Mechanical versus biological isolated aortic valvular replacement after the age of 70: equivalent long-term results


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Abstract

Objective: In order to evaluate the long-term outcome of valvular substitutes in the elderly, we retrospectively analyzed two comparative groups of patients consecutively operated on by the same team for an isolated valvular aortic replacement using either a mechanical or a pericardial prosthesis. Methods: From 1982 to 1996, 206 patients over 70 years (mean 76.5 ± 4.4) underwent an isolated aortic valvular replacement using either a St. Jude Medical (Group I, n = 93) or a Mitroflow (Group II, n = 113) prosthesis depending on the surgeon’s preference at the time of surgery. Both groups matched for the following pre-operative variables: sex ratio, type of aortic valve disease, NYHA status, cardiac rhythm, mean pulmonary arterial pressure, left ventricular end-diastolic pressure, LV-AO gradient, cardiac index and ejection fraction. Results: Given an early mortality rate of 6.4% in Group I and 4.4% in Group II (NS), follow-up (mean 4.4 ± 3.7 years in Group I and 5.3 ± 3.1 years in Group II) was 100% complete. Actuarial survival was 69.9 ± 6 and 70.2 ± 4.6% at 5 years for Group I and Group II, respectively, and 49.6 ± 7.7 vs. 51.4 ± 6.3% at 10 years (NS). Freedom from valve-related death was 86.5 ± 4.8% in Group I vs. 82.7 ± 4% in Group II at 5 years (NS) and 66.7 ± 8.7 vs. 66.3 ± 7% at 10 years (NS). There were no anticoagulant-related deaths or severe accidents in Group I. A secondary valvular replacement was necessary in 4 patients in Group II vs. none in Group I. Conclusion: The study shows a similar late survival in both groups, with a strikingly low incidence of anticoagulant-related deaths in this population. Given a higher rate of reoperation after biological valve replacement, the use of mechanical valve in this aging population seems to be a valid option. © 1998 Elsevier Science B.V.

Keywords: Aortic valve; Elderly; Long term results

1. Introduction

Elderly patients who need an aortic valve replacement come with the desire of receiving, according to their conditions, the most appropriate valve substitute for the rest of their life. They hope to be operated on only once and to be free of complications. The use of bioprostheses for the replacement of aortic valve in the elderly is well established on the main grounds of anticoagulant related adverse events [1–3]. In order to analyze if the use of a mechanical valve, with their higher structural durability and very low reoperation rate is a valid option, in patients who nowadays have a longer life expectancy, we retrospectively evaluated the outcome of two groups of patients aged more than 70 years at the time of surgery, who received either a mechanical bileaflet valve or a pericardial bioprosthesis in aortic position.
2. Patients and methods

2.1. Patients

Between 1982 and 1996, a total number of 1975 patients received at least an aortic valve replacement in our service. In this overall population of patients, we have retrospectively isolated 206 patients who were more than 70 years old at the time of surgery and underwent an isolated aortic valvular replacement for an isolated aortic valvular disease. No patients had a concomitant coronary artery disease and none had a previous cardiac operation. These selected patients were divided into two groups according to the type of valvular substitute. In Group I (93 patients), a standard St. Jude Medical prosthesis was implanted, while in Group II (113 patients), a pericardial Mitroflow prosthesis was used. The choice of the type of prosthesis was only depending on the surgeon’s preference at the time of surgery.

2.2. Pre-operative data

Clinical data are shown in Table 1. All patients had normal coronary vessels or without significant lesions on pre-operative coronary angiogram. Pre-operative hemodynamic data are shown in Table 2. The two groups matched for the following pre-operative variables: sex ratio, type of aortic valve disease, NYHA status, cardiac rhythm, mean pulmonary artery pressure, left ventricular end-diastolic pressure, LV-AO gradient, cardiac index and ejection fraction.

2.3. Surgical procedures

Operations were carried out by the same team using a standard technique of cardiopulmonary by-pass with moderate hypothermia (28–32°C) and cold anterograde crystalloid cardioplegia combined with topical cooling. All prosthesis were implanted with an interrupted inversed mattress suture technique. Procedure time and diameters of prosthesis are shown in Table 3. The two groups also matched in aortic cross-clamping time and by-pass time.

