

The Early Outcome of Aortic Valve Replacement Surgery for Dialysis Patients

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ABSTRACT

OBJECTIVES: Although the “mechanical valve” has historically been the popular choice to use as a prosthetic valve to treat dialysis patients requiring aortic valve replacement (AVR) for aortic stenosis, bioprosthetic valves have also started to be considered for use, due to improvements of surgical outcomes observed through its technical improvements. In this study, we demonstrated our valve treatment strategy and investigated the early outcome to patients with dialysis.

METHODS: 470 patients received an AVR between January 2009 and December 2012. We retrospectively reviewed and analyzed the clinical course of 32 patients with dialysis. 15 patients were male and 17 patients were female, with an average age of 72.4 ± 7.3 years (range: 57-86 years). The mean duration of hemodialysis was 8.7

years (range: 0.1-36 years). The mean Society of Thoracic Surgery score and Euro Score II was 17.0% and 8.9%, respectively. We used a bioprosthetic valve for patients aged >65 years.

RESULTS: Mean observation period was 958 days. Regarding early mortality, there were 5 operative deaths within 30 days after operation (15.6%). There were 6 operative late deaths (20.7%). 1- and 3-year survivals in the bioprosthetic valve group were 68% and 46%, respectively. On the other hand, those in the mechanical valve group were 75% and 50%, respectively.

CONCLUSION: The use of bioprosthetic valves should be considered due to its added benefits and because there is no statistically significant difference on survival and valve-related complications between bioprosthetic and mechanical valve group.

Key words: Aortic valve replacement; Dialysis; Bioprosthetic valve; Mechanical valve

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INTRODUCTION

The number of dialysis patients in Japan has been gradually increasing every year, exceeding 340,000 patients in 2016. Dialysis therapy is essential for patients with renal failure in Japan due to fewer kidney transplants and thus greater reliance on dialysis for treatment comparatively to Western countries. One review showed that heart failure accounted for more than 25% of the cause of death for dialysis patients, and morbidity of heart diseases could make it more difficult to continue dialysis^[1]. Until now, selecting bioprosthetic valves for the patients requiring aortic valve replacement (AVR) in order to continue dialysis was thought to produce the risk of dysfunction due to valve calcification in the early term after replacement^[2-5]. However recently, due to technical advancements in

anti-calcification measures in bioprosthetic valves, the guidelines of The Japan Circulation Society have accepted not only the application of mechanical valves but also that of bioprosthetic valves to the patients with dialysis due to the improvement of surgical outcome by selecting bioprosthetic valve⁶, and our institution also conducted AVR in accordance with the guidelines. Although one report for the Japanese patients in 2015 has already demonstrated that overall survivals among non- and dialysis patients who underwent AVR with a prosthetic valve were significantly worse in the dialysis patients⁵, in this study, we focused on our strategy of valve application and investigated the early outcomes to patients with dialysis.

MATERIALS AND METHODS

Study design and patient population

In total, 470 patients received an aortic valve replacement between January 2009 and December 2012. We retrospectively reviewed and analyzed the clinical course of 32 patients with dialysis. 15 patients were male and 17 patients were female, with an average age of 72.4 ± 7.3 years (range: 57-86 years). The most common original disease was diabetic nephropathy (13 patients; 40.6%). The preoperative data are listed in Table 1. The mean Society of Thoracic Surgery score and Euro Score II was 17.0% and 8.9%, respectively. We have used a bioprosthetic valve for the patients aged > 65 years in accordance with the guideline of The Japan Circulation Society for Surgical and Interventional Treatment of Valvular Heart Disease (JCS2012).

Surgical technique

The typical surgical procedure used is described as follows. All procedures were performed using a total median sternotomy. Standard cardiopulmonary bypass (CPB) techniques were used, including a cannulation from right atrium. Myocardial protection was achieved with retrograde intermittent blood cardioplegia. After clumping and transecting the ascending aorta, the aortic valve was excised. Calcification of the annulus was removed as much as possible by Ultrasonic Surgical Aspirator (CUSA® Excel plus system; Integra LifeSciences, NJ, USA). Prosthetic aortic valves (< 23mm and > 23mm) were fixed to supra annular position by an average of 15 stitches and non-everted mattress suture, respectively. In the case of minimally invasive cardiac surgery (MICS), the surgical approach to the aortic valve was through the right 4th anterior intercostal space with a 5-6 cm skin incision; right femoral artery and vein cannulations were used to establish CPB.

