Original Article

Mid-term Results of the Hancock II Valve and Carpentier-Edward Perimount Valve in the Pulmonary Portion in Congenital Heart Disease

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Background: As the number of cases with artificial pulmonary valve implantation increases for congenital heart disease, the number of young adults with artificial pulmonary valves has also increased.

Methods: From 2000 to 2007, 146 artificial valves, such as the Carpentier-Edward Perimount, Hancock II, Biocor, homograft and hand-made valves were implanted for pulmonary valve in 132 patients with various forms of congenital heart disease. Among them, the outcomes of the Carpentier-Edward Perimount (\(n=63\)) and the Hancock II (\(n=40\)) valves were reviewed retrospectively. The mean age at initial implantation was 12.8 ± 6.6 years. The overall duration of follow up was 36.0 ± 24.2 months.

Results: There was an early death due to right ventricular failure with intractable ventricular arrhythmia and 3 late deaths due to progressive right ventricular failure, dilated cardiomyopathy and infective endocarditis. The overall survival and re-operation free rate was 96.3% and 89.8% respectively. Eight out of 63 Carpentier-Edward patients (12.6%) underwent re-replacement at 49.2 ± 25.2 months. The re-operation free rates were 97.7%, 87.7% and 50% at 1, 3 and 5 years respectively. There was no re-operation required for the 40 Hancock II patients over 18.0 ± 10.8 months. There was no statistical significance in the re-operation free rates between these 2 valves (\(p\)-value = 0.51).

Conclusions: The overall survival rate associated with pulmonary valve bioprosthetic valve implantation was acceptable. However, the re-operation freedom rate was not satisfactory at mid-term for the Carpentier-Edward.

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Keywords: Congenital heart disease; Heart valve, prosthesis; Heart valve, allograft; Pulmonary valve replacement

Introduction

As the long term results of the surgical treatment for congenital heart disease have been improved, the number of adolescent and adult patients with congenital heart disease has increased. Patients with Tetralogy of Fallot or pulmonary atresia especially have shown satisfactory long-term surgical outcomes, although they have persistent right ventricle and pulmonary artery associated problems. A significant number of these patients require one or more re-operations for the right ventricular outflow problems, such as stenosis and/or insufficiency of the pulmonary valve, right ventricular dilatation or aneurysmal changes after total surgical correction of these congenital anomalies [1]. The aim of this study was to review the mid-term results of bioprosthetic pulmonary valve implantation, especially, the Hancock II porcine valve (H) and the Carpentier-Edward Perimount pericardial valve (C) for the patients with congenital heart disease.

Methods and patients

From December 2000 to October 2007, 132 patients underwent pulmonary valve implantation and were enrolled in this retrospective study. Including re-replacement of artificial valve, 146 pulmonary valve implantation procedures were performed on these patients. Carpentier-Edward Perimount pericardial valve (\(n=69\)), Hancock II porcine valve (\(n=43\)), St. Jude Biocor porcine valve (\(n=29\)), Homograft (\(n=4\)) and hand-made valve including the Gore-Tex membrane leaflet (\(n=1\)) were used. Among these, 63 Carpentier-Edward Perimount pericardial valves and 40 Hancock II porcine valves were used for the initial artificial pulmonary valve. The choice of valves’ type was depend
on the surgeons’ preference. The medical records of these 103 patients were reviewed retrospectively.

The mean age of the patients was 12.8 ± 6.6 years at their first pulmonary valve surgery after a previous total correction of their congenital cardiac anomalies. Eight redo operations for pulmonary valve replacement were performed at 5.3 ± 2.9 years after the first pulmonary valve implantation. The overall follow up duration was 36.0 ± 24.2 months. We were able to follow up all the enrolled patients with regular echocardiography in outpatient clinic. In the cases requiring the additional operation, we further performed cardiac computed tomography (CT) and magnetic resonance imaging (MRI) for the evaluation of pulmonary arteries’ status and cardiac function.

