Original Article

Comparison of four aortic bioprostheses: Hancock II *vs.* St Jude Trifecta *vs.* Carpentier-Edwards Perimount Magna *vs.* Magna Ease—mid-term results (COMPARE SAVR study)

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Background: In the era of percutaneous aortic valve implantation, biological valves are the preferred prostheses implanted in patients undergoing surgical aortic valve replacement (sAVR). The aim was to present a real-life analysis of mid-term sAVR outcomes for the four aortic bioprostheses: the Hancock II, the Carpentier-Edwards Perimount Magna, the Carpentier-Edwards Perimount Magna Ease and the Trifecta valve.

Methods: This is a retrospective study based on data from the Polish National Cardiac Surgery Database. The study population comprised of 1,589 consecutive patients, of whom 432 were in the Hancock II group, 356 in the Carpentier-Edwards Perimount Magna group, 427 in the Carpentier-Edwards Magna Ease group, and 374 in the Trifecta group. A comparison of the four groups was performed using analysis of variance (ANOVA) or Kruskal-Wallis test with appropriate post hoc tests (Tukey HSD or Steel-Dwass, respectively).

Results: Patients in the Hancock II group were older, had higher New York Heart Association (NYHA) and Canadian Cardiovascular Society (CCS) classes, had lower prevalence of hypertension and hyperlipidemia but higher prevalence of diabetes. The lowest mean valve size was observed in Trifecta group and the highest was in the Magna group (P<0.001). Survival analysis showed no significant differences in in-hospital mortality: 3.9% in Hancock II, 3.1% in Perimount, 3.3% in Magna and 2.1% in Trifecta group. Five-year mortality was significantly higher in Hancock II group (25.7%) compared to the other bioprostheses: 12.1% in Perimount, 9.1% in Magna and 10.70% in Trifecta group respectively.

Conclusions: The 5-year mortality rate was significantly higher in the Hancock II group compared to the other bioprostheses. In contrast, Trifecta, Perimount Magna, and Magna Ease had similar 5-year mortality rates.

Keywords: Bioprosthesis; Hancock II; Trifecta; Magna

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Introduction

Despite the intense development of percutaneous techniques seen in recent years, surgical aortic valve replacement (sAVR) remains one of the most commonly performed cardiac procedures worldwide with a class I indication for symptomatic aortic stenosis (1,2) Currently, mechanical valve prostheses have been dethroned in favour of tissue valves due to several reasons, the most common being patients' preference to anticoagulation (1-3). Improved durability of bioprostheses, cessation of lifelong anticoagulation, and enhanced quality of life have led to the rising incidence of bioprosthetic implantations, even among younger patients (1,3,4). The American guidelines consider this trend in patients aged over 55 years (1), while the European guidelines specify a cutoff of over 60 years of age (2). There are numerous bioprostheses available in the market, with the technology of leaflet construction and preservation evolving with each valve generation.

Although there are several studies in the literature comparing different groups (e.g., stented *vs.* stentless, bovine *vs.* porcine) or specific models of bioprostheses in terms of their durability, hemodynamic, and clinical outcomes, direct comparisons of bioprostheses, in general, are lacking. Driven by this fact, we designed an analysis that examines the results of the four most commonly used bioprosthesis types with respect to morbidity and mortality based on a real-life data registry. We believe that this analysis of 10-year long sAVR experience using bioprostheses will provide important results that can be translated to improve the daily practice of valve selection in sAVR.

We compared short and long-term outcomes and survival of the four most commonly used aortic bioprostheses: Hancock II, the Carpentier-Edwards Perimount Magna, the Carpentier-Edwards Perimount Magna Ease, and the Trifecta valve. We present this article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-1761/rc).

Highlight box

Key findings

- Surgical aortic valve replacement is a common procedure, with a shift towards bioprostheses.
- Comparative analysis of four bioprostheses revealed no significant differences in short-term mortality.
- Long-term survival up to 5 years showed higher mortality in the Hancock II group.
- Trifecta bioprosthesis demonstrated superior hemodynamics, while Perimount Magna Ease showed good mid-term durability.

What is known and what is new?

- Bioprostheses are increasingly used, and their performance has been extensively studied.
- This study adds comparative data on four commonly used bioprostheses, highlighting their differences in mortality and hemodynamics.

What are the implications, and what should change now?

- Surgeons can use these findings to inform bioprosthesis selection, particularly for younger patients.
- Further studies and longer follow-up are needed to validate the results and assess structural degeneration and mortality.
- Consideration of factors like hemodynamics, durability, and risk of complications should guide bioprosthesis choices.

Methods

This study used retrospective data from the Polish National Cardiac Surgery Database ("KROK" registry; www.krok.csioz.gov.pl). The registry is an ongoing, nationwide, registry of cardiac surgical procedures in Poland and an initiative of the Club of Polish Cardiac Surgeons in cooperation with the Polish Ministry of Health. Centers enrolling patients into the KROK registry are required to transfer the data regarding every cardiac surgery to the central database in the National Centre for Healthcare Information Systems at the Ministry of Health and are financially liable for data integrity and completeness (4). The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Ethical review and approval and patient consent were waived by the ethics committee of Jagiellonian University Bioethics Committee due to the retrospective nature of the study.