2.4. Anticoagulation

Intravenous continuous heparin anticoagulation therapy was started on the first postoperative day in all patients. In patients of Group I (SJM prosthesis), heparin was continued until the prothrombin time could be adjusted by daily warfarin administration. The recommended anticoagulation level was a prothrombin time

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Table 1
Clinical data (n = 206)

<table>
<thead>
<tr>
<th>variable</th>
<th>Group I</th>
<th>Group II</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of patients</td>
<td>93</td>
<td>113</td>
<td></td>
</tr>
<tr>
<td>Age (70–80)</td>
<td>75.4 ± 3.7</td>
<td>77.4 ± 4.5</td>
<td>NS</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>50 (53%)</td>
<td>49 (43%)</td>
<td>NS</td>
</tr>
<tr>
<td>Female</td>
<td>43 (47%)</td>
<td>64 (57%)</td>
<td>NS</td>
</tr>
<tr>
<td>Pathology</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aortic stenosis</td>
<td>60 (64.6%)</td>
<td>81 (74.4%)</td>
<td>NS</td>
</tr>
<tr>
<td>Aortic insufficiency</td>
<td>11 (11.8%)</td>
<td>10 (9.7%)</td>
<td>NS</td>
</tr>
<tr>
<td>Aortic disease</td>
<td>22 (23.6%)</td>
<td>22 (15.9%)</td>
<td>NS</td>
</tr>
<tr>
<td>NYHA class</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>1</td>
<td>3</td>
<td>NS</td>
</tr>
<tr>
<td>II</td>
<td>46</td>
<td>52</td>
<td>NS</td>
</tr>
<tr>
<td>III</td>
<td>38</td>
<td>47</td>
<td>NS</td>
</tr>
<tr>
<td>IV</td>
<td>8</td>
<td>11</td>
<td>NS</td>
</tr>
<tr>
<td>Rhythm ECG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sinusal</td>
<td>77 (82%)</td>
<td>100 (88%)</td>
<td>NS</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>15 (16%)</td>
<td>11 (10%)</td>
<td>NS</td>
</tr>
<tr>
<td>Other</td>
<td>1 (1%)</td>
<td>2 (1%)</td>
<td>NS</td>
</tr>
<tr>
<td>History of embolism</td>
<td>3</td>
<td>2</td>
<td>NS</td>
</tr>
<tr>
<td>Syncops</td>
<td>9</td>
<td>12</td>
<td>NS</td>
</tr>
</tbody>
</table>

Group I, SJM prosthesis; Group II, Mitroflow prosthesis.

Table 2
Pre-operative hemodynamic and angiographic data

<table>
<thead>
<tr>
<th>variable</th>
<th>Group I</th>
<th>Group II</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean PAP (mmHg)</td>
<td>19.3 ± 9.1</td>
<td>20.7 ± 9.7</td>
<td>NS</td>
</tr>
<tr>
<td>LVEDP (mmHg)</td>
<td>15.8 ± 8.1</td>
<td>16 ± 17.9</td>
<td>NS</td>
</tr>
<tr>
<td>LV-AO gradient (AS) (mmHg)</td>
<td>78 ± 26</td>
<td>77 ± 25.1</td>
<td>NS</td>
</tr>
<tr>
<td>Cardiac index</td>
<td>2.3 ± 0.5</td>
<td>2.3 ± 0.46</td>
<td>NS</td>
</tr>
<tr>
<td>Ejection fraction (%)</td>
<td>60 ± 16</td>
<td>52.8 ± 17.1</td>
<td>NS</td>
</tr>
</tbody>
</table>

Results are indicated as mean ± S.D.
PAP, pulmonary artery pressure; LVEDP, left ventricular end diastolic pressure; AS, aortic stenosis.

Group I, SJM prosthesis; Group II, Mitroflow prosthesis.
of 20–35%, and more recently an INR of 2.5–3. Patients of Group II (Mitroflow prosthesis) in sinus rhythm were discharged from the hospital under aspirin therapy. After hospital discharge, the referring physician was in charge of the anticoagulation protocol.

