Surgery for Valvular Heart Disease

Prospectively Randomized Comparison of Different Mechanical Aortic Valves

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Background—The aim of this prospectively randomized study was to evaluate the hemodynamic and functional outcomes after aortic valve replacement with 3 different bileaflet mechanical valves.

Methods and Results—Three hundred consecutive patients were randomly assigned to receive ATS (n=100), Carbomedics (n=100), or St Jude Medical Hemodynamic Plus (n=100) mechanical aortic valve replacement. There were no significant differences regarding patient age (average 61±8 years), body surface area (1.9±0.2 m²), left ventricular function (ejection fraction 0.59±0.17), and presence of aortic stenosis (90%, 89%, and 91%), respectively. All patients had postoperative as well as 6-month and 1-year follow-ups that included transthoracic echocardiography. Multivariate statistical analysis was performed. Implanted valve sizes were comparable at 24±2 (ATS), 23.7±1.6 (CM), and 23.6±1.9 (SJMHP) mm (NS). At 1-year follow-up, the following incidence of events was noted: death 3/1/1, all non–valve related; stroke 0/1/1; trivial transvalvular incompetence 3/3/2; paravalvular leak 2/3/2; and reoperation 0/1/1, respectively (NS). Transvalvular flow velocities were 2.5/2.6/2.4 m/s postoperatively (P=0.03) and 2.4/2.4/2.3 m/s at 6-month follow-up, respectively (NS). There was a significant decrease in left ventricular mass for all patients but no significant differences among the groups.

Conclusions—There are no clinically relevant differences among the tested bileaflet aortic valves. Regardless of valve type, there was a low complication rate. On the basis of these findings, all 3 bileaflet prostheses are well suited for aortic valve replacement. (Circulation. 2000;102[suppl III]:III-1-III-4.)

Key Words: aorta ■ valves ■ echocardiography

Mechanical heart valves (MHVs) are the standard therapeutic option for aortic valve replacement (AVR) because tissue valves do not offer sufficient durability for all patient and age groups. The first bileaflet MHV was not introduced until 1977, having a more advanced design.¹ In experimental studies, the bileaflet design was shown to provide a flow field closest to that of the native aortic valve compared with any other type of MHV.² Today, several bileaflet MHVs, which are similar in design, are available. All of them are considered to offer good hemodynamic function and almost unlimited durability. Thus, they serve as the current standard for mechanical valve replacement. Nevertheless, a perfect artificial heart valve does not exist.³–²⁸

Among the different bileaflet MHVs that are most commonly implanted in the aortic position are the ATS valve (ATS; ATS Medical, Inc), the Carbomedics valve (CM; Sulzer Carbomedics, Inc), and the St Jude Medical Hemodynamic Plus valve (SJMHP; St Jude Medical, Inc). The aim of the present study was to evaluate these 3 bileaflet MHVs regarding hemodynamic and functional outcome with a prospectively randomized protocol.

Methods

Three hundred patients with aortic valve disease were included in the study. Patients were operated on between March 1996 and August 1998. The study was approved by the local ethics committee. All patients gave informed consent after the study protocol had been outlined in detail. Patients with the indication for nonemergent AVR with an MHV were randomized to receive an ATS, a CM, or an SJMHP valve. Postoperative examinations before discharge from the hospital were taken as baseline measurements. Follow-up was performed at our outpatient clinic after 6 and 12 months; no patient was lost to follow-up. Due to long distances between their homes and the hospital, 17% of the patients were followed by their family physicians; for these patients, no echocardiographic measurements were available. At all visits, patients were assessed for functional state and quality of life; in addition, they underwent routine trans-thoracic echocardiography (TTE).

