Six Month Postoperative Hemodynamics of the Hancock Heterograft and the Björk-Shiley Prosthesis: Results of a Veterans Administration Cooperative Prospective Randomized Trial

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In a Veterans Administration Cooperative Study involving 13 medical centers, 575 patients undergoing single valve replacement were prospectively randomized to receive either the standard Björk-Shiley prosthesis or the Hancock porcine heterograft (with a modified orifice for sizes 23 and smaller). The hemodynamic data in the 268 patients who underwent cardiac catheterization an average of 6 months (range 3 to 12) postoperatively are reported. Statistical analyses were performed at seven sites 23, 25 and 27 in the aortic position, and 29, 31 and 33 in the mitral position.

A wide variation was observed in mean pressure gradient and calculated orifice area in both valve types within all sizes in both the aortic and the mitral positions. In the aortic position, the Björk-Shiley prosthesis tended to have a lower pressure gradient and larger calculated orifice area than the Hancock heterograft, but the differences in gradient between the two valve types were significant only in the larger-sized valves. The difference in calculated area between the two valve types was not significant within each valve size. In the mitral position, there were no differences in gradient and calculated orifice area between the two types of prostheses.

The postoperative cardiac index, regurgitant volume, pulmonary artery systolic and mean pressures, left ventricular end-diastolic pressure, left ventricular ejection fraction and left ventricular end-diastolic volume index did not differ in patients receiving the Björk-Shiley prosthesis from values in patients receiving the Hancock heterograft. Hence, the overall hemodynamic performance of both types of valves is remarkably similar. The choice between these two prostheses should, therefore, be governed not by the hemodynamic performance, but by other factors such as valve durability, risk of anticoagulation and incidence of valve-related complications.

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Beginning in October 1977, a cooperative study entitled "Prognosis and Outcome Following Heart Valve Replacement" was initiated in 13 Veterans Administration Medical Centers. The study consisted of two overlapping parts. The first part was a "Prognosis Study" aimed at assessing the capability of left ventricular function and other clinical and hemodynamic variables in predicting prognosis in patients with valvular heart disease. The second part was a "Randomized Therapeutic Trial" (RTT) aimed at comparing hemodynamic function, left ventricular function, postoperative complications and survival rates in patients receiving one of two valve types: a nonbiologic valve, the Björk-Shiley standard prosthesis, and a tissue valve, the Hancock porcine heterograft. To evaluate the late postoperative hemodynamic function of the prostheses, all randomized patients were asked to undergo cardiac catheterization 6 months after surgery. The present communication reports the results of
these postoperative hemodynamic studies in the Randomized Therapeutic Trial.

Methods

Study patients and protocol. The 13 participating centers and the investigators in the study are listed in the Appendix. The details of the methodology and trial design have been published elsewhere (1); hence, only a brief description of the methods will be furnished here. A total of 964 patients undergoing single valve replacement were entered into the Prognosis Study and were followed up by the principal investigators in each of the 13 centers for an average of 5 years (range 3 to 8). Of these patients, 575 (60%) were randomized to receive either the standard Björk-Shiley prosthesis or the Hancock porcine heterograft. The flow chart describing the Randomized Therapeutic Trial protocol is shown in Figure 1. After the valve anulus was measured in the operating room, the randomization took place with use of instructions obtained from a sealed, numbered envelope. Exclusions to randomization included requirement for antiplatelet therapy (8 patients), patient refusal (134 patients), surgeon's preference (47 patients), contraindication to anticoagulation (100 patients), active endocarditis (18 patients), and inability to place a prosthesis 21 mm or larger in the aortic position and 27 mm or larger in the mitral position (51 patients). Patients were randomized in strata defined by New York Heart Association functional class (I-IV) and valve position and participating center. Patients receiving a 21 or 23 mm aortic prosthesis were randomized separately between the modified orifice Hancock valve (57 patients) and the standard Björk-Shiley valve (53 patients). No concave-convex valves were used in the study.

