Experience with percardiac interventions for multiple congenital heart diseases in children

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Abstract

OBJECTIVES: To report our experience with percardiac interventions for multiple congenital heart diseases in children.

METHODS: From April 2010 to December 2013, a total of 64 patients (33 males and 31 females), aged 4.38 ± 2.97 years, with multiple congenital heart diseases underwent attempted percardiac interventional procedures. The cohort included 34 ventricular septal defects (VSDs) with atrial septal defect (ASD), 9 VSDs with patent foramen ovale (PFO), 17 VSDs with patent ductus arteriosus (PDA), 2 VSDs with pulmonary stenosis (PS) and 2 VSDs with ASD and PDA. A mini-incision in the inferior sternum was made, and percardiac device closure and balloon valvuloplasty were performed for VSD, ASD, PDA and PS.

RESULTS: Fifty-nine patients (92%) were successfully occluded, and 5 (8%) were converted to open-heart surgery after the failure of occlusion. A total of 111 devices were implanted in the patients (average of 1.88 devices/patient). No severe complications occurred. Incomplete right bundle branch block (IRBBB) occurred in 5 patients (8%) after the operation. Atrioventricular valve regurgitation decreased in 4 patients (6%), but new trivial regurgitation was detected in another patient (2%). A trivial residual shunt without murmur was found in 1 patient (2%), and the residual shunt was closed in the 3-month follow-up. Pericardial effusion occurred in 1 patient (2%).

CONCLUSIONS: Treating the patients who have multiple congenital heart diseases with a percardiac intervention is feasible, and the results should be satisfactory. However, more experience and long-term follow-up are mandatory to assess the safety and effectiveness of these procedures as alternatives to conventional therapy.

Keywords: Percardiac intervention • Congenital heart diseases • Children

INTRODUCTION

Multiple congenital cardiac deformities are not rare in patients with congenital heart disease (CHD). Some patients need early invention because of the high risk and mortality associated with an unrestricted left to right shunt. Traditional open-heart surgery with cardiopulmonary bypass (CPB) has been criticized because of associated complications [1], and percutaneous intervention is limited for infants because of small vascular diameters. As a new technology that combines the advantages of percutaneous intervention and traditional surgery, percardiac intervention for CHD has been increasingly used in clinical practice [2–5]. To date, combined CHDs have not been addressed simultaneously by percardiac interventional procedures. Therefore, we present our experience with percardiac interventions for combined CHDs and discuss the efficacy and safety of these simultaneous procedures in children.

MATERIALS AND METHODS

Clinical data

From April 2010 to December 2013, 64 children with combined CHDs were enrolled in this study. The following selection criteria were applied: (i) the patients were clinically recommended for device closure or balloon valvuloplasty; (ii) with no other malformations requiring surgical repair under CPB; (iii) mild atrioventricular valve regurgitation was considered; and (iv) the existence of aortic valve prolapse with moderate to severe aortic valve regurgitation was excluded. All patients were evaluated by transthoracic echocardiography (TTE) before the operation. No other important intracardiac malformations were found. More patient details are given in Table 1.

Materials

Previous reports have described the device and the delivery system (Shanghai Shape Memory Alloy Co. Ltd, Shanghai, China) used in this cohort [5–7]. The atrial septal defect (ASD) occluder has two discs with different diameters: the right disc is 8–10 mm larger and the left disc is 12–14 mm larger than the connecting waist. Four types of ventricular septal defect (VSD) occluder were designed. The symmetric occluder is concentric, and both discs are 2 mm larger than the waist. The small waist big edge-type occluder is concentric and has two discs with different diameters: the right disc is 4 mm larger and the left disc is 8 mm larger than...
valve and then removed the needle. A guide wire was passed obliquely puncture through the RV towards the pulmonary artery annulus was chosen as the puncture site. We used a trocar to percutaneous intervention.

The anatomical types of the failures were 2 VSD + ASD, 1 VSD + PDA, 1 VSD + pulmonary stenosis (PS) and 1 VSD + PFO. Statistical analysis showed that none of the indices [gender (P = 0.93), age (P = 0.76), weight (P = 0.81), aortic valve prolapse (P = 0.21), tricuspid regurgitation (P = 0.38), mitral regurgitation (P = 0.15) or anatomical type (P = 0.11)] showed significant differences in the closure failure rates.

Procedure

Two venous access lines were established after general anaesthesia. We performed a further estimate of the suitability of the percutaneous intervention and determined whether any undiagnosed but important cardiac abnormalities exist using transoesophageal echocardiography (TEE; Vivid 7 Dimension, GE, USA). The patient was systemically heparinized with 1 mg/kg heparin. Then, a 3-cm incision in the inferior sternum was made to expose the right ventricle (RV) and right atrium. All the VSD, ASD and PDA operations followed an established procedure [2–7].

We performed the balloon valvuloplasty through the RV, which is different from the percutaneous interventional approach. The right ventricular outflow tract (5 mm–1 cm) below the pulmonary annulus was chosen as the puncture site. We used a trocar to obliquely puncture through the RV towards the pulmonary artery valve and then removed the needle. A guide wire was passed across the pulmonary valve into the pulmonary artery. Then, a delivery sheath was advanced over the wire and delivered the selected balloon to dilate the pulmonary artery valve.

Upon occlusion failure, the patient’s incision was lengthened, and open-heart surgery was performed under CPB.

Statistical analysis

All results were expressed as the mean ± standard deviation for continuous variables and as percentages for nominal variables. SPSS for Windows version 20.0 (IBM, USA) was used for the statistical analysis. Gender, age, weight, aortic valve prolapse, mitral regurgitation, tricuspid regurgitation, anatomical type and defect diameter were analysed by binary logistic regression to estimate the closure failure. A P-value of <0.05 was considered statistically significant.

