Original Article

Valve Replacement with the Omnicarbon Valve Prosthesis. A 10-Year Follow-Up

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Objective

We retrospectively examined the outcomes of 264 patients who underwent consecutive Omnicarbon valve implantation surgery between April 1985 and May 1995.

Methods

At the time of surgery, patients who received this mechanical prosthesis averaged 57±11 years of age. Omnicarbon valves were placed in the aortic position in 36% of the cases, in the mitral position in 44%, and in both positions in 20%. Follow-up was carefully performed, with most patients undergoing physical examination at our clinic. While taking the case history, cardiac physicians specifically questioned the patient about valve-related complications.

Results

Accumulated total patient-years is 1291, with a mean follow-up time of 5.4 years. Survival at 10 years is 79.4±3.9%, including all causes of death and early mortality. Complications recorded during the 11-year study include: thromboembolism (0.1%), hemorrhage (0.4%), endocarditis (0.2%), and nonstructural failure (1.2%). No hemolytic anemia, valve thrombosis, or structural failure was detected during this long-term experience. Functional capability of these patients was subjectively assessed by the NYHA classification system. With follow-up time averaging over 5 years, 97% of our Omnicarbon valve patients are in NYHA I or II.

Conclusion

The Omnicarbon mechanical prosthesis provides a good clinical performance for up to 10 years in both the aortic and mitral positions. Results indicated a low incidence of thromboembolism and of hemorrhagic complications.

Key words

mechanical heart valve, morbidity, survival, thromboembolism

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Since Hufnagel implanted the first prosthetic valve in the descending aorta in 1960, continuous technological advancements have developed in structure as well as design, directed at obtaining the ideal artificial cardiac valve. However, achievements obtained in the biomedical engineering field do not always mean an improvement in clinical results. In this sense, we find retrospective studies with long-term follow-up to evaluate technical improvement particularly interesting from a clinical point of view.

Our department began using the Omnicarbon valve (Medical Incorporated, Minneapolis, USA) in 1985. The current study comprised patients who underwent surgery from April 1985 until May 1995. We based our study on the guidelines published by Edmunds[1] to describe mortality and morbidity events.

The Omnicarbon valve is a monoleaflet valve made of a hingeless, pyrolytic carbon, curved disc supported by 2 pivots extending from the housing, which is made of the same material. The valve is mounted in a very flexible suture ring made with a seamless Teflon material. It is important to emphasize how easily the suture ring adapts to the native annulus, and that it is possible to rotate the valve housing [2].

Methods

A total of 318 Omnicarbon valvular prostheses were implanted in 264 patients in Hospital Clínico Universitario of Valladolid. This population was equally distributed between 133 men (50.4%) and 131 women (49.6%). The mean age at the time of surgery was 56.7±11.2 years, with ages ranging from 24 to 80.

Procedures included 95 (36%) aortic valve replacements (AVR), 115 (44%) mitral (MVR), and 54 (20%) cases in which both of these valves were replaced (DVR). The valve size (annulus diameter) most used in the aortic position was 25, and it was 29 in the mitral position (fig.1)

Previously, 89 operations were performed on 67 patients (25%). These included 35 valve replacements, 26 commissurotomies, 14 annuloplasties, 12 pacemaker implants, and 2 other heart repairs. At the time of surgery, 66% (174/264) of the patients were in NYHA class III or IV, 32% (84/264) were in class II, and only 2% (6/264) were in class I. Elective surgery was performed in 89% of the patients (235/264), and emergency operations were performed in the other 11% (29/264).

The operation was performed with extracorporeal circulation and moderate systemic hypothermia. In general, the mitral valve prosthesis was positioned with the large orifice toward the outflow tract of the left ventricle. Aortic prostheses were positioned with

