Bicuspid pulmonary valve implantation using polytetrafluoroethylene membrane: early results and assessment of the valve function by magnetic resonance imaging

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Abstract

OBJECTIVES: The durability of bioprosthetic valves in the pulmonary position is suboptimal. The objectives of this study were to evaluate the early results of polytetrafluoroethylene (PTFE) bicuspid pulmonary valve (PV) implantation and to better define the function of this valve by magnetic resonance imaging (MRI).

METHODS: Fifty-six patients who underwent PTFE bicuspid PV implantation between June 2009 and August 2011 were retrospectively analysed. The median age was 17.5 years and median valve size was 26 mm. Fundamental diagnoses were tetralogy of Fallot (n = 38), pulmonary atresia with ventricular septal defect (n = 8), double outlet right ventricle (n = 7) and absent PV syndrome (n = 3). Thirty-two patients with pulmonary regurgitation (PR) underwent MRI preoperatively and 22 of them underwent follow-up MRI at a median of 6.7 months postoperatively.

RESULTS: There was one early death. Postoperative echocardiography (n = 53) showed no or trivial PR in 49 patients and mild PR in 4. Median follow-up duration was 15.2 months. There was no late death or reoperation. Follow-up echocardiography (n = 41) performed at a median of 7.5 months postoperatively showed no or trivial PR in 33 patients and mild PR in 8 patients. Follow-up MRI showed a significant reduction in right ventricular volumes and improvement in biventricular function. The median PR fraction of this valve was 10%.

CONCLUSIONS: Early results of bicuspid PV implantation using PTFE membrane were satisfactory. PTFE bicuspid PV demonstrated excellent performance for the short term as evidenced by echocardiography and MRI. Long-term follow-up is mandatory to determine the durability of this valve.

Keywords: Magnetic resonance imaging • Pulmonary valve • Tetralogy of Fallot

INTRODUCTION

Pulmonary valve replacements (PVR) are frequently performed during the repair of various congenital heart diseases. Chronic pulmonary regurgitation (PR) after the relief of a right ventricular (RV) outflow tract obstruction is a typical situation that necessitates PVR. There are several valve options for PVR, including bioprostheses, homografts, mechanical valves and hand-sewn polytetrafluoroethylene (PTFE) valves [1–7]. Among these, bioprosthetic valves are currently the most widely used, because they are readily available and do not need permanent anticoagulation therapy. However, most of these bioprostheses will eventually fail and require replacement owing to structural valve deterioration, more specifically, leaflet calcification. This structural valve deterioration in the form of leaflet calcification is accelerated in children and young adults, resulting in early prosthetic valve failure and multiple reoperations [1, 2]. In an effort to overcome this limited durability of bioprosthetic valves, Quintessenza et al. introduced a new technique of implanting the bicuspid PV using PTFE material [6, 7]. Their rationale for the development of this technique was based on favourable clinical results of the PTFE monocusp valve [8]. Although promising mid-term results of this technique have been reported [9], the function of this valve has not been clearly defined. The objectives of this study were to evaluate the early results of PTFE bicuspid PV implantation and to better define the function of this valve by magnetic resonance imaging (MRI).

PATIENTS AND METHODS

The Institutional Review Board at our institution has approved this study and waived the need for individual patient consent (IRB number 2011-316).
Patients

