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ORIGINAL ARTICLE

St. Jude Trifecta Versus Carpentier-Edwards Perimount Magna valves for the treatment of aortic stenosis: comparison of early Doppler-Echocardiography and hemodynamic performance

Protesi valvolari St. Jude Trifecta Versus Carpentier-Edwards Perimount Magna per il trattamento della stenosi aortica: dati ecocardiografici e performance emodinamiche precoci a confronto

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ABSTRACT: ***St. Jude Trifecta Versus Carpentier-Edwards Perimount Magna valves for the treatment of aortic stenosis: comparison of early Doppler-Echocardiography and hemodynamic performance. G. Minardi, A. Pergolini, G. Zampi, G. Pulignano, G. Pero, F. Sbaraglia, P.G. Pino, G. Cioffi, F. Musumeci.***

Objective. **Aim of this study was to compare the hemodynamic profiles of 2 aortic valve bioprostheses: the Carpentier Edwards Perimount Magna (CEPM) valve and the Trifecta valve.**

Methods. **100 patients who underwent AVR for severe symptomatic AS between September 2011 and October 2012 were analyzed by means of standard trans-thoracic Doppler-echocardiography.**

Results. **Mean and peak gradients were significantly lower for the 21 mm Trifecta vs CEPM (11 ± 4 vs 15 ± 4 mmHg, and 20 ± 6 vs 26 ± 7 mmHg, respectively; all $p < 0.05$) and the 23 mm Trifecta vs CEPM (8 ± 2 vs 14 ± 4 mmHg, and 17 ± 6 vs 25 ± 9 mmHg; all $p < 0.05$). Effective orifice area tended to be slightly higher for the Trifecta valve.**

Conclusion. **The new bioprosthetic valve Trifecta has an excellent hemodynamic profile, and lower trans-prosthesic gradients when compared to CEPM valve.**

Keywords: aortic stenosis, bioprosthetic valve, aortic valve replacement.

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Introduction

Homografts for aortic valve replacement (AVR) were introduced in clinical practice in the 1960s but their use was abandoned because of limited availability and problematic implantation technique, so mechanical AVR come to be the prevalent therapeutic option, despite the disadvantage of life-long anticoagulation therapy [1-3]. More recently, various types of xenogeneic bioprostheses have been developed. They are implanted more easily than the previous ones but to the detriment of orifice area and may increase stress at the attachment of the stent, inducing earlier primary tissue failure.

The optimization of hemodynamic performance to prevent patient-prosthetic mismatch and the improvement in durability have revitalized the use of bioprostheses in the last two decades. Commercial heart valve companies, indeed, have sought to promote the utilization of third-generation bioprosthetic valves by promising a much higher performance than those guaranteed by previous models [4, 5].

The new third generation valves look very promising and they have two different aspects that have been developed to try to decrease the risk of structural valve deterioration where the valve breaks down and needs to be replaced. One of these concerns the fixation process which is now done at physiological pressures instead of high pressure or zero pressure fixation. This helps to take some of the tension off certain pressure points on the valve leaflets. The other aspect is the anticalcification treatment.This new technique allows a covalent bonding which keeps the preservative from leaking out of the tissue over time and theoretically this should improve the longevity of these valves.

Despite commercial claims of differing hemodynamic characteristics and clinical outcomes, few data are available about the differences in these issues among third-generation biologic heart valve prostheses. Accordingly, the aim of this study was to compare the early post-operative hemodynamic profile of 2 aortic valve bioprostheses: the well-known and largely used Carpentier-Edwards Perimount

Magna (CEPM) valve (Edwards LifeSciences, Irvine, CA) and the Trifecta valve (St. Jude Medical Inc., St. Paul, MN).

Methods

Study population

We enrolled 100 patients who underwent AVR for severe symptomatic degenerative calcific aortic stenosis (AS) in our cardiothoracic surgery center.

