPGs nor AVAs were influenced by the tested variables. More important, after final adjustment, MPGs ($P = .16$) and AVAs ($P = .92$) were not influenced by the model of implanted prosthesis.

DISCUSSION

The present study is the first, to our knowledge, to compare the new Trifecta valve with 2 well-established supra-annular aortic valve bioprostheses regarding hemodynamic results at 6-month follow-up. This study provides several interesting findings. In patients undergoing surgical aortic valve replacement with bovine pericardial valve substitutes, receiving the Trifecta, the Carpentier-Edwards Perimount Magna, or the Magna Ease bioprosthesis, hemodynamic results showed the following:

1. All evaluated bioprostheses had favorable mean pressure gradients and aortic valve areas at 6-month follow-up.
2. No significant difference existed between the 3 groups regarding mean pressure gradients (for all valve sizes) at 6-month follow-up.

FIGURE 2. Aortic valve areas (AVAs) at discharge (A) and at the 6-month follow-up (B). Black bars, group 1; white bars, group 3; gray bars, group 2.

- 3. There were significantly higher aortic valve areas for the Trifecta valve (for all valve sizes) at 6-month follow-up.
- 4. After adjustment by multivariate covariance analysis, the implanted prosthesis type could not be identified as an independent factor influencing mean pressure gradients or aortic valve area at 6-month follow-up.

Conventional surgical aortic valve replacement with bioprosthetic aortic valves is a well-established procedure, and the advantages and disadvantages of these valves are well known.¹¹ In contrast to mechanical valves, biological

valves do not require anticoagulation therapy, but they do have a limited life span because of potential structural valve deterioration; so far, they have to compete with the larger AVAs afforded by mechanical valves.¹¹ At present,

TABLE 4. Univariate covariance analysis of variables associated with MPG and AVA

Variable	Univariate analysis			
	MPG		AVA	
	F-statistic	P value	F-statistic	P value
Group membership	6.57	.001	14.82	<.001
Sex	8.73	.004	14.62	<.001
Age	2.14	.145	0.53	.466
Height	6.94	.009	27.20	<.001
Weight	0.14	.714	8.247	.005
BSA	0.42	.517	16.71	<.001
Creatinine	0.27	.605	0.11	.743
STS score	2.90	.090	7.18	.008
EuroSCORE	3.59	.056	0.08	.777
EOAI	5.73	.018	3.93	.049
Concomitant valve surgery	0.16	.694	2.13	.147
Concomitant CABG surgery	2.14	.145	4.82	.029
LV-EF	0.96	.328	4.86	.029
NYHA	0.96	.412	0.25	.859

MPG, Mean pressure gradient; AVA, aortic valve area; BSA, body surface area; STS, Society of Thoracic Surgeons; EuroSCORE, European System for Cardiac Operative Risk Evaluation; EOAI, effective orifice area index; CABG, coronary artery bypass grafting; LV, left ventricle; EF, ejection fraction; NYHA, New York Heart Association.

TABLE 3. Multivariate covariance analysis of variables associated with MPG and AVA

Variable	Multivariate analysis			
	MPG		AVA	
	F-statistic	P value	F-statistic	P value
Group membership	1.85	.160	0.10	.902
Sex	1.01	.317	0.13	.721
Height	2.05	.154	0.07	.795
Weight	—	—	0.31	.578
BSA	—	—	0.44	.507
STS score	—	—	0.31	.578
EOAI	3.30	.071	0.24	.627
Concomitant valve surgery	—	—	1.93	.167
LV-EF	—	—	1.11	.295

MPG, Mean pressure gradient; AVA, aortic valve area; BSA, body surface area; STS, Society of Thoracic Surgeons; EOAI, effective orifice area index; LV, left ventricle; EF, ejection fraction.

conventional stented bioprostheses are gaining in popularity because of increased durability, ease of implantation, and improved hemodynamics, leading to increased implantation of these valves in younger patients (aged approximately 60 years).¹¹⁻¹³ This trend has motivated many companies to enhance existing models or develop new stented pericardial aortic valve bioprostheses. The new Trifecta valve (St Jude Medical) represents one of the company's latest developments, and in contrast to other stented bioprostheses available, similar to the Mitroflow valve, goes back to a previous concept of externally mounted leaflet tissue. The hemodynamic performance of the Trifecta valve has not been investigated in detail. It, therefore, seems logical to compare the Trifecta valve with other well-established next-generation supra-annular aortic valve bioprostheses. Great emphasis has been placed on various determinants of valve performance, including aortic valve, pressure gradients, and durability, by all manufacturers. Regardless of which prosthesis is being assessed, data on valve hemodynamics should be obtained at least 6 months postoperatively, to limit the bias of hemodynamic instability in the immediate postoperative course.¹⁴ Therefore, we decided to analyze valve performance of the Trifecta, Carpentier-Edwards Perimount Magna, and Magna Ease bioprostheses, including follow-up echocardiographic data at 6 months.