By searching the database of our institution, we identified 56 patients who had undergone PTFE bicuspid PV implantation between June 2009 and August 2011. During this period, the choice of conventional bioprosthetic valves or PTFE bicuspid valves for PVR was at the discretion of the surgeon. The medical records of these patients were reviewed. The median age at the time of PVR was 17.5 years (2.3-43.1 years), and 30 patients (54%) were males. Fundamental diagnoses were tetralogy of Fallot (n = 38), pulmonary atresia with ventricular septal defect (n = 8), double outlet right ventricle (n = 7) and absent PV syndrome (n = 3). Haemodynamic indications for PVR were PR (n = 34), pulmonary stenosis (n = 10), combined pulmonary stenosis and regurgitation (n = 8) and as a part of corrective surgery (n = 4). Indications for PVR in patients with PR were symptoms and signs attributable to RV volume overload, presence of significant associated lesions such as branch pulmonary artery stenosis and tricuspid regurgitation, and sustained tachyarrhythmias. For the asymptomatic patients with PR, we prescribed PVR when RV end-diastolic volume index assessed by MRI approached 170 ml/m². The median peak pressure gradient across the RV outflow tract assessed by echocardiography or catheterization in patients with pulmonary stenosis (n = 18) was 67 mmHg (30-85 mmHg). The median number of prior operations was two (0-5) and the median interval between initial RV outflow tract reconstruction and PVR (n = 52) was 15.3 years (1.8-27.5 years). Ten patients underwent PTFE bicuspid PV implantation for bioprosthetic PV failure and two for right ventricle-to-pulmonary artery conduit failure. New York Heart Association (NYHA) functional class was I in 25 patients, II in 26 and III in 5. The median QRS duration in patients with PR was 142 ms (80-196 ms).

Surgical technique

Surgery was performed through median sternotomy on cardio-pulmonary bypass with mild hypothermia. Aortic cross-clamping was dependent on the surgeon’s preference or on concomitant procedures. Recently, we have preferred cardioplegic arrest as it provides a more optimal surgical field for valve implantation. Bicuspid PV implantation was performed using a 0.1 mm-thickness PTFE membrane (Gore Preclude Pericardial Membrane, W.L. Gore & Associates, Flagstaff, AZ, USA) as previously described [7] (Fig. 1). When suturing the valves, utmost care was taken not to cut through the thin PTFE membrane and to avoid tension on the suture line. The main pulmonary artery and RV outflow tract incisions were closed using a bovine pericardial patch or primarily. Concurrent procedures were performed in 33 patients (59%) and are summarized in Table 1. Postoperatively, daily aspirin (100 mg/day) was prescribed to all patients.

Assessment of the polytetrafluoroethylene pulmonary valve function by magnetic resonance imaging

To better define the function of these valves, preoperative and follow-up MRI data were analysed. Thirty-two patients with PR underwent MRI as a part of a routine preoperative evaluation and 22 of them underwent follow-up MRI at a median of 6.7 months (3.1-15.2 months) postoperatively. Two patients underwent only postoperative MRI without preoperative MRI. Therefore, postoperative MRI data were available in 24 patients. MRI studies were performed with a 1.5-Tesla Gyroscan Intera CV system (Philips Medical Systems, Best, Netherlands). A multi-phase acquisition was obtained using a steady-state free precession pulse...
sequence in two-chamber and four-chamber planes. From these images, 10–12 contiguous short-axis slabs perpendicular to the long axis of the left ventricle were obtained (slice thickness 6–8 mm, interslice gap 0–2 mm). Biventricular volumetric analysis was performed using Extended MR Workspace software (Philips Medical Systems, Best, Netherlands). For the evaluation of PR, through-plane velocity imaging perpendicular to the main pulmonary artery was performed using a breath-holding, electrocardiogram-triggered, cine phase contrast pulse sequence. Forward and regurgitant pulmonary volume flows were measured from the velocity-encoded images by manually tracing the main pulmonary artery contour. Flow volumes were calculated by multiplying the contour area by the average flow velocity within the contour. Flow volumes were summed to give total forward flow and total regurgitant flow per cardiac cycle. Stroke volume was calculated by deducting the end-systolic volume from the end-diastolic volume, and the ejection fraction was calculated as percent stroke volume over end-diastolic volume. PR fraction was calculated as percent backward flow over forward flow.

**Follow-up, data collection and statistical analysis**

Patient follow-up data were obtained through a review of medical records and direct telephone contact. Four patients from foreign countries could not be followed-up and were excluded from the follow-up analysis. Follow-up completeness was 93% and the median follow-up duration was 15.2 months (3.4–29.7 months). Data collection and statistical analyses adhered to the guidelines for reporting mortality and morbidity after cardiac valve interventions [10]. Categorical variables were expressed as frequencies and percentages. Continuous variables were expressed as means ± standard deviations or medians with ranges as appropriate. Comparisons between groups were performed using Wilcoxon signed ranks test. SPSS version 18.0 (SPSS, Inc., Chicago, IL, USA) was used for statistical analysis.