We studied 50 patients who underwent AVR, plus or minus concomitant procedures, with the Trifecta valve between September 2011 and October 2012. We then matched the 50 Trifecta AVR patients 1:1 with 50 CEPM AVR patients, implanted in the same period of time, with respect to variables that are known to affect valvular hemodynamic performance: age, sex, body surface area and labeled size of the implanted valve. A history of aortic valve endocarditis or concomitant procedures such as coronary artery bypass grafting or mitral/tricuspid valve repair/replacement were not considered as exclusion criteria. The following conditions however represented exclusion criteria: < 18 years of age, emergency surgery, previous aortic valve procedure or aortic root replacement, active endocarditis, or severe aortic insufficiency, in-hospital death. This study was approved by our local ethics committee and informed consent was obtained from all patients.

Valve design and AVR procedure

The CEPM valve was introduced in 2003 as a modification of the standard Perimount valve. It is a stented bioprosthesis constructed of bovine pericardium and is intended for supraannular positioning.

In 2009, the Trifecta valve was introduced into clinical practice. It is a stented tissue heart valve consisting of pericardial tissue leaflets attached to the exterior of the valve stent.

The choice of implanting CEPM or Trifecta valve was made by the surgeons in accordance with each patient. Inclusion and exclusion criteria for using the two valves were identical, although patients were not randomized.

The AVR procedure was performed by previously described techniques [6, 7]. A transverse aortotomy was performed 1 to 2 cm above the right coronary artery. Myocardial protection was achieved by intermittent anterograde warm blood cardioplegia. The aorta was opened, the native aortic valve was excised and complete removal of calcium from the annulus was performed. Prosthesis size was selected according to the size of the aortic annulus. Double armed 2-0 Ethibond sutures were passed through aortic annulus and valve ring.

Once all the sutures were placed, the prostheses were slid down to the supraannular position and the sutures were tied. They were implanted typically with noneverting pledgeted mattress sutures placed on the ventricular side of the aortic annulus. The aortotomy was closed using 3-0 polypropylene suture stitches with an over-and-over technique.

Echocardiography

All patients underwent complete trans-thoracic Doppler-echocardiography examination within 7 days after surgery, following American Society of Echocardiography guidelines [8]. The Doppler-echocardiography examinations were performed with a iE33 (Philips, Eindhoven, The Netherlands) in the same echo-laboratory by four senior sonographers, who were blinded to the prosthetic valve type and size.

The aortic mean gradient, peak velocity, and aortic valve time-velocity integral (VTI) were calculated by continuous and pulsed Doppler-echo techniques, respectively. Effective orifice area (EOA) was calculated using the continuity equation method and was indexed for body surface area (EOAi). Moreover, Doppler velocity index was calculated by the equation:

$$\text{Doppler Velocity index} = \text{VTI LVOT/VTI Ao.}$$

We also analyzed the incidence of prosthesis-patient mismatch (PPM) defined as EOAi < 0.85 cm^2/m^2 [9].

Left ventricular mass was calculated according to previously published guidelines [10].

Statistical Analysis

The continuous variables were expressed as mean values ± standard deviations (SD) and compared using a t-test and the Mann-Whitney U-test as indicated. Categorical variables are presented as frequencies and percentages and compared by Pearson's χ^2 test with continuity correction or 2-sided Fisher exact test as appropriate. Statistical significance was defined as p-value < 0.05. SPSS application software version 15.0 (SPSS Inc. Chicago, Ill) was used to perform the statistical analysis.

Results

The preoperative clinical and echocardiographic characteristics of the 50 patients into whom the CEPM valve was implanted and of the 50 patients into whom the Trifecta valve was implanted were listed and compared in Table 1. The two groups were homogeneous for the main demographic, echocardiographic and laboratory variables. Similarly, the additional intraoperative procedures performed other than AVR did not differ between the two study groups (Table 2). The labeled size of the implanted valve was similar for the two groups (mean valve size: 22 ± 2 vs 23 ± 2 for Trifecta vs CEPM, respectively, p = 0.06).

