Immediate and long-term results of aortic valve replacement with University of Cape Town aortic valve prosthesis

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Aortic valve replacement with the University of Cape Town lenticular prosthesis was performed in 149 patients during a six-year period, almost all patients being severely disabled with advanced heart disease.

There was a hospital mortality of 12 per cent.

Bacterial endocarditis was a serious complication and accounted for three hospital and five long-term deaths. The survivors were followed for periods of up to 72 months (average 24), the minimum period of observation being six months. There were 23 late deaths due to heart disease, of which 5 were due to myocardial failure. Myocardial failure unrelieved or only temporarily alleviated by the operation occurred in three surviving patients.

The main problems have been sudden death and systemic embolism. Some of the cases of sudden death were due to coronary artery embolism, but in a number the cause could not be determined even at necropsy, and they were presumed to be due to arrhythmia. Both complications appeared to be related to valve design. A bare steel seat was associated with a high incidence of both complications, whereas a woven Dacron-velour cloth-covered seat almost eliminated embolism and reduced the incidence of sudden death. Long-term anticoagulant therapy appears to be of no real value with the cloth-covered valve.

Gratifying results were obtained in the surviving patients with loss of all symptoms in 80 per cent and improvement in almost all patients. This improvement or relief of symptoms was maintained in most patients throughout the period of study.

It is six years since the University of Cape Town aortic lenticular prosthesis was introduced clinically. The basic design has been previously described (Barnard, Schrire, and Goosen, 1963) and the early results reported (Schrire *et al.*, 1967). The prosthesis has been shown to function adequately from the haemodynamic point of view (Beck, Barnard, and Schrire, 1966) in that it is completely competent and a good cardiac output can be maintained at the expense of a tolerably small gradient across the prosthesis. In this respect it compares favourably with other prosthetic designs in current use (Morrow *et al.*, 1964; Judson *et al.*, 1964; Bristow *et al.*, 1964).

Significant problems have been post-operative systemic embolism, which has however been far less than with the mitral prosthesis (Schrire and Barnard, 1970), and

sudden death. Two major changes in design resulted in three series of patients whose progress can be compared. The reduction in incidence of the two major complications mentioned above has been associated with some new complications but these have been relatively insignificant.

Subjects and methods

Between March 1963 and October 1968, aortic valve replacement was performed in 149 patients (Table 1). Since then a further 30 patients have been operated upon, but these will be excluded because a six-month follow-up period is not yet available. There were 114 male and 35 female patients; the age distribution ranged from 12 to 65, with more than half between 30 and 59, the average age being 45. Patients in whom both aortic and mitral valve replacement was performed have been excluded from this analysis but not the two patients in whom a palliative mitral valve procedure only was done. Sixty-seven patients had aortic incompetence, 58 aortic stenosis, and

24 stenosis and incompetence. Syphilis was the cause in eight, congenital heart disease in 13, and aortic dilatation (one with frank Marfan's syndrome) in five. Rheumatic fever was assumed to be the cause in the remainder, though a past history of rheumatic fever or associated valve lesions were present in less than two-thirds. One patient had severe pulmonary valve stenosis with aortic incompetence, and a pulmonary valvotomy was performed at the same time as the aortic valve replacement. One patient had a sinus of Valsalva aneurysm which had burrowed into the heart. One patient had a large coexistent ventricular septal defect repaired. One patient had previously been operated upon for aortic coarctation. Antecedent bacterial endocarditis was a particularly dangerous event precipitating severe heart failure in 20 patients, and two of these were operated upon while active disease was still present, though they had been clinically 'cured' for six months. Cases of calcific stenosis of congenital origin may have been called rheumatic in the absence of a history of a murmur dating from childhood.