Patient Population

Of the 300 consecutive patients, 100 each received an ATS, a CM, or an SJMHP valve, respectively. Randomization was performed after preoperative echocardiographic examination on the day before surgery. During the time interval mentioned, all patients who fulfilled the inclusion criteria were included after preoperative echocardiographic examination and after providing written informed consent. No patients were excluded during the conduct of the study. Preoperative patient characteristics are given in Table 1.
TABLE 1. Preoperative Patient Characteristics for the 3 Groups

<table>
<thead>
<tr>
<th></th>
<th>ATS (n=100)</th>
<th>CM (n=100)</th>
<th>SJMHP (n=100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>61 ± 8</td>
<td>62 ± 8</td>
<td>59 ± 9</td>
</tr>
<tr>
<td>Female</td>
<td>28</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>NYHA class</td>
<td>2.3 ± 0.6</td>
<td>2.4 ± 0.5</td>
<td>2.4 ± 0.6</td>
</tr>
<tr>
<td>AS, n</td>
<td>90</td>
<td>89</td>
<td>91</td>
</tr>
<tr>
<td>AI, n</td>
<td>10</td>
<td>11</td>
<td>9</td>
</tr>
<tr>
<td>EF</td>
<td>0.58 ± 0.8</td>
<td>0.61 ± 0.16</td>
<td>0.59 ± 0.17</td>
</tr>
<tr>
<td>Pmax, mm Hg</td>
<td>81 ± 38</td>
<td>81 ± 37</td>
<td>79 ± 27</td>
</tr>
<tr>
<td>CAD, n</td>
<td>25</td>
<td>26</td>
<td>22</td>
</tr>
<tr>
<td>Grafts, n</td>
<td>1.6</td>
<td>1.9</td>
<td>1.5</td>
</tr>
<tr>
<td>BSA, m²</td>
<td>1.90 ± 0.2</td>
<td>1.92 ± 0.2</td>
<td>1.96 ± 0.2</td>
</tr>
</tbody>
</table>

AS indicates predominant aortic stenosis; AI, predominant aortic incompetence that requires surgery, defined as ≥3 degrees; Pmax, maximum transaortic pressure gradient as assessed with invasive measurements; CAD, coronary artery disease; Grafts, bypass grafts; BSA, body surface area; and NYHA, New York Heart Association.

Surgical Outcome
Valve implantation was uneventful in all patients. The aortic annulus diameter was 25 ± 1.95 (ATS), 24.8 ± 1.6 (CM), and 24.6 ± 1.9 (SJMHP) mm (NS), yielding a PAI of 13.3 ± 1.5 (ATS), 13 ± 1.4 (CM), and 12.7 ± 1.2 (SJMHP) mm (P < 0.05), respectively. The size of the implanted bileaflet MHV was 24 ± 2 (ATS), 23.7 ± 1.6 (CM), and 23.6 ± 1.9 (SJMHP) mm, respectively (NS).

Aortic cross-clamp time was 54 ± 19 (ATS), 59 ± 15 (CM), and 59 ± 25 (SJMHP) minutes (NS). Additional procedures included myocardial revascularization as shown in Table 1 in 25/25/22 patients (NS), supracoronary replacement of the ascending aorta in 4/14/4 patients, and myectomy in 1/2/4 patients, respectively. All patients were safely transferred to the intensive care unit. Postoperative hospital stays were mostly uneventful. Severe ventricular arrhythmias that required intravenous antiarrhythmic therapy occurred in 2/3/2 patients. Rethoracotomy for bleeding was necessary in 1/3/1 patients. Sinus rhythm was diagnosed in 90/89/87 patients preoperatively and in 88/88/86 patients postoperatively. New onset of atrial fibrillation was noted in 2/3/1 patients. In-hospital deaths occurred in 1/2/1 of patients due to ventricular arrhythmias and sudden cardiac death the day before discharge (n=1), pneumonia (n=1), low cardiac output syndrome caused by perioperative myocardial infarction (n=1), and sepsis with subsequent multiorgan failure (n=1). All deaths were non–valve related. All patients received warfarin at an INR of 2.5 to 3.0.