Postoperative management

Postoperative characteristics including type of surgery, prosthetic valve size, and type of prosthetic valve are shown in Table 2A and 2B. Of 32 patients, 11 patients underwent single valve replacement surgery including re-operation for 1 patient and MICS for 1 patient. Valve selection consisted of 28 bioprosthetic valves and 4 mechanical valves. Of 32 patients, 21 patients received concomitant surgery in addition to AVR. 10 patients received coronary artery bypass grafting (CABG), 1 patient received mitral valve replacement, 1 patient received mitral valve annuloplasty (MVP), 1 patient received MVP and tricuspid annuloplasty (TAP), 4 patients received MVP, TAP and CABG, 2 patients TAP and Maze, 1 patient received TAP and CABG, and 1 patient received ascending aorta replacement and CABG, as shown in Table 2A. The intubation tube was removed by the morning of the next day of operation. Cardiac rehabilitation began from the morning of 1 postoperative day (POD). Regarding postoperative dialysis, continuous hemodiafiltration was started from 1POD,

Table 1 Baseline patients' characteristics.

	n = 32
Age, y, mean(± SD)	72.4 (± 7.33)
Female gender, n (%)	17 (53.1)
BSA, cm ² , mean(± SD)	1.6 (± 0.19)
HD history, y, mean (± SD)	9.0 (± 8.45)
Coexisting condition, n (%)	
Hypertension	17 (53.1)
Diabetes mellitus	13 (40.6)
Previous cardiac surgery	1 (3.1)
Coronary artery disease	20 (62.5)
Peripheral artery disease	5 (15.6)
Cerebrovascular disease	11 (34.3)
Hyperlipidemia	12 (37.5)
Chronic pulmonary disease	3 (9.4)
Atrial fibrillation	8 (25)
Cancer	13 (40.6)
LV Ejection Fraction, %, mean (± SD)	53.3 (± 15.2)
NYHA	2.8 (0.97)
I	1 (3.1)
II	15 (46.8)
III	5 (15.6)
IV	11 (34.3)
STS score(%)	17
EURO II score(%)	8.9

BSA, body surface area; HD, hemodialysis; LV, left ventricle; NYHA, New York Heart Association; SD, standard deviation; STS: Society of Thoracic Surgery.

dehydration was started gradually from 2POD, and hemodialysis was started from 3POD. Body weight was returned to preoperative dry weight around 7POD.

Statistical analysis

Continuous data are presented as mean ± standard deviation, while categorical variables are given as number and percentage of patients. Survival rate and events-free rate were analyzed using Kaplan-Meier method, while continuous variables were compared using unpaired t-test. A P value of less than 0.05 was regarded as significant. The statistical results are written according to the guidelines⁷.

Ethical approval

All subjects enrolled in this research have given their informed consent, which alongside the described protocol, has been approved by my institutional committee on human research.

RESULTS

Postoperative characteristics

Mean observation period was 958 days (bioprosthetic valve group; 972 days, mechanical valve group; 871 days). Average of patient age in the bioprosthetic valve group and mechanical valve group was 73.8 and 59.5 years old, respectively. The mean size of prosthetic valve was 21.3 mm (18-25 mm: Table 2A); 21.5 mm for the bioprosthetic valve group and 19.8 mm for the mechanical valve group. Regarding the number of prosthetic valve, CEP MAGNA accounted for 82.1% (23 of 32 patients). Average operative times were similar between both groups (335.4 ± 116.2 min in the bioprosthetic valve group vs. 377.8 ± 107.6 min in the mechanical valve group; no significant difference (NS)). Average aortic cross-

clump times and CPB times were almost the same (131.3 ± 50.2 vs 126.0 ± 34.5 min and 167.9 ± 75.1 vs 215.0 ± 33.8 min, respectively; NS). There were no significant differences between the average times of postoperative intubation, intensive care unit stay and hospital stay within the bioprosthetic valve and the mechanical valve groups (47.2 ± 100.6 hours vs 52.8 ± 53.7 hours, 8.1 ± 11.7 days vs 8.5 ± 7.2 days, and 29.4 ± 24.0 days vs 29.5 ± 32.4 days, respectively; Table 2B). Postoperative echocardiogram demonstrated that left ventricular ejection fraction, peak pressure gradient, and mean pressure in each group had no significant differences ($51.3 \pm 11.7\%$ vs 50.0 ± 22.9 , 26.1 ± 9.7 mmHg vs 32.7 ± 3.2 mmHg, and 13.3 ± 4.6 mmHg vs. 19.0 ± 6.1 mmHg, respectively; Table 2B).

Survival, mortality and morbidity

1- and 3-year survival in the bioprosthetic valve group was 68% and 46%, respectively. On the other hand, survival in the mechanical valve group was 75% and 50%, respectively ($p = 0.79$; Figure 1).

