A Retrospective Comparison of Bovine Pericardium and PTFE Patch for Closure of Ventricular Septal Defects

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This retrospective study compared the immediate post-operative (first month) and mid-term (up to 5 years post-operation) results of 22 patients with isolated ventricular septal defects who underwent surgical correction with bovine pericardium with 57 similar patients who received a polytetrafluoroethylene patch. There were no cases of early (in the first month) mortality in either group and the 3-month post-operative echocardiographical studies showed no evidence of calcification or aneurysm formation around the patch. Recurrent ventricular septal defects due to dehiscence of the patch occurred in the early follow-up period in four patients who had the polytetrafluoroethylene patch but this was not statistically significant. Annual echocardiographical examination revealed some calcification in both groups. We conclude that although there are no significant differences between the two materials in outcome after ventricular septal defects closure, we prefer bovine pericardium because of its handling characteristics, elasticity and the lower risk of endocarditis.

KEY WORDS: BOVINE PERICARDIUM; POLYTETRAFLUOROETHYLENE PATCH; VENTRICULAR SEPTAL DEFECT; SURGICAL REPAIR

Introduction

Bovine pericardium is an excellent material for reconstructive heart surgery, especially in patients with small aortic annulus, aortic root abscess and post-infarction ventricular septal defect (VSD).1 Experience with bovine pericardium as a patch material for congenital VSD is, however, limited. In this report we present a retrospective analysis of our experience with bovine pericardium for the closure of VSD. A comparison of the immediate (the first post-operative month) and mid-term (up to 5 years after the operation) results of VSD closure with bovine pericardium and a polytetrafluoroethylene (PTFE) patch is also made.

Patients and methods

The hospital records (initial results and echocardiographical data) of patients who underwent surgical correction for VSD with a patch between 1990 and 2003 at our institution were evaluated retrospectively. Both pre- and post-operative functional
status was classified according to the New York Heart Association (NYHA) classification. The outcomes noted were early (within the first post-operative month) mortality and morbidity, developing aneurysm and calcifications of the patch and recurrent VSD due to dehiscence of the patch.

From 1990 to 2000, VSD closure in patients was carried out with a PTFE patch. These patients were included in group A of the present study. From 2000 to 2003, bovine pericardium was used and the patients treated during this period were included in group B.

All patients underwent pre-operative cardiac catheterization and transthoracic echocardiographical study. The pulmonary-to-systemic blood flow ratio (Qp/Qs) and pulmonary vascular resistance were recorded.

**OPERATIVE TECHNIQUE**

All operations were carried out using modern hypothermic (28 °C) cardiopulmonary bypass. Myocardial protection was achieved using antegrade multidose crystalloid cardioplegia, topical cooling and terminal antegrade warm blood reperfusion. Patients underwent right ventriculotomy or right atriotomy. All patches were implanted with interrupted pledgeted mattress sutures. Bovine pericardium (Tutopatch, Tutogen Medical GmbH, Neunkirchen, Germany) patches were rehydrated in normal saline solution for a few minutes prior to use.

**POST-OPERATIVE PROTOCOL**

Patients with an uneventful recovery were discharged after 7 days. Echocardiography was carried out 3 months after the procedure and then once a year.

**STATISTICAL ANALYSIS**

Values are expressed as mean ± SD unless otherwise stated. Fisher’s exact test, χ² test and Student’s t-test were used for between-group comparisons of the pre-operative clinical characteristics of patients. Immediate and mid-term results were compared with Fisher’s exact test and χ² test. Statistical differences were considered significant if P ≤ 0.05.

**Results**

A total of 79 patients (69 male and 10 female) were included in the study and the majority were in NYHA functional class II or III. PTFE was used in 57 (72.2%) and bovine pericardium in 22 (27.8%) patients. Patient details and pre-operative clinical characteristics are shown in Table 1. Ten patients underwent right ventriculotomy (eight in group A, two in group B) and 69 right atriotomy (49 in group A, 20 in group B). Qp/Qs was greater than 1.5 s and pulmonary vascular resistance was lower than 8 units/m² in all patients. There were no statistically significant differences between the two groups for all variables shown.

Mean cross-clamp time was 31 ± 5 min in group A and 28 ± 4 min in group B. Mean cardiopulmonary bypass time was 43 ± 6 min in group A and 39 ± 4 min in group B.

There was no early mortality in either group. In the early post-operative period, conduction system disorder developed in six (10.5%) group A patients and two (9.1%) group B patients. This difference was not statistically significant. A permanent pacemaker was only implanted in three group A patients. The others did not need therapy.

The mean follow-up period was 5.2 years (range 2 – 13 years) in group A and 1.5 years (range 3 months to 3 years) in group B. Fifteen patients (26.3%) in group A and 5 (22.7%) patients in group B were lost to follow-up (stopped attending follow-up appointments).