Follow-Up
New York Heart Association functional class improved from 2.3 ± 0.6 (ATS), 2.4 ± 0.5 (CM), and 2.4 ± 0.6 (SJMHP) (NS) preoperatively to 1.2 ± 0.4 (ATS), 1.2 ± 0.7 (CM), and 1.1 ± 0.3 (SJMHP) (NS) at 6 months and to 1.1 ± 0.3 (ATS), 1.1 ± 0.3 (CM), and 1.1 ± 0.4 (SJMHP) (NS) at 1 year, respectively. At 1 year, transvalvular incompetence that exceeded the closing volume was diagnosed in 3/3/2 patients (NS); paravalvular leakage was diagnosed in 2/3/2 patients (NS); and reoperation had to be performed in 0/1/1 patients. During follow-up, stroke occurred in 0/1/1 patients, all patients with additional carotid artery disease and thus the stroke was non–valve related. Thus far, no thromboembolic events, valve thromboses, hemorrhages, or aortic valve endocarditis occurred. During follow-up, 2/1/1 patients died. Causes of death were mitral valve endocarditis with normal aortic valve function (n=1), pneumonia (n=1), gastric cancer (n=1), and myocardial infarction (n=1), all of which were non–valve related.

Hemodynamic, Functional, and Morphological Assessments
Postoperative TTE was performed on the fifth to seventh day. Good views were obtained in 84/85/87% of the patients and
TABLE 2. Echocardiographic Parameters at Baseline and at 6-months and 1-year Follow-Up

<table>
<thead>
<tr>
<th></th>
<th>ATS (n=100)</th>
<th>CM (n=100)</th>
<th>SJMHP (n=100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>28±8</td>
<td>29±8</td>
<td>29±11</td>
</tr>
<tr>
<td>6 mo</td>
<td>30±9</td>
<td>29±8</td>
<td>28±11</td>
</tr>
<tr>
<td>1 y</td>
<td>28±11</td>
<td>30±11</td>
<td>31±14</td>
</tr>
<tr>
<td>Vmax, m/s</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>2.5±0.4</td>
<td>2.6±0.5</td>
<td>2.4±0.4*</td>
</tr>
<tr>
<td>6 mo</td>
<td>2.35±0.3†</td>
<td>2.4±0.3†</td>
<td>2.25±0.4†</td>
</tr>
<tr>
<td>1 y</td>
<td>2.3±0.4</td>
<td>2.4±0.4</td>
<td>2.3±0.4</td>
</tr>
<tr>
<td>LVMI, g/m²</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>222±88</td>
<td>205±51</td>
<td>205±72</td>
</tr>
<tr>
<td>6 mo</td>
<td>176±69†</td>
<td>160±56†</td>
<td>161±56†</td>
</tr>
<tr>
<td>1 y</td>
<td>166±75</td>
<td>161±54</td>
<td>159±59</td>
</tr>
</tbody>
</table>

FS indicates fractional shortening to assess left ventricular function.

*P<0.05 vs the other groups.
†P<0.05 at 6 mo vs baseline within the same group.

moderately good views were obtained in 11/12/9%, whereas in 5/3/4%, only part of the measurements could be performed due to imperfect visualization. TTE revealed normal aortic valve function in all patients postoperatively.

Echocardiographic parameters regarding ventricular function (fractional shortening), transvalvular hemodynamics (maximum transaortic blood flow velocities [Vmax]), and left ventricular morphology (left ventricular mass index [LVMI]) are given in Table 2. There was a statistically significant difference in favor of the SJMHP valve at baseline Vmax measurements. Besides this, no statistically significant differences were diagnosed among the 3 groups. Ventricular function was comparable at all measurements, and there was an equal regression of LVMI until follow-up examinations. Within each group, a statistically significant decrease in Vmax and LVMI was diagnosed between baseline and 6-month follow-up examinations.

