Original Article

Mid- to Long-term Clinical Outcomes of Hancock II Bioprosthesis in Chinese Population

Yin Wang, Si Chen, Xing-Jian Hu, Jia-Wei Shi, Nian-Guo Dong

Department of Cardiovascular Surgery, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, Hubei 430022, China

Abstract

Background: Compared to the Western countries, Chinese patients present a special primary disease spectrum, diverse valvular pathogenesis, and different postoperational anticoagulation strategy. This research aimed to evaluate the mid- to long-term clinical performance of Hancock II bioprosthesis in the Chinese population.

Methods: This study retrospectively reviewed all patients who received surgical treatments with at least one Hancock II bioprosthesis implantation from January 2004 to December 2013 at a single center in China. Totally 647 patients were included in the clinical evaluation, and 629 patients were successfully discharge, among whom 605 patients were completely followed-up. The follow-up rate was 96.2%. The mean and median follow-up time was 62.0 ± 59.0 and 56.0 months, respectively. Postoperative outcomes of survival rates, reoperations and valve related morbidities were assessed. Continuous and categorical variables were compared using the *t* -test and Chi-square test, respectively. Survival and freedom from adverse events were calculated by using a Kaplan–Meier method.

Results: The overall in-hospital mortality was 2.8% (18/647) while there were 34 deaths (5.6%, 34/605) in the follow-up stage after discharge. The overall survival rate was 94.6% and 82.7% at 5 years and 10 years, respectively. The cumulative survival rate of 10 years was 82.8% in AVR group, 84.4% in MVR group, and 78.4% in DVR group. The overall rate of freedom from reoperations was 95.5% at 5 years and 86.8% at 10 years. The freedom from reoperation at 10 years was 87.0%, 88.1%, and 84.0% in AVR, MVR, and DVR group, respectively. The freedom from morbidities at 10 years was: 90.3% for thromboembolism, 95.2% for hemorrhage, 97.5% for prosthesis endocarditis, 95.9% for paravalvular leak, and 94.6% for structural valve deterioration, respectively.

Conclusions: Hancock II bioprosthesis exhibited a satisfactory mid- to long-term durability and promising clinical performance in the Chinese population. The occurrence rates of death and other adverse events in this single-center study were overall coincident and quite acceptable when compared with existing data.

Key words: Bioprosthesis; Clinical Outcome; Durability; Valve Replacement

Introduction

Innovations in valve material treatment methods and improvements in stent designs have contributed to improved bioprosthetic valve durability and efficiency.[1] The bioprosthesis has become-dominant in most developed countries while its excellent clinical effects have been confirmed in several European and American studies.[2-9] Guidelines from the 2014 American College of Cardiology/American Heart Association and the 2012 European Society of Cardiology both expanded the indications for bioprosthetic valve replacement.[10,11] Although China has a huge population of heart valve disease patients, the practice of bioprosthesis was limited since the majority of valve disease patients are young and suffer from rheumatic heart disease.[12,13] Few Chinese centers have published their clinical experiences on bioprosthetic valve replacements. Similarly, accurate evaluation of its clinical durability and postoperative outcomes in China were barely reported. Hence, we assessed the 10-year clinical outcomes of the Hancock II bioprosthesis since its first application in our center in 2004. To our knowledge, this is the first large-scale, single center retrospective study illustrating Hancock II bioprosthesis performance in China.

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Address for correspondence: Dr. Nian-Guo Dong, Department of Cardiovascular Surgery, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, Hubei 430022, China
E-Mail: dongnianguo@hotmail.com

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Methods

We retrospectively reviewed all patients who had undergone valve replacements between January 2004 and December 2013 at the Department of Cardiovascular Surgery, Wuhan Union Hospital, China. We included all patients who had received Hancock II bioprosthesis (Medtronic Inc., Minneapolis, MN, USA). Basic clinical and surgical data were acquired from the hospital medical records. Follow-up information was acquired through a periodic telephone interview, outpatient subsequent visit, and echocardiographic re-examination. The mean follow-up duration was 62.0 ± 59.0 months (median 56.0 months) and 96.2% patients were completely followed-up.