Patients and methods

This was a retrospective observational, single-center cohort study of 5,036 patients. The inclusion criterion was patients who underwent elective sAVR between 2009 and 2019. with implantation of one of the following biological valves: the Hancock II (Medtronic, Minneapolis, MA, USA), the Carpentier-Edwards Perimount Magna (Lifesciences Corp., Irvine, CA, USA), the Carpentier-Edwards Perimount Magna Ease (Lifesciences Corp.) and the Trifecta valve (Abbott, Abbott Park, IL, USA) (Figure S1).

Database

A database according to standard definitions, including demographic data, previous medical history, on-admission physical findings, pharmacological management, and outcomes, was developed. Data were collected either at presentation or by physician review of the hospital records and were forwarded to the KROK registry. The forms were reviewed to ensure clinical face validity and analytical internal validity.

Using the KROK database, we identified patients who underwent isolated aortic valve replacement as the first cardiac surgical intervention between January 2009 and December 2019. Patients who had previous cardiac surgery were excluded from the study. For patients undergoing sAVR, we collected baseline demographic characteristics including age, gender, diabetes, body mass index (BMI), body surface area (BSA), hypertension, hyperlipidemia, coronary artery disease, chronic kidney disease, extracardiac arteriopathy, chronic lung disease, asthma, pulmonary hypertension, tobacco use, left ventricle ejection fraction (LVEF), Canadian Cardiovascular Society (CCS) and New York Heart Association (NYHA) functional class, maximum preoperative aortic gradients, prosthesis size, extracorporeal circulation (ECC) time, aortic cross-clamping (ACC) time, time in the intensive care unit (ICU), total hospitalization time, in-hospital mortality, postoperative LVEF, postoperative mean gradient, postoperative maximum gradient, and complication rate. In-hospital mortality was defined as death occurring within 28 days after admission. Follow-up mortality was defined as death from any cause within 5 years after sAVR. Data on in-hospital and follow-up mortality were obtained from the National Health Fund, a mandatory public insurance institution in Poland.

Statistical analysis

Continuous variables were checked for normal distribution with the Kolmogorov-Smirnov test. Data expressed as mean ± standard deviation or median (interquartile range), unless otherwise stated elsewhere and compared using analysis of variance (ANOVA) or Kruskal-Wallis test with appropriate post hoc tests (Tukey HSD or Steel-Dwass, respectively). Categorical variables were expressed as count and percentage and compared with the chi-square test. Additionally, we performed linear regression analysis on the annual mortality data for each valve group. Furthermore, we employed the Kaplan-Meier method to assess both short-term and long-term survival rates.

All variables were screened as potential predictors of 5-year mortality using simple cox regression models. Among those with P value <0.2 and those deemed clinically important, multivariable model was created using stepwise regression with Bayes Information Criterion as target.

The model was standardized for age at the time of procedure, BMI, ejection fraction in echocardiography (%), patients' sex, hypertension, asthma, chronic lung disease. Statistical analysis was performed with R version 4.0.4 (Vienna, Austria, 2021) and with IBM SPSS Statistics for Windows, version 26.0. (IBM Corp., Armonk, NY, USA). A two-sided P value <0.05 was considered statistically significant.

Results

Patient characteristics

Among the 5,036 consecutive adult patients who underwent elective sAVR during the study period, we included 1,589 patients (31.5%) who met the inclusion criteria: 432 subjects in the Hancock group (27.2%), 356 subjects in the Perimount group (22.4%), 427 subjects in the Magna group (26.9%), and 374 patients in the Trifecta group (23.5%). The detailed data are shown in *Figure 1*.

Patients in the Hancock group were older, had lower height and body weight, had more frequently higher NYHA and CCS classes, diabetes but had significantly lower prevalence of hypertension, hyperlipidemia, and chronic lung disease in comparison with the other valves. Comparison between the other bioprostheses showed that patients in Trifecta group were also statistically older, had more cases of NYHA IV class and severe renal impairment