Postoperative cardiac catheterization. Two-hundred sixty-eight randomized patients underwent left and right heart catheterization approximately 6 months (range 3 to 12) after surgery. The studies were performed at the 13 participating centers employing generally the same techniques used for each patient's preoperative catheterization. Pressures were measured by fluid manometry. Techniques were standardized by agreement of the principal investigators and by site visits from members of the coordinating center to each participating laboratory. The prosthetic mitral valve gradient was obtained by simultaneous recording of left ventricular and pulmonary capillary wedge or left atrial pressure. The pressure gradient for aortic valves was obtained either by simultaneous transseptal left ventricular and ascending aortic readings, simultaneous retrograde left ventricular and peripheral artery pressure or by superimposed left ventricular and ascending aortic pressures from a pullback recording.
Catheterization across the Björk-Shiley valve was not performed as per the manufacturer's recommendations. Pressure gradients were recorded at a paper speed of 100 mm/s, and tracings were corrected for time delay, where necessary. All tracings were analyzed for pressure gradient and valve orifice area in a central laboratory. Mean valve gradient was derived from planimetric analysis of three consecutive beats. In patients with a prosthetic mitral valve all pulmonary capillary wedge pressure tracings were advanced 0.08 s with respect to the left ventricular pressure tracing to correct for the delay in transmission of the wedge pressure. In patients with a prosthetic aortic valve studied by simultaneous left ventricular and peripheral arterial pressures, time delay was compensated by the method of Folland et al. (2).

Cardiac output was measured before angiography and in close proximity to pressure gradient measurements. Usually the Fick cardiac output was employed, but in a few cases the dye-dilution, thermodilution or angiographic technique was used to calculate orifice area in the absence of regurgitation. Effective valve orifice area was calculated from the mean pressure gradient and cardiac output with the Gorlin formula (3). In patients with prosthetic valve regurgitation, angiographic output was employed as measured by single plane (right anterior oblique) left ventricular angiography using the area-length technique of Dodge and Sandler (4,5). Regurgitant volume was calculated as the difference between the angiographic output and the forward output measured by the Fick or the dilution technique. Regurgitation was graded as absent, mild, moderate or severe by the participating investigators using aortic root and left ventricular angiography, respectively, for aortic and mitral prosthetic valves.

Statistical methods. The study group consisted of patients in the randomized trial who had a 6 month postoperative cardiac catheterization. Any patient who was reoperated on within 6 months of the original operation or within 6 months of the postoperative catheterization was excluded from the study.

The continuous postoperative hemodynamic variables considered in this study were compared between valve types (Björk-Shiley versus Hancock) and among valve sizes using a two factor analysis of variance with interaction. Bartlett's test was used to compare cell variances. When cell variances were unequal, a logarithmic transformation of the variable used in the analysis, and the significance levels were determined from the analysis of the logarithm of the variable.

Severity of postoperative regurgitation was analyzed using a chi-square test. Preoperative hemodynamic variables were compared by type and size. None of the preoperative variables had significantly different mean values by type, but three variables had significantly different mean values by size. These were the mean gradient, the regurgitant volume and the end-diastolic volume index. These three variables were analyzed postoperatively using an analysis of covariance with the corresponding preoperative variables as a covariate to test the equality of the mean values by size.

Preoperative variables were compared between those patients with a 6 month postoperative cardiac catheterization and those without a 6 months postoperative cardiac catheterization who lived at least 6 months after surgery. Student's t test was used to compare the continuous variables, and a chi-square test was used to compare the discrete variables.

Results

Clinical characteristics. Of the 575 randomized patients, 47% (268) underwent cardiac catheterization between 3 and 12 months postoperatively. Of these patients, 177 received an aortic prosthesis and 91 received a mitral prosthesis. The reason for not undergoing postoperative cardiac catheterization was primarily patient refusal. A technically satisfactory mean prosthetic valve pressure gradient was obtained in 195 patients. Because of the small number of patients receiving 21 and 29 mm aortic valves and 27 and 35 mm mitral valves, these subgroups were omitted from statistical analysis. There were no significant differences in any of the following 21 preoperative descriptors between the patients receiving Björk-Shiley prosthesis and those receiving a Hancock heterograft: age, functional class, congestive heart failure score, angina, exertional syncope, previous heart surgery, myocardial infarction, hypertension by history, systolic and diastolic blood pressure, cardiothoracic ratio, heart rhythm (sinus or not sinus), left ventricular hypertrophy by Estes score, mean aortic/mitral valve gradient, left ventricular end-diastolic pressure, cardiac index, aortic/mitral valve area, number of stenotic coronary arteries, cardiac catheterization diagnosis, assessment of aortic/mitral regurgitation, ejection fraction, and regurgitant volume. There were also no significant differences in any of these preoperative variables between patients who underwent postoperative cardiac catheterization and those who did not.