Study endpoints

Adverse events were classified according to "Guidelines for Reporting Morbidity and Cardiac Valvular Operations" from the Society of Thoracic Surgeons/American Association for Thoracic Surgery.[14] The primary endpoint of the study was postoperative death that occurred within 30 days after the surgery or before discharge from the hospital. Late mortality was defined as death that happened after 30 days of the surgery or after discharge. The secondary endpoint was defined as valve-related complications, consisting of hemorrhage, thromboembolism, prosthetic valve endocarditis, structural valve deterioration (SVD), and nonstructural dysfunctions such as paravalvular leakage. SVD included any dysfunction or deterioration of the artificial bioprosthesis, excluding infection or thrombosis, and it was observed by echocardiography and/or reoperation. Thromboembolic events were diagnosed by clinical examinations, including stroke, transient ischemic attack and non-cerebral embolic events. Bleeding events referred to major bleeding episode requiring hospitalization or blood transfusion.[15]

Statistical analysis

All data analysis was performed with Statistical Package for Social Sciences 19.0 (SPSS, Inc., Chicago, IL, USA). Continuous variables were expressed as a mean ± standard deviation (SD), and were compared using the Student's *t*-test. Categorical variables were expressed as percentages and were compared with the Chi-square test or Fisher's exact test. The time-to-event analysis such as mid-long term survival, freedom from reoperation, and freedom from valve related morbidities were estimated by using the Kaplan–Meier technique and differences in survival were compared using the log-rank test. All tests were two-tailed, and a $P < 0.05$ was considered as statistically significant.

Results

Between January 2004 and December 2013, there were 5438 patients receiving AVR, MVR or DVR at our center. Among that, 647 patients (11.9%) underwent the valve replacement with Hancock II bioprosthesis. There was an increasing trend in choosing Hancock II bioprosthesis during last decade at our center. The annual amount and proportion of patients receiving the valve replacement with Hancock II bioprosthesis are described in Figure 1. In the overall population, the average age was 61.9 ± 18.3 years (range, 16–83 years) at the time of the surgery, 50.2% of the patients were men, and 262, 311, and 74 patients underwent aortic valve replacement (AVR), mitral valve replacement (MVR) and double valve replacement (DVR), respectively. Demographic and clinical characteristics of these patients are summarized in Table 1. The patients that underwent MVR were mostly female and more likely to suffer from mitral valve stenosis rather than regurgitation. Higher occurrences of the atrial fibrillation or tricuspid valve lesions were observed in the MVR group. Most patients who underwent AVR suffered from aortic insufficiency with a higher preoperative left ventricular ejection fraction (LVEF). The patients receiving DVR procedures were correlated with a lower preoperative LVEF.

Postoperative mortality

Eighteen patients died within the first 30 days after operations or prior to hospital discharge. The early mortality rate was 2.8% in the overall cohort, and was 2.7%, 2.3%, and 5.4% in AVR, MVR, and DVR group, respectively. The perioperative mortalities of these three groups had no significant difference. The major causes of early death were cardiac-related complications including low cardiac outputs syndrome, multiple organ failures, and malignant arrhythmias [Table 2].

Totally 18 patients died before the discharge, and 24 patients were lost during the follow-up, hence, totally 605 patients were included in the analysis of mid- to long-term outcomes. There were 34 cases of late death during the follow-up: 15 in AVR group, 13 in MVR group, and 6 in DVR group. Figure 2 shows the overall survival curve. 5- and 10-year overall survival rate was 94.6% and 82.7%, respectively. The survival curves of the three groups are presented in Figure 3. Ten-year actuarial survival rate was 82.8%, 84.4%, and 78.4% for AVR, MVR, and DVR groups, respectively. No significant difference in the late survival rate existed among the three groups ($P = 0.570$).

Reoperation

Reoperations were performed in 27 patients (12 in AVR group, 11 in MVR group, and 4 in DVR group), including 12 for SVD, 7 for endocarditis and 8 for paravalvular leak. The overall freedom from reoperation at 5 and 10 years was 95.5% and 86.8%, respectively [Figure 4]. Figure 5 shows the actuarial freedom from reoperation of the three groups. Actuarial freedom from reoperation at 10 years was 87.0%, 88.1%, and 84.0% for the AVR, MVR, and DVR groups, respectively. There was no significant difference of freedom from reoperation among the three groups ($P = 0.854$).

