Single-institution, 22-year follow-up of 786 CarboMedics mechanical valves used for both primary surgery and reoperation

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Objectives: The long-term (>20 years) results for CarboMedics mechanical valves (Sorin Group, Milano, Italy) used for both primary surgery and reoperation have never been reported or compared.

Methods: Since 1990, a total of 787 CarboMedics valves have been implanted in 694 patients for aortic valve replacement, including 19 redo cases in 220 patients; for mitral valve replacement, including 108 redo cases in 381 patents; and for double (aortic and mitral) valve replacement, including 29 redo cases in 93 patients. The follow-up data were complete for 7201 patient-years in 99.3% of the patients.

Results: The hospital mortality rate of the aortic, mitral, and double valve replacement groups was 0.9%, 3.7%, and 4.3%, respectively. The corresponding freedom from valve-related morbidity rates in each group were 66.0%, 40.6%, and 48.0% at 20 years ($P = .0206$). A higher incidence of paravalvular leakage was observed in the mitral and double valve replacement groups than in the aortic valve replacement group ($P = .0019$). Of the cases of mitral paravalvular leakage after single mitral valve replacement, 97% occurred after redo single mitral valve replacement; 73% of the cases of mitral paravalvular leakage after double valve replacement occurred after redo double valve replacement.

Conclusions: CarboMedics mechanical valves used for both primary surgery and reoperation for aortic, mitral, and double valve replacement can achieve satisfactory early and long-term results, even 20 years after surgery. Care should be taken, however, to prevent paravalvular leakage in the mitral position during reoperation. (J Thorac Cardiovasc Surg 2014;147:1493-8)

ACD

The use of bioprostheses has been increasing with the improvements in durability[1,2]; however, mechanical valves are still useful prostheses, especially for younger patients, owing to the excellent long-term durability and freedom from reoperation. We have used CarboMedics (CM) bileaflet mechanical heart valves (Sorin Group, Milano, Italy), made of pyrolitic carbon, since 1990 and previously reported preferable 10-year results for this prosthesis.[3] With this experience, we have noted the advantages and problems with the CM prostheses, especially in redo cases, after preceding valve replacement.

Using the European system for cardiac operative risk evaluation and Society of Thoracic Surgeons scores, redo heart surgery itself has been considered a risk factor, and the number of reoperations after valve surgery, especially when implanted with bioprostheses, has been observed to increase during long-term follow-up. In contrast, mechanical prostheses implanted in relatively younger patients have been expected to be reliable and durable without the need for additional surgery during the long-term (>20 years after surgery). However, the long-term results of the CM prosthesis, used for both primary and redo operations, have not yet been reported or compared. In particular, the rates of thromboembolic and hemorrhagic complications associated with CM valves have not been well described in existing studies. We have analyzed our 22-year clinical experience with the CM valve for both primary and redo operations to evaluate the reliance of this second-generation bileaflet valve.

METHODS

A total of 760 patients underwent valve replacement with a CM prosthesis from May 1990 to August 2012. Of these patients, 16, who had undergone tricuspid valve replacement, were excluded for simplicity of the analysis, and 50, who had undergone double valve replacement (DVR; aortic valve replacement [AVR] plus mitral valve replacement [MVR]), were excluded because they had undergone AVR with other prostheses. Therefore, a total of 787 CM prostheses had been implanted in 694 patients (AVR in 220 patients, MVR in 381 patients, and DVR in 93 patients) and were included in the present study. The mean patient age was 54.9 ± 0.94 years in the AVR group, 60.0 ± 0.56 years in the MVR group ($P < .05$ vs other groups), and 56.2 ± 1.1 years in the DVR group.

The predominant cause of valve disease was rheumatic or degenerative heart disease in all groups (Table 1). Various aorta-related diseases were also observed in the AVR group. Previous valve replacement surgery was observed in 19 patients (8.6%) in the AVR group, 108 patients (28.3%) in the MVR group, and 29 patients (31.2%) in the DVR group (Table 1).

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Abbreviations and Acronyms

AVR = aortic valve replacement
CM = CarboMedics
DVR = double valve replacement
MVR = mitral valve replacement
%/Pt-Yrs = percentage per patient-years
Pt-Yrs = patient-years
PVE = prosthetic valve endocarditis
PVL = paravalvular leakage

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The details regarding surgery and patient care have been previously described.[3,4] In brief, all patients underwent surgery using standard cardiopulmonary bypass with moderate hypothermia (at 28-34°C). Either cold crystalloid[5] or blood cardioplegia, associated with ice slush topical cooling, was delivered, either antegrade or retrograde, or both. Everting mattress sutures with 2-0 braided polyester sutures reinforced with polytetrafluoroethylene (Teflon) felt pledgets were the predominant method used to suture the valves.[6] Horizontal mattress sutures, the single suture technique, or the annular enlargement technique[4] were applied for AVR of the small aortic annulus. The modified Bentall operation with direct suturing of the coronary button to a tube graft with CM prosthesis was applied in 31 patients, and the Cabrol modification was applied in 2 patients. In the AVR, MVR, and DVR groups, concomitant coronary artery bypass grafting was performed in 17, 25, and 2 patients, respectively. In 6 patients with paravalvular leakage (PVL), glutaraldehyde-preserved pericardial xenografts were used to repair and reinforced the mitral annulus responsible for the PVL.

