

Restitution of Sinus Rhythm plus Stentless Mitral Valve Replacement at Three Years

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Background and aim of the study: The study aim was to examine results after stentless mitral valve (SMV) replacement (Quattro™) and restitution of physiological cardiac rhythm by intraoperative left atrial ablation therapy.

Methods: Twenty patients (13 females; mean age 69.7 ± 5.9 years) with severe degenerative mitral valve disease (six with valve stenosis, six with valve incompetence, eight with combined lesion) were prospectively evaluated since 1998. The mean NYHA functional class was 3.2 ± 0.4, and cardiac index 1.8 ± 0.5 l/min/m². Ablation therapy was performed by inducing left atrial linear lesion lines to avoid re-entrant circuits.

Results: Surgery was performed using conventional sternotomy (n = 10) or lateral minithoracotomy (n = 10). Sinus rhythm was successfully restituted in 17 patients either postoperatively or in the long term

(success rate 85%). However, three patients required DDD-pacemaker implantation, and another three had to be discharged with persistent atrial fibrillation. Intermittent medical therapy (sotalol or amiodarone) was required in nine patients postoperatively, in four patients at six months, and in two patients at one-year follow up. One patient was reoperated on for paravalvular leak after one year, but subsequently died due to sepsis. In the other patients, echocardiographic control proved good SMV function with atrial contraction.

Conclusion: Restitution of physiological cardiac function is possible by combined stentless MV implantation and left atrial ablation therapy. A persistent benefit, without need for additional re-intervention, was shown at mid-term follow up.

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Atrial fibrillation (AF) is the most commonly reported sustained arrhythmia, and is associated with substantial morbidity and mortality (1,2). A number of interventional concepts that are based on eliminating the initiating trigger or modifying the maintaining substrate have evolved within the past years. Catheter-based interventions for controlling the ventricular rate, including atrioventricular junction ablation or atrioventricular nodal modification, have the disadvantage of persistence of AF (3). Surgical techniques such as the corridor operation (4) or left atrial isolation (5) effectively restore sinus rhythm, but not biatrial transport function. The maze procedure (6,7) and the so-called radial approach (8,9),

although highly effective, are technically demanding and time-consuming, and therefore have not found widespread application.

Significant mitral valve disease is often associated with chronic AF and left atrial enlargement due to pressure or volume overload. Valve replacement must be performed whenever mitral valve reconstruction is not feasible, as in some cases with degenerative disease. In these patients, valve selection remains controversial as no ideal prosthesis is yet available. Whereas stented conventional bioprostheses are at a high risk for structural failure, mechanical valves are associated with the need for lifelong anticoagulation, thromboembolic events, and hemorrhage (10).

Recently, a stentless mitral valve (SMV) (Quattro™; St. Jude Medical Inc., St. Paul, MN, USA) has been implanted, and has shown good mid-term clinical results (11,12). This pericardial valve is flexible, and is supported by chordae that are attached to the native papillary muscles. By virtue of its design, the Quattro valve preserves annuloventricular continuity, and no long-term anticoagulation is required when sinus rhythm is pres-

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ent in these patients. In order to restore both physiological mitral valve function and cardiac rhythm, SMV implantation was combined with intraoperative ablation therapy. Subsequently, an evaluation was carried out to determine whether patients acquire a persistent benefit from this combined approach at up to three years of follow up.

Clinical material and methods

Patients

Since July 1998, 20 patients (13 females, seven males; mean age 69.7 ± 5.9 years) have undergone combined intraoperative left atrial ablation therapy and SMV implantation at the authors' institution. The indication for treatment was that concomitant chronic AF had persisted for longer than six months. These subjects formed a subset from a total of 52 patients who received a SMV from August 1997 onwards. The implantation of a prosthetic mitral valve was necessary in all patients due to mitral stenosis or degenerative disease that was not amenable to reconstructive surgery. Approval to conduct this clinical trial was provided by the International Freiburger ethical committee, by the federal 'Regierungspräsidium', and by the local ethical committee. All patients provided their informed consent on the day before surgery.

The predominant mitral valve pathology was stenosis in six patients, combined lesion in six, and valve incompetence in eight. The mean body surface area was $1.76 \pm 0.19 \text{ m}^2$, mean NYHA functional class 3.2 ± 0.4 , left ventricular ejection fraction (as assessed by cineangiography) $61.7 \pm 12.4\%$, and cardiac index $1.8 \pm 0.5 \text{ l/min/m}^2$.

All patients were scheduled for routine follow up visits at the outpatient clinic after six and 12 months, and annually thereafter. The mean follow up was 3.1 ± 1.2 years (range: 0.2 to 4.5 years), and was 100% complete. At all follow up visits the patients were assessed for functional state, the specific activity questionnaire (13) was applied, and a clinical examination and routine transthoracic echocardiography were performed.