The echocardiographical study done 3 months after surgery showed no
TABLE 1: Pre-operative clinical characteristics of the patients with an isolated ventricular septal defect (VSD) that was surgically corrected with bovine pericardium or a polytetrafluoroethylene (PTFE) patch

<table>
<thead>
<tr>
<th></th>
<th>Group A (PTFE patch; n = 57)</th>
<th>Group B&lt;sup&gt;a&lt;/sup&gt; (bovine pericardium patch; n = 22)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male/female</td>
<td>50/7</td>
<td>19/3</td>
</tr>
<tr>
<td>Age in years (mean ± SD)</td>
<td>21.5 ± 2.2</td>
<td>22 ± 1.8</td>
</tr>
<tr>
<td>New York Heart Association class (mean ± SD)</td>
<td>3.0 ± 0.5</td>
<td>2.9 ± 0.5</td>
</tr>
<tr>
<td>Perimembraneous VSD</td>
<td>45 (78.9%)</td>
<td>17 (77.2%)</td>
</tr>
<tr>
<td>Muscular VSD</td>
<td>8 (14%)</td>
<td>4 (18.1%)</td>
</tr>
<tr>
<td>Inlet VSD</td>
<td>3 (5.2%)</td>
<td>1 (4.5%)</td>
</tr>
<tr>
<td>Outlet VSD</td>
<td>1 (1.7%)</td>
<td>–</td>
</tr>
<tr>
<td>Defect size in mm (mean ± SD)</td>
<td>21 ± 0.2</td>
<td>22 ± 2.3</td>
</tr>
<tr>
<td>Pulmonary-to-systemic flow ratio (Qp/Qs)</td>
<td>1.7 ± 0.7</td>
<td>1.9 ± 0.8</td>
</tr>
<tr>
<td>Pulmonary vascular resistance (units/m²)</td>
<td>6 ± 0.5</td>
<td>5.8 ± 1.1</td>
</tr>
</tbody>
</table>

<sup>a</sup>There were no significant differences between the groups.

Calcification and aneurysm formation of the patch in either group. Recurrent VSD due to dehiscence of the patch developed in two (3.5%) patients in group A but was not detected in group B. The patients were asymptomatic and their Qp/Qs ratios were less than 1.5. Surgical correction was not necessary. After another 2 months, two more group A patients were admitted for exercise dyspnoea. Echocardiography revealed recurrent VSD and Qp/Qs ratios were greater than 2. Re-opened VSDs were corrected by additional buttressed stitches through the patch using cardiopulmonary bypass.

The annual echocardiographical examination during the mid-term follow-up period did not reveal any further dehiscence and aneurysm formation of the patches in either group, but there was patch calcification of different degrees in almost all patients. The Qp/Qs ratios of two patients who had not needed re-operation were still less than 1.5.

The NYHA class of patients improved to I or II after the operation in both groups except patients who underwent re-operation due to recurrent VSD. Their NYHA class improved after re-operation. All patients who continued to attend for follow-up study are alive.

Discussion

Our institution is one of two military hospitals in Turkey where open-heart surgery is carried out. The age range of the patients in the present study is comparatively advanced. This is because our patient population is usually between 20 and 25 years of age and these defects are usually treated in childhood. Unfortunately, their condition was not diagnosed before admission to our institution.

It is well known that small defects may be repaired by primary sutures but in most cases a patch is required. The material used...
for the patch varies widely since there is no ideal material. Native pericardium can calcify and become aneurysmal and prosthetic materials carry a risk of endocarditis. Fresh autologous pericardial patches may be more susceptible to aneurysm formation. Glutaraldehyde fixation of autologous pericardial patches may make this complication less likely. Schoof and co-workers documented that aneurysm formation can occur due to not only the use of fresh autologous pericardial patches but also intra-operative patch oversizing. In our study, we did not use native pericardium and no aneurysm formation was detected. We believe that bovine pericardium is more resistant to aneurysm formation than native pericardium.

The incidence of endocarditis subsequent to successful VSD closure is too uncommon to generate incidence data. It should not be forgotten, however, that this complication may be fatal and bioprosthetic materials, such as bovine pericardium, carry a lower risk of endocarditis.

Recurrent VSD due to dehiscence is another unfortunate complication and is often associated with the size of the patch. Its incidence is perhaps below 5% but no definitive data are available at present. We found dehiscence of the patch in four patients (7.0%) in group A, although the patch size was small relative to the patient’s total body surface area. No case of dehiscence was detected in group B but no significant differences were found between the two groups.

In our experience the handling characteristics of bovine pericardium are better than other materials. We also find that the elastic bovine pericardium is more in harmony with septal movements than synthetic prosthetic materials, such as PTFE and Dacron. For these reasons, since 2000 we have preferred to use this kind of patch and we advocate that bovine pericardium is an optimal material for VSD closure.

References

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