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Functional results with aortic ball valve prostheses (Starr-Edwards) followed for two to three years

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It is now believed that aortic insufficiency and calcific aortic stenosis must be treated with total valve replacement. Until recently this was performed with the aid of prostheses of teflon and similar materials. Even if the short-term results were promising, follow-up studies revealed a high percentage of breakdown of these prostheses (Björk, Cullhed, and Lodin, 1963 ; Larson and Kirklin, 1964). For the last three years we have used a ball valve prosthesis of the Starr and Edwards type (Björk, 1964). The aim of this paper is to report the 'long-term' clinical and haemodynamic results with this valve.

MATERIAL

Of the first 100 patients operated on with this technique, the first 20 survivors have been followed for between two and three years (see Table). There were four women and 16 men. The five oldest surviving patients were between 50 and 57 years old. The pre-operative heart size was increased in 17 patients. In cases 4 and 16 tight mitral stenosis was present and transventricular mitral dilatation had to be performed at the same operation as replacement of the aortic valve. In case 2 a single teflon cusp had been inserted one year before the total valve replacement, when this cusp was found to be fractured (case 1 in an earlier report by Björk *et al.*, 1963).

METHODS

Our methods for the pre-operative clinical, haemodynamic, and angiocardiographic evaluation of aortic valve disease have recently been reported (Cullhed, 1964). Peroral anticoagulant therapy was begun post-operatively in all patients. The post-operative haemodynamic studies were made nine to 16 months after the operation. The peak systolic pressure gradient was measured between the left ventricle after transseptal catheterization and, in all cases except two, the central aorta after percutaneous catheterization of the brachial artery. Cardiac output was measured according to Fick's principle. Pressure and flow at rest and exercise was measured in the supine position. The physical working capacity in the sitting position was evaluated with the aid of a bicycle ergometer. As this test for several reasons often had to be stopped at a relatively low heart rate, the maximal physical working capacity (Wahlund, 1948) could not always be calculated. We therefore report the highest load at which the patient could work for 4 minutes. The heart rate on this load is also given. The presence of atrial fibrillation (cases 4 and 16) or second-degree atrioventricular block (case 3) limits the significance of the attained heart rates.

The radiological heart volume was calculated according to Jonsell (1939). With this method the heart volume in healthy adults seldom exceeds 450 ml./m.^{2} for women and 500 ml./m.^{2} for men. In the Table absolute as well as relative volumes are given.

RESULTS

MORTALITY In the first 50 operated patients there was an early mortality of 56%. In the next 50 patients the mortality had decreased to 26%. In the 20 patients reported here there have been three late deaths. Patient 5 died with sepsis one and a half years after the operation. Patient 8, in spite of post-operative renal insufficiency, had made a good recovery and returned to full-time work when two years after the operation he died of an acute dissecting aortic aneurysm. Patient 16 made a slow recovery and died one and a half years after the operation from a coronary artery embolus.

HAEMODYNAMIC FINDINGS A basal systolic murmur of slight to moderate intensity was found in all patients at follow-up. In 10 patients left heart catheterization was performed (see Table and Figure). In most there was no gradient or only a small gradient at rest. During exercise, when the cardiac output increased to 13 to 15 l./min., the peak gradient rose to 35 to 55 mm. Hg.

TABLE

CLINICAL AND HAEMODYNAMIC FINDINGS

Case	Sex	Age	Pre-op. Diagnosis	Starr Prosthesis No.	Post-op. Aortic Insufficiency		Roentgenological Heart Volume				Exercise Test			
							Before		After		Before		After	
					Diastolic Murmur	Thoracic Aortography	Total (ml.)	Relative (ml./m.²)	Total (ml.)	Relative (ml./m.²)	kpm./min.	Heart Rate	kpm./min.	Heart Rate
1	F	24	A.I.+ruptured sinus Valsalva aneurysm	12	0	0	1,260	800	700	440	150	124	600	176
2	M	30	A.I. reoperated	13	0	—	1,100	700	920	575	600	135	300	132
3	M	43	A.I.	13	0	—	1,500	890	1,250	720	400	132	400	80
4	M	54	A.S.+A.I.+M.S.	12	0	0	1,240	690	1,110	590	350	124	400	124
5	M	54	A.S.+A.I.	13	0	—	1,500	735	1,340	650	600	110	300	134
6	M	39	A.S.+A.I.	11	0	—	760	415	630	320	600	164	600	175
7	M	28	A.S.+A.I.	13	0	0	1,240	640	1,100	680	900	154	800	162
8	M	50	A.I.	14	0	0	1,470	770	1,130	600	600	136	600	160
9	M	56	A.S.+A.I.	12	0	1	970	510	890	460	900	162	900	185
10	F	46	A.I.	11	0	1	900	510	730	440	300	144	300	150
11	M	42	A.I.	13	0	—	1,670	740	1,660	730	900	175	600	162
12	M	40	A.S.+A.I.	13	2	2	980	550	1,140	580	600	151	600	160
13	M	27	A.I.	11	+	1	1,380	735	1,100	590	800	182	400	161
14	F	29	A.I.	11	2	1	1,020	640	690	430	300	152	450	160
15	M	34	A.I.	12	+	0	1,300	625	980	470	800	160	600	158
16	M	49	A.S.+A.I.+M.S.	10	+	—	1,160	620	—	—	500	142	—	—
17	M	57	A.I.	12	0	1	1,710	790	1,300	640	300	92	—	—
18	F	49	A.I.	10	0	—	830	470	850	510	250	114	450	174
19	M	40	A.S.+A.I.	9	0	—	1,100	680	—	—	200	110	—	—
20	M	39	A.S.+A.I.	10	+	4	730	430	1,030	610	400	116	600	128