**RESULTS**

**Surgical and postoperative outcomes**

The median valve size was 26 mm (18–30 mm). The median cardiopulmonary bypass time was 140 min (89–352 min) and

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number</th>
<th>Per cent (%)</th>
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<tbody>
<tr>
<td>PA angioplasty</td>
<td>18</td>
<td>32.1</td>
</tr>
<tr>
<td>RVOT muscle resection</td>
<td>6</td>
<td>10.7</td>
</tr>
<tr>
<td>VSD closure</td>
<td>5</td>
<td>8.9</td>
</tr>
<tr>
<td>ASD/PFO closure</td>
<td>3</td>
<td>5.4</td>
</tr>
<tr>
<td>Absent PV repair</td>
<td>2</td>
<td>3.6</td>
</tr>
<tr>
<td>TOF repair</td>
<td>2</td>
<td>3.6</td>
</tr>
<tr>
<td>RVOT cryoablation</td>
<td>2</td>
<td>3.6</td>
</tr>
<tr>
<td>RVOT aneurysm plication</td>
<td>1</td>
<td>1.8</td>
</tr>
<tr>
<td>RV remodelling</td>
<td>1</td>
<td>1.8</td>
</tr>
<tr>
<td>Others</td>
<td>3</td>
<td>5.4</td>
</tr>
</tbody>
</table>

ASD: atrial septal defect; PA: pulmonary artery; PFO: patent foramen ovale; PV: pulmonary valve; RV: right ventricular; RVOT: RV outflow tract; TOF: tetralogy of Fallot; VSD: ventricular septal defect.

the median aortic cross-clamp time \( n = 46 \) was 85 min (49–210 min). The seemingly long bypass time for the PVR was possibly due to the frequently performed concurrent procedures. The median systolic pressure ratio between the right and left ventricles \( n = 54 \) was 0.43 (0.24–0.90), and the median systolic pressure gradient across the PV \( n = 30 \) was 10 mmHg (0–25 mmHg) by direct pressure measurement. Intraoperative transoesophageal echocardiography \( n = 51 \) showed no or trivial PR in 44 patients and mild PR in 7.

There was one early death (30-day hospital mortality, 1.8%). A 17-year-old boy, who had undergone a repair of the double outlet right ventricle at the age of 7 years, died of ventricular dysfunction and multiple organ failure 4 days after operation despite extracorporeal membrane oxygenation support. The median intensive care unit stay was 1 day (1–7 days) and the median hospital stay was 9 days (6–56 days). Predischarge echocardiography \( n = 53 \) showed no or trivial PR in 49 patients and mild PR in 4. The median systolic pressure gradient across the PV was 8 mmHg (0–30 mmHg). Postoperative computed tomography showed a wide orifice of this valve (Fig. 2).

**Follow-up outcomes**

There was no late death. Follow-up echocardiography \( n = 41 \) performed at a median of 7.5 months (2.3–28.1 months) postoperatively showed no or trivial PR in 33 patients and mild PR in 8 patients. The median systolic pressure gradient across the PV was 16 mmHg (0–50 mmHg). Two patients showed a pressure gradient ≥40 mmHg. A 24-year-old female patient, who had received a 26 mm valve after a prior absent PV repair, showed a pressure gradient of 47 mmHg 8 months postoperatively. She had no pressure gradient at the time of hospital discharge. A 4-year-old boy, who had received an 18 mm valve after a prior Rastelli procedure for pulmonary atresia with ventricular septal defect, showed a pressure gradient of 50 mmHg 10 months postoperatively. He suffered from infective endocarditis involving the PTFE valve in the postoperative period, which was cured with antibiotic treatment. At the time of hospital discharge, he had a pressure gradient of 13 mmHg.
The QRS duration in patients with preoperative PR decreased significantly after PVR (141 ± 29 versus 137 ± 24 ms, \( P < 0.001 \)). NYHA functional class improved from 1.7 ± 0.6 to 1.1 ± 0.2 \( (P < 0.001) \). One patient underwent balloon catheter intervention for branch pulmonary artery stenosis. There was no reoperation or catheter intervention for the bicuspid PV. There was no thromboembolic or bleeding event during follow-up.