After surgery, patients implanted with Trifecta vs CEPM bioprosthetic valves had similar systolic blood pressure (130 ± 10 vs 124 ± 20 mmHg, p = 0.06), heart rate (80 ± 10 vs 75 ± 10 bpm, p = 0.07), serum hemoglobin levels (9.6 ± 0.7 vs 10.0 ± 1.1 g/dl, p = 0.10) and estimated glomerular filtration rate (81 ± 31 vs 91 ± 40 ml/min/1.73m^2).

Valvular hemodynamic data measured within one week after surgery are shown in Table 3 and Table 4. Mean and peak trans-valvular gradients for the Trifecta valves were significantly lower than those of CEPM valves. EOA, EOAi, arterial blood pressure, left ventricular ejection fraction and pulmonary artery systolic pressure were similar in the

Table 1. - Principal characteristics of the study population divided according to the type of Bioprostheses implanted

Variables	Trifecta (n = 50)	Magna (n = 50)	*p*
Age (years)	75.5 ± 5	72.5 ± 7	0.07
Gender, male n (%)	18 (36)	25 (50)	0.15
Body mass index (kg/m^2)	26.9 ± 4.52	27.24 ± 4.02	0.76
Body surface area(m^2)	1.78 ± 0.16	1.86 ± 0.18	0.08
NYHA class III or IV n (%)	25 (50)	21 (42)	0.42
Hypertension n (%)	6 (12)	5 (10)	0.74
Diabetes mellitus n (%)	9 (18)	9 (18)	1.0
Current smokers n (%)	5 (10)	9 (18)	0.24
Former smokers n (%)	8 (16)	7 (14)	0.77
Hyperlipidemia n (%)	12 (24)	13 (26)	0.81
COPD n (%)	11 (22)	7 (14)	0.29
Myocardial Infarction n (%)	12 (24)	10 (20)	0.62
TIA/ stroke n (%)	2 (4)	3 (6)	0.64
Pace-Maker n (%)	2 (4)	1 (2)	0.56
Peripheral vascular disease n (%)	13 (26)	8 (16)	0.21
Previous CV surgery n (%)	3 (6)	2 (4)	0.64
Hemoglobin, g/dl	12.3 ± 1.19	12.51 ± 1.63	0.56
Hematocrit, %	37.15 ± 2.9	37.5 ± 4.4	0.65
Atrial Fibrillation n (%)	2 (4)	2 (4)	1.0
Heart Rate (bpm)	73 ± 10	69 ± 8	0.12
Systolic Blood Pressure (mmHg)	133 ± 10	128 ± 11	0.06
eGFR (CKD-EPI) (ml/min/1.73m^2)	74.2 ± 22	84 ± 32	0.15
Echocardiogram			
Aortic diameter (mm)	35.6 ± 4.7	37.9 ± 4.4	0.13
Aortic valve area (cm^2)	0.69 ± 0.34	0.81 ± 0.29	0.15
Aortic valve area index (cm^2/m^2)	0.39 ± 0.18	0.41 ± 0.09	0.54
LV ejection fraction (%)	58 ± 11	60 ± 7	0.42
LV ejection fraction < 0.40 n (%)	4 (8)	2 (4)	0.39
LV outflow tract (mm)	20.1 ± 1.9	21.2 ± 2.4	0.06
Transaortic valve mean gradient before surgery (mmHg)	47.4 ± 14.6	50.7 ± 18.2	0.44
LV mass index, g/m^2	153 ± 42	153 ± 45	0.96
PASP (mmHg)	39 ± 10	37 ± 9	0.36
Pharmacological therapy			
Acetyl salicylic acid n (%)	38 (76)	30 (60)	0.08
Anticoagulant n (%)	7 (14)	5 (10)	0.53
ACE-I n (%)	29 (58)	24 (48)	0.31
ARBs n (%)	9 (18)	13 (26)	0.33
Beta-Blocker n (%)	29 (58)	31 (62)	0.68
Ca-Channel Blocker n (%)	12 (24)	13 (26)	0.81
Diuretics n (%)	15 (30)	12 (24)	0.49
Statins n (%)	15 (30)	21 (42)	0.21