Regarding early mortality, there were 5 operative deaths within 30 days after operation (15.6%). One patient with EF 23% underwent AVR with a bioprosthetic valve, MVP, TAP, and CABG, however, percutaneous cardiopulmonary support was additionally installed due to low output syndrome immediately after the operation. Nonetheless, the patient died on 5 POD. Another patient with heart failure supported by ventilator and intra-aortic balloon pumping underwent AVR with a bioprosthetic valve, however died on 29 POD. Two patients in the mechanical valve group died of non-occlusive mesenteric ischemia (NOMI) and sepsis on 5 POD and 4 POD, respectively. The other patient in the bioprosthetic valve group died of multiple organ failure on 22 POD.

There was 1 operative death 60 days after operation (3.7%). The patient was discharged from our hospital, however, the patient died of sepsis accompanying adult respiratory distress syndrome on 58 POD. There were no operative deaths 90 days after operation, but there were 5 operative late deaths (19.2%). Two patients died of sepsis following amputation of lower extremity on 203 and 518 POD, respectively. The other 3 patients died unexpectedly at home on 928 POD and died of pneumonia on 147 POD and cerebral infarction on 101 POD, respectively.

Although there were no operative complications including non-structural dysfunction, valve thrombosis and valve endocarditis, there was 1 case of structural deterioration due to early calcification of an implanted valve (Trifecta 19 mm). This patient underwent re-AVR with a mechanical valve on 71 POD. In terms of embolism, there were 2 cases of cerebral infarction. In regards to bleeding events, there was 1 case of cerebellar hemorrhage and 1 case of gastrointestinal hemorrhage.

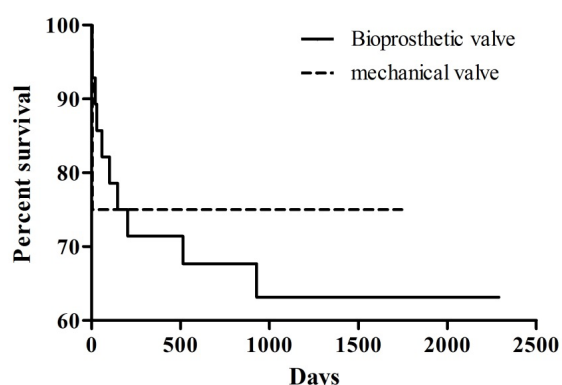


Figure 1 Overall survivals in the bioprosthetic and mechanical valve group.

DISCUSSION

With regard to the prosthetic valve selection of AVR for the patients with dialysis, AVR by mechanical valves became the main stream choice by the 1990's and was recommended within the guidelines^[4]. Gradually, however, AVR by bioprosthetic valves was recommended due to the effectiveness of anti-calcification pretreatment for bioprosthetic valves^[8-14], in which a study has reported that there was no significant difference in the 2-year survival rate between the bioprosthetic and mechanical valve group^[15]. Recently in 2006, the guidelines for the American Heart Association on the use of mechanical valves in hemodialysis patients were rescinded^[16]. In accordance with the trend^[5] and the latest guidelines, the standard strategy of valve

Table 2a Operative characteristics.

	bioprosthetic (n = 28)	mechanical (n = 4)
Elective operation, n (%)	26 (92.9)	4 (100.0)
Concomitant procedure, n (%)	18 (64.3)	3 (75.0)
CABG	9 (50.0)	1 (33.3)
MVR	1 (5.6)	0 (0.0)
MVP	0 (0.0)	1 (33.3)
MVP, TAP	1 (5.6)	0 (0.0)
MVP, TAP, CABG	3 (16.7)	1 (33.3)
TAP, Maze	2 (11.1)	0 (0.0)
TAP, CABG	1 (5.6)	0 (0.0)
Ascending aorta replace, CABG	1 (5.6)	0 (0.0)
Size of prosthesis, n (%)		
18 mm	0 (0.0)	2 (50.0)
19 mm	8 (28.6)	1 (25.0)
20 mm	0 (0.0)	0 (0.0)
21 mm	7 (25.0)	0 (0.0)
22 mm	0 (0.0)	0 (0.0)
23 mm	11 (39.3)	0 (0.0)
24 mm	0 (0.0)	1 (25.0)
25 mm	2 (7.1)	0 (0.0)
Number of prosthesis, n (%)		
CEP MAGNA	23 (82.1)	
Trifecta	3 (10.7)	
Epic	1 (3.6)	
Crown	1 (3.6)	
ATS-AP		3 (75.0)
SJM Regent		1 (25.0)

CABG: coronary artery bypass grafting; MVP: mitral valve annuloplasty; MVR: mitral valve replacement; TAP: tricuspid annuloplasty.