Comparison of Valve Types in the Aortic Position

Mean pressure gradient (Table 1). The mean pressure gradients measured in 114 patients are grouped according to valve size and type in Figure 2. Data for two patients receiving a size 31 and 35 aortic prosthesis were excluded from this figure and from Figure 3. Within each valve size and type, wide variations in mean pressure gradients were observed, resulting in large standard deviations. The mean pressure gradient was consistently lower in the Björk-Shiley prosthesis than in the Hancock heterograft (p = 0.002). However, the difference in mean pressure gradient between the two valve types was most significant for size 27 and was not significant for size 23.
Calculated orifice area (Table 1). The prosthetic valve orifice area was calculated using the Gorlin formula in 104 patients. Again, a wide variation in the calculated area was observed in both valve types and in all valve sizes (Fig. 3). The mean calculated orifice area for all valve sizes was somewhat larger in the Björk-Shiley prosthesis than in the Hancock heterograft ($p = 0.025$). However, for each valve size, the area of the Björk-Shiley prosthesis was consistently, but not significantly, larger than the area of the Hancock heterograft.

Regurgitation (Table 2). Seven (6%) of 122 patients with aortic valve replacement were graded qualitatively by aortic

<table>
<thead>
<tr>
<th>Table 1. Six Month Postoperative Hemodynamic Evaluation of 177 Aortic Valve Prostheses Compared According to Valve Type (Björk-Shiley versus Hancock)</th>
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<tbody>
<tr>
<td><strong>No. of Valves</strong></td>
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<tr>
<td><strong>Mean gradient</strong></td>
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<tr>
<td>(mm Hg)</td>
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<tr>
<td>Cardiac index</td>
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<tr>
<td>(liters/min)</td>
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<tr>
<td>(liters/min/m²)</td>
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<tr>
<td>Blood volume</td>
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<tr>
<td>(liters/min)</td>
</tr>
<tr>
<td>PA systolic*</td>
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<tr>
<td>(mm Hg)</td>
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<tr>
<td>PA mean*</td>
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<tr>
<td>(mm Hg)</td>
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<tr>
<td>LVEDP*</td>
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<td>(mm Hg)</td>
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<tr>
<td>LVEF (%)</td>
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<tr>
<td>LVEDVI (cm²/m²)</td>
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</table>

*Analysis of variance performed on the basis of the transformed variable. Number in parentheses = number of valves. BS = Björk-Shiley valve; H = Hancock valve; LVEDP = left ventricular end-diastolic pressure; LVEF = left ventricular ejection fraction; LVEDVI = left ventricular end-diastolic volume index; PA = pulmonary artery pressure.

Figure 2. Six month postoperative transprosthetic mean pressure gradients (ordinate) in patients in the Randomized Therapeutic Trial who received an aortic valve prosthesis. BS = Björk-Shiley prosthesis; H = Hancock porcine heterograft (asterisk). Mean values ± 1 SD are shown for sizes 23, 25 and 27.

Figure 3. Prosthetic valve areas calculated by the Gorlin formula (ordinate) from 6 month postoperative cardiocatheterization data obtained from patients in the Randomized Therapeutic Trial who received an aortic valve prosthesis. Mean values ± 1 SD are shown for sizes 23, 25 and 27. Abbreviations and symbols as in Figure 2.
mot angiography as having moderate or severe regurgitation. There was no difference in the distribution between valve types when patients with moderate or severe regurgitation were compared with patients with no or mild regurgitation (p = 0.715). However, a significant difference between valve types was seen when all four grades of regurgitation were compared, largely because of the fact that mild aortic regurgitation was more commonly reported in patients receiving the Björk-Shiley prosthesis (35; 157% of 61) than patients receiving the Hancock heterograft (13; 122% of 61).