COPD: chronic obstructive pulmonary disease; CV: cardiovascular; LV: left ventricular; CAD: coronary artery disease; eGFR: Estimated glomerular filtration rate; CKD-EPI: Chronic Kidney Disease Epidemiology; NYHA: New York Heart Association; TIA: transient ischemic attack; PASP: Pulmonary Artery Systolic Pressure; ACE-I: angiotensin converting enzyme inhibitor; ARBS: Angiotensin II Receptor Blockers.

Table 2. - Intraoperative procedures other than aortic valve replacement performed in the two study groups

Variables	Trifecta (n = 50)	Magna (n = 50)	*p*
Coronary artery bypass grafting n (%)	12 (24)	11 (22)	0.81
Mitral Valve Surgery n (%)	2 (4)	1 (2)	0.55
Tricuspid valve surgery n (%)	1 (2)	0	0.31
Replacement ascending aorta n (%)	0	2 (4)	0.15
Septal myectomy n (%)	3 (6)	2 (4)	0.64
Conventional approach n (%)	36 (72)	33 (66)	0.51
Minimally invasive approach n (%)	14 (28)	17 (34)	0.51
Aortic cross-clamp time (min)	64 ± 22	74 ± 21	0.09
Cardiopulmonary bypass time (min)	78 ± 22	88 ± 24	0.09

Table 3. - Hemodynamic profile of Trifecta vs Magna bioprosthetic valve

Variables	Trifecta (n = 50)	Magna (n = 50)	*p*
Peak gradient (mmHg)	19.5 ± 5.75	26.6 ± 7	< 0.001
Mean gradient (mmHg)	10.35 ± 3.5	14.5 ± 4	< 0.001
Effective orifice area (cm^2)	1.77 ± 0.4	1.62 ± 0.45	0.17
Effective orifice area indexed (cm^2/m^2)	0.96 ± 0.25	0.93 ± 0.16	0.58
Doppler Velocity Index	0.54 ± 0.1	0.51 ± 0.08	0.32
Prosthesis-patient mismatch n (%)	14 (28)	14 (28)	0.99
Paraprosthetic leakage n (%)	0	1 (2)	0.31
Trivial intraprosthetic regurgitation n (%)	15 (30)	17 (34)	0.66
Pulmonary Artery Systolic Pressure (mmHg)	33 ± 7	32 ± 8	0.72
Left ventricular ejection Fraction (%)	58 ± 8	60 ± 7	0.40
Heart Rate (bpm)	80 ± 10	75 ± 10	0.07
Hemoglobin (g/dl)	9.5 ± 0.9	10 ± 1.1	0.08
Hemotocrit (%)	29.1 ± 2.4	30.2 ± 3.2	0.15

two study groups. Analyzing the hemodynamic performance of the bioprostheses according to the different labeled size, the mean and peak gradients were significantly lower both for the 21 mm and the 23 mm Trifecta than 21 mm and 23 mm CEPM valves (peak gradients 20 ± 6 vs 26 ± 7 and 17 ± 6 vs 25 ± 9 mmHg, respectively; mean gradients 11 ± 4 vs 15 ± 5 and 8 ± 2 vs 14 ± 4 mmHg, respectively). All other hemodynamic parameters were comparable in the two study groups, including the incidence of PPM detected in 14 patients (28%) in both groups. However, in no patient did severe PPM occur (identified as EOAi < 0.65 cm^2/m^2).

The main post-operative and in-hospital complications are listed in Table 5.

The patients were all discharged asymptomatic and in good clinical conditions.

Discussion

This study evaluated possible hemodynamic differences between two biological valves under realistic clinical conditions during the early post-operative period.

