European Heart Journal (1980) **1**, 123–127

Isolated aortic valve replacement with the Björk-Shiley tilting disc prosthesis and the porcine bioprosthesis

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KEY WORDS: Björk-Shiley tilting disc prosthesis, porcine bioprosthesis, aortic valve replacement.

Between 1977 and 1978, 239 patients underwent aortic valve replacement with either a bioprosthesis (100, BIO) or a Björk-Shiley tilting disc prosthesis (139, BS). Early mortality was 2%, late mortality 4%. There was no statistically significant difference between the two groups. Anticoagulation was maintained indefinitively in patients with a BS, after implantation of a BIO only for three months except in the presence of atrial fibrillation or a history of emboli. Thromboembolic complications and anticoagulant hemorrhages were almost twice as frequent in patients with BS than with BIO (5·3 versus 2·8 episodes/100 patient years). This difference however is statistically not significant. There were an equal number (two) of reoperations because of paravalvular leaks due to endocarditis or torn sutures in the two groups. A regurgitant murmur, though hemodynamically not significant, occurred more frequently in patients with BIO than with BS (10% versus 2%, $P < 0{\cdot}05$). Its cause and importance cannot yet be determined. Postoperative results judged by the NYHA classification and reduction of heart size were similar in both groups. Of all patients, 13% with preoperative valvular incompetence and 15% with stenosis showed little or no reduction of the cardiothoracic ratio on X-ray indicating a worse long-term prognosis. The porcine BIO has become our preferred valvular substitute because of its low thromboembolic complication rate. The BS is mainly reserved for patients already on anticoagulants for other reasons.

From 1971 to 1977 the Björk-Shiley prosthesis (BS) has been our preferred valvular substitute for aortic valve replacement (AVR). We have since started to use porcine bioprostheses (BIO) in increasing numbers because of their lower reported incidence of thromboembolic complications as compared to mechanical devices[1–4]. This retrospective study analyses first results with BIO in reference to valve related complications and compares them to those achieved with the BS over the same time period.

Patients and methods

During 1977 and 1978, 239 patients underwent isolated AVR with either a BIO or a BS. BIO of three different manufacturers were used: Carpentier Edwards (51), Angell-Shiley (41) and Hancock (8). Indications for implanting a BIO or BS varied during this time period, the BS being the preferred choice during the early part of this series, whereas later the BIO was used more often. The preoperative and operative data are outlined in Table 1. On statistical analysis (Student's *t*-test, chi-square test) patients receiving a BIO were generally younger with less advanced disease. Operative technique was the same in both groups (moderate hypothermia to 26–28°C, K^+ induced cardioplegia and topical hypothermia). Postoperatively all patients with a BS received long-term anticoagulants. Patients with a BIO were anticoagulated for three months; in these patients anticoagulation was continued only in the presence of atrial fibrillation or a history of preoperative emboli. The follow-up period lasted to June 1979 with a mean of 13 months for the BIO patients and 20 months for patients with a BS. To evaluate reduction in heart size postoperatively the cardiothoracic ratio (CTR) in pre- and six months postoperative chest X-rays were compared. Only postero-anterior views in the upright position were considered for comparison.

Received for publication 28 January 1980.

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0195-668X/80/020123+05 $01.00/0

Table 1 Preoperative and operative data

	BIO	BS	Total
Number of patients	100	139	239
Male/female ratio	81/19	112/27	193/46
Mean age (years)	45(5–73)*	51(22–72)*	48
Predominant stenosis	45	56	101
Predominant regurgitation	40	63	103
Mixed lesion	15	20	35
NYHA class (mean)	2·5*	2·8*	2·7
c.i. (mean)	2·9*	2·6*	2·7
Concomitant procedures	18*	54*	72
CABG	3	12	15
Patch enlargement of aortic root	4	6	10
Resection of asc. aortic aneurysm	3	15	18
Resection of coarctation	0	2	2
Closure of VSD	2	4	6
Miscellaneous	6	15	21
Average valve size	28·2	28·2	28·2

NYHA = New York Heart Association; c.i. = cardiac index; CABG = coronary artery bypass grafting; VSD = ventricular septal defect.
*$P < 0.005$.

Table 2 Mortality

	BIO	BS	Total
Early (<30 days)	1	4	5 (2%)
Late	4	6	10 (4%)

Mean follow-up time 13 and 20 months for patients with BIO and BS, respectively.

Table 3 Thromboembolic and anticoagulation related complications

	BIO	BS
Emboli	3	8
Valve thrombosis	–	–
Hemorrhage	–	4
Total	3*	12*
Episodes/100 patient-years	2·8	5·3

*P = not significant; (n BIO, 99; n BS, 135).

Results

MORTALITY

Early and late mortality have been similar in both groups (Table 2). The cause of death was cardiac, but not valve related, in all patients [myocardial failure in nine (four early, five late), sudden unexplained death in six (one early, five late)]. Autopsies in three of the four late deaths with BIO and two of the six late deaths with BS were obtained. The prostheses in all cases examined were intact and functioning normally.

INCIDENCE OF THROMBOEMBOLISM (TE) AND ANTICOAGULANT HEMORRHAGE

All recorded emboli were cerebral; none was fatal. Emboli in patients with BIO caused minor transient symptoms only whereas three patients with BS sustained a hemiplegia with variable recovery. The total incidence of episodes however has statistically not been significantly different between the two groups, although calculated per 100 patient years (Table 3), it has been almost twice as high in patients with BS.