Valve related morbidities

Hemorrhage

A major bleeding episode requiring hospitalization or blood transfusion occurred in 21 patients (3.5%). All of these patients were concomitant with atrial fibrillation and treated with warfarin sodium for anticoagulation after the valve replacement. At 5 years, the actuarial freedom from hemorrhage was 97.8%, 95.8%, and 95.4% in the AVR, MVR, and DVR group, respectively. At the last follow-up contact, 96.1%, 94.2%, and 95.4% of the patients in AVR, MVR, and DVR groups were free from hemorrhage complications, respectively [Table 3].

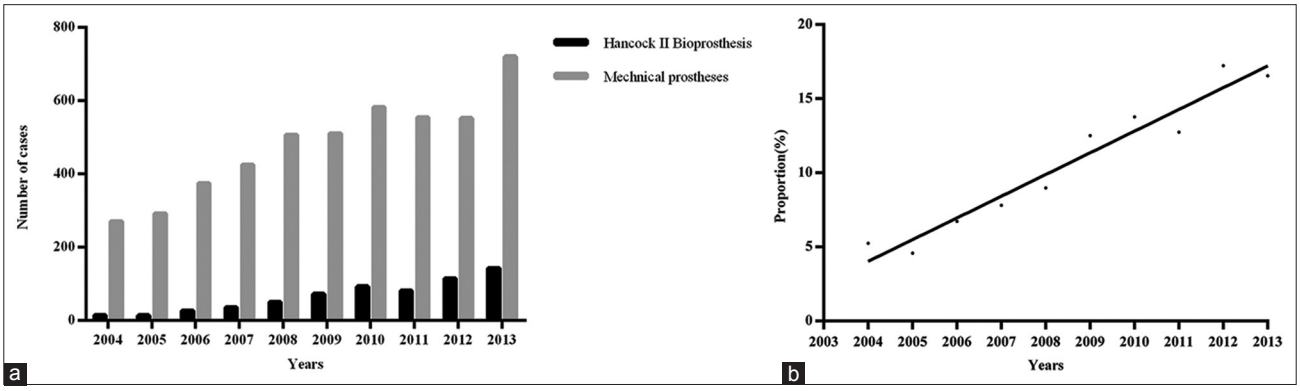

Figure 1: Variations of annual cases (a) and proportion (b) of patients with Hancock II bioprosthesis replacement during the last decade.