Initially, when the procedure was on trial, it was reserved for the severely disabled and often terminal patients, but when the results were found to be so rewarding and improvement was sustained over several years without any valve wear, operation was advised in patients with grade 2 disability (New York Heart Association classification), and, rarely, for patients in grade 1 with severe haemodynamic abnormality. The indications for operation were almost always apparent on the basis of the symptoms and clinical examination (Schrire, 1966). As shown in Table 1, there were 59 patients in grade 4, 74 in grade 3, 14 in grade 2, and two in grade 1. Pre-operative cardiac catheterization and angiocardigraphic studies were made in 62 of the first 74 patients. Thereafter investigation was only performed in cases of doubt or under special circumstances (26 patients). Operation for aortic stenosis was never undertaken unless the peak gradient across the aortic valve was at least 50 mm. Hg, except in a few patients with particularly low cardiac outputs. Operation was not refused on the grounds of advanced heart failure or age; the oldest patient successfully operated to date being 73. Intractable heart failure despite adequate medical therapy was no bar, and strenuous efforts to remove all oedema before operation were not made.

Changes in valve design The operative management has been described elsewhere (Barnard *et al.*, 1963; Schrire *et al.*, 1967).

The valve consists of two components, one of which is secured in the aortic root and the other freely mobile (Fig. 1). The fixed portion is made from a single piece of stainless steel. It has a ring forming the seat of the mobile unit to which a rim of plastic material is attached to permit the valve to be sutured in the subcoronary position. In addition, the steel ring carries two polished stainless steel arms, the one above projecting into the aorta and the one below in the left ventri-

TABLE 1 Age, sex, and pre-operative disability

Lesion	No. of cases	Sex		Age range (yr.)	Functional grade			
		M	F		1	2	3	4
Aortic incompetence	67	55	12	15-64 (Av. 37)	2	5	24	36
Aortic stenosis	58	43	13	29-65 (Av. 51)		9	36	13
Aortic stenosis and incompetence	24	16	8	12-65 (Av. 46)			14	10
Total	149	114	35	12-65	2	14	74	59

FIG. 1 The three types of valve. a. Type 1 showing the Teflon-covered ring. b. Type 2 with bare steel ring. c. Type 3 with Dacron-velour cloth-covered seat.

cular outflow area. Both arms end in a small ring which serves to limit and guide the movement of the mobile portion of the prosthesis. The entire stainless steel unit is highly polished. The mobile portion of the valve is hemispherical on the ventricular aspect and cone-shaped on the aortic aspect. In *Type 1*, the seat was covered with closely-woven Teflon cloth (Fig. 1a). In *Type 2* (Fig. 1b) the mobile portion of the valve closed on a bare stainless steel seat. In *Type 3* (Fig. 1c) the steel seat was covered with Dacron-velour cloth.

Anticoagulant policy Routine permanent long-term anticoagulant therapy was begun in 1966 using oral anticoagulants (phenindione or warfarin) starting shortly after operation. This therapy is still being maintained in patients with our first two valves in the hope that this will prevent bulky thrombus formation, but from 1968 in our last 63 patients we have discontinued anticoagulants three months after operation.

Follow-up All local patients (53) were seen by two of us in the Cardiac Clinic Outpatients' Service at monthly or bimonthly intervals, but this was later extended to three-monthly intervals. Patients living at a long distance were seen at least once a year. Follow-up information was obtained by letters written to patients and their doctors with whom a close liaison was kept two or three times a year, or by direct visits to outlying centres. Particular attention was paid to any history suggesting embolism. Cardiac catheterization with angiography was performed in 19 patients, usually a year after operation, and in two repeat studies were performed three years after operation. Only two patients have been lost to follow-up. A period of at least six months was available with these two exceptions on all patients surviving this period of time.