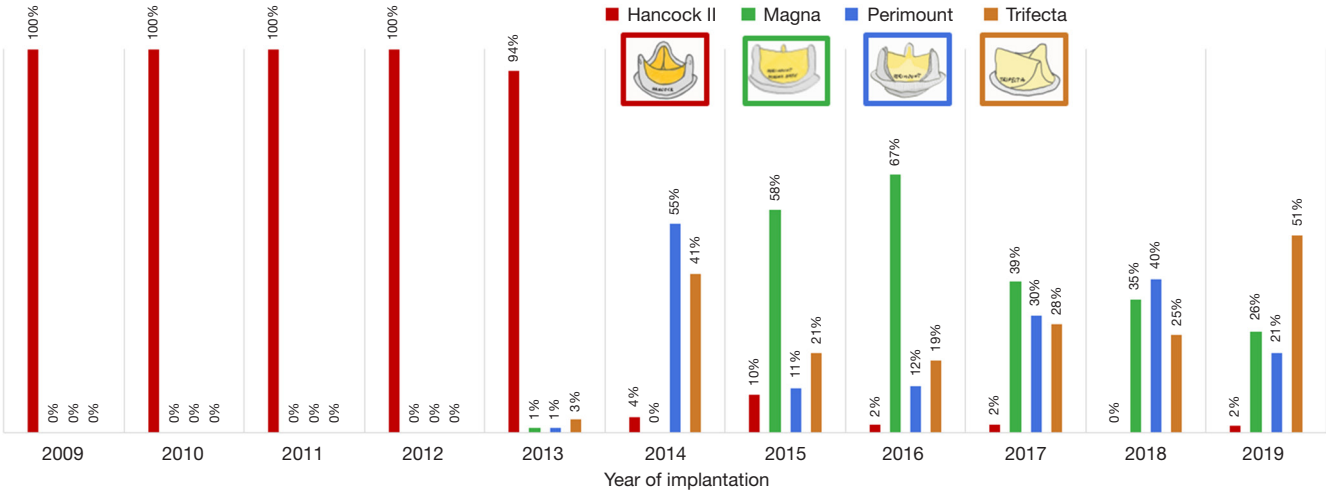


Figure 1 Type of bioprosthesis implanted in each year.

than the patients receiving Magna prosthesis. In Magna group there were less cases of coronary artery disease and renal impairment than in Perimount group, but on the other hand, the Perimount group had less cases of hypertension. Pair-comparison between Perimount, Magna and Trifecta did not show any statistical significance regarding the other parameters. Detailed patient characteristics are presented in *Table 1*.

Procedure and hospitalization

The lowest mean valve size was observed in Trifecta group, the highest in Magna group (P<0.05). The longest mean ECC time was observed in Hancock, the shortest in Magna group (P<0.05). The length of ICU hospitalization and overall rates of complications were significantly higher in Hancock group. Detailed procedural data are presented in *Table 2*.

Mortality

Survival analysis presented no significant differences (P=0.19) for in-hospital mortality period. In Hancock group in-hospital mortality was 3.94% (17/432), 3.09% in Perimount (11/356), 3.28% in Magna group (14/427) and 2.14% in Trifecta group (8/374). The detailed data are shown in *Figure 2*.

Five-year mortality was significantly higher (P<0.001) in Hancock group (25.64%) compared to other bioprostheses: 12.08% in Perimount group, 9.13% in Magna group and 10.70% in Trifecta group respectively (*Figure 3*). The overall 5 years mortality (with the death occurrence data last acquired in March 2020) was 40.65% in Hancock group, 9.37% in Magna group, 12.92% in Perimount group and 11.50% in Trifecta group. Comparison between other pairs apart from the Hancock group did not meet statistical significance regarding mortality rate. The overall observation time for all patients was 7,950 patient years. In that respect, there were 5.13 deaths/100 patient-years in Hancock group, 1.83 in Magna group, 2.42 in Perimount group and 2.14 in Trifecta group.

Cumulative event probability over time for Magna, Perimount and Trifecta groups rises significantly in the first year after procedure and then stabilizes over the next years, whereas for Hancock group, the probability gradually rises over time (*Figure 3*). An additional linear regression of the annual mortality of the four bioprostheses is shown in *Figure 4*.

Risk factor models for mortality using simple and complex Cox regression models showed that patient sex, BMI, and prevalence of asthma and chronic lung disease had no individual effect on mortality, whereas age at surgery, length of hospital stay, ejection fraction (EF) and prevalence of hypertension were risk factors for mortality. Cox regression showed that Hancock II valve is an independent risk factor and compared to other valves increases the risk by 94% (*vs.* Trifecta), 87% (*vs.* Magna Ease) and 49% (*vs.* Perimount Magna) (*Table 3*).