Intraoperative techniques

Left atrial ablation was performed using different techniques. The five most recent patients underwent cryoablation, while the other 15 patients underwent radiofrequency ablation. A left atrial approach was used to eliminate macro-re-entrant circuits involving isolation of all pulmonary veins and connecting lesion lines to the mitral annulus. After opening the left atrium, ablation was performed under direct vision. Continuous lesion lines were placed endocardially. Initially, lesion lines were induced from the posterolateral mitral valve annulus (P3) to the left lower pulmonary vein (PV), then to the left upper PV, via the atrial roof to the right upper PV, to the right lower PV,

and finally connection lines to the atriotomy incision. More recently, oval-shaped lesion lines were induced around the left and right pulmonary veins, and then connected to the mitral valve annulus and to the atriotomy. The entire procedure was performed in a bloodless field.

The Quattro SMV has been described in detail previously (11,12). The valve is constructed from glutaraldehyde-tanned bovine pericardium that is treated with a polyol anticalcification agent. The valve is D-shaped and flexible, and consists of one large anterior leaflet and a posterior leaflet with three scallops, supported by two joint papillary flaps.

Intraoperatively, a conventional median sternotomy and a lateral minithoracotomy were each used in 10 patients. Extracorporeal circulation and cold crystalloid cardioplegia ($n = 16$; Bretschneider HTK solution, Köhler Chemie, Alsbach, Germany) or blood cardioplegia ($n = 4$) were applied.

The diseased mitral valve was excised completely and the SMV implanted at the papillary muscles and at the mitral valve annulus, thus preserving annuloventricular continuity. The left atrial ablation procedure was then performed as described above. Control transesophageal echocardiography was applied routinely at standard views. Cardiac morphology (chamber and wall sizes, wall motion, valve structure), cardiac function (fractional shortening, ejection fraction), and transvalvular hemodynamics (Doppler and color Doppler) were assessed.

Postoperative valve-related morbidity and mortality was evaluated accord to standard guidelines (14). Results were expressed as mean \pm SD, and absolute and relative frequencies calculated.

Postoperative management and follow up

Postoperatively, all patients were monitored daily with 12-lead electrocardiography recordings for the first five postoperative days. In addition, two 24-h electrocardiographic recordings were performed in all patients. In cases of postoperative AF occurring within 10 days after the operation, electric cardioversion was performed either alone or in combination with the administration of amiodarone or sotalol. Patients in stable sinus rhythm (as defined by the presence of a P-wave) without additional anti-arrhythmic therapy received no further systemic anticoagulation; all patients who were receiving additional anti-arrhythmic drugs received anticoagulation for six months.

Results

Stentless mitral valve implantation and additional intraoperative left atrial ablation therapy were performed safely in all 20 patients. Intraoperative left atrial ablation therapy required an additional 16 ± 4 min of

cross-clamp time, but this did not impair the postoperative outcome. Both the sternotomy (n = 10) and lateral minithoracotomy approach (n = 10) provided good access for valve implantation and intraoperative left atrial ablation therapy. Additional procedures were as follows: coronary artery bypass grafting in one patient, tricuspid valve repair in three patients, xenograft aortic replacement in two, left atrial size reduction in two, and left atrial thrombus resection in two. On admission to the intensive care unit, patients were either in spontaneous sinus rhythm (80%) or were electrically paced in atrioventricular universal (DDD) or atrial-inhibited (AAI) mode (20%). Five interventions had to be performed during the initial in-hospital stay. These included medical therapy with sotalol in four patients, and with amiodarone in five. Electrical cardioversion was necessary in four patients. Seventeen patients were discharged either in sinus rhythm (n = 14) or after DDD-pacemaker implantation due to III° atrioventricular block (n = 3). Three patients were discharged with persistent AF which was refractory to all interventions. All patients were discharged from the hospital in time, according to the German standards.

After six months, four patients received medical therapy with either sotalol (n = 3) or amiodarone (n = 1). At the one-year follow up, two patients required medical therapy with sotalol.

One patient who had received a DDD pacemaker due to a III° atrioventricular block postoperatively had to undergo reoperation after nine months for paravalvular leak. This patient received a mechanical valve, but subsequently suffered pneumonia, sepsis and multiple organ failure and died after 28 days in the intensive care unit.

During further follow up three patients died from non-cardiac causes; one death was due to spine fracture and renal failure, another to stroke (without evidence of thrombi at the most recent echocardiographic examina-

tion), and the third to pneumonia. By comparison, these four patients were slightly older (mean age 71 ± 5.6 years) than the other patients, their body surface area was greater ($1.63 \pm 0.1 \text{ m}^2$; $p < 0.05$ versus other patients), and their preoperative cardiac index reduced ($1.38 \pm 0.1 \text{ l/min/m}^2$; $p < 0.01$ versus other patients).

