Clinical and Hemodynamic Results of Mitral Valve Replacement with Autologous Fascia Lata Grafts

Studies in Patients with Competent Prostheses


SUMMARY
Nine patients with severe mitral disease were studied before and six months after mitral valve replacement with a three-cusp stented prosthesis using fresh autologous fascia lata tissue. Only patients in whom there was no auscultatory and angiographic evidence of incompetence of the replaced valve were selected for restudy. All patients claimed a marked improvement in their exercise capacity after operation and there was a significant reduction in radiographic heart size. The cardiac output at rest and the response to exercise were both reduced before operation and were unchanged after valve replacement. The elevated pulmonary arterial and wedge pressures were significantly reduced after operation in all patients both at rest and during exercise, but in no instance were the postoperative exercise values within normal limits. Left ventricular end-diastolic pressure was within normal limits at rest and during exercise in all patients after valve replacement but the average pressure gradient across the fascia lata valve was 6 ± 1 mm Hg at rest and 18 ± 3 mm Hg during exercise. These findings indicate that although replacement of the diseased mitral valve with a competent fascia lata prosthesis afforded substantial symptomatic relief, reduction of cardiac enlargement and a lowering of the pulmonary vascular pressures, this artificial valve offered a significant obstruction to left ventricular diastolic filling, particularly during exercise.

The majority of mechanical prostheses used in mitral valve replacement have serious clinical hemodynamic limitations; these include thrombus formation, poor hydraulic function, high inertial loading, mechanical interference with ventricular contraction, failure of the prosthesis and chronic hemolysis. Recent attention has, therefore, been directed to the use of prostheses using biological tissues. In order to simulate the functional architecture of the natural semilunar valves and thus allow unobstructed axial flow, the majority of these prostheses have been fashioned as a three-cusp structure supported on a plastic-coated rigid metal ring. The cusps have been constructed from a variety of pliant tissues, including aortic valve homografts,1-3 and pig4 and calf5 heterografts. However, the durability of many of these valves has been relatively short-lived and stronger tissues from which to construct the cusps have been sought. Senning6 reported that aortic valves fashioned from fascia lata had survived over four years in patients without degeneration, calcification or thromboembolic complications. In view of the theoretical advantages of valves fashioned from the host's own tissues, this technique has recently been applied to the replacement of the mitral valve with a prosthesis constructed from the patient's own fascia lata.7-9 This report concerns an appraisal of the clinical and hemodynamic effects of mitral valve replacement with such prostheses in patients with severe rheumatic heart disease, with particular respect to the results in patients in whom the replaced valve was functionally competent.

Methods

Subjects
Nine patients, including five females, who had undergone mitral valve replacement with fascia lata grafts, were selected for reinvestigation from a larger group of surgically treated patients on the basis of having no auscultatory evidence of important incompetence of the mitral fascia lata valve during the six months immediately following operation. Clinical auscultatory findings were confirmed by phonocardiograms and left ventricular angiography. Their average age was 45 years (range 34-53), average weight 59 kg (range 48-63) and the average body surface area 1.65 m² (range 1.49-1.92). Before operation all were disabled by acquired isolated mixed mitral valve disease with severe limitation of exercise capacity. All patients were in atrial
fibrillation at the time of both pre and postoperative studies. None were in congestive heart failure immediately before operation and all were taking digitoxin at the time of both pre and postoperative studies.

The preoperative investigations formed an essential part of the diagnostic assessment in each patient. The purpose of the postoperative studies and their possible value in the assessment of the usefulness of this type of valve in patients with valvular heart disease was explained to each patient. Without inducement all patients consented willingly to these studies.10, 11

Design of Investigation

The patients were studied a few days before and approximately six months after mitral valve replacement. Six months was chosen as the optimum time for restudy for two reasons. First, it is probably the earliest time at which cardiac function can be expected to have recovered from the effects of operation and the effects of postoperative bed rest. Second, it is reasonable to expect that there would have been no substantial evolution in the clinical and hemodynamic course of the underlying disease over this relatively short time. The grade of physical disability of the patients was determined before and after operation from their historical accounts. The grading used was based on that of the New York Heart Association (1955),19 with the modification of the stated ability of the patient to walk a defined distance or climb a specified number of stairs at a normal pace. Cardiac size was measured from standing, full-inspiration, six-foot postero-anterior chest radiographs. Before study, patients were familiarized with the laboratory procedure and the techniques and personnel involved; the highest level of supine bicycle exercise which each could comfortably perform was determined. The definitive studies were then carried out two hours after a light breakfast and without sedation.

After percutaneous insertion and positioning of the venous and arterial catheters under radiographic screening control the study was commenced with a six minute period of supine bicycle exercise followed by a twenty minute period of rest. Measurements of cardiac output, heart rate, systemic arterial, left ventricular and pulmonary arterial and wedge pressures were made during the last two minutes of exercise and during the final four minutes of the rest period. Left ventricular cineangiography was carried out immediately after the hemodynamic studies to assess the degree of mitral valve incompetence.