Table 1 Patient characteristic

Variables	Trifecta (N=374)	Hancock II (N=432)	Perimount (N=356)	Magna Ease (N=427)	P
Age (years)	68 [63–68]	74 [70–78]	68 [63–74]	67 [61–72]	<0.001
Gender					<0.001
Female	193 (51.6)	201 (46.5)	156 (43.8)	156 (36.5)	
Male	181 (48.4)	231 (53.5)	200 (56.2)	271 (63.5)	
BMI (kg/m^2)	29.3 [25.6–32.5]	28.2 [24.8–31.2]	29.5 [25.7–32.0]	28.8 [25.6–31.2]	0.03
BSA (m^2)	1.85 [1.71–1.99]	1.79 [1.68–1.91]	1.85 [1.74–1.99]	1.88 [1.76–1.99]	<0.001
EuroSCORE II	1.6 [0.9–1.7]	1.5 [0.9–1.8]	1.5 [0.9–1.6]	1.4 [0.8–1.4]	0.40
LVEF (%)	60 [50–65]	57 [45–64]	60 [50–62]	58 [50–60]	<0.001
Coronary artery disease (>50% stenosis)					<0.001
One artery	19 (5.1)	64 (14.8)	25 (7.0)	17 (3.9)	
Two arteries	2 (0.5)	18 (4.2)	6 (1.7)	5 (1.2)	
Three arteries	2 (0.5)	12 (2.8)	2 (0.6)	1 (0.2)	
Left main artery	9 (2.4)	4 (0.9)	10 (2.8)	11 (2.6)	
CCS					<0.001
CCS 1	156 (41.7)	132 (30.6)	164 (46.1)	181 (42.4)	
CCS 2	162 (43.3)	231 (53.5)	151 (42.4)	167 (39.1)	
CCS 3	19 (5.1)	48 (11.1)	13 (3.7)	18 (4.2)	
CCS 4	1 (0.3)	6 (1.3)	1 (0.3)	1 (0.2)	
NYHA					<0.001
NYHA 1	112 (30.0)	1 (0.2)	108 (30.3)	133 (31.2)	
NYHA 2	187 (50.1)	204 (47.2)	175 (49.2)	219 (51.4)	
NYHA 3	63 (16.8)	162 (37.5)	61 (17.1)	60 (14.1)	
NYHA 4	8 (2.1)	23 (5.3)	2 (0.6)	2 (0.5)	
Acute HF	1 (0.3)	0 (0.0)	(0.0)	2 (0.5)	
Hyperlipidemia	165 (44.1)	89 (20.6)	113 (31.7)	245 (57.4)	<0.001
Hypertension	349 (93.1)	369 (85.4)	321 (90.2)	404 (94.6)	<0.001
Atrial fibrillation	11 (2.9)	73 (17.0)	21 (5.9)	0 (0.0)	0.001
Chronic lung disease	172 (46.0)	40 (9.3)	161 (45.2)	170 (39.8)	<0.001
Diabetes insulin dependent	44 (11.8)	38 (8.8)	35 (9.8)	50 (11.7)	<0.001
Renal impairment		*N=162			
Normal (CC ≥85 mL/min)	257 (68.7)	97 (22.4)	245 (68.8)	324 (75.9)	<0.001
Moderate (CC ≥50 & <85 mL/min)	84 (22.5)	47 (10.9)	91 (25.6)	100 (23.4)	
Severe (CC <50 mL/min)	30 (8.0)	16 (3.7)	18 (5.1)	2 (0.5)	
Dialysis (regardless of CC)	3 (0.8)	2 (0.5)	2 (0.6)	1 (0.2)	

Table 1 (*continued*)

Table 1 (*continued*)

Variables	Trifecta (N=374)	Hancock II (N=432)	Perimount (N=356)	Magna Ease (N=427)	P
Pulmonary hypertension (mmHg)		*N=199			
Severe [>55]	6 (1.6)	2 (0.5)	4 (1.1)	2 (0.5)	<0.001
Moderate [31–55]	163 (43.7)	12 (2.8)	153 (43.0)	161 (37.7)	
None	205 (54.8)	178 (41.2)	199 (55.9)	264 (62.0)	
Extracardiac arteriopathy	5 (1.3)	7 (1.6)	5 (1.4)	5 (1.2)	0.95
Smoking					
Active smoker	20 (5.3)	38 (8.8)	18 (5.1)	21 (4.9)	0.16
Former smoker	19 (5.1)	26 (6.0)	28 (7.9)	29 (6.8)	
Never smoker	335 (89.6)	368 (85.2)	310 (87.1)	376 (88.1)	
Max. preoperative aortic gradients (mmHg)	85.6 [72.5–97.0]	89.3 [72.0–103.0]	83.5 [70.0–94.0]	84.2 [74.0–92.0]	0.02

Data are presented as median [lower quartile – upper quartile] or n (%). *, some patient data is missing here. BMI, body mass index; BSA, body surface area; LVEF, left ventricular ejection fraction; CCS, Canadian Cardiovascular Society; NYHA, New York Heart Association; HF, heart failure; CC, creatinine clearance.

Table 2 Procedural details

Variables	Trifecta (N=374)	Hancock II (N=432)	Perimount (N=356)	MAGNA (N=427)	P
Prosthesis size					<0.001
17 mm	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
19 mm	41 (11.0)	0 (0.0)	22 (6.2)	18 (4.2)	
21 mm	131 (35.0)	0 (0.0)	104 (29.2)	124 (29.0)	
23 mm	143 (38.2)	202 (46.8)	138 (38.8)	149 (34.9)	
25 mm	56 (15.0)	153 (35.4)	75 (21.1)	109 (25.5)	
27 mm	2 (0.5)	63 (14.6)	17 (4.8)	26 (6.1)	
29 mm	1 (0.3)	9 (2.1)	0 (0.0)	0 (0.0)	
31 mm	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	
33 mm	0 (0.0)	5 (1.1)	1 (0.3)	0 (0.0)	
35 mm	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	
ECC time (min)	106 [84–120]	113 [90–129]	108 [86–122]	105 [85–120]	<0.001
ACC (min)	70 [55–81]	72 [58–83]	69 [57–80]	67 [56–83]	0.047
Time on ICU (day)	2.5 [2–6]	4.5 [2-9]	2.7 [2–6]	2.4 [2–7]	<0.001
Hospitalization (day)	12.0 [9–14]	12.9 [9–15]	11.8 [9–13]	12.2 [9–14]	<0.001
In hospital mortality	8 (2.1)	17 (3.9)	11 (3.1)	14 (3.3)	0.54
Complication rate	31 (8.3)	81 (18.75)	41 (11.5)	37 (8.7)	<0.001
Postoperative LVEF (%)	47 [42–55]	43 [35–48]	46 [41–50]	47 [43–50]	<0.001
Mean gradient (mmHg)	10 [8–10]	17 [12–22]	13 [10–17]	14 [10–18]	<0.001
Maximum gradient (mmHg)	18 [13–23]	28 [21–35]	22 [18–29]	23 [18–30]	<0.001