2.5. Follow-up

Follow-up data was completed in March 1997 and was based on questionnaires addressed to the physicians or cardiologists in charge of the patients and by telephone interview with all living patients or the patient’s family in case of death. Follow-up was 100% complete and represented 955 patient-years with a mean of 4.4 ± 3.7 years in Group I and 5.3 ± 3.1 years in Group II, and a maximum of 14.3 years. The guidelines of the Society of Thoracic Surgeons and the American Association for Thoracic Surgery were used for definitions of morbid events and mortality [4].

Student’s t-test (discrete variables) and χ² test (continuous variables) were used for inter-group comparisons. Actuarial survival and event-free curves were plotted according to the Kaplan-Meier method. Univariate comparisons of survival were made with the log-rank test.

3. Results

3.1. In-hospital mortality (< 30 days)

There were 11 early deaths (5.3% in the whole population under study). In Group I, 6 patients died (6.4%) while 5 patients (4.4%) in Group II died during the post-operative course (NS). The causes of in-hospital deaths were, respectively, the following for Group I and Group II: sudden lethal hemorrhage in three cases, progressive left ventricular failure in two cases and pulmonary infection in one case (Group I); cardiac insufficiency in two cases, one post-operative hemorrhage, one cerebral stroke and one pulmonary infection (Group II). By univariate analysis, no risk factors for early death was found.

3.2. Late deaths, overall deaths and survival

There were 66 late deaths during the follow-up in the overall surviving population at a linearized rate of 6.7% patient-years. A total of 28 patients of Group I (SJM valve) died during the follow-up (6.8%/patient-years), while 38 patients of Group II (Mitroflow valve) died during the same period (6.3%/patient-years). The causes of late death (Table 4) are as follows: 2 patients in Group I and 5 patients in Group II died of a documented valve-related complication. A sudden death occurred in 4 patients in Group I and 8 patients of Group II. Cardiac failure was directly responsible for death in 4 patients of Group I and in 6 patients of Group II. Non cardiac etiology appeared in 13 cases in Group I and nine cases in Group II. At least the cause of death remained unknown in five and ten cases, respectively, for Group I and Group II. Thus, 11 patients in Group I and 23 patients in Group II died during the follow-up of a presumed valve-related death.

Including early mortality, actuarial survival (Fig. 1) was, respectively, 69.9 ± 6 and 70.2 ± 4.6% at 5 years for Group I and Group II, and 49.6 ± 7.7 vs. 51.4 ± 6.3% at 10 years (NS). After excluding the non-valve-related deaths in the two groups, there was no difference in late survival in patients who received either a mechanical or a biological prosthesis. Freedom from valve-related death (Fig. 2) was 86.5 ± 4.8% in Group I vs. 82.7 ± 4% in Group II at 5 years (NS) and 66.7 ± 8.7 vs. 66.3 ± 7% at 10 years (NS) where 15 patients in Group I and 20 in Group II were still followed-up.

![Fig. 1. Actuarial overall survival for the two groups including the early mortality. Group I, SJM valve; Group II, Mitroflow valve.](https://academic.oup.com/ejcts/article-abstract/13/1/84/490505)
Fig. 2. Actuarial freedom from valve-related death. Group I, SJM valve; Group II, Mitroflow valve.

3.3. Late non-fatal valve-related events

3.3.1. Group I (SJM group)
During follow-up, there was no evidence of thromboembolic episodes in the surviving patients. No patients had any evidence of peri-valvular leakage. There was also no incidence of prosthesis endocarditis.

Two patients were hospitalized for an episode of intestinal hemorrhage induced by the oral anticoagulant therapy: ulcer hemorrhage in one case, medically treated, and hematenaemia in one case also successfully medically treated.

Three patients needed the implantation of cardiac pace-makers at 2, 4 and 8 years, respectively, post-operatively for low rate arrhythmia or conduction disturbances during follow-up.