Results

Beneficial results of operation One hundred and thirty-one patients were discharged from hospital, and in these cardiovascular function was remarkably improved as shown in Table 2. Syncope, effort dyspnoea, paroxysmal dyspnoea, pulmonary oedema, congestive failure, and even angina pectoris

TABLE 2 *Functional classification of patients surviving 6 months*

Pre-operative status	Post-operative status			
	Grade 1	Grade 2	Grade 3	Grade 4
Grade 1	2	0	0	0
Grade 2	12	0	0	0
Grade 3	50	7	0	0
Grade 4	25	15	0	3

TABLE 3 *Hospital deaths*

Type of valve	Cases	Deaths	Percentage
Type 1	37	6	16
Type 2	37	3	8
Type 3	75	9	12
Total	149	18	12

disappeared in almost every patient, and generally all cardiac therapy could be discontinued soon after discharge from hospital. Return to full normal activity including physical work was the rule. Eighty-nine of the patients were asymptomatic six months after operation and, with eight exceptions, remained so throughout the period of observation. Radiological improvement was noted particularly in patients with aortic incompetence in whom considerable reduction in heart size occurred.

Hospital mortality Eighteen patients (12%) died without leaving hospital (Table 3). Fourteen died in the immediate post-operative period or within a few days or more after operation, usually from uncontrolled arrhythmias. Initial experience indicated that particular attention must be paid to potassium administration in the immediate post-operative period, especially in patients with aortic incompetence. In at least two patients (one not included in this series), however, cardiac infarction directly attributable to the perfusion procedure was shown at necropsy to be responsible.

Four patients died later; three from bacterial endocarditis, and one from cerebral haemorrhage associated with anticoagulant therapy. Two of the three patients who died from endocarditis were operated upon six months after apparent cure of staphylococcal endocarditis, but active endocarditis was found at the time of operation in both; one contracted candida endocarditis and died from the results of this infection on the prosthetic valve.

Long-term mortality Twenty-eight of the 131 patients who left hospital alive died later from cardiovascular disease (Table 4). Two further patients died of unassociated causes; one of gastric carcinoma and one of a fractured skull but these have not been included in the analyses.

Five patients died from bacterial endocarditis. In four of these the infection had probably been implanted at the time of opera-

tion, and staphylococci, coagulase positive or negative, were usually the offending organisms. One patient, however, contracted endocarditis and died more than two years after operation, and at necropsy the prosthetic valve was free of infection but the mitral valve showed old rheumatic disease with superimposed fresh bacterial endocarditis. Bacterial endocarditis on a prosthetic valve is not an inevitably fatal disease, for the condition was cured in three patients with prosthetic aortic valves and in four patients with prosthetic mitral valves (Schrire and Barnard, 1970). Two of our patients with bacterial endocarditis superimposed upon a tricuspid prosthetic valve have also been cured. Treatment, however, has been intensive and has been continued for up to six months.

Five patients died in congestive failure. Only one died of valve disease and this was from uncorrected mitral incompetence (necropsy confirmation). Four died from 26 to 50 months after operation. Congestive failure usually developed after an interval of several months and in one case four years after operation. Three more patients are now in chronic congestive failure, one of whom has undergone heart transplantation. Necropsy evidence in three patients indicated that the valves were intact, massive generalized cardiac failure being a feature. One patient with profound non-responsive heart failure with recurrent bouts of ventricular fibrillation requiring repeated defibrillation and resuscitation died suddenly 3 months after operation and has been included in the sudden death series (see below).

Seventeen patients died suddenly. In 11 the clinical syndrome was that of cardiac infarction, with chest pain and shock. Necropsy examination in three of these 11 patients (all Type 2 valve) showed coronary embolism to be the cause. These men were 43, 47, and 61 years old, respectively, and all had had severe angina pectoris before operation. Necropsies were not obtained in the other eight so that in these the exact cause of the presumed coronary occlusion was uncertain. All these patients were male, three were over 60, three were over 50, one was 48, and one was 35. In five, a Type 2 valve was used, and in three, a Type 3 valve. Death in these patients could have been due to coexistent coronary atheroma or coronary embolism, and angina pectoris was present in the majority before operation. In addition to the 11 patients who died with the clinical syndrome of cardiac infarction, there were five who died more or less instantaneously

and unexpectedly. They were aged 22, 50, 55, 58, and 65 years, respectively. Necropsy examination in four showed no macroscopical cause apart from cardiomegaly. The aortic valve was intact and there was no thrombosis *in situ*. Death was attributed to an arrhythmia. There was also one patient with cardiac failure and repeated episodes of ventricular fibrillation who, as mentioned above, died instantaneously but not unexpectedly.