When preoperatively regurgitation was compared between the valve types, no significant difference was seen.

Other hemodynamics (Table 1). The 6 month postoperative cardiac index, regurgitant volume, pulmonary artery systolic and mean pressure, left ventricular end-diastolic pressure, left ventricular ejection fraction and left ventricular end-diastolic volume index were compared by valve type and size. There were no significant differences at the 0.1 level between the two valve types in any of these measurements.

Comparison of Valve Types in the Mitral Position

Valve pressure gradient and area and hemodynamics (Table 3). A wide variation was observed in the mean diastolic pressure gradient and the calculated orifice area in both types of valves and for all sizes (Fig. 4 and 5). There were no differences in mean pressure gradient, cardiac index, calculated orifice area, regurgitant volume, left ventricular ejection fraction and left ventricular end-diastolic volume index between the Björk-Shiley prosthesis and the Hancock heterograft. Postoperative pulmonary artery systolic and mean pressure and left ventricular end-diastolic pressure were slightly lower in patients receiving the Hancock heterograft.

Regurgitation (Table 4). Nine (12%) of 73 patients with mitral valve replacement were observed to have moderate mitral regurgitation during postoperative left ventricular angiography. Only one was graded as severe. There was no difference between valve types when patients with moderate or severe regurgitation were compared with those with no or mild regurgitation (p = 0.133). As also observed in those who received an aortic valve, a significant difference between valve types emerged when all four grades of regurgitation were compared. Once again, this was a result of a larger proportion of patients with a Hancock valve displaying no degree of regurgitation (82%) compared with patients with a Björk-Shiley valve (43%).

Comparison of Valve Sizes in the Aortic and Mitral Positions

Three variables were statistically significant when comparing hemodynamics between combined Björk-Shiley and Hancock aortic valve prostheses of different sizes. The mean pressure gradients decreased as valve size increased: 19.0 ± 8.4, 16.1 ± 8.4 and 13.2 ± 8.3 mm Hg for sizes 23, 25 and 27, respectively (p = 0.022). Calculated orifice area increased as valve size increased: 1.3 ± 0.4, 1.6 ± 0.4 and 1.9 ± 0.6 cm² for sizes 23, 25 and 27, respectively (p < 0.001). Mean pulmonary artery pressure decreased with the larger valve sizes: 19.0 ± 7.8, 16.7 ± 5.9 and 15.0 ± 4.5 mm Hg for sizes 23, 25 and 27, respectively (p = 0.031). None of the other hemodynamic variables was significantly different between the different aortic valve sizes.

In the mitral position, only one variable was significant between the different valve sizes in combined types. Calculated area was 1.7 ± 0.6, 2.1 ± 0.6 and 1.7 ± 0.5 for the sizes 29, 31 and 33, respectively (p = 0.025).

Errors of randomization and analysis as per valve assigned. The preceding analyses were all performed on the basis of
the valve type received, and not on the basis of the valve type assigned by the randomization process. In this study, there were five randomization errors (0.9%) in which the patients received a valve other than the type assigned. When errors of randomization occur, it is customary in randomized trials to analyze the data according to the treatment assigned and not the treatment received. Hence, in this study, the statistical analyses for valve area and gradients were repeated according to the valve assigned, not the valve received. Both sets of analyses were similar, and the only notable difference between them was that the calculated valve orifice area in patients undergoing aortic valve replacement differed at the 0.025 level in the analysis per valve received, whereas it differed at the 0.072 level in the analysis per valve assigned.

Figure 4. Six month postoperative transprosthetic mean pressure gradients (ordinate) in patients in the Randomized Therapeutic Trial who received a mitral valve prosthesis. Mean values ± 1 SD are shown for sizes 29, 31, and 35. Abbreviations and symbols as in Figure 2.