Table 1: Preoperative characteristics and operative data of the study population

Variables	Total (n = 647)	AVR (n = 262)	MVR (n = 311)	DVR (n = 74)	χ^2 or t value			P value		
					AVR vs MVR	AVR vs DVR	MVR vs DVR	AVR vs MVR	AVR vs DVR	MVR vs DVR
Age (years)	61.9 ± 18.3	61.1 ± 19.6	62.8 ± 17.3	60.9 ± 15.3	1.10	0.08	0.88	0.754	0.897	0.103
Male	325 (50.2)	175 (66.8)	114 (36.7)	36 (48.6)	51.67	8.13	3.62	<0.001†	0.004*	0.057
NYHA Class III/IV	438 (67.7)	177 (67.6)	204 (65.6)	47 (63.5)	0.01	0.06	0.11	0.909	0.515	0.557
Left ventricular function										
LVEF >50%	422 (65.2)	163 (62.2)	214 (68.8)	45 (60.8)	2.75	0.05	1.74	0.040	0.827	0.111
30%< LVEF ≤50%	187 (28.9)	88 (33.6)	81 (26.0)	18 (24.3)	3.89	2.29	0.09	0.049*	0.130	0.701
LVEF ≤30%	38 (5.9)	11 (4.2)	16 (5.1)	11 (14.9)	0.28	10.73	8.66	0.594	0.001†	0.003†
Cardiac rhythm										
Sinus rhythm	454 (70.2)	213 (81.3)	186 (59.8)	55 (74.3)	31.06	1.74	5.38	<0.001†	0.187	0.020*
Atrial fibrillation	175 (27.0)	43 (16.4)	118 (37.9)	14 (18.9)	32.63	0.26	9.60	<0.001†	0.612	0.002†
Others	18 (2.8)	6 (2.3)	7 (2.3)	5 (6.8)	0.46	3.64	4.02	0.975	0.057	0.045
History of stroke	39 (6.0)	11 (4.2)	24 (7.7)	4 (5.4)	3.07	0.20	0.47	0.080	0.657	0.491
Previous cardiac surgery	37 (5.7)	16 (6.1)	18 (5.8)	3 (4.1)	0.03	0.46	0.35	0.872	0.500	0.555
Isolated valve implantation	417 (64.5)	177 (67.6)	203 (65.3)	37 (50.0)	0.33	7.71	0.02	0.564	0.006†	0.015
Combined procedure	230 (35.5)	85 (32.4)	108 (34.7)	37 (50.0)	0.17	7.07	5.94	0.564	0.006†	0.015*
CABG	87 (13.4)	39 (14.9)	38 (12.2)	10 (13.5)	0.87	0.09	0.09	0.351	0.768	0.762
Ascending aorta surgery	10 (1.5)	9 (3.4)	–	1 (1.4)	10.85	0.87	4.23	<0.001†	0.352	0.040*
Tricuspid valve surgery	80 (12.4)	13 (5.0)	45 (14.5)	22 (29.7)	14.13	37.92	9.68	<0.001†	<0.001†	0.002†
Congenital heart disease	43 (6.6)	19 (7.3)	21 (6.8)	3 (4.1)	0.05	0.96	0.74	0.815	0.326	0.388
Others	10 (1.5)	5 (1.9)	4 (1.3)	1 (1.4)	0.36	0.10	0.01	0.551	0.749	0.964
Valve lesion										
Stenosis	182 (28.1)	49 (18.7)	89 (28.7)	17 (23.0)	7.65	0.67	0.95	0.006*	0.414	0.329
Insufficiency	279 (43.1)	170 (64.9)	96 (30.9)	15 (20.3)	66.16	46.42	3.27	<0.001†	<0.001†	0.070
Mixed lesion	186 (28.7)	43 (16.4)	111 (35.7)	32 (43.2)	26.89	23.96	1.46	<0.001†	<0.001†	0.227
Implanted valve size				AVR/MVR[a]						
21 mm	63 (9.7)	44 (16.8)	–	19 (25.7)/–						
23 mm	124 (19.2)	98 (37.4)	–	26 (35.1)/–						
25 mm	111 (17.2)	92 (35.1)	–	19 (25.7)/–						
27 mm	140 (21.6)	28 (10.7)	87 (28.0)	10 (13.5)/ 15 (20.3)						
29 mm	156 (24.1)	–	125 (40.2)	–/31 (42.0)						
31 mm	127 (19.6)	–	99 (31.8)	–/28 (37.8)						

Values are n (%) or mean±SD; *P<0.05; †P<0.001. NYHA: New York Heart Association; CABG: Coronary artery bypass grafting; LVEF: Left ventricular ejection fraction. AVR: Aortic valve replacement; MVR: Mitral valve replacement; DVR: Double valve replacement; "AVR vs MVR" means the difference between AVR and MVR group; "AVR vs DVR" means the difference between AVR and DVR group; "MVR vs DVR" means the difference between MVR and DVR group. "a" means numbers of implanted valve sizes (21mm-27mm) at aortic position/numbers of implanted valve sizes (27mm-31mm) at mitral position.

Table 2: Postoperative morality and survival of the study population

Variables	Total (n = 647)	AVR (n = 262)	MVR (n = 311)	DVR (n = 74)	χ^2 value			*P* value		
					AVR vs MVR	AVR vs DVR	MVR vs DVR	AVR vs MVR	AVR vs DVR	MVR vs DVR
Perioperative mortality	18 (2.8)	7 (2.7)	7 (2.3)	4 (5.4)	0.12	1.56	2.46	0.73	0.21	0.117
Causes of death										
Low cardiac output	7 (1.1)	4 (1.5)	1 (0.3)	2 (2.7)	2.43	0.54	4.72	0.12	0.46	0.03*
Multiple organ failure	5 (0.8)	2 (0.8)	2 (0.6)	1 (1.4)	0.03	0.27	0.45	0.85	0.61	0.50
Malignant arrhythmia	4 (0.6)	1 (0.4)	2 (0.6)	1 (1.4)	0.18	0.99	0.45	0.67	0.32	0.50
Others	2 (0.3)	-	2 (0.6)	-						
Discharge from the hospital	629 (97.2)	255 (97.3)	304 (97.7)	70 (94.6)						
Lost in follow-up	24 (3.8)	10 (3.9)	10 (3.3)	4 (5.7)						
No. in follow-up	605 (96.2)	245 (96.1)	294 (96.7)	66 (94.3)						
Late mortality	34 (5.6)	15 (6.1)	13 (4.4)	6 (9.1)	0.80	0.73	2.35	0.38	0.39	0.13
Survival (%)										
1 year	99.5	99.6	99.7	98.5						
3 years	97.0	96.5	97.4	96.8						
5 years	94.6	94.3	95.9	91.0						
10 years	82.7	82.8	84.4	78.4	0.50	0.23	0.99	0.48	0.63	0.32