A.I.=aortic insufficiency; M.S.=mitral stenosis; A.S.=aortic stenosis; kpm.=kilopondmeter.

A high-pitched basal or mid-sternal diastolic murmur was found in six patients. This murmur was usually of low intensity and in two patients could be heard only in the sitting position at expiratory apnoea. Thoracic aortography was performed in 11 patients. There was no regurgitation in five patients, a slight regurgitation (grade 1 to 2 (Cullhed, 1964)) in five patients, and severe aortic regurgitation in patient 20. This man was re-operated on with a good primary result.

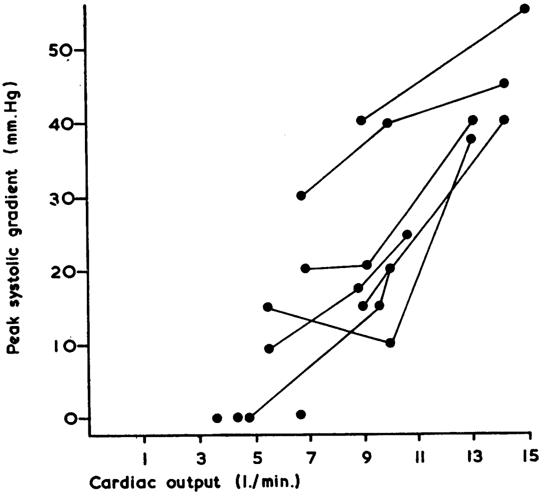

FIGURE. *The systolic pressure gradient at different cardiac outputs over the Starr-Edwards ball valve prosthesis.*

HEART SIZE At follow-up the heart volume was smaller in all but four patients. A decrease in relative heart volume of at least 10% of the pre-operative volume was found in 11 patients, whereas an increase in excess of this percentage was noted only in patient 20. In this patient, who had recurrent aortic insufficiency, the heart volume rapidly became normal after re-operation.

EXERCISE TEST In spite of differences in heart rate at the highest tolerated load in pre- and post-operative exercise tests, it can be seen from the Table that the working capacity was usually the same. A pronounced increase was noted in patient 1, who was in left ventricular failure before the operation. Three years later she works full time as a secretary. In patients 5, 11, and 13 a lower working capacity was noted. These patients were subjectively improved, and patient 13 had returned to full-time work.

SYSTEMIC THROMBO-EMBOLISM This was noted in two patients who were both operated on for mitral stenosis as well and who had chronic atrial fibrillation. In patient 4 the embolus became lodged in the calf, resulting in only transient ischaemic symptoms. He had discontinued the prophylactic anticoagulant regimen, which was then immediately started again. There have been no more embolic episodes in this man. In patient 16 a coronary artery embolus was found at necropsy.

TABLE—*continued*

Post-op. Pressure-flow (Haemodynamic) Findings						Observation (yrs)	Results
Cardiac Output (l./min.)			Peak Systolic Gradient (mm. Hg)				
Rest	I	II	Rest	I	II		
—	8·9	13·0	0	15	35	3	Excellent; working full time
—	—	—	—	—	—	3	Excellent; working full time
—	—	—	—	—	—	3	Good; not working
3·4	5·1	—	0	0	—	3	Good; not working
4·7	—	—	0	—	—	1½	Died after 1½ years in sepsis
—	—	—	—	—	—	34 months	Excellent; working full time
6·8	9·2	13·1	20	20	40	2¾	Excellent; working full time
5·4	8·8	10·5	8	18	24	2	Excellent until death from dissociated aortic aneurysm 2 yrs 1 mth
—	—	—	—	—	—	2	Excellent; working full time
6·7	9·3	—	0	0	—	2	Excellent; working full time
—	—	—	—	—	—	2	Good; not working
5·4	10·0	12·8	15	10	38	2	Fair; not working
6·7	9·8	14·2	30	42	45	2	Excellent; working full time
4·7	9·3	9·8	0	15	20	2	Excellent; working full time
9·1	11·4	15·0	40	40	55	2	Excellent; not working
—	—	—	—	—	—	1½	Died from left coronary artery emboli
—	—	—	—	—	—	2	Good; not working. Infarction six months post-op.
—	—	—	—	—	—	2	Excellent; not working
—	—	—	—	—	—	22 months	Excellent; working full time
—	—	—	—	—	—	20 months	Reop. for recurrence, then excellent result without diastolic murmur Heart 430 ml./m.^{2}

In patient 17 myocardial infarction occurred six months after the operation. As he survived the aetiology is unknown. At necropsy no thrombi were found on the ball valve in patients 8 and 16, nor in patient 20 at re-operation. Such aggregations were found in patient 5, who died in sepsis.