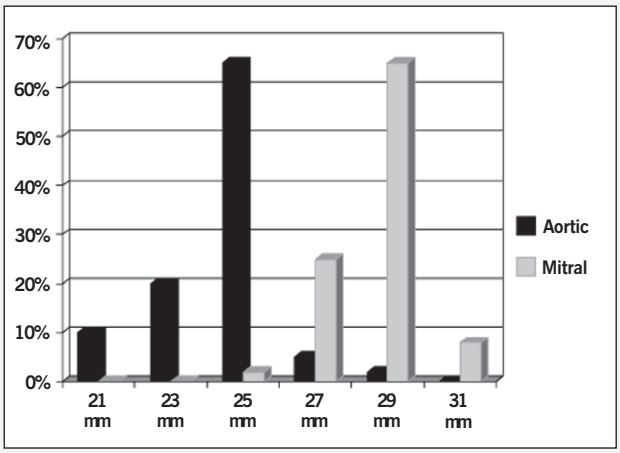

Fig. 1 - Valve size in mitral and aortic position.

the disc motion toward the right anterior direction. Our suture technique mostly used interrupted sutures of polyester 2/0 thread supported with Teflon pledgets.

Systematically, anticoagulation was initiated with heparin sodium until effective protection with acenocoumarol was achieved. Oral anticoagulation with acenocoumarol was begun when drainage had been removed, and anticoagulation was maintained indefinitely. Postoperative valvular thromboembolic potential was individualized, with special emphasis on the period of maximum risk, which was the first hours or days following surgery. In this sense, very early treatment with heparin simultaneously with oral anticoagulants until the patients reached the desired level of anticoagulation was beneficial. Association of acenocoumarol with dipyridamole was combined in patients with a higher risk for thromboembolic complications, as for example atrial fibrillation and a history of embolic events. The acenocoumarol dosage was adjusted with respect to prothrombin time (PT) expressed in activity percentage (25-35%) or, in more recent years, according to the international normalized ratio (INR). Anticoagulant therapy was adjusted for each patient to maintain an INR between 2.5 and 3.5 in DVR or MVR patients and between 2.0 and 3.0 in AVR patients.

We performed follow-up of most patients by outpatient examination (180/226 patients, 80%), by phone with 26 (12%), by letter with 6 (3%), and in 14 (6%) by reviewing clinical records. It was impossible to contact 13 patients; therefore, this 11-year study has follow-up information for 95.1% of the patients.

The maximum follow-up was 11.1 years with an average of 5.4±0.2 years, which means a total of 1291 patient-years involving 239 patients at risk (AVR: 491, MVR: 546, and DVR: 254).

Echocardiographic follow-up was performed with conventional transthoracic echocardiography. Only when echocardiographers detected anomalies did they perform transesophageal echocardiography to define the problem.

Classification of the causes of morbidity and mortality was performed following the guidelines published by the *Society of Thoracic Surgeons* and the *American Association for Thoracic Surgery* [1]. Data are expressed when appropriate as mean ± standard deviation, simple percentages, or linearized rate of events with standard error.

All the survival curves and event-free curves were calculated by using the actuarial method, and probabilities are expressed with the standard error.

Results

Twenty-five patients died during the postoperative period (<30 days or before hospital discharge), which means an early mortality rate of 9.5% (4.2% AVR, 12.2% MVR, 13% DVR). The mean age of this group was 59.6±13.2 years, which is significantly higher than the mean age for all patients (P<0.001).

The most common cause of death was low cardiac output (7/25), followed by multiorgan failure on 6 occasions, 3 uncontrollable hemorrhages, 2 malignant ventricular arrhythmias, 1 cerebral embolism, 1 acute myocardial infarction, 1 generalized sepsis, and the remaining 4 patients died of noncardiac causes.

Thirty patients (9 AVR, 14 MVR, 7 DVR) died after surviving the postoperative period, which yields a linearized rate of 2.3±0.4%/patient-year (pty) (1.8±0.6% for AVR, 2.6±0.7% for MVR and 2.8±1.0% for DVR). Eleven patients died due to valve-related complications, as defined by Edmunds [1]: sudden death (5), hemorrhage (2), endocarditis (2), and perivalvular leak (2). The same number of patients (11/30) died from heart-related causes: 10 from cardiac failure and 1 from arrhythmia. The cause of death of 3 patients is unknown and in the remaining 5 patients, death was attributed to noncardiac causes.

The total survival at 10 years, considering all causes of death and including early mortality, is 79.4±3.9% (81.2±6.4% in AVR, 78.5±5.5% in MVR, and 78.8±7.5% in DVR). Survival curves according to each group of patients are shown in figure 2. If only late mortality associated with valve replacement is considered, survival at 10 years is 95.5±1.8% (95.7±2.5% in AVR, 90.2±4.4% in MVR, and 93.3±4.6% in DVR).