Echocardiography revealed normal mitral valve function postoperatively and at follow up. Overall perioperative and follow up results are listed in Table I. Transprosthetic blood flow velocities, as well as mean gradients, were in the normal range after mitral valve replacement therapy, and the transvalvular blood flow profile was laminar in most patients. At echocardiography, atrial contraction was documented.

Discussion

Outcome after mitral valve surgery is influenced not only by the type of valve that is implanted but also by the persistence of chronic AF. These patients have a reduced quality of life due to impaired hemodynamic function, a need for long-term systemic anticoagulation therapy, and also an increased risk of thromboembolic events.

Among patients requiring mitral valve replacement, complete restoration of hemodynamic function can be expected only for a prosthesis that has all of the features of the native mitral valve, is easy to implant, and is durable (11,12). Most importantly, the valve should be flexible, and annuloventricular continuity should be preserved (15). The Quattro SMV meets most of these criteria (11,12,16).

In order to restore both physiological sinus rhythm and close-to-normal mitral valve function, the combined approach was chosen, and the short- and mid-term follow up results thus obtained showed great promise. Only one patient among 20 required long-term systemic anticoagulation and anti-arrhythmia medica-

Table I: Hemodynamic and functional outcome after combined left atrial ablation therapy and stentless mitral valve replacement.

| Parameter | Discharge | Follow up (months) | | | |
|---------------------------|-----------------|--------------------|-----------------|-----------------|-----------------|
| | | 6 | 12 | 24 | 36 |
| Patients (n) | 20 | 20 | 17 | 11 | 9 |
| SR (n) | 17 | 18 | 16 | 11 | 9 |
| E/A ratio MV | 1.9 ± 0.7 | 1.5 ± 0.4 | 1.5 ± 0.3 | 1.5 ± 0.3 | 1.5 ± 0.3 |
| NYHA class | 1.6 ± 0.4 | 1.2 ± 0.4 | 1.2 ± 0.2 | 1.3 ± 0.3 | 1.5 ± 0.7 |
| EF (%) | 56.2 ± 12.2 | 55.2 ± 18.0 | 53.3 ± 11.5 | 58.9 ± 17.1 | 51.5 ± 13.1 |
| MV V_{max} (m/s) | 1.62 ± 0.2 | 1.61 ± 0.3 | 1.81 ± 0.1 | 1.71 ± 0.4 | 1.47 ± 0.3 |
| MOA (cm^2) | 2.89 ± 0.9 | 2.29 ± 0.4 | 2.7 ± 0.6 | 3.27 ± 0.6 | 3.0 ± 0.9 |

Values are mean \pm SD.

E/A ratio: Passive inflow:atrial contraction ratio in flow pressure curve; EF: Ejection fraction; MOA: Mitral valve opening area; MV V_{max} : Maximum trans-mitral blood flow; SR: Sinus rhythm.

tion. All other patients were in sinus rhythm or had undergone atrioventricular pacemaker implantation. Nevertheless, intermittent intervention has been frequent, mostly due to the onset of atypical atrial flutter. With adequate medication, electrical cardioversion sinus rhythm can also be re-established in some patients to yield a favorable outcome. In order to perform left atrial ablation therapy, an additional cross-clamp time of approximately 16 minutes was required, but with liberal delivery of cardioplegia to protect the heart this prolonged cross-clamping did not have any negative impact on surgical outcome. On control echocardiography, all patients in sinus rhythm showed a functional left atrium with active left ventricular filling - an important condition for a functionally improved outcome.

Intraoperatively, SMV insertion together with ablation therapy can be performed safely using a conventional or a lateral minithoracotomy approach. With the latter, the combination of direct and videoscopic vision allowed a better visualization of the valve and the left atrium.

Mortality during follow up reflects the severe condition of most patients suffering from chronic mitral valve disease and severe comorbidities. It must be emphasized that among the four patients who preoperatively had a severely reduced cardiac index (which usually reflects hemodynamic function close to cardiogenic shock), only one patient - the one with paravalvular leak - had their SMV implanted early in the series. However, to date there have been no SMV failures in any of these patients.

The avoidance of systemic anticoagulation is advantageous in elderly patients, and among the present cohort no complications were seen when SMV patients were discharged with persistent sinus rhythm, but without anticoagulation. Thus, the combined approach - if successful - is advantageous and no further anticoagulation is required.

In conclusion, the combined approach of sinus rhythm restitution and stentless mitral valve replacement is a safe and effective therapy. However, future confirmatory studies should include a larger patient cohort and a longer period of follow up.

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