Figure 5. Prosthetic valve areas calculated by the Gorlin formula (ordinate) from 6 month postoperative cardiac catheterization data obtained from patients in the Randomized Therapeutic Trial who received a mitral valve prosthesis. Mean values ± 1 SD are shown for sizes 29, 31, 33 and 35. Abbreviations and symbols as in Figure 2.
Discussion

Björk-Shiley tilting disc prosthesis versus Hancock porcine heterograft. This study is the first randomized comparison trial of the postoperative hemodynamic function of the standard Björk-Shiley tilting disc prosthesis and the Hancock porcine heterograft (modified orifice for sizes 23 and smaller) in patients undergoing single valve replacement. Bloomfield et al. (6) reported on a prospective randomized evaluation of these two types of valves, but their evaluation did not include prospective hemodynamic studies. These two specific valves were chosen for the study for three reasons: they were widely used, they had undergone no appreciable design changes since their introduction and they were representative of two large classes of valves now in use (a totally prosthetic valve and a tissue valve). The data in this study showed that 1) the overall hemodynamic performance of the two valve types was similar in both the aortic and the mitral positions, 2) a very wide variation in postoperative pressure gradients and calculated orifice areas existed within each valve size in both valve types, and 3) other measures of cardiac performance were not different between the two valve types. Although overall, in the aortic position, the Björk-Shiley prosthesis had a smaller pressure gradient and a larger calculated orifice area than in the Hancock heterograft, the difference in gradient between the two valve types was only significant in the larger-sized prostheses. Within each valve size in the aortic position, the difference in calculated orifice area between the two valve types did not attain statistical significance.

We were unable to make any comparison between the modified and the standard orifice porcine heterograft valve because only the modified orifice Hancock valve was used for sizes 21 and 23 in the aortic position and the standard Hancock valve was used in larger sizes.

Surgical implications. Although this study showed that the larger-sized prostheses in the aortic root were slightly more advantageous hemodynamically than smaller prostheses, the data varied over wide ranges and the differences in mean pressure gradient and calculated orifice area between sizes 23 and 25 were small. Within each valve type, these differences did not attain statistical significance. Hence, on the basis of the small and inconsistent hemodynamic advantage of a 25 mm prosthesis over a 23 mm prosthesis, attempting to force a 25 mm prosthesis into a narrow root, if it is technically safer to insert a 23 mm prosthesis, seems to be unwarranted, particularly if the prosthesis used is a Björk-Shiley prosthesis. These data also lead us to question the wisdom of surgically widening the aortic root in an attempt to avoid inserting a 23 mm prosthesis.

Comparison with other hemodynamic studies of aortic valve prostheses. Although no randomized postoperative hemodynamic studies involving the Björk-Shiley prosthesis and the Hancock heterograft have been published, there are several studies (7–25) that report these hemodynamics for each valve separately or in comparison with other types of prostheses. Table 5 summarizes some of the reported data on the postoperative pressure gradient and the calculated orifice area of these two types of valves in the aortic position. In these studies, most of the catheterization procedures were performed several months postoperatively, except in three (9, 16, 18) where the data were obtained intraoperatively after the valve replacement. The intraoperative studies performed on Hancock heterografts tended to report a lower valvular pressure gradient and a larger calculated area than most other studies, including ours. As in our study, wide variations in transcatheter aortic pressure gradient and calculated orifice area were observed in most of the published studies (Table 5). The variation in methodology and results and the relatively small number of observations in some of these published studies markedly limit their ability to provide, collectively, a meaningful comparison.
between the postoperative performance of the Björk-Shiley prosthesis and the Hancock heterograft.

Comparison with other hemodynamic studies of mitral valve prostheses. Table 6 summarizes some of the reported data on the postoperative pressure gradient and calculated valve area in patients undergoing single mitral valve replacement with either the Björk-Shiley prosthesis or the Hancock heterograft. Again, there were no randomized studies comparing these two valves together. Variations in pressure gradient and calculated orifice area were also wide within each size and both valve types in most of these studies. Variations between the studies themselves were also wide, again underscoring the need for a randomized prospective study such as this one.