3.3.2. Group II (Mitroflow group)
During the follow-up, several non-fatal complications occurred in this group. A documented cerebral embolism with persistent hemiparesis occurred in 2 patients. Two patients who received long-term anticoagulant therapy for persistent cardiac arrhythmia presented a severe intestinal hemorrhage necessitating hospitalization and blood transfusions. Valve endocarditis occurred in 1 patient. This patient was reoperated on 7 years after the initial operation and received a mechanical prosthesis.

During the follow-up, 6 patients (5.5%) had echographic aspects of valve degenerescence with progressive elevation of LV-AO gradient or apparition of aortic insufficiency.

3.4. Reoperation
Five reoperations were performed in 5 patients. In Group I, only 1 patient was reoperated on for a mitral valve replacement 10 years after the initial aortic valvular replacement. The aortic prosthesis was functioning normally, but the patient died of left ventricular insufficiency during the early post-operative course. In Group II, 4 patients underwent a secondary aortic valvular replacement, 4, 7, 10 and 11 years after initial operation, required either for valve degenerescence in three cases or valvular endocarditis in one case, respectively. Two patients received a second biological valve, while in the 2 other patients, a mechanical SJM valve was implanted. In this subset, one patient with very poor pre-operative left ventricular function died postoperatively of left ventricular failure.

Two other patients in this group with valvular degenerescence appearing at 8 and 10 years of follow-up, respectively, were not reoperated on because of their advanced age or severe left ventricular dysfunction.

3.5. Functional improvement
In survivors, the functional result was excellent in each group. At the time of the study, 93 and 87% of the survivors in Group I and II, respectively, were in functional class NYHA I or II.

4. Discussion
Given the actual progressive aging of the general population, elderly patients are being increasingly referred to and being accepted by the cardiac surgeon for the surgical management of aortic valvular diseases [5]. The debate continues to focus on the question of the choice of the best valvular substitute in this aged population [6]. Age alone is no longer a valid criteria for therapeutic decisions. Individual characteristics of each elderly patient, as regard to the stage of the disease, associated pathologies, or social conditions, are different and allow stratification of risk factors for particular therapy [7,8].

With a low incidence of thromboembolism, valve thrombosis and freedom from the risk of anticoagulant-related hemorrhage, bioprosthesis are generally supposed to provide patients with a superior quality of life [3,9]. Most published studies recommended the use of bioprosthesis for patients over 70 years of age [1–3,6]. However, 10–15 years after the implantation of a bioprosthesis, surgeons will be faced with increasing numbers of reoperations for valve failure or degenerescence in patients who have become octogenarians, in whom the mortality risk could be as high as 14–25% in patients older than 70 years at the time of surgery [10]. Meanwhile, the experience of mechanical aortic valve replacement in the elderly, as in this study, shows somewhat satisfactory long-term results in this age group, with a strikingly low rate of anticoagulant-related complications. There may be two explanations for this apparently unusual outcome. Firstly, most patients in this series (82 and 88% for Group I and Group II, respectively) operated on for isolated aortic valve re-
placement, were in sinus rhythm pre-operatively, and were thus less exposed to thrombo-embolic complications. Secondly, recently published studies suggested and recommended anticoagulant therapy protocols based on lower doses of warfarin protocols, minimizing the exposure of this population to a lower rate of anticoagulant-related hemorrhage [11–14].

The early mortality rate in the global study clearly demonstrates that isolated aortic valve replacement in elderly patients may now be very safe, as in other series [8,15]. The population under study was a very homogeneous group of patients with isolated aortic valve disease, no associated coronary pathology and generally good LV function (Table 2). Thus, causes of early mortality are represented by either poor pre-operative hemodynamic conditions or technical problems, like hemorrhage related to a more fragile aortic wall as often observed in this age group [5]. There was no correlation between the type of valvular substitute or valve sizes and in-hospital mortality, although some studies [5] had shown that patients receiving small valves had a significantly higher mortality than those receiving valves larger than 23 mm. The vast majority of patients in the study had a rather small aortic annulus accommodating a 19–21 aortic valve in 73 and 72%, respectively, of Group I and Group II patients.

