

Favorable Results in Patients with Small Size CarboMedics Heart Valves in the Aortic Position

Kazuhito Imanaka, MD,¹ Shinichi Takamoto, MD,¹ and Akira Furuse, MD²

Hemodynamic performance of the CarboMedics (CM) heart valve in the aortic position and its clinical impacts were investigated in 126 consecutive patients. The actuarial survival rates of patients who had undergone isolated aortic valve replacement and concomitant aortic and mitral valve replacement were $82.6 \pm 5.7\%$ and $71.0 \pm 9.2\%$ at 8 years, respectively. Morbid events were rare, and almost all late survivors were free from evident cardiac symptoms regardless of the valve size. Echocardiography revealed suboptimal transvalvular pressure gradients and effective orifice areas of 19 mm and 21 mm valves. However, relief of the left ventricular overload and improvement of the clinical symptoms as well as cardiac function were comparable to those of patients with larger valves. Valve function measured by echocardiography did not show significant correlation to late outcome. Good results can be expected even in the presence of echocardiographic data such as peak pressure gradient over 40 mmHg, effective orifice area less than 1.0 cm^2 , and effective orifice area index less than $0.7 \text{ cm}^2/\text{m}^2$. (Ann Thorac Cardiovasc Surg 2001; 7: 150–4)

Key words: CarboMedics heart valve, small aortic annulus, aortic valve replacement, long-term effects, effective orifice area

Introduction

Prosthetic valves have been improved in performance. It is, however, still controversial to use small prostheses for aortic valve replacement (AVR).^{1–9)} Doppler ultrasonography (UCG) has proved to be a reliable modality for the evaluation of prosthetic valve function,^{10–12)} and has become the main method in the current era. As yet, however, few papers show the acceptable range of valve function measured by UCG. In the present study, hemodynamic performance of the CarboMedics (CM) Heart Valve (CarboMedics Inc., TX, USA) after AVR and its clinical impacts were investigated.

From the ¹Department of Cardiothoracic Surgery, University of Tokyo, and ²JR General Hospital, Tokyo, Japan

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Address reprint requests to Kazuhito Imanaka, MD: First Department of Surgery, Saitama Medical school, 38 Morohongo, Moroyama-machi, Iruma-gun, Saitama 350-0495, Japan.

Patients and Methods

Between August 1990 and September 1996, 126 consecutive patients (75 males and 51 females) underwent AVR using the CM valve. Their mean age was 51.2 years (range 12–78 years). Preoperative New York Heart Association (NYHA) functional class was II in 30, III in 72 and IV in 24. Urgent operations were performed in 12 cases (2 of acute aortic dissection and 10 of active infective endocarditis). Concomitant aortic and mitral valve replacement (DVR) was performed in 31 patients. Other associated procedures were as follows: aortic root replacement 9, coronary bypass 7, aortic annulus enlargement 3, and miscellaneous 22. A standard hypothermic cardiopulmonary bypass with multiple dose cold cardioplegia was used at surgery. Patients were followed up at our outpatient clinic or by the referring physicians. Information on the patients was gathered at the outpatient clinic or by direct telephone calls to them.

Prosthetic valve function

Prosthetic valve function was evaluated in 102 (87.9%)

Table 1. Clinical results

	19	21	23	25	27
n	10	30	47	27	12
NYHA IV	2	7	7	4	5
Male : Female	2 : 8	4 : 26	37 : 10	20 : 7	12 : 0
AS : ASR : AR	5 : 4 : 1	8 : 10 : 12	13 : 7 : 27	4 : 3 : 20	1 : 3 : 8
AVR : DVR	7 : 3	16 : 14	36 : 10	24 : 3	9 : 3
AGE (year)	55.7 ± 26.3	53.9 ± 18.9	45.4 ± 19.8	49.4 ± 15.8	57.2 ± 9.0
BSA (m ²)	1.41 ± 0.15	1.43 ± 0.16	1.61 ± 0.15	1.64 ± 0.16	1.69 ± 0.09
Hospital death	0	3	1	4	0
Late death (except cancer)	1	2	1	1	0
Morbid events	1	0	4	0	1

Patients with 19-mm or 21-mm valves showed a significant predominance of aortic stenoses, and smaller builds than those with larger valves ($p < 0.01$). Small valve size was not a significant risk factor neither for early and late mortality and morbidity

NYHA: New York Heart Association functional class, AS: aortic stenosis, ASR: combined aortic stenosis and regurgitation, AR: aortic regurgitation, AVR: aortic valve replacement, DVR: concomitant aortic and mitral valve replacement, BSA: body surface area.

operative survivors using UCG with a Toshiba SSA-380A ultrasound scanner (Toshiba, Japan). Stroke volume was estimated by the Pombo method.¹³⁾ Subvalvular and transvalvular flow was measured by the pulsed or continuous wave Doppler method. Peak and mean transvalvular pressure gradients were calculated using a modified form of Bernoulli's equation: $\Delta P = 4 \times V^2$.