Results

The patient diagnoses included Tetralogy of Fallot (76), double outlet right ventricle (7), pulmonary atresia with ventricular septal defect (VSD) (6), transposition of the great arteries with pulmonary stenosis (4), pulmonary atresia with intact ventricular septum (2), isolated pulmonary stenosis (2), absent pulmonary valve syndrome (2) and coarctation of aorta with VSD (1) (Table 1). The last patient, with coarctation of aorta, presented the infective endocarditis at the pulmonary valve area after total correction of coarctation of aorta and ventricular septal defect.

There was one early death. This patient had already shown severe right ventricular failure and intractable ventricular arrhythmia before the valve implantation. There were three late mortalities due to progressive right ventricular failure, dilated cardiomyopathy and infective endocarditis, respectively. Overall survival rate was 96.3% and overall re-operation freedom rate was 89.8%.

Since 2004, we have performed the cardiac MRI pre- and postoperatively to evaluate right ventricular function and intractable ventricular arrhythmia before the valve implantation. There were three late mortalities due to progressive right ventricular failure, dilated cardiomyopathy and infective endocarditis, respectively. Overall survival rate was 96.3% and overall re-operation freedom rate was 89.8%.

We divided the patients into two groups, the Carpentier-Edward Perimount pericardial valve group (group C, n = 63) and the Hancock II porcine valve group (group H, n = 40). For group C, there were 8 re-operations among the 63 patients, all of the re-operations were performed in group C patients at 49.2 ± 25.2 months after the first pulmonary valve implantation. Re-operation freedom rates were 97.7%, 93.4%, 87.7% and 50% at 1, 2, 3 and 5 years respectively. In group H, none of the 40 patients required valve replacement at 18.8 ± 10.8 months after the first valve operation. However, the difference between the two groups with regard to rate of freedom from re-operation was not statistically significant (p-value = 0.51). The implanted valve size was 25.0 ± 1.9 mm (range, 19–27 mm) in group C and 24.3 ± 1.5 mm (range, 21–27 mm) in group H.

The main reason for re-operation was stenosis-insufficiency of the artificial pulmonary valve due to severe calcification of the leaflet and cusp retraction due to degeneration. We used two Carpentier-Edward Perimount pericardial valves, two Hancock II pericardial valves and four St. Jude Biocor pericardial valves for the re-operations.

Discussion

In this study, we compared Hancock II porcine valves (Medtronic Heart Valve Division, Irvine, CA, USA) and Carpentier-Edward Perimount pericardial valves (CE valve, Edwards Lifesciences LLC, Irvine, CA, USA) used for pulmonary valve replacement in patients with congenital heart disease. Most of the patients were adolescents. Previous studies have reported on the mid-term and long-term outcomes as well as the pathologic findings after explantation and the causes of failure of these two valves, however, mainly for aortic valves [2–5]. There are few reports on comparison between the porcine and pericardial bioprostheses used for pulmonary valve replacement with the exception of the study reported by Fiore et al.’s study [6]. Fiore et al. compared the Medtronic

Table 1. Diagnoses of Patients

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Number of Patients</th>
</tr>
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<tbody>
<tr>
<td>Tetralogy of Fallot</td>
<td>76</td>
</tr>
<tr>
<td>Double outlet right ventricle</td>
<td>7</td>
</tr>
<tr>
<td>Pulmonary atresia with ventricular septal defect</td>
<td>6</td>
</tr>
<tr>
<td>Transposition of great arteries with pulmonary stenosis</td>
<td>4</td>
</tr>
<tr>
<td>Pulmonary atresia with intact ventricular septum</td>
<td>2</td>
</tr>
<tr>
<td>Isolated pulmonary stenosis</td>
<td>3</td>
</tr>
<tr>
<td>Truncus arteriosus</td>
<td>2</td>
</tr>
<tr>
<td>Absent pulmonary valve syndrome</td>
<td>2</td>
</tr>
<tr>
<td>Coarctation of aorta with ventricular septal defect</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>103</td>
</tr>
</tbody>
</table>