The results clearly show that the majority of patients do well, with the 5-year and 10-year survival far better than that for untreated symptomatic aortic valve pathology [5,16]. Late results are quite similar in our two groups of patients. The 5-year and 10-year actuarial survival rate are not different for patients receiving either a SJM valve or a Mitroflow valve. There are also no significant differences in freedom from valve-related death rates.

Causes of valve-related late mortality in the two groups are interesting to analyze. Only 2 patients in Group I died of a documented cerebral embolism. This confirms the published low incidence of thrombo-embolic events with the SJM valve in the aortic position [16–19]. Anticoagulation-related hemorrhage is curiously the cause of four deaths in patients in Group II, while no patient in Group I died of an hemorrhagic complication. So the use of biological valves in patients who need long-term oral anticoagulation therapy, generally prescribed for atrial dysrhythmias, does not seem to bring any advantage. Furthermore, several studies have demonstrated that the use of a low-dose warfarin protocol in patients receiving isolated mechanical valve is accompanied by a lower incidence of anticoagulant-related hemorrhage, without increasing incidence of thrombo-embolic events [11–14].

Sudden death occurred as often as it does in patients receiving a Mitroflow valve than a SJM valve, suggesting that this particular complication is not mandatory related to the valve [17,20].

Non-cardiac deaths (22 cases for the whole population at risk), and particularly cancer-related deaths, occurred very often in this older population. Finally, the high incidence of intricate pathologies in aging patients makes the choice of a prosthesis more relative.

Four patients of Group II required reoperation for valve degenerescence and/or failure, despite the fact that it is known today that bioprostheses implanted in older patients have a better durability as that of younger patients [21]. Actually, the benefit of a primary anticoagulation-free bioprosthesis does not outweigh the risk of its limited durability due to structural deterioration, with a prohibitive risk of re-replacements in octogenarians [7].

The potential bias of this study is 2-fold. Firstly, although we tried to minimize the effect of a retrospective study by precise questionnaires, the incidence of events such as transient ischemic attacks, for example, may be underestimated. Secondly, some causes of late death remained unknown despite a most accurate retrospective inquiry. However, in the two groups of patients, the distribution of this late event remained similar (5/23 in Group I vs. 10/28 in Group II, NS).

In conclusion, the study clearly demonstrates that two comparable populations of patients over 70 years of age receiving an isolated aortic valve replacement for an isolated aortic valvular disease have equivalent long-term results using either a SJM valve or a Mitroflow valve. Thus, in disagreement with previous studies, but according to more recent ones [11,17], we think that a mechanical bileaflet valve in aged patients for aortic valvular replacement is a valid option. This choice, associated with the recommended low-dose of anticoagulation therapy protocol allows an acceptable risk of anticoagulant-related complication, and limits morbidity and mortality risks associated with reoperation for replacement of a degenerated bioprosthesis. The use of pericardial bioprosthesis in this pathology could remain indicated in very old patients (octogenarians or over), patients exposed to high-risk of hemorrhage or after expressed desire of the patient.

References

Appendix A. Conference discussion

Dr D. Wheatley (Glasgow, UK): Well, there are other viewpoints, obviously, but our experience of patients of this age would echo very much what you say. I think you can get just as good results with a mechanical valve as with a bioprosthesis. The Mitroflow valve was probably not the best pericardial valve to look at, but it was good enough, I think, and I would not disagree with your findings.

Dr A. Scheule (Tuebingen, Germany): If I remember right, you said it was the decision of the surgeon which valve was used. Was the surgeon’s choice based on personal preference only or was the decision which valve to implant made by taking patient-related data into account also? Did you ask the patient before the operation which type of valve he wanted?

Dr J. Ninet: Regarding the choice of the valve, the type of valvular prosthesis was not dictated by cardiologists or any other consideration but was only dependent on the judgment of the members of the surgical team.

Dr Scheule: What kind of judgments were these?

Dr Ninet: It’s personal preference. In our team, some surgeons preferred bioprostheses in aged patients and some others had the preference to implant mechanical prostheses.