End-systolic pressure of the left ventricle (LV) was estimated as cuff systolic blood pressure plus peak transvalvular pressure gradient. Effective orifice area (EOA) was calculated using the continuity equation method:¹⁴⁾

$EOA = (LV \text{ outflow cross-sectional area}) \times (\text{subvalvular flow} / \text{supravalvular flow})$.

Effective orifice area index (EOAI), discharge coefficient and performance index were derived by dividing EOA by body surface area (BSA), calculated orifice area, and sewing ring area, respectively.

Long-term effects

Only patients who underwent isolated AVR were included in the following analyses.

LV mass index (LVMI), LV end-systolic wall stress (ESWS) and percent fractional shortening (%FS) were calculated with the following formulae:^{15,16)}

$LVMI \text{ (g/m}^2\text{)} = BSA^{-1} \cdot 1.04 \{ (LVDd + IVS_{thd} + PW_{thd})^3 - LVDd^3 \} - 14$

$ESWS \text{ (Kdyn/cm}^2\text{)} = 0.33 \cdot ELVP \cdot LVDs / PW_{ths} \cdot (1 + PW_{ths} / LVDs)$ and

$\%FS = 100 \cdot (LVDd - LVDs) / LVDd$

where LVDd, LVDs, Pwthd and Pwths are end-dias-

tolic and end-systolic dimension and posterior wall thickness of the LV, respectively, LVP is end-systolic pressure of the LV, and IVS_{thd} is the end-diastolic thickness of the interventricular septum.

SV1+RV5 and ST-T change on electrocardiography (ECG) in patients without conduction block, cardiothoracic ratio (CTR) on chest X-ray, and the serum lactate dehydrogenase (LDH) level were evaluated. Relationships between parameters written above and prosthetic valve size and function were investigated.

Statistical analysis

Postoperative events were defined according to the previously published guidelines.¹⁷⁾ Survival and morbidity rates were calculated by the Kaplan-Meier life-table method, and are given as mean ± standard error. Other data are shown as mean ± standard deviation. Student's *t* test or χ^2 test were used to compare the groups. Correlation was analyzed with Pearson's method. Differences were regarded as statistically significant at $p < 0.05$.

Results

Patient characteristics and clinical results according to the valve size are shown in Table 1. Patients with a valve diameter of 19 mm or 21 mm showed a significant predominance of aortic stenoses, females, and smaller builds than patients with larger valves ($p < 0.01$).

There were 8 hospital deaths. Causes of death were low output syndrome (LOS) in 5, cerebral hemorrhage 1, respiratory failure in 1 and late bleeding in 1. Univariate

Table 2. Prosthetic valve function

	19	21	23	25	27
SV (ml)	57.1 ± 23.0	64.5 ± 25.8	69.4 ± 19.9	66.7 ± 17.4	61.9 ± 11.3
peak ΔPG (mmHg)	42.5 ± 11.3	24.5 ± 10.3	22.4 ± 7.5	15.9 ± 6.0	10.5 ± 2.7
mean ΔPG (mmHg)	19.1 ± 8.3	10.4 ± 5.0	9.2 ± 3.6	6.8 ± 3.0	4.5 ± 1.3
LVP (mmHg)	166 ± 12	153 ± 19	144 ± 20	132 ± 17	139 ± 20
EOA (cm ²)	0.83 ± 0.25	1.09 ± 0.23	1.32 ± 0.31	1.61 ± 0.25	2.23 ± 0.45
EOAI (cm ² /m ²)	0.60 ± 0.20	0.76 ± 0.17	0.83 ± 0.21	0.99 ± 0.20	1.32 ± 0.27
DC	0.78 ± 0.24	0.77 ± 0.16	0.75 ± 0.18	0.74 ± 0.11	0.85 ± 0.17
PI	0.27 ± 0.08	0.29 ± 0.06	0.30 ± 0.07	0.31 ± 0.05	0.37 ± 0.08

Small valves showed large pressure gradients and narrow orifice areas. Peak and mean pressure gradients, EOA and EOAI were significantly different between each pair of groups ($p < 0.05$). Estimated LVP of 19 mm group was significantly higher than the other groups ($p < 0.05$).