Excellent hemodynamic results have been reported for supra-annular aortic bioprostheses, including the Carpentier-Edwards Perimount Magna and the Magna Ease.^{4-7,10,13,15} To the best of our knowledge, the present study represents the first hemodynamic comparison between the bovine, pericardial Trifecta, Carpentier-Edwards Perimount Magna, and Magna Ease prostheses. Just recently, an initial experience evaluating the Trifecta valve in a single-center study has been published.⁸ In this single-center study, the Trifecta valve was implanted in 70 patients, and in 19 patients, the authors evaluated the hemodynamic performance during the direct postoperative course, including echocardiographic data at discharge. The published MPGs of the Trifecta valve at discharge are comparable to those values shown in this present study.⁸ The 6-month follow-up data of the present study demonstrate excellent mean pressure gradients for all valve sizes in the 3 groups, without any statistically significant differences. In addition, the results of Dell'Aquila and colleagues⁸ support our valve size-specific results of MPGs for the Trifecta valve at the 6-month follow-up.

As already mentioned, the Trifecta bioprosthesis goes back to the concept of external mounted pericardium, similar to the Mitroflow prosthesis, the only other 1 prosthesis with an external mounted pericardium. The hemodynamic performance of the pericardial Mitroflow valve is well documented in the literature.¹⁶ Suri and colleagues¹⁵ recently published a randomized trial evaluating the hemodynamic performance

of the Edwards Perimount Magna, the Sorin Mitroflow, and the St Jude Epic bioprostheses. They could show excellent hemodynamic results, as revealed by dismissal echocardiography on postoperative day 4 for all randomized third-generation porcine and pericardial valves.¹⁵ Over all valve sizes, the results of Suri and colleagues are more or less consistent with our results regarding AVA and MPG. However, the authors could show small, but consistent, early postoperative hemodynamic differences, with slightly lower MPGs and higher AVAs for the Magna valve.

Concerning the hemodynamics of the Mitroflow prosthesis, Jamieson and colleagues¹⁷ published detailed documentation of the hemodynamic performance of the Mitroflow bioprosthesis in 2010. This study of 55 patients from a Canadian multicenter evaluation provides the opportunity to develop reference-effective orifice areas (EOAs) for the Mitroflow prosthesis.¹⁷ The mean EOAs were 1.4 cm² for the 19-mm valve, 1.4 cm² for the 21-mm valve, and 1.8 cm² for the 23- and 25-mm valves. The corresponding mean pressure gradients for the Mitroflow prosthesis were 8.6 mm Hg for the 19-mm valve, 10 mm Hg for the 21-mm valve, 8.5 mm Hg for the 23-mm valve, and 7.5 mm Hg for the 25-mm valve.¹⁷ These results of Jamieson and colleagues¹⁷ showed excellent hemodynamic results of the Mitroflow prosthesis compared with the valves tested in the present study, especially when comparing mean pressure gradients. Moreover, for the small aortic annulus, the Mitroflow prosthesis offers excellent hemodynamics, with mean pressure gradients of 8.6 mm Hg for the 19-mm valve, as documented in 13 patients.¹⁷ However, these results are not comparable to the present study, because only six patients in the Trifecta group received a 19-mm valve. On the other hand, another study by Conte and colleagues¹⁸ evaluated the Mitroflow bioprosthesis in a large, prospective, multicenter trial. Within this study, echocardiography at 1 year showed mean pressure gradients ranging between 7.3 and 13.4 mm Hg and EOAs ranging between 1.05 and 1.82 cm² (for all valve sizes), which are more comparable to our results. In detail, the Mitroflow bioprosthesis showed mean pressure gradients of 13.4 mm Hg for the 19-mm valve, 11.5 mm Hg for the 21-mm valve, 10.6 mm Hg for the 23-mm valve, 8.6 mm Hg for the 25-mm valve, and 7.3 mm Hg for the 27-mm valve.¹⁸ Comparing the results of the Mitroflow prosthesis with those of the present study, over all valve sizes, the results of Jamieson¹⁷ and Conte¹⁸ and colleagues are more or less consistent with our results regarding AVA and MPG, with slightly better results favoring the tested valves of the present study. As an example, Conte and colleagues¹⁸ reported EOAs for the size 23-mm Mitroflow prosthesis of 1.37 cm² in 194 patients, whereas we observed EOAs of 1.73 cm² for the Perimount Magna Ease, 1.65 cm² for the Perimount Magna, and 2.16 cm² for the Trifecta valve at the 6-month follow-up.

