Midterm Results After Stentless Mitral Valve Replacement

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Background—To analyze the midterm clinical results after stentless mitral valve (SMV) replacement.

Methods and Results—Fifty one patients (68.3±8.4 years, 35 female) with severe mitral valve disease (stenosis 25, incompetence 17, mixed lesion 9) received a chordally supported SMV (Quattro™, St. Jude Medical Inc.) since August 1997. Preoperative New York Heart Association class was 3.1±0.6; left ventricular ejection fraction 64±13%, and cardiac index 2.1±0.8 l/min/m². Additional intraoperative ablation therapy was performed on 19 patients with chronic atrial fibrillation. Mean follow-up is 35.4±19.2 months (range 5 to 63).

SMV implantation was performed using a conventional (32) or a minimally invasive (19) approach, valve size was 29±1.5 mm, cross-clamp duration was 81±33 minutes. Atrial rhythm was reestablished in 16 of 19 patients. Five patients required reoperation early in this series, two for paravalvular leakage, two for functional stenosis, and one with underlying rheumatoid disease. Mortality was one perioperative (1.96%, non-valve-related), one after reoperation as a result of multiple organ failure (MOF), and five during late follow-up (30±7 months postoperatively) for noncardiac causes. Regular echocardiographic control revealed good SMV function (V max 1.7±0.2m/s, P mean 3.9±1.2 mm Hg) and well-preserved ejection fraction postoperatively and at most recent follow-up.

Conclusions—Midterm results after SMV implantation are promising. Preservation of the anuloventricular continuity leads to stable left ventricular function and combined with ablation therapy to physiological hemodynamics. Long-term durability remains to be proven. (Circulation. 2003;108[suppl II]:II-85-II-89.)

Key Words: mitral valve replacement ▪ stentless bioprostheses ▪ stentless mitral valve

Mitral valve (MV) replacement is indicated in symptomatic patients who cannot be treated by surgical repair techniques. These are patients with complex pathology having severe destruction or calcification of the native MV. Indication and results are related to the underlying pathology and surgical experience. For all patients, the choice of MV prosthesis remains controversial because no ideal device is available. Individual factors, including life expectancy and comorbidities, need to be taken into account.1–6 In the presence of state-of-the-art anticalcification treatments, xenografts may reach better longevity and will be an option even for younger patients.7 For MV xenografts, current results indicate a freedom from structural valve degeneration and reoperation in 63% to 78% of patients at 10 years and in 21% to 45% of patients at 15 years, respectively. In patients older than 70 years, freedom from structural valve degeneration has been reported as 77% to 100% at 10 years and 34% to 90% at 15 years.5,7,8

When replacing the MV, its complex individual anatomical structure and physiological function need to be taken into account. Preservation of the anuloventricular continuity and eventually of annular flexibility are important for long-term valvular and ventricular performance.9–11 Thus, the implantation of a chordally supported stentless mitral valve (SMV) is an appealing concept. Early experience with SMV replacement has been promising.12,13 Good hemodynamic and functional results have been proven in comparison with conventional MV repair or replacement.13 The aim of the present study was to evaluate the midterm results after up to 5 years of SMV implantation.

Patients and Methods
Fifty one patients with nonischemic mitral valve disease received SMV replacement (Quattro™, St Jude Medical, St Paul, MN) since August 1997. This prospective clinical trial was approved by the local ethical committee; all patients gave informed consent after the study protocol had been outlined in detail. Patients with an indication for bioprosthetic MV replacement (age ≥65 years, special request, or contraindication for anticoagulation) received SMV implantation only if MV repair was not feasible intraoperatively.

The SMV is made from glutaraldehyde tanned bovine pericardium with an additional Polyol anticalcification treatment, as described...
The two papillary flaps are anchored at the patients papillary muscles and the three layered annulus is designed to prevent dilatation. Figure 1 gives a lateral view as well as an inflow aspect of the SMV xenograft. The valve is “D”-shaped and it is available in three sizes: large (30 mm), medium (28 mm), and small (26 mm). These sizes are equivalent to the straight line of the “D”, resembling the diameter between the two commissures.

Surgery was performed through a median sternotomy (n=32) or a lateral minithoracotomy (n=19). Extracorporeal circulation was instituted using bicaual plus ascending aorta or jugular and femoral vein plus femoral artery cannulation; antegrade cold crystalloid cardioplegia (Bretschneider HTK solution, Köhler Chemie, Alsbach, Germany) and moderate hypothermia were applied. Following complete excision of the diseased MV SMV size selection was preformed according to direct measurement of the distance between the commissures. Then the papillary flaps were implanted according to direct and echocardiographic measurements. For each of those, two Teflon–armed Tevdek II 3/0 sutures (Deknatel) were used. Implantation was performed approximately 10 mm above the tips of the papillary muscles after checking for sufficient tissue strength. Then the annulus was attached using two or three running sutures (Prolene 3–0). Additional left atrial ablation therapy to restore sinus rhythm was performed in selected patients with chronic atrial fibrillation as described previously.