DISCUSSION

The rapid decrease in early mortality is striking. There were three late deaths, but the fatal outcome was not related to the function of the ball valve. The occurrence of systemic embolism in patients with a mitral ball valve prosthesis evidently has no counterpart in those in whom an aortic prosthesis has been used. Thrombi on the base of the aortic ball valve have been found only in patients with septicaemia. This difference is probably related to differences in the flow rate.

The haemodynamic studies show that at rest there was as a rule no significant obstruction to left ventricular outflow. In some patients a high cardiac output was found on exercise, and in these a moderate pressure gradient was registered. This may have been due to an obstructive effect of the prosthesis. However, the role of increased turbulence, due to the high flow rate and the construction of the valve, should be taken into consideration. The size of the prosthesis was no. 11 or larger in our patients with post-operative left heart catheterization. The correlation between the gradient and the size of the prosthesis will have to be studied in a larger series.

With a similar type of aortic ball valve Harken and his co-workers found a peak gradient of 25 mm. Hg in a pulse duplicator, and in two patients who had been operated upon a mean systolic gradient of 17 and 12 mm. Hg (Harken, Soroff, Taylor, Lefemine, Gupta, Lunzer, and Low, 1961; Wagner, Soroff, Fossberg, and Harken, 1963). Starr, Edwards, McCord, and Griswold (1963) found no peak gradient in 11 patients when measured at operation by means of direct left ventricular puncture. In a later study of the same group 10 were investigated six to 12 months after the operation (Bristow, McCord, Starr, Ritzmann, and Griswold, 1964). A peak gradient of between 14 and 30 mm. Hg was found at rest. In only one did the gradient increase during exercise. However, the work load was probably slight, resulting in only a moderate increase in cardiac output. In five patients with aortic and mitral ball valve prostheses a peak gradient over the aortic valve at follow-up was found in only one (15 mm. Hg) (Starr, McCord, Wood, Herr, and Edwards, 1964). Judson, Ardaiz, Strach, and Jennings (1964) re-investigated eight patients with the Starr–Edwards aortic prosthesis. In five there was no gradient, but in three gradients of 20, 25, and 90 mm. Hg were measured. The highest cardiac index, 4·4 l./min./m.^{2}, was found in a patient with the highest gradient. In another isoproterenol infusion increased the gradient from 25 to 75 mm. Hg while the cardiac index increased from 3·00 to 4·66 l./min./m.[2]

Significant aortic insufficiency was present only in patient 20. In some patients a diastolic murmur of aortic insufficiency was heard. Thoracic aortography demonstrated in some of these a slight regurgitation into the left ventricle. This could be physiological if a small amount of contrast is present in early diastole between the ball and the base of the valve. However, the diastolic murmur was heard well after the second aortic sound, which seems to indicate a leak during diastole. Further, if a physiological leak exists this should be demonstrable more constantly. Functional pulmonary valvular insufficiency (Graham–Steell) can be excluded in these patients who have normal pulmonary artery pressures at rest.

The decrease in heart size is one of the most obvious objective signs at follow-up. If cardiomegaly is of long duration myocardial fibrosis is present; and thus in the older age-groups only small reductions in heart size can be expected.

This myocardial factor probably explains why some patients achieved only slight or moderate subjective and objective clinical improvement in spite of a good valve function. The exercise test gives a general idea of the functional status of the patient. The lack of correlation between the post-operative working capacity and the social rehabilitation is of interest. This is partly explained by the long post-operative period of inactivity.

SUMMARY

More than 100 patients have been operated upon and Starr–Edwards aortic ball valve prostheses have been inserted. The first 20 survivors have been followed for two to three years. Post-operative left heart catheterization has been performed in 10 patients and thoracic aortography in twelve.

At rest no gradient or a small gradient over the ball valve was found. With exercise the gradient increased to a maximum of 55 mm. Hg in this series. Thus there is an obstruction to left ventricular outflow, but this is only slight and probably has no effect on the end result.

The diastolic murmur of aortic regurgitation was found in some patients. The degree of regurgitation was minimal in all except one, and this patient underwent another operation.

The post-operative heart volume was unaltered or decreased in all patients except in the one who had a recurrence of severe regurgitation.

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