SV: stroke volume, ΔPG: pressure gradient, LVP: end-systolic left ventricular pressure, EOA: effective orifice area, EOAI: effective orifice area index, DC: discharge coefficient, PI: performance index.

analysis revealed that NYHA class IV (3 class II or III (2.9%), 5 class IV (20.8%) patients), emergent operation (5 elective (4.3%), 3 emergent (25%) patients), and concomitant mitral valve replacement [4 AVR (4.1%), 4 DVR (12.9%) patients] were significant risk factors for early mortality, but small valve size (19 mm and 21 mm) was not.

Follow-up information was 98.3% complete (two were lost to follow-up). The mean follow-up period was 75.3 months. Late death occurred in 10 patients and 4 deaths (3.4%) were valve-related. Causes of death were cerebral hemorrhage in 2 and sudden death in 2, and the 21 mm valve patients comprised one each. One patient with a 19-mm valve who underwent surgery for newly developed ischemic heart disease died of LOS. The rest 5 patients died of cancer.

Morbid events were severe paravalvular leak 1 (0.9%), thromboembolism 2 (1.7%), gastrointestinal bleeding 2 (1.7%), and prosthetic valve endocarditis 1 (0.9%). One patient with a 19-mm valve suffered gastrointestinal bleeding. Actuarial survival rates of patients who underwent AVR and DVR were 82.6 ± 5.7 and 71.0 ± 9.2 , and the valve-related event-free rates were 88.9 ± 4.7 and 88.1 ± 8.4 at 8 years, respectively. These rates were similar when only patients with small size valves were included in the analyses.

All long-term survivors remained in NYHA classes I or II. Patients with 19 mm and 21 mm valves also lived normal daily social lives without evident cardiac symptoms.

Thus, small valve size was not a significant risk factor for poor clinical outcome.

Prosthetic valve function

The pressure gradient of 19mm valves was large and that of 21mm valves was moderate (Table 2). Valve diameter had significant correlations with peak ($r = -0.66$) and mean ($r = -0.60$) pressure gradients, EOA ($r = 0.76$), and EOAI ($r = 0.50$). Differences in those parameters between each pair of valve sizes attained statistical significance. Discharge coefficient and performance index was unrelated to the valve diameter. Estimated LVP of patients with a 19-mm valve was significantly higher than the other patients ($p < 0.05$).

Long-term effects

In Table 3, LVMI markedly decreased following AVR in all patients. However, most patients still showed moderate left ventricular hypertrophy, and only the LVMI of several young patients were within the normal range. Nonetheless for the large pressure gradients of small valves, the mean postoperative LVMI were around 150 g/m² in all valve size groups. The postoperative LVMI and its reduction ratio showed no correlation with valve diameter, peak or mean pressure gradients, EOA, or EOAI.

Mean %FS was significantly higher in patients with 19 mm and 21 mm valves before and after surgery ($p < 0.05$), but it did not change significantly following AVR in any valve size groups although it somewhat improved in the 25-mm and 27-mm groups.

SV1+RV5 of ECG decreased significantly following AVR in each valve size group ($p < 0.01$), but the reduction ratio did not correlate with any parameters of the valve function. Significant ST-T changes were observed before AVR in all cases. Less marked ST-T changes still

Table 3. Cardiac function and left ventricular overload

		19	21	23	25	27
LVMI (g/m ²)	before	198 ± 67	207 ± 81	230 ± 71	250 ± 80	317 ± 86
	after	129 ± 48**	149 ± 42**	150 ± 40**	140 ± 32**	162 ± 27**
%FS	before	45.2 ± 15.4	38.8 ± 9.7	34.1 ± 10.2	32.1 ± 6.3	27.3 ± 9.6
	after	42.2 ± 7.2	40.8 ± 8.6	34.4 ± 7.5	35.8 ± 7.0	30.1 ± 9.4
SV1+RV5 (mV)	before	5.74 ± 1.63	5.27 ± 0.47	5.32 ± 2.03	6.05 ± 1.94	5.95 ± 2.24
	after	3.56 ± 1.04*	3.71 ± 0.45*	4.01 ± 1.71**	4.23 ± 1.01**	4.28 ± 1.43*
CTR	before	54.3 ± 4.8	56.7 ± 4.8	55.9 ± 8.2	56.7 ± 5.0	57.7 ± 6.9
	after	48.4 ± 4.5*	51.3 ± 3.3*	51.1 ± 7.4*	49.1 ± 4.1**	51.2 ± 4.2*
ESWS (Kdyn/cm ²)		54.9 ± 52.3	61.9 ± 38.1	62.3 ± 26.2	55.5 ± 12.8	66.4 ± 27.3
LDH (IU/l)		298 ± 78	271 ± 51	294 ± 75	277 ± 51	307 ± 48

Left ventricular overload was significantly relieved following surgery in all valve size groups. All data of patients with small size valves were comparable to those of patients with larger valves.