Heparin calcium of 5000 or 7500 U was administered subcutaneously every 12 hours starting on the first postoperative day until the international normalized ratio of the prothrombin time reached a therapeutic range with oral warfarin administration. After discharge from our hospital, the international normalized ratio of the prothrombin time was measured at least every 4 weeks and maintained at 2.0 to 2.8 in the MVR or DVR patients and 1.8 to 2.4 in the AVR patients.

Early postoperative and then monthly or annual follow-up was performed for most patients by us in our outpatient clinic. We directly interviewed the "visit-interrupted" patients themselves, their families, or physicians using questionnaires sent by mail or telephone. If we were informed of the patient's death in the response to our questionnaire, we directly interviewed the physician in charge to reconfirm the cause of death and/or any related complications.

Five patients could not be contacted; thus, the follow-up data were complete for 99.3% of the patients. The mean follow-up period was 10.4 years (12.0 ± 0.4 years in the AVR group, 9.1 ± 0.3 years in the MVR group, and 11.7 ± 0.7 years in the DVR group), with 7201 patient-years (Pt-Yrs). The cumulative follow-up included 2628 Pt-Yrs in the AVR group, 3482 Pt-Yrs in the MVR group, and 1091 Pt-Yrs in the DVR group.

Hospital and late deaths and all valve-related mortalities and complications were strictly defined according to the published guidelines of the American Association of Thoracic Surgery and the Society of Thoracic Surgeons.[7] All continuous variables are presented as the mean ± standard error of the mean. Fisher's exact test and Student's t test were used for the univariate analyses. The incidence of death and events is expressed in linearized form (percentage per Pt-Yrs [%/Pt-Yrs]). The actuarial[8] survival rates and freedom from valve-related morbidities were calculated using the actuarial life table (Kaplan-Meier) method and reported using the standard error of the mean. Comparisons of these estimates were made using the log-rank test. $P < .05$ was considered to be significant.

RESULTS

Early Mortality (Primary Plus Redo Cases)

A total of 20 early deaths occurred within 30 days of surgery and 18 in-hospital deaths that occurred within any interval after surgery. The early mortality rate was 2.9% (20 of 694) for all patients, 0.9% (2 of 220) in the AVR group, 3.7% (14 of 381) in the MVR group, and 4.3% (4 of 93) in the DVR group. The cause of early death was predominantly low output syndrome (in 15 patients) due to a prolonged cardiac ischemic time during surgery. No valve-related death due to prosthetic valve endocarditis (PVE), PVL, or other valve dysfunction was observed. Renal failure (in 3 patients), colon perforation (in 1 patient), and cerebral bleeding (in 1 patient) due to head trauma were the other causes of early death.

Late Mortality (Primary Plus Redo Cases)

Figure 1 shows the rates of freedom from valve-related death and cardiac death and actuarial survival. The linearized ratio of the AVR, MVR, and DVR groups was 1.0%, 1.1%, and 0.8%/Pt-Yrs for valve-related death, 1.3%, 1.8%, and 1.3%/Pt-Yrs for cardiac death, and 2.8%, 3.9%, and 3.3%/Pt-Yrs for all-cause death, respectively. The predominant cause of late death was sudden or unexpected death (from unknown causes) for the valve-related deaths, chronic heart failure for the non–valve-related cardiac deaths, and cancer for the noncardiac deaths. Regarding the other causes of late death, no significant differences were observed in the incidence of thromboembolism, bleeding events, thrombosed valves, or PVE among the 3 groups.

Valve-Related Morbidity (Primary Plus Redo Cases)

No structural valve deterioration was observed in the AVR, MVR, and DVR groups. PVL, pannus formation, bleeding events, thromboembolism, valve thrombosis, PVE, and additional reoperations were associated with the valve-related morbidity. The linearized ratios for each event are listed in Table 2. The actuarial freedom from valve-related morbidity was significantly higher in the AVR group than in the MVR or DVR groups ($P = .0068$; Table 2).

A total of 61 bleeding events were observed (Table 1), including 38 cases of intracranial bleeding, 21 cases of gastrointestinal bleeding, 1 case of urinary tract bleeding, and 1 case of peripheral bleeding. The actuarial freedom from bleeding events at 10 and 20 years after surgery was 93.5% ± 1.8% and 88.4% ± 3.6% in the AVR group, 91.5% ± 1.8% and 82.2% ± 4.0% in the MVR group, and 93.2% ± 2.9% and 84.9% ± 5.5% in the DVR group, respectively.

A total of 73 thromboembolism events were observed (Table 2), including 60 cases of brain infarction, 8 cases of peripheral events, and 5 cases of transient ischemic