Data are presented as median [lower quartile – upper quartile] or n (%). ECC, extracorporeal circulation time; ACC, aortic cross clamping; ICU, intensive care unit; LVEF, left ventricle ejection fraction.

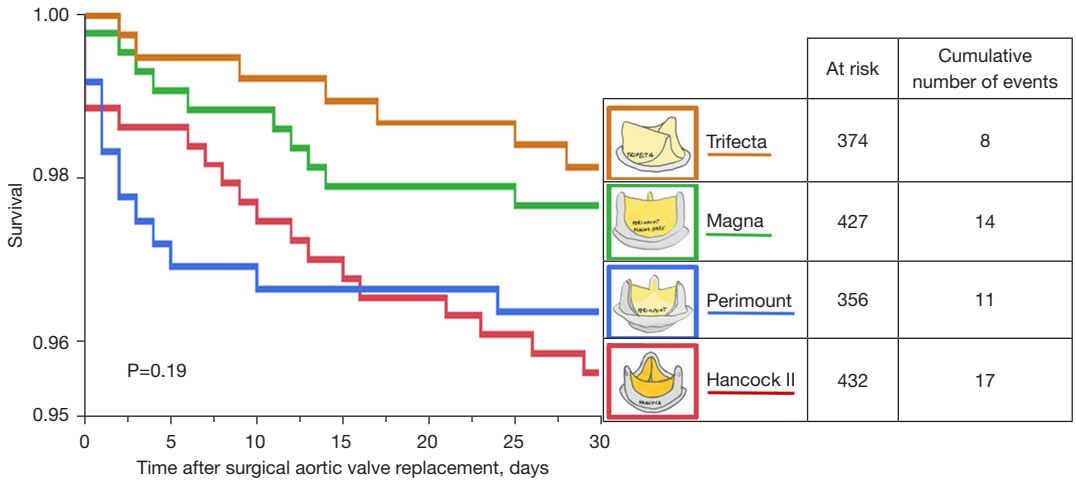
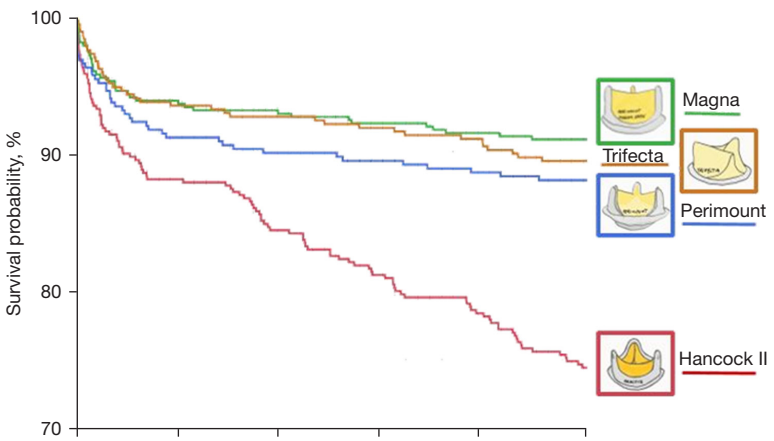


Figure 2 In-hospital mortality estimated by the Kaplan-Meier methods for the Hancock II, the Carpentier-Edwards Perimount Magna, the Carpentier-Edwards Perimount Magna Ease, and the Trifecta bioprostheses (log-rank test P=0.19).



		Year	0	1	2	3	4	5
	Hancock II	At risk	433	381	365	351	338	332
		Cumulative No. of events	5	52	68	82	95	111
	Trifecta	At risk	374	349	346	343	338	334
		Cumulative No. of events	0	25	28	31	36	40
	Magna Ease	At risk	427	399	396	393	390	388
		Cumulative No. of events	1	28	31	34	37	39
	Perimount Magna	At risk	356	324	320	318	315	313
		Cumulative No. of events	3	32	36	38	41	43

Figure 3 The long-term survival estimated by the Kaplan-Meier methods for the Hancock II, the Carpentier-Edwards Perimount Magna, the Carpentier-Edwards Perimount Magna Ease, and the Trifecta bioprostheses (log-rank test P<0.001) and the cumulative risk of mortality events for each group of valves.