Following these studies, surgery was performed during which the mitral valve was replaced by an autologous fascia lata prosthesis; the internal diameter of the dacron-covered titannium frame was either 26 or 28 mm in all nine patients. Fascia lata was obtained from the patient's thigh and fashioned into a three-cusp valve at the time of the operation; all operations were performed by the same surgeon (M.I.I.). None of the patients received anticoagulants during the six months after the operation.

The clinical, radiographic and hemodynamic studies were repeated in a similar manner to the preoperative studies six months after the operation. The same level of exercise was used in both studies in each patient.

Laboratory Techniques, Measurements and Statistics

Cardiac output was measured by the direct oxygen Fick method. Expired air was collected in a Tissot spirometer and analyzed on a Lloyd-Haldane apparatus (A. Gallenkamp and Co., Ltd.). Two systemic arterial and four mixed venous blood samples were taken during each cardiac output estimation and analyzed in duplicate for percentage oxygen saturation on a Brickman-type hemoreflector (Kipp Co., Ltd.). Blood oxygen carrying capacity was determined by measuring the transmission of light through arterial blood hemolyzed with Drabkins solution in a densitometer (Evans Electroselenium Ltd.).

Pulmonary wedge and arterial pressures were measured through the distal and proximal lumens respectively of a double-lumen catheter (9F gauge; U.S. Catheter Co.). The pulmonary wedge pressure measurement was made by impacting the catheter in a peripheral site in the right lower lung. The criteria of “wedging” required to be satisfied in all instances were that the pressure contour was distinctly different and the phasic and mean pressures lower than those recorded simultaneously from the pulmonary artery, and that aspiration of the catheter drew either fully saturated blood or no blood. To ensure that the catheter tip was not end-impacted against the vessel wall, in which case it would give erroneously low measurements, saline in an open column was required to fall freely to the same level as the electrically transduced pressure when connected to the pulmonary wedge catheter.

Pulmonary and systemic vascular pressures were transduced with strain-gauge manometers (SEM 486), integrated electronically and recorded on an ultra-violet light recorder (SEM 3012). Left ventricular end-diastolic pressure was measured immediately before the onset of ventricular systole. Pressures were measured over two respiratory cycles during each minute and averaged over the same four minutes of rest and final two minutes of exercise as the cardiac output determination. In this laboratory, using such methods under similar conditions of study, measurements of oxygen uptake, cardiac output and intracardiac pressures have been found to be repeatable within 5%, 7% and 8%, respectively. The pressure gradient across the mitral fascia lata graft was measured from the pulmonary wedge — mean left ventricular end-diastolic pressure gradient. In thirty-six subjects without mitral valve disease studied under similar conditions in this laboratory, the mean mitral valve pressure gradient (PMW-LVED pressure difference) was 0.0 ± 1 mm Hg (SD = 2) both at rest and during supine bicycle exercise at similar work loads to those used in the present study; at this level of exercise and oxygen uptake the pulmonary wedge mean pressure did not exceed 20 mm Hg in any of the 36 subjects.

Left ventricular angiography was carried out through a pigtail multi-lumen catheter (110 cm; Cordis Europa N.V.) introduced percutaneously into a femoral artery with retrograde manipulation under radiographic screening control across the aortic valve.

The cardiothoracic ratio was measured from postero-anterior standing six-foot chest radiographs taken in full inspiration. The ratio was taken as the proportion of the thoracic width occupied by the maximum horizontal cardiac diameter.

The probability of statistical significance of differences was calculated by Student's t-test for paired data.

Results

Clinical Changes after Mitral Valve Replacement

Before operation all patients had conspicuous clinical and angiographic evidence of severe mitral valve disease with predominant incompetence. All were severely disabled by breathlessness on exertion;
none were able to walk more than a few hundred yards on the flat in equable weather or climb a flight of twelve stairs at a normal pace or do manual work without undue breathlessness. Although no patient was in congestive heart failure immediately before operation, three were orthopneic and two had suffered from attacks of nocturnal dyspnea in the months immediately preceding admission to hospital.

**After operation** none had a mitral pansystolic murmur but four of the nine patients had a short early systolic murmur audible at the left sternal border. All had an unmistakable mitral opening-snap and five had a distinct mid-diastolic murmur. None had any angiographic evidence of incompetence of the prosthesis. All nine patients claimed a significant improvement in their capacity to exercise; all stated that they could now walk more than a mile or climb a flight of stairs at a normal pace without undue breathlessness and all claimed they were able to undertake normal manual work. None suffered orthopnea or attacks of nocturnal breathlessness during the six months after operation.