One patient died as a result of aortic dissection at the aortotomy scar two months after operation.

No post-operative complications or deaths resulted from mechanical breakdown of the prosthesis, and to date no patient has required further operation due to the prosthesis tearing loose from the aortic root. No significant wear has been detected on close examination of the prosthesis, especially of the mobile portion, at necropsies performed up to 50 months after operation. Because of the design of the valve, unlike the Starr valve (Ablaza *et al.*, 1965), minor wear cannot result in escape of the mobile unit from the retaining mechanism of the prosthesis.

Long-term complications Aortic incompetence, haemolytic anaemia, systemic embolism, and angina were the main long-term complications.

Aortic incompetence

An early diastolic murmur was uncommon post-operatively with the first two types of valve (7 patients) but has occurred in one-third of the patients in whom the Dacron-velour cloth-covered valve was used. This was purely an auscultatory finding with no haemodynamic effects and with no progression, except in four patients. It could usually be heard shortly after the operation. In two,

TABLE 4 *Long-term deaths*

Type of valve	Cases	Bacterial endocarditis	Sudden death	Congestive cardiac failure	Other	Total	Follow-up (mth.)
Type 1	31	1	3	5	(2)*	9 (19%)	3-72 (Av. 44)
Type 2	34	2	11			13 (38%)	2-42 (Av. 24)
Type 3	66	2	3		1	6 (9%)	2-28 (Av. 13)
Total	131	5	17	5	1	28 (21%)	

* Patients dying of carcinoma of stomach and trauma, respectively, are excluded from analysis.

the valve had to be replaced because of severe incompetence and in both of these the incompetence was due to faulty surgical technique. A third patient developed bacterial endocarditis after operation and though he has responded to antibiotic therapy he has been left with severe incompetence and will require a further operation. The fourth has moderate incompetence and will not require another operation.

Haemolytic anaemia

Haemolytic anaemia was only encountered in the cloth-covered valve. In one this was transient and settled after a few months. One symptom-free patient ran a persistent mild chronic anaemia. In our total series of 104 patients with cloth-covered valves, haemolysis has been present in four, in two of whom aortic incompetence has been associated.

Systemic embolism

How many sudden deaths could be attributed to embolism could not be determined,

but a certain proportion undoubtedly were, and this constitutes a serious problem. Unlike the mitral valve prosthesis, however, serious neurological episodes were exceptional. Emboli were presumably small platelet fibrin thrombi producing transient focal symptoms such as dysphasia, numbness of a limb, or hemiplegia lasting from an hour or two to a few days, and leaving no residua. The following factors were shown to have no bearing on these complications: the nature of the pre-existing lesion, the haemodynamic status before operation (pulmonary vascular resistance, pulmonary artery pressure, pulmonary wedge or left atrial pressure, the aortic valve gradient or degree of incompetence, and the cardiac index), the age of the patient, the size of the heart, the disability before operation, the presence or absence of angina pectoris and the state of the electrocardiogram, including the presence or absence of left axis deviation.

The difficulties of assessing the effects of long-term anticoagulant therapy have been discussed elsewhere (Schrire and Barnard,

FIG. 2 Long-term follow-up of patients with Type I prosthesis. The Type I valve was inserted into 37 patients (1-37 on the ordinate), all but the last two between March 1963 and July 1965. Duration of follow-up is shown in months on the abscissa. In this and the succeeding two figures, emboli are shown as transverse lines, the width of which denotes the severity. Cross-hatching refers to severe neurological deficit. LTA = long-term anticoagulants, CCF = congestive cardiac failure, SBE or ABE = subacute or acute bacterial endocarditis, † = death, CT = cardiac infarction and ×-hatched cubes = sudden death. Systemic emboli manifesting with one exception as cerebral episodes occurred in 7 patients and sudden death in 3. In Case 28 the valve was replaced because of valve thrombosis.

