Reassessment of Usefulness of Porcine Heterografts in Mitral Position in Children

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SUMMARY. The use of porcine heterograft valves in children is restricted because of valve calcification and dysfunction at follow-up. Because of inability to monitor the anticoagulant status or of desire of some teenage girls to get married and get pregnant, several pediatric patients received porcine heterografts. The purpose of this paper is to examine the issue of heterografts in children, based on our experience with children and adolescents, aged 1 to 20 years, who underwent left heart valve replacement during a 7-year period ending April 1985. Ninety-four percent of the lesions were rheumatic in origin, 4% congenital, and 2% infectious. Of 168 mitral valves replaced, 54 (32%) were porcine heterografts and 114 (68%) were mechanical valves. These were divided into four groups, based on type of valve implanted and age at implantation: mechanical (M), age >15 years (M > 15), 49 cases; heterografts (H) age >15 years (H > 15), 34 cases; mechanical, age ≤15 years (M ≤ 15), 65 cases; and heterografts, age ≤15 years (H ≤ 15), 20 cases. None of the patients with heterografts received anticoagulation. Five-year actuarial valve survival was 86% for M > 15, 96% for H > 15, 82% for M ≤ 15, and 60% for H ≤ 15. The respective 9-year valve survival was 86%, 72%, 75%, and 18%. The valve survival data indicate that heterograft valves in patients older than 15 years are comparable (p = 0.97) to mechanical valves, while heterografts in children less 15 years do poorly (p = 0.015). Based on 8- to 10-year follow-up data, heterografts should not be inserted into children ≤15 years of age. Heterografts may be used in children over 15 years of age with the expectation of valve survival comparable to that of mechanical valves and with little or no threat of thromboembolic complications.

KEY WORDS: Porcine heterografts — Mechanical valves — Prosthetic valves — Children

When porcine heterografts became available [3, 5, 32], they were rapidly adopted in children [12, 18, 24, 28] because of multiple problems with mechanical valves, particularly thromboembolic/bleeding complications. Soon it became clear that the heterografts rapidly calcified with functional deterioration [4, 6–9, 11, 13, 17, 21, 23, 25–27, 29]. Therefore, the use of heterografts in children was restricted. Because of inability to closely monitor the anticoagulant status and the desire of some of the teenage girls to get married and to get pregnant, several pediatric-aged patients received porcine heterografts. The purpose of this paper is to present our experience with heterografts in children and adolescents ≤ 20 years of age, compare their performance with that of mechanical valves, and to reassess their usefulness in teenagers > 15 years of age.

Subjects and Methods

During a 7-year period ending April 1985, 186 children, aged 1–20 years, underwent left-sided valve replacement at the King Faisal Specialist Hospital and Research Center. This series includes the 130 children, aged 1–19 years, who we previously reported [22] with regard to anticoagulant therapy. Ninety-four percent of the valvular lesions were rheumatic in origin, 4%
Table 1. Major events in the various groups

<table>
<thead>
<tr>
<th></th>
<th>M &gt; 15</th>
<th>H &gt; 15</th>
<th>M ≤ 15</th>
<th>H ≤ 15</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total no. of valves</td>
<td>49</td>
<td>34</td>
<td>65</td>
<td>20</td>
<td>168</td>
</tr>
<tr>
<td>Operative deaths*</td>
<td>4</td>
<td>1</td>
<td>8</td>
<td>0</td>
<td>13</td>
</tr>
<tr>
<td>Late mortality</td>
<td>9</td>
<td>0</td>
<td>10</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>Repeat valve replacement</td>
<td>4</td>
<td>5</td>
<td>10</td>
<td>11</td>
<td>30</td>
</tr>
<tr>
<td>Embolic complications</td>
<td>6</td>
<td>0</td>
<td>9</td>
<td>1</td>
<td>16</td>
</tr>
<tr>
<td>Endocarditis</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Hemolysis</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

M > 15, mechanical valve replacement in patients older than 15 years; H > 15, porcine heterograft valve replacement in patients older than 15 years; M ≤ 15, mechanical valve replacement in patients who are 15 years of age and younger; M ≤ 15, porcine heterograft valve replacement in patients who are 15 years of age and younger.

* Operative death is defined as death occurring within 30 days of surgery.

congenital, and 2% infectious. The operative mortality was 2%, 4%, and 19% when aortic, mitral, or both valves were replaced, respectively. Five-year actuarial survival was 94% for aortic, 88% mitral, and 75% for double valve replacement. Five-year major event-free (complication-free) actuarial survival was 93% for aortic, 80% for mitral, and 52% for double valves.

Fifty-five patients had only aortic valve replacement; all but one were mechanical valves and were excluded from further analysis. Ninety-five patients had mitral valve replacement alone, and 36 had both mitral and aortic valves replaced. Thirty-seven additional mitral valves were replaced either in patients with previous aortic valve replacement or in patients requiring repeat mitral valve replacement. Thus, there were a total of 168 mitral valves replaced in 139 patients: 54 (32%) were heterografts and 114 (68%) were mechanical valves. Of the 54 heterografts, 47 (87%) were Hancock prostheses and 7 (13%) Ionescu-Shiley valves. Of the 114 mechanical valves, 45 (39.5%) were Beall valves, 45 (39.5%) St. Jude Medical, 21 (18%) Björk-Shiley, and 3 (3%) Starr-Edwards valves. These were divided into four groups: age at implantation >15 years, mechanical (M > 15), 49 cases; heterografts (H > 15), 34 cases; age at implantation ≤15 years, mechanical (M ≤ 15), 65 cases; heterografts (H ≤ 15), 20 cases. Thirteen patients did not survive the operation. The remaining patients were followed for 2 months to 10 years (mean, 4.8 years) for a total of 614 patient-years (seven patients were lost to follow-up 2 months to 4.3 years after surgery). They were followed in the pediatric cardiology clinic at 6- to 12-week intervals initially, and at 6- to 12-month intervals subsequently, and monitored for valve-related complications.

No anticoagulants were prescribed for patients with porcine heterografts. Some form of anticoagulant therapy was prescribed for all patients with mechanical prosthetic valves. The subgrouping based on anticoagulant therapy, and thromboembolic bleeding complications and recommendations based on these results, were presented elsewhere [22] and will only be mentioned briefly here.

The actuarial method of Grunkemeier and Starr [14], was used for expressing the patient survival and complication-free survival rates as well as for valve survival rates. Survival curves were statistically compared by logrank test. Thromboembolic and bleeding complications were expressed as linearized rates—that is, number of events per 100 patient-years, expressed as percentage [20]. Statistical significance was set at p < 0.05.

Results

Early Mortality

There were 13 operative deaths during the 168 mitral valve replacements, giving a total operative mortality of 7.7%; the mortality figures include initial valve replacement as well as reoperations. Eleven of these deaths occurred during initial valve replacement, and two following valve replacement for the second time. Five of the 11 deaths in the initial valve-replacement group occurred in patients undergoing isolated mitral replacement, while the remaining six occurred in patients undergoing double valve (aortic plus mitral) replacement. The cause of death in these patients is severe myocardial dysfunction, present preoperatively, and is not related to the type of valve (mechanical versus heterografts) replaced.

Late Mortality

There were 20 late deaths; nine were related to progressive myocardial failure, four occurred after severe cerebrovascular accident, two at reoperation for replacement of the first prosthetic valve with a second prosthetic valve, two secondary to bacterial endocarditis, and three were noncardiac deaths. The distribution of these deaths in relation to groups is listed in Tables 1 and 2.

Reoperation

Repeat surgery to replace the prosthetic valve was required in 30 patients (Table 1). The reasons for re-