In our study we compared the hemodynamic performance of the St. Jude Trifecta valve to the one of the CEPM, the most reliable and used bioprosthesis in our cardiothoracic center.

Although study-to-study comparisons of different aortic prostheses are confounded by many factors, the Trifecta valve showed more favorable hemodynamics than other bioprostheses (Table 6) [11-13].

However, in the study of Suri and coworkers [11] the patients were divided into 3 similar-size groups for comparison (obtaining the following cohorts of commercially labeled valve size: nos. 19 and 21, no. 23 and nos. 25 and 27), and this kind of analysis could have influenced the results, resulting in a slighting higher EOA for the Epic and the Mitraflow compared to Trifecta.

The data of our study regarding the hemodynamic performance of the Trifecta valve are consistent with the ones recently published by Dell'Aquila [14], by Bavaria [15] and by Permanyer [16] who studied the Trifecta valve in the perioperative setting.

Our data are slightly different from those recently published by Wendt and co-workers [17]. In their study, comparing the Trifecta valve to another two bioprostheses, Trifecta valve n° 25 had a larger effective orifice area despite a higher MPG compared to n° 23 and n° 21. The authors did not provide any explanation for this datum, although it disappears at 6 month follow-up.

According to this information, analyzing the performance of the Trifecta valve, we found lower gradients compared with CEPM. Nowadays, although the effects of mismatch after AVR continue to be a matter of debate [18], there is consensus that prosthetic valves with low transprosthetic gradients and/or longer durability must be preferred.

A recent published study [19], investigates the performance of the Trifecta valve during exercise. The author concluded that the Trifecta valve *"offers promising haemodynamic results at rest and during moderate exercise with an almost physiological dynamic pattern"*.

In fact, the EOA is a variable flow-dependent, and when different valve designs are compared, we need to combine pressure gradient data with more flow-independent variables. In patients undergoing AVR, the mean left ventricle pressure will decrease due to reduced afterload and thereby the wall tension will decrease as well (Laplace's law). The reduced left ventricle (LV) pressure burden after AVR starts a favourable process of LV remodelling with reduction in LV volume, improved systolic and diastolic function and reduction in LV mass.

This implies that the LV pressure is higher in patients with higher pressure gradients, leading to a less pronounced regression in LV mass index [20].

Although in our study there is no follow-up determining the LV mass regression in our cohort of patients, in a very interesting meta-analysis performed by Kunadian and co-workers [21] it was demonstrated that, across all studies, replacement with an aortic valve that had a reduced aortic valve gradient determines an increased reduction in LVMI at 6 months, although this improvement in LVMI disappears after one year. The authors hypothesized that lower gradients allow the myocardium to recover more rapidly from LVH owing to the reduced residual gradient in the aortic annulus.

Regarding late durability of bioprostheses, David and coworkers [22] studied a large popula-

Table 4. - Main Early Doppler-Echocardiography and Hemodynamic Characteristic of the studied valves