**Radiographic Changes after Mitral Valve Replacement**

Before operation the average cardiothoracic ratio was 0.59 (range 0.54–0.63); six months after operation the average ratio was 0.54 (range 0.51–0.60) ($P < 0.05$).

**Hemodynamic Changes after Mitral Valve Replacement**

**Changes at Rest** (fig. 1, table 1). There was a significant reduction in the postoperative resting pulmonary wedge and pulmonary arterial mean pressures compared with the preoperative measurements; other hemodynamic variables were not significantly changed.

At rest, after operation the left ventricular end-diastolic pressure was within normal limits in all patients. The average pulmonary wedge mean-left ventricular end-diastolic pressure gradient across the fascia lata valve was 6 ± 1 mm Hg compared with a mitral valve gradient of 0 ± 1 mm Hg measured under similar conditions in this laboratory in subjects without mitral valve disease ($P < 0.001$).

**Changes during Exercise** (fig. 1, table 1). After operation, at the same level of exertion and oxygen uptake, there was a significant reduction in the pulmonary wedge and pulmonary arterial mean pressures compared with the preoperative measurements. But, in all patients, the pulmonary pressures during exercise exceeded normal limits (PAP < 30 mm Hg, PWP < 20 mm Hg at oxygen uptake < 400 ml/min/m²). There were no statistically significant changes in any of the other hemodynamic variables measured.

After valve replacement, the left ventricular end-diastolic pressure during exercise was within normal limits in all patients. The average pulmonary wedge mean-left ventricular end-diastolic pressure gradient across the fascia lata valve was 18 ± 3 mm Hg; this was significantly greater than the average resting gradient in these patients ($P < 0.001$) and significantly in excess of the mitral valve gradient of 0 ± 1 mm Hg measured at similar levels of exercise in subjects without mitral valve disease.

**Discussion**

This study was concerned with the clinical and hemodynamic effectiveness of mitral valve replacement with autologous fascia lata valves in patients severely disabled by mitral valve disease and in whom the replaced valve was functionally competent. Patients satisfying these criteria all experienced a marked improvement in their capacity to exercise without undue breathlessness and all claimed they were able to perform normal physical activities after operation. The size of the heart was significantly reduced in all patients. There was no consistent change in cardiac output, heart rate or systemic arterial pressure, but there was a significant reduction in the pulmonary wedge and arterial pressures both at rest and during exercise in all patients. However, it must be emphasized that in all patients the postoperative pulmonary pressures continued to exceed upper normal limits, although the left ventricular end-diastolic pressure was within the normal range in all subjects both at rest and during exercise. Thus, although the largest possible diameter of prosthesis was used in each patient these findings indicate that the mitral fascia lata valve graft offered significant obstruction to blood flow. In this respect, it is of interest that all patients had an opening snap and a distinct mid-diastolic murmur was audible in five.

The relation of these hemodynamic findings, improved by operation but still quite abnormal, to the nearly complete relief of breathlessness claimed by these patients is worthy of further consideration. Despite their claims to the contrary, it is doubtful that these patients had a normal capacity to exercise, particularly in view of the residual high mitral valve pressure gradient and high pulmonary pressure even during mild exertion. In fact others have found that many patients who claim to be entirely well are quite unable to meet the ordinary daily requirements of physical activity. No single explanation for this lack of correlation between symptoms and hemodynamic evidence of impairment of pumping function can be offered. Patients are often grateful for any relief of
symptoms and in their anxiety for benefit may overstate their improvement. Furthermore, their appreciation of a limited improvement in exercise tolerance may be exaggerated by the chronic and severe restriction of their physical activities before operation. It must also be emphasized that the evaluation of a patient's disability by an historical account of his symptoms is open to errors of appreciation and expression by the patient and subsequent errors of quantitative interpretation by the physician. Recent evaluation of symptoms of breathlessness in patients with valvular heart disease in our laboratory has demonstrated the wide variability in their account to different physicians, the lack of agreement between their statements and objective proof of their exercise disability, and the lack of individual correlation between symptoms and hemodynamic improvement after operation. In these circumstances the validity of any comparison of symptoms as a measurement of improvement must be seriously questioned. This is not to denigrate the subjective benefits of operation claimed by many of these patients, but only to focus attention