Follow-up consisted of annual examinations at our outpatient clinic. Mean follow-up was 35.4±19.2 months (range, 5 to 63). Total follow-up consisted of 147.4 patient years. Patients living more than 150 km from the hospital (n=5) were followed by telephone interview; in addition physical and echocardiographic examinations were performed by their family physicians and transferred to the hospital. All patients were instructed to contact the hospital in the event of any unexpected deterioration of health conditions immediately. No patient was lost to follow-up.

Transthoracic echocardiographic examinations (TTE) were performed preoperatively, before discharge and at every follow-up visit. Multiplane transesophageal echocardiography (TEE) was used intraoperatively or whenever additional information other than TTE measurements was required. Cardiac morphology and function as well as valve hemodynamics were assessed using standard measurements. Echocardiograms were performed according to standard guidelines and were interpreted by a single physician.

Valve related morbidity and mortality were evaluated according to standard guidelines. Absolute and relative frequencies were calculated. Results are given as mean ± standard deviation. After assessing for normal distribution the Student t test for matched pairs was applied. A probability value <0.05 was considered significant.

Results

Fifty one patients received the SMV between August 1997 and May 2002, 35 of whom were female, and the mean age was 68.3±8.4 years. Predominant mitral valve disease was stenosis in 25 patients, severe incompetence in 17 patients, and combined disease in 9 patients, respectively. The preoperative New York Heart Association (NYHA) functional class was 3.1±0.4 and body surface area 1.76±0.2 m².

Previous interventions were mitral valve repair in two and balloon commissurotomy for mitral stenosis in four patients, another three patients had had mitral valve endocarditis previously. Preoperatively, 17 patients were in sinus rhythm, 28 patients had atrial fibrillation, and 6 patients had a permanent pacemaker. The additive Euroscore was 5.2±2.3 and the anticipated risk for perioperative mortality according to the logistic Euroscore 5.9±4.4%.

Preoperative hemodynamic measurements at cardiac catheterization were as follows: left ventricular ejection fraction 64±14% (including patients having mitral incompetence); left atrial mean pressure was 21±6 mm Hg, left atrial a-wave 23±7 mm Hg, and left atrial v-wave 35±14 mm Hg; left ventricular enddiastolic pressure was 14±5 mm Hg, mixed venous oxygen saturation was 61±9%, and cardiac index was 3.1±0.8 l/min/m².

Mean implanted SMV size was 29±1.5 mm, 26 patients received a large-sized prosthesis, 22 patients received a medium-sized prosthesis, and 3 patients received a small-sized prosthesis, respectively. Cross-clamp time was 81±33 minutes. All papillary muscles were sufficient to suspend the papillary flaps and all patients had uneventful valve implantation. Additional procedures were as follows: myocardial revascularization in 6 patients (one graft each), tricuspid valve repair in 6 patients, xenograft aortic valve replacement in 2 patients, left atrial size reduction in 4 patients, left atrial

Stentless mitral valve (Quattro™). (A) Lateral view with both papillary flaps. (B) Inflow aspect with the annulus consisting of three layers of pericardium.
thrombus resection in 2 patients, and left atrial ablation therapy in 19 patients, respectively.

Initial surgery was uneventful in all patients. However, re-exploration for bleeding had to be performed in three patients. One of those (aged 85 years) died because of low cardiac output syndrome; bleeding had been caused by a tear in a left internal thoracic artery bypass graft. All other patients were discharged in time from the hospital according to the German standards. In-hospital mortality was 1.96%. Patients were discharged on continuous anticoagulation therapy (warfarin) only if additional atrial fibrillation was present. All others received aspirin 100 mg daily. All patients received ACE inhibitors or angiotensin receptor blockers and eventually a 0.6% antihypertensive therapy.

During follow-up five patients required reoperation with subsequent explantation of the SMV, one for posterior paravalvular leakage having a calcified annulus at 10 months, one for anterior paravalvular leakage because of constant pressure on the papillary flaps at 7 months, one for functional stenosis of a 30 mm SMV (this patient received a 25-mm mechanical valve at 8 months), one for functional stenosis at 15 months, and one for degenerative alterations with pannus ingrowth of the prosthesis most certainly because of underlying collagenosis at 4 months. The second of these five patients died four weeks after reoperation because of multiple organ failure, all others were discharged in good condition.