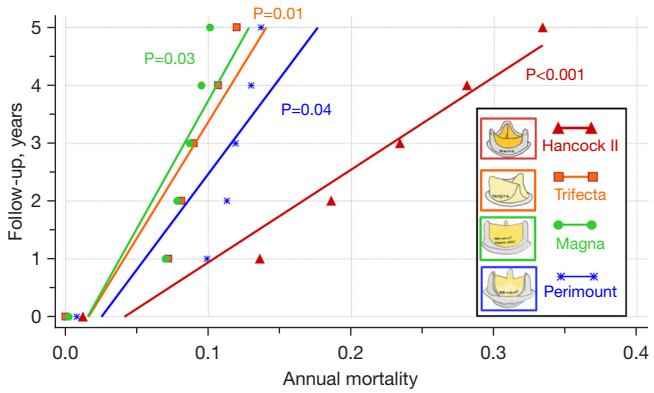


Figure 4 Linear regression of the annual mortality for each group of valves.

In addition, we calculated a sensitivity analysis for 5-year mortality for two groups: Hancock II *vs.* other bioprostheses (Trifecta/Perimount/Magna) matched (Figures S2-S4) for age, sex, EuroSCORE II, and postoperative indexed effective orifice area (iEOA) (Tables S1,S2). Sensitivity analysis for long-term mortality showed no significant differences (Figure S5).

Discussion

sAVR is one of the most common cardiac surgical procedures worldwide (1,2). Recently, more patients are becoming candidates for a bioprosthesis rather than a mechanical valve (3,5). This has been accompanied by the invention of new types and generations of biological valves with the aim of improving durability and reducing the risk of structural valve degeneration (SVD) (6).

Currently, various medical device manufacturers offer at least over a dozen bioprostheses, so the natural question arises: Is any of them superior or, on the other hand, less reliable than others. This is a valid question that could help surgeons decide on which bioprosthesis is the best option for patients. There are many studies investigating the short, medium, and long-term performance of different types of valves, as well as comparative studies of two or three types of bioprostheses. To our knowledge, this is the first report with a comparative description of these four valve types. The results obtained will allow more efficient selection of the implanted prosthesis, especially in the group of younger patients in whom percutaneous aortic valve implantation may be required in the future.

The Hancock II was one of the first bioprostheses used in our institution, with the earliest implantation dating back to 2009. Hancock II was first introduced in 1982 and is a second generation stented porcine valve. Originally, this valve was intended for elderly patients with multiple comorbidities, short life expectancy and increased risk of mortality and morbidity. In later years, as confidence in bioprostheses increased and the number of indications grew, other valve types became part of our daily clinical routine (*Figure 1*). There were no significant differences in in-hospital and 30-day mortality between all bioprosthesis types compared (*Figure 2*). Significant differences were observed in long-term survival up to 5 years of observation, with mortality in the Hancock II group at least twice that of the other bioprostheses (*Figure 3*). This observation raises the question whether the increased mortality is due to increased morbidity and age of the patients or whether Hancock II itself is a risk factor for long-term mortality. Our multiple regression analysis showed that the use of Hancock II valve was an independent risk factor. As clinicians, we also believe that one of the factors associated with increased long-term mortality in the Hancock II group is the fact that it was the first type of valve implanted in our center. This is related to the learning curve of valve implantation, postoperative management, and follow-up care provided by the primary care physician or cardiologist. In the case of subsequent valve implantations, both our center and other units caring for the patient after surgery had gained experience from the use of Hancock II.

However, what the authors want to emphasize, that patients in the Hancock II group were older and had more comorbidities than in the other groups. This presumably resulted in a higher cumulative risk of death over the years and higher mortality in the Hancock II group. Furthermore, sensitivity analysis for 5-year mortality (Hanock II *vs.* other bioprostheses) matched for age, sex, EuroSCORE II, and iEOA showed no statistically significant differences. Therefore, the obtained results should be interpreted with caution.

Borger *et al.* published a matched hemodynamic comparison of Carpentier-Edwards Perimount Magna and Hancock II (7). They found significantly lower transvalvular gradients, fewer cases of patients with prosthesis mismatch, and a trend toward greater EOAs for the Magna valve during short-term follow-up. These data may suggest that a worse hemodynamic effect that negatively impacts survival in the Hancock group. In our work, the Hancock II had

Table 3 Simple cox regression models and multiple regression model for risk ratios for mortality