	Trifecta	Magna	*p*
Size 19	**9 (18)**	**2 (4)**	**0.025**
Peak gradient, mmHg	22 ± 4	33 ± 4	0.04
Mean gradient, mmHg	11 ± 2	14 ± 5.6	0.27
EOA, cm^2	1.53 ± 0.04	1.43 ± 0.45	0.77
EOAi, cm^2/m^2	0.89 ± 0.27	0.88 ± 0.04	0.94
DVI	0.52 ± 0.07	0.52 ± 0.03	0.94
PPM	3 (6)	1 (2)	0.65
EDV, ml	82 ± 26	95 ± 55	0.63
ESV, ml	30 ± 12	43 ± 28	0.30
EF, %	60 ± 6	55 ± 4	0.34
Heart rate, b.p.m.	78 ± 3	69 ± 6	0.12
Systolic Blood Pressure (mmHg)	146 ± 34	110 ± 14	0.20
Size 21	**23 (46)**	**22 (44)**	**0.84**
Peak gradient, mmHg	20 ± 6	26 ± 7	0.004
Mean gradient, mmHg	10.7 ± 3.97	15 ± 5	0.001
EOA, cm^2	1.67 ± 0.31	1.58 ± 0.34	0.75
EOAi, cm^2/m^2	0.97 ± 0.19	0.91 ± 0.19	0.71
DVI	0.55 ± 0.11	0.56 ± 0.09	0.84
PPM	7 (14)	6 (12)	0.81
EDV, ml	94 ± 29	80 ± 24	0.08
ESV, ml	37 ± 18	32 ± 14	0.38
EF, %	61 ± 8	59 ± 8	0.49
Heart rate, b.p.m.	72 ± 6	80 ± 9	0.32
Systolic Blood Pressure (mmHg)	129 ± 7	123 ± 7	0.04
Size 23	**15 (30)**	**17 (34)**	**0.66**
Peak gradient, mmHg	16.8 ± 5.5	25 ± 9	0.004
Mean gradient, mmHg	8.4 ± 2.5	14.4 ± 4	< 0.001
EOA, cm^2	2 ± 0.57	1.77 ± 0.49	0.19
EOAi, cm^2/m^2	1.15 ± 0.36	1.05 ± 0.17	0.68
DVI	0.58 ± 0.13	0.5 ± 0.11	0.05
PPM	3 (6)	5 (10)	0.53
EDV, ml	107 ± 22	131 ± 46	0.08
ESV, ml	43 ± 14	53 ± 23	0.15
EF, %	60 ± 6	59 ± 7	0.65
Heart rate, b.p.m.	82 ± 4	79 ± 9	0.52
Systolic Blood Pressure (mmHg)	127 ± 13	124 ± 10	0.44
Size 25	**3 (6)**	**9 (18)**	**0.10**
Peak gradient, mmHg	16 ± 5	24 ± 9	0.16
Mean gradient, mmHg	8.6 ± 2.3	13.8 ± 5	0.13
EOA, cm^2	2.05 ± 0.43	2.02 ± 0.5	0.93
EOAi, cm^2/m^2	1.01 ± 0.14	0.91 ± 0.18	0.43
DVI	0.54 ± 0.05	0.47 ± 0.06	0.15
PPM	1 (2)	2 (4)	0.78
EDV, ml	146 ± 14	153 ± 39	0.77
ESV, ml	72 ± 8	67 ± 26	0.76
EF, %	50 ± 9	58 ± 8	0.16
Heart rate, b.p.m.	83 ± 10	71 ± 7	0.48
Systolic Blood Pressure (mmHg)	133 ± 10	125 ± 9	0.22

* Continuous variables are expressed as mean ± standard deviation; categoric variables are presented as number (%). EOA: effective orifice area; EOAi: effective orifice area indexed; DVI: Doppler Velocity Index; PPM: prosthesis-patient mismatch; EDV: end-diastolic volume; ESV: end-systolic volume; EF: ejection fraction.

tion of 1134 patients undergoing AVR with the Hancock II porcine bioprosthesis and reported that the freedom from structural valve deterioration at 20 years was 99.8% in patients > 70 years. Even after accounting for this report, there remains a paucity of comparative effectiveness data detailing the late durability of contemporary porcine versus bovine pericardial valves in the current era.

The problem of structural valve deterioration is still a matter of debate, although long-term studies confirm the durability of other pericardial valves in the aortic position with a low probability of explantation [23].

However, further studies with a long follow-up are needed to understand what kind of benefit could yield from these results on patient's survival and prostheses deterioration.

Table 5. - Early Postoperative Outcomes for the Two Groups of Patients

Variable*	Trifecta	Magna	*p*
Myocardial Infarction	0	0	1.0
Reoperation for bleeding	1 (2)	2 (4)	0.55
Renal Failure	0	2 (4)	0.15
Atrial Fibrillation	4 (8)	6 (12)	0.5
Mean Hemoglobin loss	2.69 ±0.92	2.5 ± 1.35	0.85

* Continuous variables are presented as means ± standard deviation; categoric variables are presented as number (%).