Valve related complications - During the follow-up period, the actuarial rate of freedom from suffering a thromboembolic event at 10 years was 99.5±0.5% (97.6±2.4% for DVR). Only one patient had a thromboembolic event (DVR, nonfatal). The linearized rate is 0.1±0.1%/pty (0.4±0.4%/pty DVR). No valvular thrombotic events occurred.

The linearized rate for hemorrhage is 0.4±0.2%/pty (0.6±0.4%/pty AVR and 0.8±0.6%/pty DVR). The 10-year actuarial rate of freedom from hemorrhagic events is 96. 1%±2.5 (94.2±4.3% in AVR and 92.3±3.1% in DVR). Five major bleeding accidents related to the use of anticoagulants occurred in 3 patients (2 AVR, 1 DVR). On 3 occasions, hemorrhage was of digestive origin; also 1 fatal case of intracerebral hemorrhage and 1 nonfatal

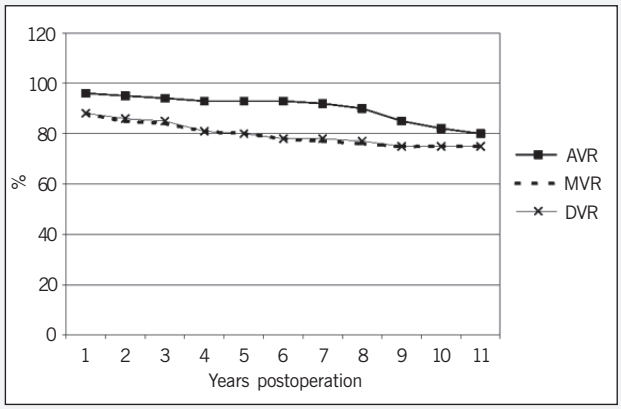

Fig. 2 - Survival.

urological bleed occurred. The 2 patients who died as a result of hemorrhage had been previously diagnosed with aortic perivalvular leakage with clinical repercussion and were pending reoperation. The third patient (DVR) who experienced bleeding also suffered from severe pulmonary hypertension and right ventricular insufficiency with secondary hepatic deterioration, and required hospitalizations due to digestive bleeding and hematuria. This patient died 2 years after surgery to improve cardiac failure.

The combined incidence of thromboembolism and hemorrhage is 0.5±0.2%/pty.

Two cases of late postoperative prosthetic endocarditis were diagnosed (1 MVR, 1 DVR). This corresponds to a linearized rate of 0.2±0.1%/pty (0.2±0.2%/pty in MVR and 0.4±0.4%/pty in DVR). Both patients were reoperated on, replacing the infected valves, and both died during the postoperative recovery period. The actuarial rate of freedom from endocarditis at 10 years is 98.0±0.6% (98.2±1.3% for MVR and 96.1±2.1% for DVR).

Nonstructural failure was diagnosed according to transthoracic echocardiographic data, and as we noted in the Methods section, transesophageal echocardiography was performed when echocardiographers needed to define the problem. The therapeutic decisions were made using standard criteria, according to echocardiographic data and the clinical situation (hemodynamic compromise and hemolytic anemia).

Nonstructural failures were detected in the form of valvular dehiscence or pannus growth in 15 patients (6 AVR, 6 MYR, 3 DVR). This corresponds to a linearized rate of 1.2±0.3%/pty (1.2±0.5%/pty for AVR, I.1±0.4%/pty for MYR, and 1.2±0.7%/pty for DVR). The actuarial rate of freedom from nonstructural failure at 10 years is 87.9±3.9% (89.1±5.4% for AVR, 80.7±10.3% for MYR, and 92.2±4.3% for DVR). In this group of 15 patients, 13 (87%) experienced significant perivalvular dehiscence with hemodynamic compromise or hemolytic anemia, or both of these (6 AVR, 5 MVR, 2 DVR). It was not possible to surgically correct this problem in 3 patients: 2 died before surgery due to major hemorrhage (previously discussed), and surgery was not considered for the third due to the extreme clinical situation. Two of the remaining 10 patients did not survive the reoperation. Dehiscence events correspond to a linearized rate of 1.0±0.3%/pty (I.2±0.5%/pty in AVR, 0.9±0.4%pty in MVR, and 0.8±0.6%pty in DVR).