Variables	Simple cox regression models		Multiple cox regression model (best model)	
	OR (95% CI)	P value	OR (95% CI)	P value
Age at the time of procedure (1 year)	1.06 (1.04–1.08)	<0.001	1.05 (1.03–1.07)	<0.001
Gender				
Male	1	–	1	–
Female	1.05 (0.81–1.35)	0.73	1.025 (0.78–1.38)	0.86
BMI	0.983 (0.956–1.011)	0.23	0.997 (0.97–1.03)	0.85
Hospitalization time (10 days)	1.37 (1.29–1.45)	<0.001	–	–
ICU time (10 days)	1.08 (1.04–1.10)	<0.001	–	–
LVEF (10%)	0.81 (0.74–0.9)	<0.001	–	–
ECT (10 minutes)	1.08 (1.05–1.11)	<0.001	–	–
Hypertension				
Lack	1	–	1	–
Yes—treated	0.62 (0.42–0.92)	0.02	0.657 (0.43–0.98)	0.04
Yes—not treated	6.42 (1.53–26.93)	0.01	5.784 (1.31–25.46)	0.02
Asthma				
Lack	1	–	1	–
Yes—treated	2.22 (1.1–4.5)	0.03	2.21 (1.09–4.51)	0.03
Yes—treated with steroids	5.28 (0.74–37.66)	0.10	7.25 (0.99–52.99)	0.05
Chronic lung disease				
Lack	1	–	1	–
Yes—treated	0.623	0.002	0.83 (0.602–1.147)	0.26
Implanted bioprosthesis				
Hancock II *vs.* Trifecta	2.56 (1.78–3.68)	<0.001	1.95 (1.31–2.89)	<0.001
Hancock II *vs.* Perimount	2.23 (1.56–3.16)	<0.001	1.5 (1.02–2.2)	0.04
Hancock II *vs.* Magna Ease	3.0 (2.08–4.32)	<0.001	1.88 (1.26–2.79)	0.002
Mean postoperative gradient	0.87 (0.71–1.06)	0.13	0.98 (0.81–1.21)	0.76
Max. postoperative gradient	0.98 (0.71–1.37)	0.79	1.15 (0.82–1.62)	0.51

BMI, body mass index; ICU, intensive care unit; LVEF, left ventricular ejection fraction; ECT, extracorporeal circulation time; OR, odds ratio; 95% CI, 95% confidence interval.

the highest postoperative transvalvular mean and maximum gradients. In 2010, David *et al.* published the results of more than twenty years of experience with Hancock II. Freedom from SVD at 20 years was 63.4% in the entire cohort, 29.2% in patients younger than 60 years, 85.2% in patients aged 60 to 70 years, and 99.8% in patients older than 70 years (truncated at 18 years). The overall freedom from AVR at 20 years was 65.1% for any reason, 29.8% in patients younger than 60 years, 86.8% in patients between 60 and 70 years, and 98.3% in patients older than 70. Survival at 20 years was 54.9% in patients younger than 60 years, 22.7% in those between 60 and 70, and 2.4% in those older than 70 (P=0.01). Only 6.6% of deaths were valve-related (8).

For the other three valve types, there was no statistically significant difference between short- and long-term mortalities in our study. Better survival rates were noted in the Trifecta group, but the results did not reach statistical significance.

Perimount Magna Ease is a stented bovine pericardial valve available in the market since 2005. A few changes were made to the pre-existing Perimount Magna valve such as lower valve profile and lower cusp height with a scalloped sewing ring. This valve proved to have good hemodynamics that translated onto improved post-procedure NYHA class. In addition, this valve has been found to demonstrate good mid-term durability, with no evidence of structural valve deterioration or patient-prosthesis mismatch (9,10)

The Trifecta bioprosthesis is a bovine pericardial valve mounted on a titanium stent. In 2019, Kilic *et al.* reported the mid-term results of the Trifecta valve from a large population of approximately 2,000 patients and presented the mid-term durability and hemodynamic parameters (11). The 5-year survival rate was 70% for the entire study cohort and 78% for elective isolated SAVRs. The overall freedom from aortic valve reintervention at 5 years was 96%, and the freedom from reoperation for SVD was 99%. Patients in this series had severe PPM and the rate of moderate PPM was 13%. Kaneyuki *et al.* reported a case series with early failure of the Trifecta valve. During follow-up, 6.5% of implanted Trifecta bioprostheses showed evidence of stenosis or severe regurgitation due to pannus formation with avulsion of the non-coronary cusp and calcification of the leaflet in patients with higher rates of preoperative end-stage disease and postoperative PPM (12). Fukuhara *et al.* from the University of Michigan came to similar conclusions (13). The authors retrospectively studied 1,058 cases of bioprosthesis implantation and found that the incidence of SVD was higher in patients implanted with a Trifecta bioprosthesis, with a significant increase in cases between 5 and 7 years after implantation. In our study, the mean time to death was shorter than the time to SVD in the above studies. When discussing the Trifecta valve, it should be noted that in 2023 the Food and Drug Administration (FDA) has received reports of early structural valve deterioration (SVD) among Abbott Trifecta heart valve replacement devices, especially within 3 to 4 years of implantation. However, based on our data, we cannot confirm or refute these findings. This is due to the fact that SVD was not evaluated in our study. Of note, there are also reports in the literature of intraoperative Trifecta malfunction requiring immediate bioprosthesis reimplantation (14).