**Magnetic resonance imaging data**

Follow-up MRI revealed good motion and coaptation of the bicuspid PV (Fig. 3). Analysis of the MRI parameters in patients with preoperative PR who had undergone both preoperative and follow-up MRI examinations \( (n = 22) \) showed significant reduction in RV volumes and improvement in biventricular function (Table 2). The median PR fraction \( (n = 24) \) of this valve was 10% \( (1–31\%) \). Two patients from the earlier part of our experience showed moderate PR (PR fraction 23 and 26%) due to anterior leaflet dehiscence at the apical portion.

**DISCUSSION**

Surgical relief of RV outflow tract obstruction in children with various congenital heart diseases often leaves the native PV incompetent or requires placement of a conduit between the right ventricle and the pulmonary artery. As these patients grow, many of them will require PVR owing to chronic PR or a failed conduit. Although there are several valve substitutes for PVR, bioprosthetic valves are currently the most widely used. However, bioprostheses are subject to structural valve deterioration due to calcification, making future reoperations inevitable. Recently, in a study of 181 patients with various congenital heart diseases who had undergone bioprosthetic PV, we showed that the overall freedom from redo PVR was 52% at 10 years [1]. Zubairi et al. [2], in a study of 169 patients with tetralogy of Fallot or isolated PV stenosis, reported that the freedom from redo PVR was 71% at 10 years. Chen et al. [11], in a study of 227 patients with tetralogy of Fallot, reported that the freedom from structural valve deterioration was 54% at 7 years.

In an effort to overcome this limited durability of bioprosthetic valves, Quintessenza et al. introduced a new technique of implanting bicuspid PV using PTFE material [6, 7]. In the earlier part of their experience, they used 0.6 mm-thickness PTFE material and experienced a few cases of redo PVR due to calcified leaflets [9]. Currently, they are using 0.1 mm-thickness PTFE membrane anticipating improved valve durability due to the non-porous nature of this material, which does not allow cellular ingrowth and thickening.

In our study, PTFE bicuspid PV implantation has proven to be a simple, safe and reproducible technique demonstrating excellent early postoperative function as evidenced by echocardiography and MRI. According to the studies that performed MRI after PVR, the mean PR fraction of homografts or commercial bioprostheses was ~5% [12-14]. Although the mean PR fraction of our bicuspid valve (12%) was higher than that of homografts or commercial bioprostheses, this mild amount of PR was not a problem in remodelling the dilated right ventricle of the patients with PR as evidenced by our MRI data (Table 2). Follow-up echocardiography showed a pressure gradient ≥40 mmHg across the bicuspid PV in two patients. One patient suffered from infective endocarditis directly involving the PTFE valve in the early postoperative period. Follow-up echocardiography performed at 10 months postoperatively showed thickened leaflets with a pressure gradient of 50 mmHg. Based on the fact that he had shown good PV function by intraoperative transoesophageal echocardiography, it is our speculation that the healing process of endocarditis might have caused the leaflet thickening and stenosis. Another patient with PV stenosis (pressure gradient of 47 mmHg) showed rather restricted motion of the leaflets on follow-up cine-MRI images. The exact cause of the restricted leaflet motion in this patient remains unclear. Of note, we experienced two cases of leaflet dehiscence that resulted in a moderate amount of PR. The dehiscence occurred at the apical portion of the anterior leaflet in both patients. It is possible that undue tension on the suture line might have caused