Preoperative variables: relation to prosthetic valve size. Although preoperative variables did not differ between valve types, they differed between valve sizes in 3 of 21 variables tested in patients undergoing aortic valve replacement. These three variables (mean pressure gradient, regurgitant volume, end-diastolic volume index) were significantly different among aortic valve sizes in a clinically predictable way. Those patients with largest preoperative pressure gradients (for example, patients with aortic stenosis) tended to receive the smaller valves. Those with largest regurgitant volume and end-diastolic volume index (for example, patients with aortic regurgitation) tended to receive the larger valves. This relation was not demonstrated in patients undergoing mitral valve replacement.

Variation in pressure gradient: role of cardiac output. Because our patients were evaluated as part of a study protocol and not for clinical indications, they provide a somewhat surprising statement about the degree of variation in valve hemodynamics compatible with a clinically successful single valve replacement. The wide range of pressure gradient and orifice area among valves of the same type and size in this study may be a result of several factors. Pressure gradient is a direct function of cardiac output. For any one valve type and size, the case-to-case variation in cardiac output was considerable, accounting, at least in part, for the variation in pressure gradient.

Variation in pressure gradient: role of regurgitation. Perivalvular or central valvular regurgitation, which was present in some cases, causes augmented forward flow through the valve in direct proportion to the degree of regurgitation, which in turn increases the forward flow gradient. Although 7 (6%) of 122 patients with an aortic valve prosthesis were designated as having moderate to severe regurgitation by aortic root angiography, none of these patients exhibited a mean pressure gradient >24 mm Hg. Among 10 (14%) of 73 patients with a mitral valve prosthesis
designated as having moderate or severe regurgitation angiographically, only 3 exhibited a gradient >10 mm Hg. Therefore, we cannot explain cases with an unusually large pressure gradient on the basis of regurgitation.

**Calculated prosthetic valve area: flow dependency.**

Effective area of prosthetic valves calculated by the Gorlin formula might be flow-dependent as suggested by the report of Ubago et al. (26) on Hancock porcine prostheses. In fact, we found flow dependency not only in Hancock valves, but also in Björk-Shiley valves. For any given valve size and type, the calculated orifice area varied directly with the forward flow. For example, all size 33 valves in the mitral position exhibited an area of 1.7 ± 0.50 cm². The much smaller size 27 valves exhibited an area of 1.9 ± 0.70 cm² when exposed to the higher flow rates in the aortic position. Furthermore, analysis of data from our study but not included in this report showed that size 29 valves, which were placed in both mitral and aortic positions, exhibited a similar valve area in cases where flow rates were similar.

**Limitations of the Gorlin formula.** The apparent flow dependency of these valves may be artificial as a result of the inherent inaccuracy of the Gorlin formula. Cannon et al. (27) analyzed the orifice area of the Hancock valve in a pulse simulator and found that the area varied by <0.1 cm² throughout the range of normal flow rates. Orifice area decreased only at very low flow rates. On the basis of their in vitro studies, they proposed a correction to the Gorlin formula, which more accurately predicted manufactured orifice area of 19 Hancock valves implanted in a subset of patients from our cooperative study. Further testing of this corrected formula is planned for all patients in this study.

**Clinical implications of the variation in calculated orifice areas.** The cardiac catheterization techniques and analyses employed in this study are the same as those used by virtually all clinical laboratories. The wide variation observed in the calculated orifice area in this and virtually all other published studies is in part due to inadequacies of the Gorlin formula. Hence, decision-making regarding valve

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**Table 6. Resting Postoperative Gradient and Effective Prosthetic Valve Area in Reported Cases of Single Mitral Valve Replacement With the Björk-Shiley Prosthesis or the Hancock Heterograft**