VALVE FAILURE

Severe regurgitation requiring reoperation occurred in both groups with almost equal frequency (Table 4). A murmur of mild, hemodynamically insignificant regurgitation was observed more often in patients with BIO ($P<0.05$); its cause and consequences remain unknown. The average valve size of patients with such a murmur was 29 and 28·6 in the BIO and BS groups, respectively. This is statistically not different from the mean valve size

Table 4 Prosthetic valve dysfunction and endocarditis

	BIO	BS
Reoperation because of endocarditis	1	1
Reoperation in absence of endocarditis (paravalvular leak)	1	1
Endocarditis, conservatively treated	1	1
Regurgitant murmur of unknown cause, no reoperation	9*	3*

*$P<0{\cdot}05$; (*n* BIO, 99; *n* BS, 135).

Table 5 Postoperative clinical classification compared to preoperative class (NYHA)

Preoperative class	Average postoperative class	
	BIO	BS
II	1·3	1·3
III	1·8	1·6
IV	1·8	2·0

used in the entire group of patients. Seven of the nine patients with a murmur complicating a BIO had a Carpentier Edwards, one an Angell-Shiley and one a Hancock prosthesis.

POSTOPERATIVE CLINICAL CLASSIFICATION AND REDUCTION IN HEART SIZE

The average six months postoperative clinical improvement has been similar in both groups (Table 5). Objectively this was documented by a reduction in heart size assessed by pre- and postoperative CTR (Table 6). Good quality chest X-rays were available in 188 patients preoperatively and in 155 postoperatively. Patients with aortic regurgitation (AR) showed a greater reduction of their postoperative CTR than patients with aortic stenosis (AS). Little change (< 5% reduction) was observed in eight of 60 patients with AR (two BIO, six BS). Nine of 59 patients with AS demonstrated an increase in postoperative CTR (five BIO, four BS); of 18 patients with AS and a small prosthesis (25 or smaller, six BIO and 12 BS) the heart size enlarged postoperatively in only three (all BS).

Comment

The purpose of this analysis has been to point out clinical characteristics of the BIO compared to the BS. Although the two groups of patients are not prospectively randomized and are different in some respects, certain comparisons are still justified.

As expected there are no differences in early and late mortality. Sudden unexplained death represents half of the late mortality in both groups. Perioperative tachyarrhythmias were a predisposing factor since all of these patients had to be treated for arrhythmias early postoperatively; four of the five patients had aortic regurgitation preoperatively. A similarly high incidence of sudden late death has been reported in the series of Copeland[5] and Davila[6].

The lower TE complication rate is the major advantage of the BIO over the BS. Comparing the two groups in our series with regard to TE is, however, difficult because they differ in age and state of the disease. BS patients, who represent the less favourable group, show a higher incidence of emboli, although it is statistically not significant. The fact that the great majority of BIO patients have not been on long-term anticoagulants and that emboli in this group presented as minor transient episodes only, contrary to BS patients, weighs in favour of this type of valvular substitute. Our incidence of 2·8 episodes per 100 patient years for BIO patients is within the range of what is generally reported[1–10]. As the follow-up period extends, this rate is likely to drop for BIO patients[9]. This, however, is not the case for patients with a BS as has been reported from our institution in patients followed over a six year period[11].

An unexplained complication, though not yet assessable in its significance, has been the occurrence of a regurgitant murmur in the absence of endocarditis in 10% of patients with BIO (compared to 2% in BS patients). A similar observation has been made by Pipkin[2]. Whether the origin of this murmur is valvular or paravalvular cannot be determined clinically nor by echocardiography. The valve size *per se* is not a predictor for the occurrence of such a murmur. On the other hand we always have tried to insert a BIO as large as possible to minimize the postoperative gradients which have been described in clinical and experimental studies with this type of valvular device[12,13]. One might speculate that the intention to insert a large prosthesis has led to a disproportion between anulus and prosthetic ring resulting in a paravalvular leak. The bulkier ring of the Angell-Shiley prosthesis may also provide a better seal than the Carpentier Edwards ring since most murmurs appeared in patients with the latter

*Table 6 Postoperative reduction of CTR**

Preoperative lesion	Preoperative CTR (mean)	Postoperative CTR (mean)	%Reduction
Regurgitation			
BIO	0·56	0·50	11
BS	0·57	0·51	11
Stenosis			
BIO	0·50	0·48	4
BS	0·54	0·50	7
Mixed lesion			
BIO	0·50	0·47	6
BS	0·53	0·50	6

*CTR = Cardiothoracic ratio.

valve. We now pay particular attention so as not to insert too large a prosthesis for a given anulus. If necessary a patch enlargement of the aortic root into the non-coronary sinus will allow implantation of a prosthesis of appropriate size. Postoperative results, judged by the NYHA classification have been good in both groups without significant differences. As a more objective parameter to follow postoperative recovery we have compared CTR of pre- and six months postoperative chest X-rays. Reduction in CTR has been independent of valve type. There were altogether 13% of AR patients and 15% of AS patients with poor reduction or an increase of their postoperative CTR. This is of prognostic importance, particularly for patients with AR. In an earlier series of AVR with various mechanical devices Rothlin[11] has statistically documented a worse prognosis for patients with little or no reduction in heart size postoperatively (six years follow-up). This has been the case also for patients with marked preoperative cardiomegaly (CTR > 0·6) and those in preoperative clinical class IV.

At present we continue to use BS and BIO for AVR, but the latter has become the prosthesis of first choice because of the lower incidence of thromboembolism. Uncertain durability, however, remains its major drawback, but our earlier experience with patients with fascia lata valves supports the concept that a reoperation after several years because of valve fatigue or degeneration is preferable to the continued risk of thromboembolism and anticoagulant hemorrhage[14]. We reserve the BS, therefore, for patients already on anticoagulants for other reasons, those already reoperated, or patients in an advanced state of disease.

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