During follow-up, five patients died as a result of spine fracture and renal failure, stroke without evidence of thrombi, large bowel malignoma, heart failure, and pneumonia. All had normal SMV function at most recent echocardiographic follow-up. Mean interval since the operation was 30 ± 7 months (range 12 to 49). These patients were slightly older than the others at SMV implantation (71 ± 5.6 years; range, 62 to 77 years); the underlying mitral valve disease was stenosis in 3 patients, incompetence in 1 patient, and a combined lesion in 1 patient; body surface area was 1.63 ± 0.1 m² (P < 0.05 versus all other patients) and preoperative cardiac index had been 1.38 ± 0.1 l/min/m² (P < 0.01 versus all other patients).

At discharge 29 patients were in sinus rhythm, 13 patients were in atrial fibrillation and 9 patients had a pacemaker. Six of those patients had a pacemaker preoperatively and three required pacemaker implantation after additional left atrial ablation therapy. Of the 19 patients receiving ablation therapy, 13 were discharged in sinus rhythm and three with an atrioventricular pacemaker, leading to a success rate for reinstitution of atrial rhythm in 84.2% of patients. However, during in-hospital stay additional medical therapy was required in 11 and electrical cardioversion in 8 patients, respectively. During follow-up all patients remained in stable sinus rhythm.

Echocardiography proved good valve function in all patients intraoperatively. Trivial transvalvular refluxes as caused by the closing volume and seen with most conventional heart valve prostheses were accepted. Patients had a typical uniform diastolic transvalvular flow profile without relevant turbulences. Comparative echocardiographic results are given for 50, 35, and 23 patients at discharge, 12 months and 48 months in Table 1, respectively. During follow-up, there was no relevant difference in mitral orifice area index. On serial echocardiographic measurements, there was no relevant increase in mitral incompetence in any patient despite those mentioned with paravalvular leakage. At present follow-up, there was no evidence of SMV calcification in any patient.

At most recent follow-up, all patients (n=39) had clinically improved and tolerated more physical activities at no or only little dyspnea. NYHA functional class was 1.35 ± 0.6. There were no complications in any patient with the exception of one patient (76 years old) who suffered dyspnea while climbing up stairs. Neither embolic nor transitory ischemic neurological events occurred. Exercise capacity had improved in 64.1% and was constantly the same as preoperatively in the other 35.9% of patients, respectively; 35.9% of patients were on continuous warfarin without further problems. According to the specific activity questionnaire the patients reached a level of moderate gardening and regular walking without constraints yielding a value of 4.5 ± 1.9, respectively.

**Discussion**

In western civilizations, MV surgery can be divided into two subsets of patients: the majority of approximately 75% percent who will receive valve repair using modern repair techniques and eventually anuloplasty ring implantation. The remaining patients usually present with complex pathology as a result of degenerative disease and require valve replacement therapy. In the latter patients, valve selection is based on the underlying MV pathology and overall life expectancy and relevant comorbidities. However, no optimal prosthesis exists and the native MV has an almost optimal design. As such, preservation of the anuloplasty ring continuity has a clinical benefit after conventional stented MV replacement.

Homograft implantation remains challenging and cannot be considered a standard procedure yet. The SMV has to be regarded as an alternative to conventional MV xenografts for selected patients. It combines physiological MV principles, such as fixation at the papillary

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**Table 1.** Postoperative and Follow-up Transcatheter Echocardiographic Results After Stentless Mitral Valve Implantation

<table>
<thead>
<tr>
<th></th>
<th>Postoperative</th>
<th>12 Months</th>
<th>48 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>50</td>
<td>35</td>
<td>23</td>
</tr>
<tr>
<td>EF (%)</td>
<td>55 ± 12</td>
<td>53 ± 11</td>
<td>57 ± 12</td>
</tr>
<tr>
<td>MV V max (m/s)</td>
<td>1.6 ± 0.2</td>
<td>1.8 ± 0.3</td>
<td>1.8 ± 0.2</td>
</tr>
<tr>
<td>MV P mean (mm Hg)</td>
<td>4.5 ± 1.7</td>
<td>4.6 ± 1.4</td>
<td>4.9 ± 1.4</td>
</tr>
<tr>
<td>MOA (cm²)</td>
<td>2.7 ± 0.7</td>
<td>2.6 ± 0.6</td>
<td>2.6 ± 0.3</td>
</tr>
<tr>
<td>MOA index (cm²/m²)</td>
<td>1.5 ± 0.4</td>
<td>1.5 ± 0.5</td>
<td>1.5 ± 0.6</td>
</tr>
<tr>
<td>CI (L/min/m²)</td>
<td>2.5 ± 1</td>
<td>2.6 ± 1</td>
<td>2.3 ± 0.7</td>
</tr>
<tr>
<td>MI (grade 0–3)</td>
<td>0.4 ± 0.6</td>
<td>0.8 ± 0.6</td>
<td>0.7 ± 0.4</td>
</tr>
</tbody>
</table>