Table 1

Summary of Statistical Analysis

<table>
<thead>
<tr>
<th>Variable</th>
<th>Rest</th>
<th>Exercise</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before</td>
<td>After</td>
</tr>
<tr>
<td>Oxygen uptake (ml/min/m²)</td>
<td>136 ± 6*</td>
<td>139 ± 7</td>
</tr>
<tr>
<td>Heart rate (beats/min)</td>
<td>88 ± 3</td>
<td>90 ± 4</td>
</tr>
<tr>
<td>Cardiac output (L/min/m²)</td>
<td>2.4 ± 0.2</td>
<td>2.5 ± 0.2</td>
</tr>
<tr>
<td>Mean systemic arterial pressure (mm Hg)</td>
<td>107 ± 5</td>
<td>104 ± 5</td>
</tr>
<tr>
<td>Mean pulmonary arterial pressure (mm Hg)</td>
<td>37 ± 3</td>
<td>24 ± 2†</td>
</tr>
<tr>
<td>Mean pulmonary wedge pressure (mm Hg)</td>
<td>23 ± 1</td>
<td>13 ± 1†</td>
</tr>
<tr>
<td>Left ventricular end-diastolic pressure (mm Hg)</td>
<td>-</td>
<td>7 ± 1</td>
</tr>
<tr>
<td>Mitral valve gradient (mm Hg)</td>
<td>-</td>
<td>6 ± 1</td>
</tr>
</tbody>
</table>

*Data expressed as mean ± SEM.
†P < 0.001, before valve replacement vs after valve replacement values.
on their unreliability as an objective measure of improvement.

In order to place these results in clinical perspective, it must be emphasized that the patients in this study were selected for re-investigation on the basis of the auscultatory and angiographic competence of the fascia lata valve. Therefore, these are probably the best results likely to be achieved with this type of mitral valve prosthesis. This particular study was not designed to give an assessment of the over-all results of this technique of mitral valve replacement and neither was it concerned with the long-term durability of this type of biological tissue graft; these objectives have been the subject of other reports.14-16

Despite the large number of patients subjected to valve replacement with biological tissue prostheses, very little information is available on the hemodynamic results of their implantation in patients with mitral valve disease.17 The authors are aware of only one previous report of the medium-term hemodynamic results of mitral valve replacement with fascia lata. Talavlikar and his colleagues18 reported results similar to our own in eighteen patients following mitral valve replacement with two types of fascia lata prosthesis. Although their patients were studied only at rest, they also found an abnormal pressure gradient across the prosthesis and a reduction in left atrial pressure without change in the cardiac output. In fact the pressure gradients across the fascia lata valve in both studies were similar to those observed in moderately severe mitral stenosis.

It is apparent therefore that the function of the replaced fascia lata valve in situ is quite abnormal. Presystolic approximation of the cusps of the normal mitral valve is dependent upon ring-vortex formation under the cusps;18 this does not occur in three-cusp valves constructed from fascia lata,19 possibly due to the relative stiffness of fascia lata tissue. Closure of the valve is therefore dependent upon the rise in ventricular pressure during early systole; the 'late' closure of the valve probably accounts for the early systolic murmur audible in many of these patients and the puff of radio-opaque dye sometimes seen in early systole.18 Furthermore, in these artificial valves there is no papillary muscle-chordae tendineae apparatus either to assist tensioning the edges of the valve cusps during ventricular systole or to assist in their early diastolic retraction. The fascia lata valve as usually constructed is therefore entirely dependent upon atrioventricular pressure differentials for its function and the results of our studies and those of others suggest that normal differentials are insufficient to result in ideal operation of these valves. It must also be emphasized that the fascia lata valve was intentionally designed to imitate the normal aortic valve largely for the simplicity of construction. However, the originators of these valves appear to have ignored the dissimilar mechanical and hydraulic functions of the aortic and mitral valves. One of the most important differences is that the aortic annulus is relatively rigid and fixed while the mitral annulus is a more mobile structure.19-21 Splinting of the annulus with a rigid metal ring may, therefore, seriously interfere with left ventricular function. During systole the normal contraction geometry of the left ventricle may be distorted and during diastole the normal relaxation and active widening of a mitral orifice may be impaired; this can be expected to be particularly limiting at the high blood flow rates and short diastolic filling periods that occur during exercise. Finally, poor architectural siting of the valve may play an important role in the inadequate hemodynamic performance of these valves in many patients. Angiographic studies have shown the importance of valve alignment in relation to the geometric relationship of the inflow and outflow tracts of the ventricle in contributing to the adequacy of valve function.20 Relatively small errors in alignment of the replaced valve may result in large changes in intraventricular flow patterns. Although it has been suggested that left ventricular performance may be abnormal in chronic rheumatic heart disease,22,23 little quantitative information has been presented to support this clinical contention. But, whatever is finally concluded regarding the role of the myocardial factor in these patients, the abnormalities of left heart function engendered by these biological tissue valves are certainly of sufficient magnitude to account for the continued impairment of pumping activity of the heart so commonly observed when they are used for mitral valve replacement.

The introduction of this valve was a noteworthy surgical achievement and these clinical and hemodynamic results are the equal of those obtained with mechanical prostheses24-26 or other biological tissue valves.27-32 However, despite the potential advantages of this type of valve, these findings would suggest that its design and siting may still impose a significant hemodynamic penalty when the valve is used in the mitral orifice.

Acknowledgment

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