Table 2. Cardiac MRI Findings, Pre- and Postoperatively

<table>
<thead>
<tr>
<th>Time</th>
<th>RV Ejection Fraction (%)</th>
<th>RV EDV (mL)</th>
<th>RV ESV (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preop</td>
<td>36.35 ± 8.50</td>
<td>149.42 ± 25.48</td>
<td>91.08 ± 26.71</td>
</tr>
<tr>
<td>Postop</td>
<td>41.68 ± 9.30</td>
<td>103.50 ± 24.60</td>
<td>60.84 ± 22.39</td>
</tr>
</tbody>
</table>

* n = number of patients, RV Ejection Fraction, RV EDV: right ventricular end diastolic volume, RV ESV: right ventricular end systolic volume, group preoperative, postop: postoperative.
pressure and dynamic pressure treatment strategies have improved in vitro compliance and mechanical properties [16].

In our study, re-operation for prosthetic valve failure occurred only in group C at 49.2 ± 25.2 months (2 months to 6.8 years) after the initial valve surgery. Inspection after the explantation of the previously implanted bioprosthetic valves revealed mixed features of calcified degeneration causing stenosis and non-calcified degeneration, such as leaflet retraction, causing insufficiency. Stent deterioration was not detected (Fig. 1). The re-operation freedom rates for the CE Perimount pericardial valve were 97.7%, 93.4%, 87.7% and 50% at one, two, three and five years respectively. This was a poorer outcome when compared to the outcomes with aortic valves in adult patients, although the pulmonary circulation is exposed to lower pressure than the systemic circulation. It is well known that, in pediatric or adolescent patients, bioprosthetic material show more rapid and aggressive calcified degeneration due to the more active and dynamic metabolic process associated with the growth of these age groups. There was no re-operation in group H at 18.0 ± 10.8 months (range, 2 months to 3.8 years). However, the shorter follow up duration for the Hancock II valve might explain the absence of additional surgery in this group. The statistical analysis showed no difference in the freedom from re-operation (p-value = 0.51). And, relatively short term follow duration of H group is limitation in this study.

Because there was no re-operation in the H group, we could not compare the pathological differences between these two valves. However, we could confirm that the...
pathological features of the CE Perimount valve at pul-
monary position in adolescent patients were not very
different from the aortic or mitral valve outcomes of adult
patients. However, long-term follow up of Hancock II
patients is required.

In addition, appropriate timing of pulmonary valve
implantation after total correction of Tetralogy of Fal-
lot and pulmonary atresia needs to be determined. If
clinicians wait until the patient complains of symptoms
associated with right heart failure such as dyspnea, hep-
atomegaly or low extremity oedema, the patient might
be at risk for a poor outcome even with appropriate pul-
monary valve replacement. Since 2004, we have performed
cardiac MRI to help to decide on the operation timing and
to evaluate the right ventricular function pre- and post-
operatively. Although not all patients in this cohort could
be evaluated by cardiac MRI, the postoperative MRI find-
ings showed improvement in the right ventricular ejection
fraction and right ventricular end diastolic and systolic
volume, compared to the preoperative findings (Table 2).
Our protocol includes pulmonary valve implantation for
patients who underwent the total correction of right ven-
tricular outflow problems such as TOF, PA with VSD or
PA with IVS, truncus arteriosus, RV end diastolic volume
of 150 mL, RV ejection fraction of 40% by cardiac MRI
operations. We have no financial or other interest in the product in this
Conflict of interest

Conclusions
The overall survival after bioprosthetic valve implantation
at the pulmonary portion was acceptable. However, the re-
operation freedom rate was not satisfactory in mid-term
results in the Carpentier-Edward valve. Though Hancock
II valve showed fewer re-operations, we cannot conclude
that it was superior to the Carpentier-Edward paracar-
dial valve because of the shorter follow up duration in the
former group. We need a large and long-term follow up for Hancock II valve patients for the comparison with
Carpentier-Edward paracardial valve.

Conflict of interest
We have no financial or other interest in the product in this
paper and have no relationship with the manufacturer or
distributor of the product.

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