LVMI: left ventricular mass index, %FS: percent fractional shortening, CTR: cardiothoracic ratio, ESWS: left ventricular end-systolic wall stress, LDH: serum lactate dehydrogenase level.

*: $p < 0.05$, **: $p < 0.01$ vs. before surgery.

remained several years later in about half of all patients, regardless of the valve size (19 mm, 2/4; 21 mm, 3/7; 23 mm, 7/19; 25 mm, 6/14; 27 mm, 5/9).

Mean postoperative CTR was around 50 % in all valve size groups. The reduction ratio was larger in patients with aortic regurgitation, but was unrelated to any parameters of the valve function.

ESWS values were within the normal range in all valve size groups. No significant correlation was observed with any UCG parameters including peak pressure gradient. LDH level was only slightly above the normal range (125-237 IU/l) regardless of the valve size, and was unrelated to any parameters of the valve function.

To find out the acceptable ranges of the valve function measured by UCG, cut-off values were determined; 40 mmHg for peak pressure gradient,¹⁸⁾ 1.0 cm² for EOA,¹⁹⁾ and 0.7 cm²/m² for EOAI. However, neither of these values caused significant difference of postoperative values and changing ratio of LVMI, %FS, SV1+RV5, and CTR.

Discussion

As bioprosthetic valves show limited durability and allografts are not readily available in Japan, mechanical valves are the first-choice devices for AVR in most institutes despite their potential drawbacks. The residual pressure gradient of small mechanical valves in the aortic position is a major concern. There are some reports that state that 19 mm valves are acceptable even for patients of bigger build,³⁻⁵⁾ whereas some authors insist that 19 mm (or 21 mm) valves are unacceptable because of the large pressure gradients.⁶⁻⁹⁾

The clinical results obtained in our patient series were comparable to those of other reports.^{20,21)} Valve-related early and late mortality and morbidity were low. All late survivors were doing well, and cardiac symptoms were rare late after surgery. No detrimental effect of small valves was observed.

UCG revealed satisfactory functions of 25 mm and 27 mm CM valves, while it suggested that 19 mm and 21 mm valves were very narrow and that the pressure gradient might cause significant afterload mismatch.²²⁾ The EOA were much smaller than those of normal native valves. Even the data of the 23-mm valve seemed to be suboptimal.

In all valve size groups, however, ESWS were within the normal limit. LVMI and SV1+RV5 were significantly decreased and ST-T changes disappeared or became much less evident following AVR. Even in patients with 19 mm and 21 mm valves, relief of the LV overload was comparable to that in patients with 25 mm and 27 mm valves, suggesting that those small size valves were also functioning satisfactorily. In addition, mean %FS and CTR were well within the normal range late after surgery.

In our patient population, no UCG data of prosthetic valve function at rest showed significant correlation with late results, and thus did not prove to be useful. The cut-off values of the valve function imply marked aortic stenosis. There was, however, no significant difference in postoperative data whether UCG data was above or below the cut-off values. This discrepancy may be caused by the overestimation of Doppler UCG. Anyway, when UCG is used for evaluation, peak pressure gradient over 40 mmHg, EOA less than 1.0 cm², or EOAI less than 0.7

cm²/m² do not always mean prohibitively poor prosthetic valve function.

In the present study, patients were not divided into subgroups according to the aortic valve diseases, as the number of the study population was not large. Patients were not randomized as to the valve size. So we observed the impacts of moderate patient-prosthesis mismatch, whereas the effects of extreme mismatch are unknown. In addition, usefulness of the evaluation of the prosthetic valve function on exercise should be determined by further study.

Conclusion

Successful relief of LV overload in patients with 19 mm and 21 mm CM valves was observed despite large pressure gradients and small EOA. UCG data such as peak pressure gradient over 40 mmHg, EOA less than 1.0 cm², and EOAI less than 0.7 cm²/m² can be acceptable.

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