The Role of Prosthetic Valves in the Treatment of Valvular Disease of the Heart

— With Particular Attention to the Quality of Life
after Valve Replacement —

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Whenever we talk about the surgical treatment of valvular disease of the heart (VHD), we must mention the use of prosthetic valves to restore valve function. Cardiac surgeons recommend prosthetic valve replacement to patients, explaining that they will be rehabilitated by this operation. The patients then undergo surgery taking their rehabilitation for granted. In fact, we have seen a marked improvement in the quality of life in these patients after prosthetic valve replacement.

In 1973 our institute established an outpatient clinic for patients with prosthetic valve. The objective of this clinic was to make the best use of prosthetic valves in life-long treatment programs for valve disease patients.

In the present study, we have surveyed the cases encountered in our daily practice, particularly, over the last 10 years at our outpatient clinic.

SUBJECTS

1. We performed valve replacement in a total of 1,465 patients over the 19 years between January 1964 and December 1982. An initial operation was performed in 1,358 cases, and reoperation in 107.

There were 507 cases of aortic valve replacement, 657 cases of mitral valve replacement, 25 cases of tricuspid valve replacement, and 276 cases of multiple valve replacement. Operative mortality for adult patients was 1.8% in 1976. The mortality rose over the next 3 years. Since 1980 the operative results have improved. The average mortality for the last 6 years was 3.0% for new cases and 2.2% for reoperations (Fig. 1).

2. The highest age at reoperation was 10–15 years for cases receiving bioprosthetic valves (Fig. 2).

The reoperation rate was very high for patients who had received the SAM and the Starr-Edwards valves which were introduced in the early days (Fig. 3). For patients with bioprosthetic valves, the reoperation rate was moderately low. Reoperation for these patients was performed mainly in children in whom the bioprosthetic valves had calcified. The remaining valves, the Björk-Shiley valve and the SJM valve, are still used with very low reoperation rates. We are satisfied that we have selected the appropriate prosthetic valves.

Figure 4 shows the results in patients with isolated mitral valve replacement. The results were satisfactory for all patients, with the exception of those receiving the second generation SAM valve. After 11 years 96% of 181 Björk-Shiley valves were still working and 100% of 162 SJM valve were satisfactory after 5 years. Thus, the results were satisfactory with both Björk-Shiley and SJM valves.

Of patients operated on between 1977 and 1982, 97.9% have not required reoperation.

The actuarial survival rate for patients under-
going MVR reoperation was 84% from 3–13 years postoperatively (Fig. 5). This means that cardiac function retained after the initial operation was maintained even after reoperation. This shows that lift-long treatment programs for mitral valve disease patients can be formulated if valvotomy or valve replacement is performed at a suitable time.

Two-dimensional echocardiography is now capable of demonstrating the presence of mitral valve disease, and its findings enable surgeons to select either valve reconstruction or valve replacement, irrespective of the hemodynamics.

3. We performed valve replacement in 62 patients with native infective endocarditis (IE) (Fig. 6).

4. We performed valve replacement in 516 female patients of whom 32 became pregnant, a total of 42 times.

### Fig. 2. Reoperation free proportion isolated MVR.

<table>
<thead>
<tr>
<th>No. Case</th>
<th>SAM</th>
<th>Xenografts</th>
<th>Björk-Shiley</th>
<th>Others (SE, KS, OS)</th>
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### Fig. 3. Clinical course of patients without previous surgery.

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METHODS

1. We examined operative mortality rates chronologically in patients undergoing an initial operation and patients undergoing reoperation. We also studied the relations between operative mortality and indications for surgery (i.e., severity, clinical grade and functional classification), the types of prosthetic valve, and surgical aids (i.e., cardioplegia, cardiopulmonary bypass and anesthesia).

2. Postoperative complications were also investigated, such as low cardiac output syndrome (LOS), arrhythmia, respiratory insufficiency, central nervous system disorders, acute renal failure and infection. We also investigated the relationship between these complications and the postoperative hospital mortality rate.

3. The relationship between the decision-making process for the treatment of infective endocarditis and the execution of valve replacement was investigated.

Two topics related to the quality of healing in the chronic phase were also considered.