Two patients (1 MVR, 1 DVR) required reoperation to correct a periprosthetic pannus. It is interesting that both cases also had slight (not hemodynamically significant) perivalvular leakage. The linearized rate of this nonstructural complication is 0.2±0.1% (0.2±0.2% for MYR, 0.4±0.4% for DVR).

Except for the cases of perivalvular leakage accompanied by clinical hemolysis, we have not observed any Omnicarbon valve patient with hemolytic anemia. Furthermore, no case of prosthetic structural failure occurred.

Fourteen patients (6 AVR, 6 MVR, 2 DVR) underwent reoperation, which represents a linearized rate of 11±0.3%/pty (I.2±0.5%/pty for AVR, 11±0.4%/pty for MVR, and 0.8±0.6%/pty for DVR). Indications for reoperation were dehiscence (10), pannus (2), and endocarditis (2). Of this group of reoperated on patients, 4 did not survive surgery or died during the early postoperative period (2 from perivalvular leaks and 2 from endocarditis). This represents a mortality rate associated with reoperation of 28.6%. The actuarial rate of freedom from reoperation at 10 years is 88.7±3.9% (88.8±2.6% for AVR, 89.6±4.1 for MYR, and 92.3±3.8% for DVR).

Tables I and II summarize the linearized rates of complications and the actuarial probabilities of freedom from morbidity. At the current follow-up examination (mean postoperative time of 5.4 years), 96.9% of the patients were in NYHA class I or II.

Discussion

The Omnicarbon mechanical prosthesis was available as a valve substitute in Spain in 1984. Scientific investigation to produce the third generation of the Omni design (hingeless disc inside an integral housing) resulted in the Omnicarbon valve; its predecessors were the Lillehei-Kaster and omniscience prostheses [2]. The Omnicarbon valve is a monoleaflet prosthesis with a low profile and is totally made of pyrolytic carbon.

In this retrospective study, the long-term results obtained from a significant number of patient studies, 264 with 318 valves implanted, are analyzed. The follow-up period (average of 5.4±0.2 years, with a maximum of 11.1 years) permits evaluation of Omnicarbon valve clinical performance on a long-term basis.

Hospital mortality in this series was 9.5%, similar to results obtained by other investigators [3-6]. Hospital mortality is related to the preoperative functional situation of the patients, the degree of ventricular deterioration, and age. The main cause of early mortality in our group was low cardiac output syndrome (28% of all deaths).

During the follow-up period, 30 patients died, representing a linearized rate of 2.3±0.4%/pty. Eleven (37%) of these deaths were due to causes related to the valve replacement (hemorrhage,

Table I - Complications: linearized rates %/pty

Complication	AVR	MVR	DVR	All patients
Thromboembolism	0	0	0.4±0.4	0.1±0.1
Hemorrhage	0.6±0.4	0	0.8±0.6	0.4±0.2
Endocarditis	0	0.2±0.2	0.4±0.4	0.2±0.1
Nonstructural failure	1.2±0.5	1.1±0.4	1.2±0.7	1.2±0.3
Hemolytic anemia	0	0	0	0
Structural failure	0	0	0	0
Reoperation	1.2±0.5	1.1±0.4	0.8±0.6	1.1±0.3
Late mortality, all causes	1.8±0.6	2.6±0.7	2.8±1.0	2.3±0.4

AVR - aortic valve replacement; MVR - mitral valve replacement; DVR - double valve replacement.