FIG. 3 Long-term follow-up of patients with Type 2 prosthesis. The Type 2 valve was inserted into 37 patients, between May 1965 and October 1966. Sudden death occurred in 11 and systemic embolism in six. Key as for Fig. 2.

1970). On the whole, our experience has been unfavourable. One patient died of cerebral haemorrhage in hospital, and three had gastro-intestinal haemorrhages, one in the immediate post-operative period and two 22 and 40 months after operation, respectively. For one reason or another several of our patients with a Type 3 valve failed to continue with this therapy and showed no

untoward effect. In our last 63 patients we have stopped anticoagulants three months after operation and the only patient who suffered systemic embolism (and later died) was in fact on anticoagulants at the time.

The most important factor appeared to be the type of prosthesis used. With the Type 1 valve, small emboli manifesting as transient cerebral episodes occurred in seven patients

FIG. 4 Long-term follow-up of patients with Type 3 prosthesis. The Type 3 valve was inserted into 75 patients between November 1966 and October 1968. Sudden death occurred in three patients. Case 6, dying suddenly 20 months after operation, sustained severe cerebral damage from air embolism at the time of operation, and Case 48 developed a hemiplegia after operation. Case 52 developed complete heart block after operation and required insertion of a permanent pacemaker; Case 68 had complete heart block before operation. Only one patient had a transient hemiplegia presumably due to a small embolus. Key as for Fig. 2.

(Fig. 2) but produced significant residual neurological disability in only one. Sudden death occurred in three patients and in one thrombosis of the valve occurred requiring replacement. With the Type 2 valve, there was an immediate increase in sudden death to 11, with embolic episodes in six (Fig. 3). With the Type 3 valve, there was an immediate reduction in incidence of sudden deaths to three patients (Fig. 4). In the 104 patients in whom this valve has been used there was only one other sudden death in hospital (not in this series), the cause of which was not disclosed at necropsy. Only two patients had systemic embolism. One of these showed occlusion of a small retinal artery in the post-operative period, with slight transient visual impairment; the other developed transient hemiplegia and died suddenly some months later.

Angina pectoris

Two young patients (one a male aged 20, the other a female aged 26) suffered from angina pectoris for the first time after valve replacement for severe aortic incompetence. In both, laboratory study including coronary angiography failed to show the cause, but in one the effort electrocardiogram was positive. With the passage of time this symptom either disappeared or became infrequent.

Discussion

In the initial stages, replacement of the aortic valve with the University of Cape Town prosthesis was considered entirely as an experimental procedure. For this reason only desperately ill patients with a limited life expectancy and much restricted lives were offered this type of operation. Coexistent mitral valve disease was only occasionally present. As confidence in the operative management increased and the relatively complication-free course associated with the remarkable benefit to patients was observed, earlier operation became justified. None the less, severe haemodynamic disturbance alone was seldom regarded as an indication for operation.

Bacterial endocarditis was a particularly devastating disease, precipitating heart failure in 20 patients, necessitating early surgical intervention. As far as possible, however, operation was not attempted in the face of florid infection.

Despite the late stage of the disease in most patients a hospital mortality of 12 per cent was obtained. In the surviving patients

clinical evidence indicated that cardiovascular function had been considerably improved. The first 11 patients who survived one year after operation had a haemodynamic assessment of cardiac function by catheterization at rest and during exercise (Beck *et al.*, 1966). The valve was shown to be moderately stenotic without significant incompetence, and in only one of these patients was persistent left ventricular failure observed; whether this was due to intimal sclerosis of the muscular coronary arteries as described by Barratt-Boyes (1964), altered flow patterns past the coronary ostia caused by the mobile portion of the valve, irreversible myocardial damage, the result of long-standing aortic valve disease, coronary emboli, or myocardial damage sustained during cardiac bypass and coronary perfusion, was not known. This is an unusual result, however, and was noted in only seven subsequent patients.