4. The occurrence of thromboembolism after the insertion of bioprosthetic valves and mechanical valve, and the incidence and severity of thromboembolism with each type of prosthetic valve.

5. Thromboembolism and problems with anticoagulant therapy in 32 female patients having between then a total of 42 pregnancies and deliveries.

RESULTS

1. The operative mortality over the last 18 years was 16.3% for initial operations and 10.3% for reoperations.

When 3 periods of 6 years each were considered, the mortality for reoperations was lower than that for initial operations in the first period. During the second period, the operative mortality for both reoperations and initial operations fell. In the third period, from 1976 until 1981, the operative mortality was 3.0% for initial operations and 2.2% for reoperations.

2. For both initial operations and reoperations the hospital mortality declined, while the incidence of postoperative complications increased. Deaths from low cardiac output
syndrome decreased gradually, while the incidence of LOS as a complication increased. There were correlations between an increased incidence of complications and high age at operation, increased numbers of multiple valve replacements, and a decrease in deaths from LOS.

3. In active and healed IE patients, the death rate with medical treatment was 7 out of 39 or 17.9%, and for surgical treatment it was 3 out of 62 or 4.8%. Thus, surgery produced better results. Underlying disease was present in 74% of IE patients, and it was closely related to the pathophysiology, diagnosis and treatment of IE. Fraction shortening or FS value in two-dimensional echocardiography, a noninvasive examination of active IE, gave a good gride to the patient's prognosis.

4. The incidence of cerebral embolism after mitral valve replacement was 2.0% per patient year for mechanical valves and 1.0% per patient year for bioprosthetic valves. Thus, there was no significant difference between both types of valve. The incidence after aortic valve replacement was 0.3% per patient year for mechanical valves and 4.3% per patient year for bioprosthetic valves. The incidence after tricuspid valve replacement was 0% per patient year for both types of valves. The incidence after multiple valve replacement was 1.4% per patient year for mechanical valves and 0% per patient year for bioprosthetic valves.

We classified the severity of cerebral embolism into three grades and examined whether there was a difference in severity between mechanical valves and bioprosthetic valves. There was a clear difference: patients with mechanical valves tended to have more serious cerebral embolism than patients with bioprosthetic valves, and have a poorer prognosis.

5. We have performed valve replacement in 516 female patients of whom 32 became pregnant on a combined total of 42 occasions. Warfarin was administered in 24 of 42 pregnancies between onset and delivery. It was not given in the remaining 18 cases. The warfarin treatment group had 8 live births (including one mentally retarded baby), 3 stillborn babies, 1 spontaneous abortion, 12 induced abortions, 2 maternal deaths associated thrombosed valves, and 1 cerebral embolism. The non-treatment group had 8 live births, 2 spontaneous abortions, 6 induced abortions, no stillborn babies, no maternal deaths, and no complications. Cardiac insufficiency occurred in 6 of 42 pregnancies, but was brought under control.

CONCLUSION

1. Valve replacement has now become a very safe operation with the help of cardioplegia, cardiopulmonary bypass and appropriate prosthetic valves.

2. As the hospital mortality rate falls, the problems of patients who have undergone valve replacement become clearer. Low cardiac output syndrome, arrhythmias and coronary disease are

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the important complications of surgery.

3. If the cause of heart disease is IE, surgical treatment is effective. The time to operate, however, differs somewhat from other situations because infection is present in the patient. Whether to operate or not should be decided with consideration for the presence of infection. A decision-making tree is suggested based on the type of causative organism, the type of underlying disease, hemodynamics, cardiac rhythm, drug efficacy, and the two-dimensional echocardiogram (or fraction shortening value). This is useful in deciding whether to operate.

4. The anticoagulant therapy in current use is not entirely satisfactory and may not completely alleviate thromboembolism in patients undergoing mitral valve replacement. The rheologic properties of the prosthetic valves are related to the severity of thromboembolism.

5. Valve-implant patients on anticoagulant therapy encounter many difficulties when they are pregnant. We observed 2 maternal deaths in these patients.

6. Our clinic for outpatients implanted with prosthetic valves has improved the quality of care for these patients.