There are several comparative studies in the literature between the Trifecta valve and other aortic bioprostheses. A multicenter European study comparing 469 Magna Ease versus 322 Trifecta implants demonstrated the superior hemodynamic performance of the Trifecta valve across all valve sizes at echocardiographic follow-up 6 to 12 months after implantation (15). The incidence of severe PPM in this study was 0.6% in the Trifecta cohort and 8.5% in the Magna Ease cohort, which was highly significant. Our work confirms these results: Trifecta had the best hemodynamic parameters and achieved the lowest mean and maximum transvalvular gradients.

Another study from Finland comparing Trifecta and Magna Ease valves showed that Trifecta was associated with a higher incidence of repeat aortic valve replacement due to SVD after 7 years of follow-up compared with Perimount Magna Ease. However, similar to our analysis, mortality was comparable between these two bioprostheses (16).

In 2016, Bach *et al.* showed the results of a prospective, randomized trial comparing three bioprosthesis types: Freestyle, Magna Ease, and Trifecta at rest and with weight bearing 6 months after surgery. The study showed, in agreement with previous studies that were mainly retrospective, that all three valves had good hemodynamics at rest and on load, with statistically significant but relatively small differences in favor of Trifecta over Magna Ease (17). In contrast, a retrospective study by Wendt *et al.* compared the hemodynamic performance of the Trifecta valve with the Perimount-Magna and Perimount Magna-Ease valves. Mean pressure gradients and aortic valve areas appeared to be beneficial for the Trifecta valve at 6-month follow-up, but on further analysis, the type of prosthesis itself had no effect on these parameters (18).

Compared with Hancock II these three bioprostheses: Trifecta, Perimount Magna, and Perimount Magna Ease are relatively new to the market with limited long-term data. Currently, there is no evidence or robust data to support or strongly oppose the use of any of the three valves.

Each year, biologic valves are implanted with increasing frequency in younger patients (1,5,19). This is not only due to the longer durability of the prosthesis, but also due to the rapid development of the valve-in-valve technique of transcatheter aortic valve replacement (VIV TAVR), which cannot be performed after a mechanical prosthesis (20). However, valve-in-valve remains challenging and may fail, especially in patients with small implanted bioprosthesis who are at increased risk of PPM. To avoid PPM, a

technique to dilate the aortic annulus is recommended, but due to the difficulty of these techniques, it is only performed in the most experienced centres. In our study, none of the patients had aortic annular dilation. Therefore, most surgeons who decide to implant a prosthesis with a small size choose a bioprosthesis with the largest EOA.

In our study, Trifecta was the most commonly implanted bioprosthesis in patients with a narrow ring (size 19–21 mm), having the best hemodynamic profile and the largest EOA among the compared prostheses (9). Despite its better hemodynamics, the Trifecta bioprosthesis, similar to the Hancock bioprosthesis, cannot be fractured with high pressure balloons (HPB) (21). Therefore, in the group of younger patients who plan to undergo the procedure in the future, the choice of Perimount or Magna Ease seems reasonable. The plastic stent of these bioprostheses can be easily fractured by HPB, which allows the implantation of a larger size valve, reducing the risk of PPM (21).

It should be mentioned here that the latest generation of biologic bioprostheses using RESILIA tissue with flexible ring design for further VIV TAVR procedures have excellent short-term and 5-year results (4,22) with the low rate of SVD, but long-term data are still awaited.

Conclusions

Comparison of the four commonly used bioprostheses showed that Trifecta, Perimount Magna, and Magna Ease had similar 5-year mortality rates. Observed mortality was higher in the Hancock group compared to the other valves. However, patients in the Hancock II group were older and had more concomitant diseases than in the other groups. This probably led to a higher cumulative risk of death over the years and higher mortality in the Hancock II group. Furthermore, sensitivity analysis for 5-year mortality (Hanock II *vs.* other bioprostheses) adjusted for age, sex, EuroSCORE II, and iEOA showed no statistically significant differences. Therefore, the obtained results should be interpreted with caution.

The authors would like to emphasize that the present study only provides initial data that represent a hypothesis and that prospective controlled studies are needed to further confirm the study results. Also, a longer follow-up (10 years) could be useful to detect more cases of structural bioprosthesis degeneration and mortality.

Study limitations

This study has several limitations. This is a non-randomized, retrospective, observational study. Due to the retrospective nature of the registry used to construct our database, we do not have data on the specific cause of death. There is a lack of follow-up echocardiographic data. In addition, the study does not evaluate the incidence of SVD, which is a crucial factor in the choice of prosthetic valves and has a direct impact on mortality and the need for reoperation. The study does not analyze the phenomenon of patient prosthesis mismatch. Follow-up period is limited to 5 years, extended follow up (10 years) may be useful to detect more cases of SVD and mortality. Due to the retrospective nature of the registry, other factors unrelated to the patient and the prosthesis could have influenced the results, such as the surgeon's experience and preferences in valve selection, the learning curve, the year of bioprosthesis implantation, and the primary care physician's experience in managing patients with a biological prosthesis. Lack of propensity matching limits conclusions about Hancock II valve and mortality: there may be unmatched confounders responsible for higher mortality associated with this older generation valve.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Ethical review and approval and patient consent were waived by the ethics committee of Jagiellonian University Bioethics Committee due to the retrospective nature of the study.

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