Values are n (%); *P<0.05, AVR: Aortic valve replacement; MVR: Mitral valve replacement; DVR: Double valve replacement; "AVR vs MVR" means the difference between AVR and MVR group; "AVR vs DVR" means the difference between AVR and DVR group; "MVR vs DVR" means the difference between MVR and DVR group. The mid- to long-term survival between different groups was compared using the 10-year survival rate and χ^2 values were calculated by the log-rank test.

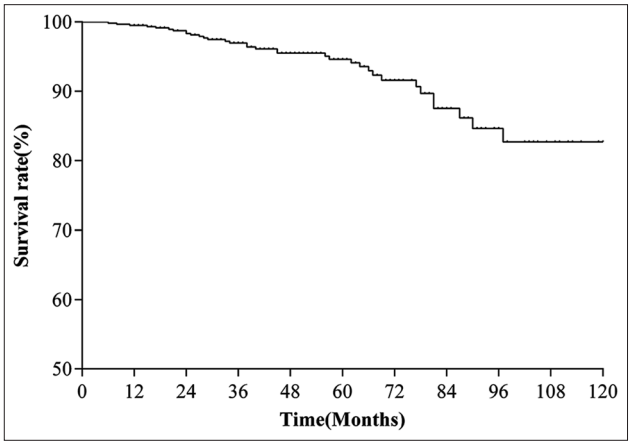

Figure 2: Survival curve of the overall cohort.

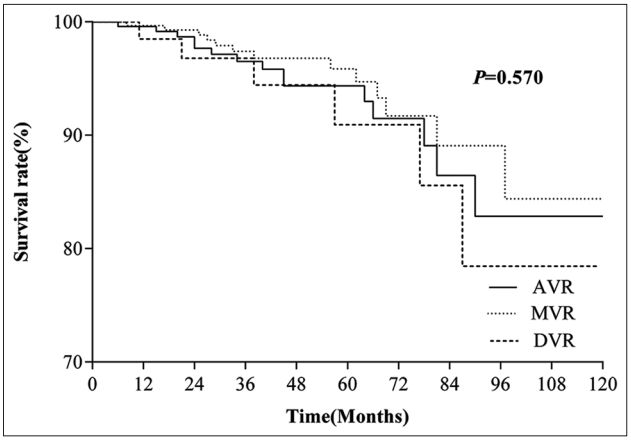

Figure 3: Survival curves according to the type of operation.

Thromboembolism

Twenty-six patients suffered from thromboembolic complications in our study (9 in AVR group, 13 in MVR group, and 4 in DVR group). At 5 years, the actuarial freedom from thromboembolism in AVR, MVR, and DVR groups was 96.0%, 94.9%, and 94.7%, respectively. At 10 years, this rate in AVR, MVR, and DVR groups was 91.4%, 90.9%, and 86.8%, respectively [Table 3].

Bioprosthesis endocarditis

During the follow-up period, 8 patients suffered from endocarditis (4 in AVR group, 3 in MVR group, and 1 in DVR group). Six patients needed a surgical intervention and 2 patients were treated with the medical therapy. None of them died. The actuarial freedom from prosthetic valve endocarditis at 5 and 10 years were 98.4% and 96.0% in AVR group, 98.5% and 98.5% in MVR group, 98.3% and 98.3% in DVR groups [Table 3].

Paravalvular leakage

During the follow-up period, paravalvular leakages were detected in 11 cases (6 in AVR group, 4 in MVR group, and 1 in DVR group). Eight patients with severe regurgitation received reoperations. All patients survived and recovered well from the reoperation. The actuarial freedom from paravalvular leakage at 5 years was 97.1% in AVR group, 98.3% in MVR group, and 98.2% in DVR group. At 10 years, the actuarial freedom from paravalvular leak was 94.0%, 97.2%, and 98.2% in the AVR, MVR, and DVR groups, respectively [Table 3].