Radiological assessment of cardiac function was studied in 25 patients (Gotsman *et al.*, 1968) one year after operation, attention being paid to heart volume, cardiothoracic ratio, individual chamber enlargement, aortic and pulmonary arterial enlargement, and the pulmonary vascular pattern. In 15 patients heart volume and cardiothoracic ratio had returned to normal, the greatest improvement being observed in patients with aortic incompetence. Failure to return to normal was due to associated mitral valve disease, persistent aortic incompetence, or myocardial disease due either to coronary artery disease or to some form of cardiomyopathy. Pulmonary venous hypertension was present in nearly all patients before operation but persisted in only nine. There was little improvement in the size or configuration of the aorta.

The major problems have been the occurrence of sudden death and systemic embolism, and the most important factor responsible for these complications has been the design of the valve (Fig. 5). Valves with a bare steel seat were associated with the highest incidence of sudden death, and systemic embolism was also common. A cloth-covered valve has almost eliminated systemic embolism, but sudden death does still occur in these cases occasionally. The evidence regarding the effect of long-term anticoagulant therapy is equivocal, and we now believe that patients with a Dacron-velour cloth-covered valve do not require long-term anticoagulant therapy. Whether they need any anticoagulant therapy at all has not yet been determined.

Aortic valve disease has been a well-

FIG. 5 Comparative follow-up of patients with the three types of valve. To eliminate the unequal lengths of the follow-up period, the first 28 post-operative months only have been charted. The high incidence of sudden death in Type 2 valve, and the incidence of embolism in Types 1 and 2 valves contrast with the relative freedom from complications with Type 3 valve. Symbols as for Fig. 2.

recognized cause of sudden death for centuries (Bonet, 1679). This applies to all types of left ventricular outflow obstruction; supralvar, valvar, and subvalvar (fixed or hypertrophic). Death is probably due to ventricular fibrillation, but what triggers off the arrhythmia is obscure. Sudden death is also common in cases of aortic incompetence, particularly luetic aortic incompetence with or without coronary ostial involvement. Sudden death after aortic valve surgery is also often reported, but is ill understood. It has been recorded almost two years after operation even in supralvar aortic stenosis (Effler, 1964). It is extremely rare after homograft replacement of the aortic valve but has been reported by Davies *et al.* (1968) and by Barratt-Boyes (1964). The grossly

hypertrophied, often fibrosed, heart may well be vulnerable to electrical instability, and Barratt-Boyes in fact claimed to have shown small vessel disease. Irreversible heart disease may well be present at the time of operation, and this we have encountered in several of our patients.

Nothing worth while in life is obtained cheaply. The introduction of a cloth-covered valve has brought with it certain acceptable risks. Ball wear in the aortic position has not resulted in incompetence as in the mitral valve position (Schrire and Barnard, 1970). However, haemolytic anaemia is a definite problem and has occurred in four of 104 patients to date; fortunately it has been either self-limiting or readily within the patient's compensatory ability.

We thank our colleagues at Groote Schuur Hospital for referring their patients, and Dr. J. G. Burger, Medical Superintendent of Groote Schuur Hospital, for permission to publish. We especially appreciate the help given by members of the Cardio-thoracic Surgical Unit, Dr. M. Barnard, Dr. T. G. O'Donovan, and Dr. C. Venter for many of the recent operations, and members of the Cardiac Clinic for their help with the investigations. Our thanks are due to the South African Council for Scientific and Industrial Research and the City Council of Cape Town for their financial support.

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