Table 2b Operative characteristics.

	biological (n = 28)	mechanical (n = 4)	P value
Operation time, min, mean (\pm SD)	335.4 (\pm 116.2)	377.8 (\pm 107.6)	NS
CPB time, min, mean (\pm SD)	167.9 (\pm 75.1)	215.0 (\pm 33.8)	NS
Cross-clamp time, min, mean (\pm SD)	131.3 (\pm 50.2)	126.0 (\pm 34.5)	NS
Intubation time, hour, mean (\pm SD)	47.2 (\pm 100.6)	52.8 (\pm 53.7)	NS
ICU stay, day, mean (\pm SD)	8.1 (\pm 11.7)	8.5 (\pm 7.2)	NS
Hospital stay, day, mean (\pm SD)	29.4 \pm 24.0	29.5 \pm 32.4	NS
Ejection Fraction, %, mean (\pm SD)	51.3 (\pm 11.7)	50.0 (\pm 22.9)	NS
pPG, mmHg, mean (\pm SD)	26.1 (\pm 9.7)	32.7 (\pm 3.2)	NS
mPG, mmHg, mean (\pm SD)	13.3 (\pm 4.6)	19.0 (\pm 6.1)	NS

CPB: cardiopulmonary bypass; ICU: intensive care unit; mPG: mean pressure gradient, NS: no significant difference; pPG: peak pressure gradient; SD: standard deviation.

selection in our institution was that bioprosthetic valves were used for hemodialysis patients over 65 years old as with non-hemodialysis patients, which have resulted in satisfactory early outcomes.

The factors that could be controlled to potentially improve the outcome of hemodialysis patients who underwent AVR were reducing operation time and managing perioperative conditions. For instance, severe calcification of the annulus from aortic valve cusps could be removed easily and rapidly by use of CUSA. Moreover, we managed a way to effectively ameliorate patient prosthesis mismatch of the patients who underwent AVR with a prosthetic valve (< 23 mm) by fixing it with 15 interrupted single sutures to make maximum use of the prosthetic valve effective orifice area. Most of the facilities in Japan have the original protocol and strategy for the perioperative management because there are many dialysis patients in Japan compared to overseas. Our institution also implemented risk managements strategies, such as early introduction of rehabilitation and avoidance of NOMI because postoperative management of dialysis patients was different from that of non-hemodialysis patients. As a result of these efforts on risk managements, the early outcomes such as survival in the perioperative period have been improved.

Transcatheter aortic valve implantation (TAVI) to patients with aortic valve stenosis has become available in Japan since 2013, and the number of the patients has been increasing steadily^[17]. In Japan, however, patients with dialysis are excluded from TAVI treatment, and “open surgical operation” has been assigned for hemodialysis patients requiring AVR. Our early outcomes on AVR with a bioprosthetic valve to hemodialysis patients was thought to be equal to that with a mechanical valve because there was no significant difference in the morbidity of valve-related complications, bleeding and thrombosis between the bioprosthetic and mechanical valve groups.

There was one case in this study requiring re-intervention due to dysfunction of a bioprosthetic valve with severe calcification in the early period. In this case, valve calcification was thought to result from postoperative hypercalcemia. Since postoperative hypercalcemia has the possibility of damaging the bioprosthetic valves in the early term after replacement^[18], it is necessary to consider the use of mechanical valves to some patients that seem to be difficult to manage.

This present study was subject to limitations. The decision to implement the prosthetic valves was carefully considered depending on the specificities of each dialysis patient. Moreover, the size of the study was small (32 patients), and the follow-up time was fairly moderate. Therefore, although the outcomes at our center might not be completely representative of a wider and more general patient cohort, we intend to continue to investigate the benefits of this treatment in future cases.

CONCLUSION

In conclusion, the use of bioprosthetic valves to dialysis patients should be considered because there is no statistically significant difference on survival and valve-related complications between the bioprosthetic and mechanical valve groups.

Disclaimer

The data reported here have been provided by the Japanese Society for Dialysis Therapy (JSDT). The interpretation and reporting of these data are the responsibility of the authors and in no way should be seen as an official policy or interpretation of the JSDT.

Disclosure

The authors of this manuscript have no conflict of interest to disclose as described by *Journal of Cardiology and Therapy*.

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Author contribution

Conception and design: Mitsuru Iida, Kenji Nishimura and Tomoki Shimokawa; acquisition of data: Kaori Kono, Ken Chen, Tsukasa Ikeda, Hiroo Ota, Masateru Uchiyama, Naomi Ozawa, Tomohiro Imazuru; analysis and interpretation of data: Mitsuru Iida and Masateru Uchiyama; writing of the article: Mitsuru Iida, Kenji Nishimura, Kaori Kono, Ken Chen, Tsukasa Ikeda, Hiroo Ota, Masateru Uchiyama, Naomi Ozawa and Tomohiro Imazuru; critical revision of the article: Mitsuru Iida, Masateru Uchiyama and Tomoki Shimokawa.

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