Structural valve deterioration

There were 12 cases of SVD observed during the follow-up: 4 in AVR group, 6 in MVR group and 2 in DVR group. At 5 years, the actuarial freedom from SVD was 98.9%, 97.0%, and 98.0% in AVR, MVR, and DVR group, respectively. Ten years postoperatively, these numbers still remained at

Table 3: Valve related complications of the study population during the follow-up period

Variable	Total (n = 605)	AVR (n = 245)	MVR (n = 294)	DVR (n = 66)	χ^2 value			P value		
					AVR vs MVR	AVR vs DVR	MVR vs DVR	AVR vs MVR	AVR vs DVR	MVR vs DVR
Hemorrhage										
n (%)	21 (3.5)	6 (2.5)	12 (4.1)	3 (4.5)						
Freedom at 5-year (%)	96.6	97.8	95.8	95.4						
Freedom at 10-year (%)	95.2	96.1	94.2	95.4	1.16	0.67	0.01	0.281	0.411	0.927
Thromboembolism										
n (%)	26 (4.3)	9 (3.7)	13 (4.4)	4 (6.1)						
Freedom at 5-year (%)	95.3	96.0	94.9	94.7						
Freedom at 10-year (%)	90.3	91.4	90.9	86.8	0.29	0.39	0.07	0.589	0.534	0.785
Prosthesis endocarditis										
n (%)	8 (1.3)	4 (1.6)	3 (1.0)	1 (1.5)						
Freedom at 5-year (%)	98.5	98.4	98.5	98.3						
Freedom at 10-year (%)	97.5	96.0	98.5	98.3	0.11	0.64	0.03	0.675	0.413	0.872
Paravalvular leak										
n (%)	11 (1.8)	6 (2.4)	4 (1.4)	1 (1.5)						
Freedom at 5-year (%)	97.8	97.1	98.3	98.2						
Freedom at 10-year (%)	95.9	94.0	97.2	98.2	0.67	0.29	0.01	0.411	0.591	0.991
Structural valve deterioration										
n (%)	12 (2.0)	4 (1.6)	6 (2.0)	2 (3.0)						
Freedom at 5-year (%)	97.9	98.9	97.0	98.0						
Freedom at 10-year (%)	94.6	94.3	95.5	93.7	0.22	0.22	0.05	0.638	0.635	0.817
Reoperation										
n (%)	27 (4.5)	12 (4.9)	11 (3.7)	4 (6.1)						
Freedom at 5-year (%)	95.5	95.0	95.6	96.5						
Freedom at 10-year (%)	86.8	87.0	88.1	84.0	0.24	0.01	0.16	0.625	0.927	0.688

Values are n (%); AVR: Aortic valve replacement; MVR: Mitral valve replacement; DVR: Double valve replacement; "AVR vs MVR" means the difference between AVR and MVR group; "AVR vs DVR" means the difference between AVR and DVR group; "MVR vs DVR" means the difference between MVR and DVR group. The rates of mid- to long- term freedom from valve related complications between different groups were compared using the results at 10-year and χ^2 values were calculated by the log-rank test.

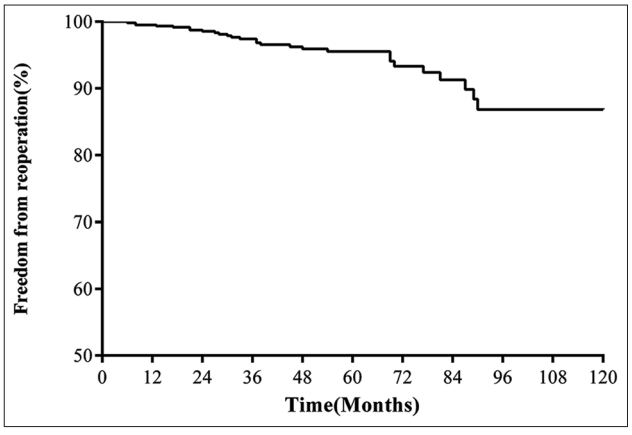

Figure 4: Curve of freedom from reoperations of the overall cohort.