Table II - Complications: actuarial probabilities of freedom from event at 10 years postoperation (%)

Complication	AVR	MVR	DVR	All Patients
Thromboembolism	100	100	97.6±2.4	99.5±0.5
Hemorrhage	94.2±4.3	100	92.3±3.1	96.1±2.5
Endocarditis	100	98.2±1.3	96.1±2.1	98.0±0.6
Non-structural failure	89.1±5.4	80.7±10.3	92.2±4.3	87.9±3.9
Hemolytic anemia	100	100	100	100
Structural failure	100	100	100	100
Reoperation	88.8±2.6	89.6±4.1	92.3±3.8	88.7±3.9
Late mortality, all causes	95.7±2.5	90.2±4.4	93.3±4.6	95.5±1.8

AVR - aortic valve replacement; MVR - mitral valve replacement; DVR - double valve replacement.

endocarditis, nonstructural dysfunction, and sudden death), and another 11 patients died due to cardiac reasons (primarily cardiac insufficiency). Therefore, congestive heart failure is considered the predominant cause of late mortality. In this sense, it is important to consider Nitter-Hauge's [7] recommendation that the durability and low thrombogenicity of currently available mechanical valves justify surgery being performed sooner, before irreversible myocardial injury occurs, thus improving long-term life expectancy [8].

After statistical analysis of the results, we have an actuarial survival rate at 10 years of 95.5±1.8%, considering only late mortality associated with valve replacement. Life expectancy is lower for the mitral valve replacement patients. Other studies related to mechanical prostheses with follow-up time equivalent to ours show similar survival rates [9-13].

Thromboembolism, which is the predominant problem related to mechanical valves, was low in our Omnicarbon valve patients. No case of prosthetic thrombosis occurred. The actuarial freedom rate from suffering a thromboembolic episode is 99.5+0.5%. It is obvious that the genesis of this complication is multifactorial, with valve design as one component. Our results are clearly favorable for the Omnicarbon prosthesis and agree with the results of other authors who studied the Omnicarbon valve [9,10,14-17].

Our combined rate of thromboembolism and hemorrhage is low at 0.5±0.2%/pty [18].

Antithrombotic therapy in cardiac valve surgery continues to be a controversial issue. The moment to initiate anticoagulation, type of heparin and controls, treatment intensity, and the association or not of antiplatelet medication is continuously being revised. The results presented in our series might be a consequence of the early and individualized anticoagulation schedule we follow. Identification and separation of subgroups of patients with a different thromboembolic risk [19,20] and standardization of the anticoagulation protocol through INR allows for individualizing anticoagulation treatment, reducing the risk of hemorrhage without reducing thromboembolic protection.

Previous studies of the Omnicarbon prosthesis in other hospitals have not reported any cases of hemolytic anemia. Knott et al [21] of the Helmholtz Institute for Biomedical Engineering (Germany) studied hydrodynamic characteristics of 10 different mechanical valves and showed that the Omnicarbon prosthesis has a comparatively lower regurgitation velocity and volume and thus a lower capacity for inducing hemolysis [22]. Our group detected hemolysis analytically or clinically, or both, only in Omnicarbon valves with perivalvular dehiscence.

Although it is completely clear that perivalvular dehiscence and endocarditis are directly related to the surgical technique or patient circumstances, or both, rather than to the valve design, these complications are important to review when evaluating results of valve replacement. In our department, periprosthetic leakage is normally evaluated through clinical examination and color Doppler echocardiography. The literature [22-25] on this subject reports a wide diversity of results, partly due to the variation in sensitivity of the different diagnostic methods used, difficulty in clinically evaluating the severity of regurgitation to include it as a valvular complication, and the occasional problem of differentiating pathological perivalvular from normal transvalvular regurgitation, which becomes extremely difficult if associated with rapid heart rates. Since color Doppler echocardiography has become routine for patients with prosthetic valves, detection of perivalvular leakage with slight to moderate degrees of regurgitation is now probably easier and more frequent.

Hemodynamic behavior of the Omnicarbon valve has been shown to exhibit clinical performance equal to that of other current mechanical valves [15-17]. Our data agree with those of researchers at the University of Bonn [26] and the University of Montpellier [27] who established expected hemodynamic values for different Omnicarbon valve sizes in both the mitral and aortic positions. Knowing the hemodynamic profile of each valve facilitates identification of prosthetic dysfunction, if it develops.

We consider that a limitation of the study is the absence of an exhaustive analysis of echocardiographic data. They are important for evaluating hemodynamic function and its repercussion in ventricular mass, and to establish the exact magnitude of nonstructural failure. In this sense, we are preparing a new prospectic study.

The clinical results we obtained after long-term experience with the Omnicarbon valve establish this prosthesis as a preferred mechanical valve. The incidence of thromboembolic complications was remarkably low. Survival and quality of life are satisfactory.

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