Table 6. - Comparison of predismissal effective orifice areas for Trifecta and other bioprosthesis according to in-vivo different studies

	19	21	23	25
Trifecta (our data)	**1.53**	**1.67**	**2**	**2.05**
Trifecta (declared by SJM)	1.41	1.63	1.81	2.02
Epic*	1.55	1.55	1.79	2.1
Mitroflow*	1.61	1.61	2.02	2.1
Medtronic Hancock II+	/	1.2	1.2	1.4
Edwards Lifescience Pericardial#	1.3	1.4	1.7	1.8
Medtronic Mosaic Porcine#	/	1.3	1.7	1.8

Ref

* Suri RM, Michelena HI, Burkhart HM, *et al*. A prospective, randomized comparison of 3 contemporary bioprosthetic aortic valves: should hemodynamic performance influence device selection? *J Thorac Cardiovasc Surg* 2012 Dec; 144 (6): 1387-95.

+ Borger MA, Nette AF, Maganti M, *et al*. Carpentier-Edwards Perimount Magna valve versus Medtronic Hancock II: a matched hemodynamic comparison. *Ann Thorac Surg* 2007 Jun; 83: 2054-8.

Seitelberger R, Bialy J, Gottardi R, *et al*. Relation between size of prosthesis and valve gradient: comparison of two aortic bioprosthesis. *Eur J Cardiothorac Surg* 2004 Mar; 25 (3): 358-63.

Study Limitations

Our study has some limitations that deserve to be acknowledged.

Firstly, we did not analyze clinical outcomes so that no prognostic implication can be deciphered by our data. With no clinical data, late follow-up or late LV mass regression data, it is hard to know if lower gradients are statistically significant, but not clinically significant.

Moreover, in our study a small number of patients were enrolled and the study was not randomized.

Another limitation lies in the fact that we focused on early postoperative hemodynamic performance and did not evaluate the long-term effect of the hemodynamic performance of the Trifecta valve on left ventricular geometry and, in particular, on the left ventricular mass regression. Furthermore, transitory early post-operative conditions such as the degree of hemodilution, hematocrit, heart rate, non-sustained arrhythmias may have influenced the echocardiographic measurement of the transprosthetic pressure gradients.

Conclusions

This comparison study reveals that there are significant differences in the hemodynamic profiles between current third-generation biological aortic valve prostheses. The new bioprosthetic valve Trifecta shows an excellent hemodynamic performance, characterized by lower transprothesic gradient compared to the CEPM.

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References

1. Ross DN. Aortic valve replacement. *Lancet* 1966; 27: 461-463.
2. Barrat-Boyes BG. Homograft aortic replacement in aortic incompetence and stenosis. *Thorax* 1964; 19: 131-150.
3. Binet JP, Duran CCT, Carpentier A, *et al*. Heterologous aortic valve transplantation. *Lancet* 1965; 2: 1275-1276.
4. Borger MA, Nette AF, Maganti M, *et al*. Carpentier-Edwards Perimount CEPM valve versus Medtronic Hancock II: a matched hemodynamic comparison. *Ann Thorac Surg* 2007; 83: 2054-8.
5. Minardi G, Pulignano G, Del Sindaco D, *et al*. Early Doppler-echocardiography evaluation of Carpentier-Edwards Standard and Carpentier-Edwards CEPM aortic prosthetic valve: comparison of hemodynamic performance. *Cardiovascular Ultrasound* 2011; 9: 37.