In the present study, there were significant differences regarding implanted valve sizes. Most of the patients across all 3 groups received a 21-, 23-, or 25-mm prosthesis. In every single case, the valve size was carefully chosen to guarantee an EOAI greater than $0.85 \text{ cm}^2/\text{m}^2$, which is predicated by a theoretical, calculated EOAI of approximately $0.9 \text{ cm}^2/\text{m}^2$. However, in some patients, a mild prosthesis-patient mismatch, resulting in a mean value of approximately $0.82 \text{ cm}^2/\text{m}^2$, was accepted, which was most frequent in group 2 and least frequent in group 3. In just 1 patient of the 346 included, a minimum theoretical indexed orifice area index of $0.74 \text{ cm}^2/\text{m}^2$ was observed. In line with these observations, additional aortic root enlargement to prevent patient-prosthesis mismatch was significantly more common in group 2 ($P = .01$) than in the other groups. Whenever necessary to guarantee an appropriate prosthesis size, an aortic root enlargement was performed in all groups, irrespective of prosthesis type. However, as indicated in Table 2, many concomitant procedures were performed in all groups, and in some cases, the surgeon decided to avoid aortic root enlargement to keep cross-clamp times as short as possible in individual, complex cases. In 20% to 60% of patients across all groups, an additional myectomy was performed, thereby eliminating the potential subvalvular influence on the transvalvular pressure gradients. As a result, subvalvular influence on postoperative transvalvular aortic gradients can be excluded in our results. Interestingly, additional root enlargement was least common in group 1. One could conclude that the Trifecta provides larger aortic valve areas than other stented bovine pericardial supra-annular bioprostheses; however, there are no reproducible scientific data available to verify such assumptions. One could, however, speculate about the underlying mechanisms for potential larger aortic valve areas offered by the Trifecta valve. The Trifecta is engineered such that the externally mounted pericardial tissue offers larger orifice areas because of the externally mounted tissue. In our institution, the valve size decision is made intraoperatively based on PPM charts provided by the manufacturer, to choose a valve size that is less likely to result in PPM. The surgeon is, therefore, reliant on the PPM charts provided by the manufacturers, and these charts are not consistent and comparable between manufacturers. There are discrepancies between the cutoff values used to define PPM, depending on whether the definitions of Pibarot¹⁹⁻²² or Rao²³ and colleagues are followed, and some manufacturers have based their recommendations only on in vitro valve evaluations or preliminary short-term follow-up data. Recommendations should be based on large-scale in vivo studies, which were thankfully usually the case. In addition, independent in vitro evaluations of all new valves are mandatory to compare their hemodynamic performance under optimal conditions.¹

The 30-day mortality was relatively high across all groups, with 8.3% in group 1, 15% in group 2, and 7.1% in group 3. However, the high estimated risk scores and the large volume of additional, concomitant procedures should be kept in mind (>50% received additional CABG, and 32% of the patients in group 1, 18% of the patients in group 2, and 16% of the patients in group 3 underwent additional mitral and/or tricuspid valve surgery). The average age in this patient cohort was higher than might have been expected, representing the increasing number of elderly patients undergoing combined cardiac surgery, and this may also have had an impact on the mortality rate. Similar in-hospital mortality (16.7%) has been reported by Bloomstein and colleagues²⁴ in geriatric patients undergoing aortic valve replacement (mean age, 76 ± 4.7 years).

Limitations

Our study was performed at a single tertiary care medical center with a relatively small sample size; however, it represents the largest patient group treated with the Trifecta valve to date. Moreover, the study was retrospective and, most notably, was not randomized; therefore, the 3 groups differed significantly, as reflected by the preoperative characteristics. The high percentage of concomitant procedures (CABG or additional valve surgery) within the groups may have biased the results, and an analysis in patients undergoing isolated aortic valve replacement would be more pertinent, especially in valve sizes of less than 21 mm. However, regardless of concomitant procedures, the hemodynamic performance of the aortic bioprostheses should be reproducible at the 6-month follow-up. Moreover, the higher AVAs within the Trifecta group might be biased by an unequal size distribution. One could speculate that if there were adequate numbers of each valve size by prosthesis size, this finding might not have been identified.

CONCLUSIONS

To our knowledge, this study is the first to compare the new Trifecta valve with 2 well-established supra-annular aortic valve bioprostheses regarding their hemodynamic results at the 6-month follow-up. All companies are in a period of extensively promoting their products and emphasizing their unique features. We observed excellent mean pressure gradients and aortic valve areas for all implanted prostheses at the 6-month follow-up. For all implanted valve sizes, we observed higher aortic valve areas for the Trifecta valve at the 6-month follow-up; however, after adjustment by multivariate covariance analysis, the implanted prosthesis type could not be identified as an independent factor influencing mean pressure gradients or aortic valve areas at 6 months postoperatively. The Trifecta valve represents a completely new product (Conformité Européenne [CE] mark approval since 2010) within the

armamentarium of cardiac surgeons, which can legitimately compete with other well-established aortic valve bioprostheses. However, the Perimount valve has the advantage of proven long-term follow-up, which has yet to be investigated in the Trifecta valve. Therefore, before advocating a specific valve bioprosthesis, further randomized studies evaluating the long-term durability, performance, and valve-related morbidity of these new and innovative biological aortic valve prostheses are needed, which should include detailed echocardiographic data. In light of the available evidence, none of the prostheses studied can be recommended as being superior to their competitors.

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