EF indicates ejection fraction according to the simpson method; MV V max, maximum transmural blood flow velocity; MV P mean, mean transmural pressure gradient; MOA, mitral valve orifice area; CI, cardiac index; MI, mitral valve incompetence.
muscles, a flexible annulus, and a large coaptation area. This is an appealing concept, because for the first time, a prosthesis with similar to native MV function became available in standard sizes. Left ventricular function can be maintained by preserving the annuloventricular continuity. Even in case of postoperative ventricular remodeling, the large coaptation area will render a competent device. Since 1997, approximately 170 patients have received the SMV at several centers worldwide. We present our midterm results in 51 patients who were not suitable for MV repair techniques.

The SMV had been designed to allow to perform simple and standard MV replacement therapy. In fact, implantation of the SMV is technically quite easy. However, exact sizing is crucial in order to adjust the papillary flaps in the neutral position and to avoid excess tissue at the annulus. Oversizing with the consequence of excess tissue, bulking, and, eventually, functional stenosis or undersizing rendering tight papillary flaps and constant tension on the annular suture row should be avoided. Preoperative TEE measurements under hemodynamically stable conditions are important to guide valve selection in addition to intraoperative mechanical sizing.

Hemodynamic results as given in Table 1 proved sustained SMV function up to 4 years of follow-up. Transprosthetic blood flow velocities and mean pressure gradients were in the normal range after MV replacement therapy. Cardiac index slightly increased over time, underlining the stable hemodynamic situation of these patients. Stable left ventricular function with preservation of left ventricular ejection fraction was seen after SMV replacement. This can be attributed to the preservation of annuloventricular continuity because of fixation of the SMV at both papillary muscles. The papillary flaps did not cause any ventricular restriction. Transvalvular blood flow profile was laminar in most patients with only minimal transvalvular reflux in some. This was equivalent to the closing volume of most conventional heart valves and attributable to the four edges of the valve between the different pieces of pericardium.

Throughout this study, there was substantial morbidity and mortality. However, this needs to be evaluated under consideration of the relatively high patient age and frequent comorbidities. Furthermore, patients requiring MV replacement therapy usually comprise the sickest subgroup of those having relevant MV disease. In-hospital mortality (one patient=1.96%) was acceptable in comparison with the STS database and to other reports.21 One other patient died after reoperation. Both deaths were non-valve-related. Five patients required valve explantation. These events could be attributed to specific factors such as a calcified annulus and difficulties in exact sizing. The last patient that required explantation had asked for a stentless xenograft despite the fact that she had severe underlying collagenosis, which eventually led to early valve degeneration. However, none of those explantations can be attributed to intrinsic structural dysfunction of the SMV.

Mortality during follow-up reflects the severe condition of most patients because of chronic mitral valve disease and other diseases. It has to be emphasized that those five patients had a severely decreased cardiac index preoperatively. MV replacement therapy obviously yielded some intermediate improvement of their condition. Most important, none of these deaths as pointed out in the results section was directly related to SMV dysfunction as shown on the most recent echocardiographic control.

The functional outcome after SMV replacement was satisfactory in most patients. This is well reflected by the constant improvement of clinical status, NYHA functional class, and the patients ability to perform activities of daily living at most recent follow-up. Furthermore there were no thromboembolic episodes, despite the fact that few patients were on systemic anticoagulation therapy only. Thus, the concept of combined SMV implantation and restoration of sinus rhythm by intraoperative ablation therapy yields an optimal hemodynamic outcome for the individual patient.

There are some limitations of the present study. Patients presented with a considerable variability regarding the type of mitral valve disease, their preoperative risk profile, and additional procedures (eg, ablation therapy) performed intraoperatively. The midterm follow-up does not yet reflect the period when bioprostheses usually show structural valve degeneration at 10 to 15 years postoperatively. Furthermore, a larger patient cohort should be studied, best would be a prospectively randomized comparison. Overall long term follow-up is warranted.

In summary, the midterm results after SMV implantation in older patients are acceptable. Hemodynamic results are satisfactory after up to 5 years. Explantation of the SMV as required in five patients occurred early in this series and underlines the importance of a careful sizing process. The mortality observed can be attributed to underlying conditions of the patients, because valve function was normal during most recent echocardiographic control in all of them. The SMV meets most criteria to become an ideal heart valve. However, long-term follow-up is required.

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