**Table 2: Changes in MRI parameters in patients with PR**

\( (n = 22) \)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Pre-PVR</th>
<th>Post-PVR</th>
<th>( P )-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>RV EDVI (ml/m²)</td>
<td>170 ± 28</td>
<td>106 ± 21</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>RV ESVI (ml/m²)</td>
<td>85 ± 18</td>
<td>50 ± 15</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>RV SVI (ml/m²)</td>
<td>85 ± 16</td>
<td>56 ± 13</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>RV EF (%)</td>
<td>50 ± 6</td>
<td>54 ± 9</td>
<td>0.029</td>
</tr>
<tr>
<td>PR fraction (%)</td>
<td>50 ± 8</td>
<td>12 ± 7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>LV EDVI (ml/m²)</td>
<td>76 ± 7</td>
<td>81 ± 12</td>
<td>0.066</td>
</tr>
<tr>
<td>LV ESVI (ml/m²)</td>
<td>31 ± 6</td>
<td>30 ± 7</td>
<td>0.330</td>
</tr>
<tr>
<td>LV SVI (ml/m²)</td>
<td>45 ± 5</td>
<td>51 ± 9</td>
<td>0.008</td>
</tr>
<tr>
<td>LV EF (%)</td>
<td>60 ± 5</td>
<td>63 ± 6</td>
<td>0.034</td>
</tr>
<tr>
<td>RV/LV EDV</td>
<td>2.2 ± 0.4</td>
<td>1.3 ± 0.2</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

EDV: end-diastolic volume; EDVI: end-diastolic volume index; EF: ejection fraction; ESVI: end-systolic volume index; LV: left ventricular; MRI: magnetic resonance imaging; PR: pulmonary regurgitation; PVR: PV replacement; SVI: stroke volume index.
the dehiscence by cutting through the thin PTFE membrane. We think that it is important to make the length of the anterior leaflet slightly redundant to avoid tension on the suture line. Although we routinely prescribed daily aspirin postoperatively, the need for anticoagulation in these patients remains unclear [6, 8, 15].

Many studies have reported favourable clinical results of using 0.1 mm-thickness PTFE membrane as a valve substitute in the pulmonary position. Brown et al. [8], in a study of 192 patients who had undergone RV outflow tract reconstruction with a PTFE monocusp valve, reported that they had not witnessed significant stenosis or calcification of the PTFE valve during a mean follow-up duration of 4.9 years. Nunn et al. [15], in a study of patients with hand-sewn RV outlet valves made of fresh autologous pericardium or 0.1 mm-thickness PTFE membrane, reported that bileaflet PTFE valves maintained competence and function up to maximum follow-up of 5 years without structural deterioration or calcification. Vast clinical experience of PTFE valve conduits in RV outflow tract reconstruction has been reported by Japanese groups [16–18]. Ando and Takahashi [17], in a study of 139 patients who had undergone RV outflow tract reconstruction with trileaflet PTFE valves Dacron conduits, reported that freedom from conduit explantation was 88% at 10 years. Notably, structural leaflet deterioration was not a cause of their reoperations, and all valves maintained their motion during the mean follow-up duration of 2.7 years. Recently, Miyazaki et al. [18], in a multicentre study of 325 patients who had undergone RV outflow tract reconstruction with trileaflet PTFE valved PTFE conduits, reported that freedom from reoperation was 95% at 10 years and PR was mild or less in 95% of the patients. Yoshiida et al. [19] reported acceptable early results of bicuspid valved PTFE conduit in 18 patients.

The PTFE membrane has a microporous structure with a pore size of <1 μm that inhibits tissue ingrowth, thereby making it resistant to calcification that would impair its mobility. According to Turrentine et al. [20], an explanted PTFE monocusp valve has been found to be covered by a thin fibrocollagenous tissue without evidence of thrombus or calcification. Although we believe that the PTFE membrane itself is resistant to calcification, there is still a possibility that the fibrocollagenous tissue covering the PTFE leaflet may limit the long-term function of the valve in some patients. In the event of late stenosis of the PTFE bicuspid PV, we speculate that percutaneous balloon dilatation may be more effective than it would be for calcified bioprostheses. Furthermore, we think that this technique does not preclude the feasibility of percutaneous PV implantation in the event of eventual valve failure. It is our speculation that a larger valve may be accommodated inside the PTFE valve than inside a stented bioprosthesis owing to the stentless nature of the PTFE bicuspid valve.

CONCLUSION

In conclusion, the early results of bicuspid PV implantation using PTFE membrane were satisfactory. PTFE bicuspid PV demonstrated excellent performance in the short term as evidenced by echocardiography and MRI. Long-term follow-up is mandatory to determine the durability of this valve.

Conflict of interest: none declared.

REFERENCES