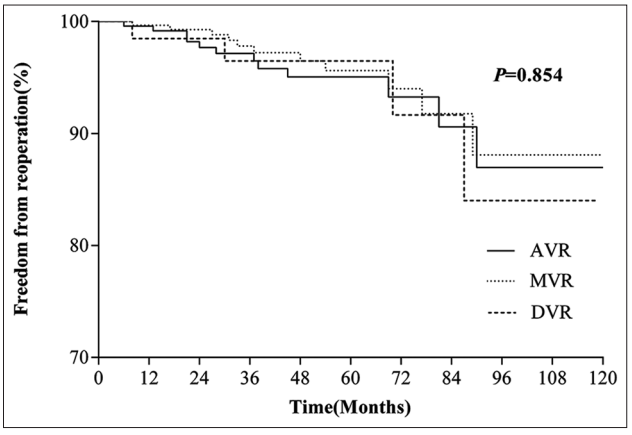

Figure 5: Curve of freedom from reoperations according to the type of operation.

94.3%, 95.5%, and 93.7% in AVR, MVR, and DVR group, respectively. The overall 10-year freedom from SVD of the overall cohort was 94.6% [Table 3].

Discussion

The prevalence of bioprosthetic valves in valvular replacement has increased over the last decade throughout the world. Although multiple studies have reported clinical outcomes of Hancock II in other countries, the present study is the first, large-scale retrospective study to report the mid-long term clinical outcomes of Hancock II bioprosthesis in the Chinese population. Hancock II bioprosthesis is a modified version of the standard Hancock, and was first introduced for clinical use in 1978. Porcine tissue is treated with sodium dodecyl sulfate detergent for anticalcification and glutaraldehyde fixation at low pressure to preserve the

natural collagen crimping. All these processes aim to retard calcification and minimize the leaflet collagen structural damage.[1] Furthermore, its Delrin stent is designed to reduce mechanical stresses which exerted on the leaflets.[1]

The clinical application of the Hancock II bioprosthesis at our center started in 2004. A total of 4791 mechanical valve prostheses and 647 bioprostheses have been implanted in 5438 valvular disease patients since then. While the prevalence of bioprosthesis in China has increased in recent years, it is still below that of developed Western countries. The low usage rate of bioprosthesic valves in China is attributed to several reasons. Firstly, the primary pathological type of heart valve disease in China is still the rheumatic lesion, which occurs at a younger age than degenerative valve diseases in the Western countries. Secondly, considering the risk and cost of the reoperation, the majority of patients prefer mechanical valves, even when they are recommended bioprosthetic valve replacement and reminded a better quality of life with the bioprosthesis replacement according to the current valvular disease guidelines. However, this study demonstrated that the mid- to long-term durability of Hancock II bioprosthesis was excellent. Ten-year freedom from reoperations due to SVD was 94.6%, which was similar to the results of other publications from America, Canada, and Italy.[2-6] Thus, the durability of this bioprosthesis does not seem to have any difference between different ethnicities. Moreover, the overall risk of reoperations has dramatically decreased due to improvements and refinements in surgical techniques and perioperative managements.[16] These results indicate that it is important for Chinese cardiovascular surgeons to inform their patients of the risk of valve related morbidities and reoperations. Meanwhile, our results are valuable to make an ideal decision between the two types of prosthetic valves. With advanced knowledge, there will be a broad prospect for the bioprosthesis application in China.

In our study, Hancock II bioprosthesis performed a stratified mid- to long-term clinical outcome in Chinese patients. The 10-year overall survival rate was 82.7% for the overall cohort (mean age of 62.9 years). The 10-year survival rate of AVR, MVR, and DVR group was 82.8%, 84.4%, and 78.4%, respectively. Valfrè *et al*.[2] had reported their long-term experience with the Hancock II valve in patients with a mean age of 64.0 ± 9.0 years. The actuarial survival rate at 10 years for AVR and MVR groups was approximately 66.2 ± 2.7% and 61.7 ± 3.3%, respectively. The 10-year survival rate in patients younger than 60 years old was 69.4 ± 6.6% and 80.1 ± 5.4% for AVR and MVR groups. However, in patients older than 60 years old, it was 65.6 ± 3.0% and 55.4 ± 3.9% for AVR and MVR groups, respectively. Une *et al*.[3] reported their long-term experience with the Hancock II bioprosthesis in the aortic position in patients aged 60 years or less. The actuarial survival at 10 years was approximately 80.7 ± 2.6%. Rizzoli *et al*.[4] reported their experience with Hancock II bioprosthesis. At 10 years, the actuarial survival rate of AVR patients (mean age of 68.4 years) was approximately 59.0 ± 2.2%. For their MVR group with a mean age of 65.8 years, the rate was 56.7 ± 2.8%.