Discussion

Mechanical heart valves do not meet all criteria of an optimal substitute for the native aortic valve. Nevertheless, after several decades of continuous efforts to minimize the side effects associated with MHV implantation, a considerable therapeutic standard has been reached. Valve replacement can be performed with low perioperative and postoperative risks. Various reports on the clinical course after AVR indicate a similar outcome for most mechanical aortic valves.13–22 However, most series include only 1 or sometimes 2 different valves. To date, no prospectively randomized comparison has been performed to evaluate different bileaflet MHVs. Therefore, the decision to implant a certain valve type is mainly based on the personal preference of the implanting surgeon. The present study was designed to provide some rationale to select the best mechanical valve available. The 3 most-often implanted bileaflet MHVs were independently compared using a prospectively randomized protocol.

The present study was conducted during the routine operative schedule of our hospital without any special surveillance by industry representatives; 5 fully trained cardiac surgeons took part in the study, reflecting the daily routine.

Overall, we did not find any relevant differences among the 3 bileaflet MHVs. During evaluation of these results, preoperative by-chance randomization could be critically discussed because intraoperative randomization may be advantageous. However, preoperative randomization is more practical during daily routine. Furthermore, in evaluation of the preoperative variables, there was no statistically significant difference among the 3 groups. Patient numbers were high enough to rule out any irregularities. Thus, with sufficiently high patient numbers, reliable conclusions can be drawn.

Some authors compare their follow-up results with preoperative variables. In our opinion, a comparison of preoperative to follow-up data does not yield any relevant answers. The use of postoperative measurements as baseline data, despite sometimes reduced echocardiographic visibility, is optimum. Potential differences observed at follow-up can then be attributed to each valve.

During the conduct of the present study, we did not observe any differences, even subjective ones, in the ease of implanting the 3 bileaflet MHVs. Later, when analyzing the results, we found that cross-clamp duration was shorter in the ATS group. It is difficult to judge whether this was valve related (the softer sewing ring may facilitate implantation) or whether these differences are just caused by chance. Given the small difference of 5 minutes, this is not of clinical importance. Despite prospective randomization and relatively high patient numbers, we found differences in PAI and implanted aortic valve size: Regarding these 2 important factors, the SJMHP group had slightly lower baseline criteria. Despite this, an equal hemodynamic function was demonstrated postoperatively and at follow-up. This proves that the SJMHP valve offers a favorable hemodynamic profile. A very positive result was the low complication rate in all groups. Although the probability of in-hospital complications could be fully evaluated, longer follow-up is required to evaluate any long-term affect of the different bileaflet MHVs.

At hemodynamic evaluation (see Table 2), maximum transvalvular blood flow velocity was chosen by intention. This is the standard measurement derived directly from the Doppler examination. Thus, Vmax is the best measure for a comparison of the different mechanical valves. All 3 bileaflet MHVs had reasonably low transvalvular blood flow velocities for the common implant sizes. Any blood flow velocity between 2 and 3 m/s is acceptable. Low blood flow velocities equal low pressure gradients, which are important for regression of left ventricular mass that results in an improvement in the individual’s prognosis.13,22 Not surprisingly, regression of LVMI was observed for all of the different bileaflet MHVs. Because there were no significant differences in blood flow velocities at follow-up, no significant differences in restoration of left ventricular geometry were expected. Ventricular function was in the normal range at follow-up and was comparable between the groups. Overall, stable ventricular function was diagnosed after AVR.
In summary, there are neither clinically relevant nor statistically significant differences among the 3 most-often used bileaflet MHVs for AVR. The future for the use of bileaflet MHVs is difficult to predict. It must be kept in mind that there is a design-related limitation regarding hemodynamic function. Any stent is obstructive in nature, and only with stentless porcine valves has close to normal transaortic blood flow been demonstrated. New materials or designs such as polymer-based valves will offer new alternatives, but their effectiveness and safety have yet to be proven. In this prospectively randomized comparison, all 3 bileaflet MHVs proved to offer a reasonably good therapeutic standard for AVR.

A limitation of the present study is that despite a lack of significant differences being observed among the 3 valves, differences could be detected if larger numbers of patients were studied.

Acknowledgment

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References

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