<table>
<thead>
<tr>
<th>Author/Year (reference)</th>
<th>Time of Postop (Cal)</th>
<th>Valve Size (n)</th>
<th>Gradient (mm Hg)</th>
<th>Effective Orifice Area (cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Björk-Shiley prosthesis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haerten et al., 1976 (19)</td>
<td>12 months</td>
<td>All sizes</td>
<td>4.2</td>
<td>2.9</td>
</tr>
<tr>
<td>Holen et al., 1978 (20)</td>
<td>2.5 days</td>
<td>27, 29 (4)</td>
<td>5.5</td>
<td>2.5</td>
</tr>
<tr>
<td>Horstkoite et al., 1981 (21)</td>
<td>12 months</td>
<td>29</td>
<td>5.3</td>
<td>1.85</td>
</tr>
<tr>
<td>Horstkoite et al., 1983 (22)</td>
<td>12 months</td>
<td>29 (19)</td>
<td>5.2</td>
<td>2.2</td>
</tr>
<tr>
<td>Hancock heterograft</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rois et al., 1971 (23)</td>
<td>3 to 6 months</td>
<td>25, 29 (9)</td>
<td>5</td>
<td>2.2</td>
</tr>
<tr>
<td>Johnson et al., 1975 (24)</td>
<td>2 weeks, 13 months</td>
<td>27 (1)</td>
<td>5.5</td>
<td>2.5</td>
</tr>
<tr>
<td>Melton et al., 1975 (25)</td>
<td>Not mentioned</td>
<td>All sizes</td>
<td>6.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Hannah et al., 1976 (11)</td>
<td>6 to 12 months</td>
<td>29</td>
<td>2</td>
<td>1.7</td>
</tr>
<tr>
<td>Cevese et al., 1977 (13)</td>
<td>36 months</td>
<td>All sizes</td>
<td>8.0</td>
<td>1.84</td>
</tr>
<tr>
<td>Lurie et al., 1977 (12)</td>
<td>19 weeks to</td>
<td>All sizes</td>
<td>7.9</td>
<td>1.84</td>
</tr>
<tr>
<td>Holen et al., 1978 (20)</td>
<td>2.3 days</td>
<td>27 (3)</td>
<td>12</td>
<td>1.24</td>
</tr>
<tr>
<td>Ubago et al., 1980* (26)</td>
<td>3 to 18 months</td>
<td>33 (9)</td>
<td>8.7</td>
<td>2.5</td>
</tr>
<tr>
<td>Levicat et al., 1981 (16)</td>
<td>(Intra-op)</td>
<td>29 (10)</td>
<td>3.7</td>
<td>2.7</td>
</tr>
</tbody>
</table>

*Data calculated from Table 1; calculated by ultrasound. Abbreviations as in Table 5.
dysfunction should not rest solely on the postoperative calculated valve area and should take into account, among other things, the flow rate at which the valve area was calculated.

Prosthetic valve regurgitation. As noted in Tables 2 and 4, the prevalence of moderate or severe postoperative regurgitation did not differ between valve types. However, a significant difference was seen between valve types if mild regurgitation was considered. In both the aortic and mitral positions, mild regurgitation was significantly more frequent in patients receiving the Björk-Shiley prosthesis than in those receiving the Hancock heterograft. We interpret this difference to be due to the small amount of regurgitation that is deliberately engineered into the Björk-Shiley prosthesis. The clearance between the disc and the seating ring when the valve is closed must be sufficiently large to prevent jarring of the disc or red cell trauma. This amount of clearance is sufficient to cause regurgitation that is angiographically detectable. In addition, a small amount of regurgitant flow early in the closing cycle may be seen in mechanical prostheses as a result of the inertia of the poppet, which is greater than that of biological leaflets. The observation of similar postoperative regurgitant volumes in these two valve types is additional evidence that the quantity of this regurgitation is trivial.

Conclusions. This study demonstrates that the hemodynamic performance of the Björk-Shiley prosthesis and the Hancock porcine heterograft are remarkably similar. Although the Björk-Shiley prosthesis in the aortic position was associated with a smaller pressure gradient, the degree of this advantage was small compared with the overall variation in individual pressure gradients. Furthermore, little or no difference was seen in other measures of cardiac function among patients receiving the two valve types. The choice between these two prostheses should, therefore, be governed more by other factors such as valve durability, risk of anticoagulation, and incidence of valve-related complications. Subsequent reports from this cooperative study will address these issues.

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Appendix

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