Valve related complications were also examined in our study. The incidence of SVD necessitating reoperation was quite low. This compared favorably with other published studies. Rizzoli *et al*.[4] reported that actuarial freedom from SVD at 10 years was approximately 97.0 ± 0.1% and 93.2 ± 0.2% for the AVR and MVR groups. The results continued to be favorable for 15 years with 84.7 ± 0.4% and 70.8 ± 0.5% in the AVR and MVR groups, respectively. The report by Une *et al*.[3] on their experience with this bioprosthesis revealed 10-year freedom from SVD of 90.9 ± 2.1% for the AVR group and actuarial freedom from reoperation due to SVD was 91.4 ± 2.1%. These results continued to be 61.6 ± 4.3% and 64.7 ± 4.3% at 15 years. Chan *et al*.[5] reported freedom from SVD at 10 years for the AVR group using the Hancock II bioprosthesis was 97.5 ± 1.1%.

Freedom from reoperation in our study also compared with other published reports. Rizzoli *et al*.[4] reported that 10-year freedom from reoperation was approximately 93.6 ± 1.3% and 91.8 ± 2.1% for the Hancock II bioprosthesis in the aortic and mitral positions, respectively. They reported that at 15 years postoperatively, freedom from reoperation was 82.3 ± 3.7% for AVR group and 71.0 ± 5.0% for MVR group, respectively. Valfrè *et al*.[2] reported their reoperation rate at 10 years to be approximately 94.6 ± 1.5% and 94.8 ± 1.8% for the AVR and MVR groups using the Hancock II bioprosthesis. The experience of Une *et al*.[3] with Hancock II bioprosthesis implanted in the aortic position demonstrated a freedom from reoperations of approximately 83.8 ± 2.6% at 10 years.

Our results also explored the incidence of other valve-related complications. The 10-year freedom from hemorrhage and thromboembolism was 95.2% and 90.3%, respectively. All of our patients with bioprosthesis were discharged home on warfarin for 3–6 months. 12% patients continued to receive anticoagulant treatment to avoid atrial fibrillation related complications. Rizzoli *et al*.[4] reported a 10-year freedom from thromboembolism events of 87.9 ± 1.6% and 85.3 ± 2.2% for the AVR and MVR groups, respectively, with 4 cases of valve thrombosis. David *et al*.[6] reported their 10- and 15-year freedom from thromboembolic events using Hancock II valve for AVR to be 88.8 ± 1.2% and 82.1 ± 1.7%, respectively. Patients in the MVR group had 12 hemorrhagic events, 6 events in the AVR group, and 3 events in the DVR group. All hemorrhagic episodes occurred in patients with atrial fibrillation that received anticoagulant treatment consistently. The result was similar to other publications as Rizzoli *et al*.[4] with Hancock II valve revealed a freedom from hemorrhagic events of 95.8 ± 0.9% and 91.7 ± 1.8% for the AVR and MVR group, respectively, at 10 years. The incidence of prosthesis endocarditis and paravalvular leak in our cohort was extremely low and consistent with other published studies.[3-5]

Study limitations

The primary limitations of the study include center bias (single center study) and recall bias during the follow-up process. Secondly, the follow-up was not fully

complete (96.2%), which might result in underestimating the complication incidences. Thirdly, since our center began to use the Hancock II bioprosthesis in 2004, this study has only reported a mid- to long-term outcomes. The long-term data will need to be collected in the future. Finally, this study lacked scientific hypotheses and new opinions, but it provided a clinical outcome report that was crucial and valuable for the development of the cardiovascular surgery in China.

In conclusion, the Hancock II bioprosthesis had a credible mid- to long-term durability and clinical performance in the Chinese population. The incidences of mortality and morbidity were quite low and consistent with the reports of developed countries. This follow-up study program will be carried on to collect more data. We will evaluate the longer-term durability and performance of the Hancock II bioprosthesis in the Chinese population in the future.

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Conflicts of interest

There are no conflicts of interest.

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