6. David TE. Surgery of the aortic valve. *Curr Probl Surg* 1999; 36: 426-501.
7. Szwec FM, Benckart DH, Wiechmann RJ, *et al*. Partial Versus Full Sternotomy for Aortic Valve Replacement. *Ann Thorac Surg* 1999; 68: 2209-14
8. Baumgartner H, Hung J, Bermejo J, *et al*. Echocardiographic Assessment of Valve Stenosis: EAE/ASE Recommendations for Clinical Practice. *J Am Soc Echocardiogr* 2009; 22: 1-106.
9. Head SJ, Mokhles MM, Osnabrugge RLJ, *et al*. The impact of prosthesis-patient mismatch on long-term survival after aortic valve replacement: a systematic review and meta-analysis of 34 observational studies comprising 27 186 patients with 133 141 patient-years. *European Heart Journal* 2012; 33: 1518-1529
10. Guidelines from the Canadian Cardiovascular Society and the Canadian Hypertension Society on the echocardiographic determination of left ventricular mass. Task Force of the Echocardiographic Section. *Can J Cardiol* 1995; 11: 391-5.
11. Suri RM, Michelena HI, Burkhart HM, *et al*. A prospective, randomized comparison of 3 contemporary bioprosthetic aortic valves: should hemodynamic performance influence device selection? J Thorac Cardiovasc Surg. 2012; 144: 1387-95
12. Borger MA, Nette AF, Maganti M, *et al*. Carpentier-Edwards Perimount Magna valve versus Medtronic Hancock II: a matched hemodynamic comparison. *Ann Thorac Surg* 2007; 83: 2054-8.
13. Seitelberger R, Bialy J, Gottardi R, *et al*. Relation between size of prosthesis and valve gradient: comparison of two aortic bioprosthesis. *Eur J Cardiothorac Surg* 2004; 25: 358-63.
14. Dell'Aquila AM, Schlarba D, Schneidera RB, *et al*. Clinical and echocardiographic outcomes after implantation of the Trifecta aortic bioprosthesis: an initial single-centre experience. *Interactive CardioVascular and Thoracic Surgery* 2013; 1-4.
15. Bavaria JE, Desai ND, Cheung A, *et al*. The St Jude Medical Trifecta aortic pericardial valve: Results from a global, multicenter, prospective clinical study. J Thorac Cardiovasc Surg. 2013
16. Permanyer E, Estigarribia AJ, Ysasi A, *et al*. St. Jude Medical Trifecta™ aortic valve perioperative performance in 200 patients. *Interact Cardiovasc Thorac Surg* 2013; 3. [Epub ahead of print]
17. Wendt D, Thielmann M, Plicht B, *et al*. The new St Jude Trifecta versus Carpentier-Edwards Perimount Magna and Magna Ease aortic bioprosthesis: Is there a hemodynamic superiority? *J Thorac Cardiovasc Surg* 2013.
18. Cotoni DA, Palac RT, Dacey LJ, *et al*. Defining patient-prosthesis mismatch and its effect on survival in patients with impaired ejection fraction. *Ann Thorac Surg* 2011; 91: 692-9.
19. Hanke T, Charitos EI, Paarmann H, *et al*. Haemodynamic performance of a new pericardial aortic bioprosthesis during exercise and recovery: comparison with pulmonary autograft, stentless aortic bioprosthesis and healthy control groups. *Eur J Cardiothorac Surg* 2013; 44: e295-301.
20. Bech-Hanssen O, Caidahl K, Wall B, *et al*. Influence of aortic valve replacement, prosthesis type, and size on functional outcome and ventricular mass in patients with aortic stenosis. *J Thorac Cardiovasc Surg* 1999; 118: 57-65.
21. Kunadian B, Vijayalakshmi K, Thornley AR, *et al*. Meta-analysis of valve hemodynamics and left ventricular mass regression for stentless versus stented aortic valves. *Ann Thorac Surg* 2007; 84: 73-8.
22. David TE, Armstrong S, Maganti M. Hancock II bioprosthesis for aortic valve replacement: the gold standard of bioprosthetic valves durability? *Ann Thorac Surg* 2010; 90: 775-81.
23. Grunkemeier GL, Furnary AP, Wu Y, Wang L, Starr A. Durability of pericardial versus porcine bioprosthetic heart valves. *J Thorac Cardiovasc Surg* 2012; 144: 1381-6.