RESULTS

No acute procedural complications or severe adverse events (embolism, complete atrioventricular block, valve injury or death) occurred. Fifty-nine patients (92%) were successfully occluded, and 5 (8%) were converted to open-heart surgery after the failure of occlusion (more details are presented in Table 2).

Occlusion

A total of 111 devices were implanted in the patients (average of 1.88 devices/patient). The occluders implanted into the patients were of various types. The symmetric occluder was implanted most often for perimembranous VSD, and the small-waist big edge-type occluder was designed for a special type of perimembranous VSD known as multi-rupture of membranous aneurysm. When the occluder was implanted into the biggest rupture of membranous aneurysm, the larger left disc of the occluder blocked the other small rupture close to the largest rupture. The asymmetric occluder was specifically designed for closing the subarterial VSD, because the left disc had 0 mm towards the aorta. One of the PDA patients was implanted with an ASD occluder because of the window type and large diameter (more details are shown in Fig. 1).

Four patients underwent conversion to open-heart surgery because of unacceptable outcomes from the VSD occlusion, and 1 underwent conversion for displacement of the occluder in the ASD occlusion. The failure of VSD occlusion was the result of a residual shunt (width >2 mm; flow rate >3 m/s) in 3 patients and of a new moderate tricuspid valve regurgitation in the other. All these complications were resolved by occluder removal and the performance of repair surgery.

The anatomical types of the failures were 2 VSD + ASD, 1 VSD + PDA, 1 VSD + pulmonary stenosis (PS) and 1 VSD + PFO.

Binary logistic regression showed that none of the indices [gender (P = 0.93), age (P = 0.76), weight (P = 0.81), aortic valve prolapse (P = 0.21), tricuspid regurgitation (P = 0.38), mitral regurgitation (P = 0.15) or anatomical type (P = 0.11)] showed significant differences in the closure failure rates.

<table>
<thead>
<tr>
<th>Table 1: Profiles of 64 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Mean age (years)</td>
</tr>
<tr>
<td>Mean weight (kg)</td>
</tr>
<tr>
<td>VSD + ASD</td>
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<tr>
<td>VSD + PFO</td>
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<tr>
<td>VSD + PDA</td>
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<tr>
<td>VSD + PS</td>
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<tr>
<td>VSD + ASD + PDA</td>
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<tr>
<td>Types of VSD</td>
</tr>
<tr>
<td>Perimembranous VSD</td>
</tr>
<tr>
<td>Subarterial VSD</td>
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<td>Muscular VSD</td>
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<tr>
<td>Types of ASD</td>
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<tr>
<td>Secundum central ASD</td>
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<td>Types of PDA</td>
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<tr>
<td>Tubular PDA</td>
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<tr>
<td>Window PDA</td>
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<tr>
<td>Types of PS</td>
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<tr>
<td>Valve stenosis</td>
</tr>
<tr>
<td>Aortic valve regurgitation</td>
</tr>
<tr>
<td>Tricuspid regurgitation</td>
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<tr>
<td>Mitral regurgitation</td>
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</tbody>
</table>

Values are mean ± standard deviation or n (%).

All regurgitant severities were mild or less than mild.

VSD: ventricular septal defect; ASD: atrial septal defect; PDA: patent ductus arteriosus; PFO: patent foramen ovale; PS: pulmonary valvular stenosis.
Complications

The total complication incidence rate was 13%. Incomplete right bundle branch block (IRBBB) was detected in 5 patients (8%) on discharge. Atrioventricular valve regurgitation decreased in 4 patients (6%), and new trivial regurgitation was detected in one other patient (2%). A trivial residual shunt (width ≤ 2 mm; flow rate ≤ 3 m/s) without murmur was found in 1 patient (2%).

Table 2: Clinical results of two groups

<table>
<thead>
<tr>
<th></th>
<th>Time of operation (min)*</th>
<th>Time of mechanical ventilation (min)</th>
<th>Time in ICU (min)</th>
<th>Length of stay after surgery (days)</th>
<th>Total length of stay (days)</th>
<th>Amount of blood transfusion (RBC and plasma)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occlusion</td>
<td>62.8 ± 5.6</td>
<td>115.3 ± 7.3</td>
<td>338.2 ± 36.2</td>
<td>4.7 ± 1.2</td>
<td>9.2 ± 1.5</td>
<td>0.1 ± 0.06 µl / 4.8 ± 0.2 ml</td>
</tr>
<tr>
<td>Conversion to surgery</td>
<td>189.4 ± 26.8</td>
<td>489.3 ± 22.5</td>
<td>1296.4 ± 79.5</td>
<td>6.7 ± 1.1</td>
<td>12.9 ± 1.2</td>
<td>2.6 ± 0.2 µl / 268.4 ± 32.7 ml</td>
</tr>
</tbody>
</table>

Values are mean ± standard deviation.
ICU: intensive care unit; RBC: red blood cell.
*Operation time of group occlusion is the time from the beginning of the skin incision to closing of the skin incision. Operation time of group open-heart surgery is the time from converting to open-heart surgery to closing the skin incision.

Figure 1: The occluders. Values are mean ± standard deviation. VSD: ventricular septal defect; ASD: atrial septal defect; PDA: patent ductus arteriosus; PFO: patent foramen ovale. The diameter of the occluder refers to the diameter of the occluder’s waist. *We used a small waist big edge-type occluder to close the defect in the membranous aneurysm.
Pericardial effusion occurred in 1 patient (2%) and was treated by using diuretics.

Follow-up

The patients were followed by clinical examination, echocardiography and TTE at the 2nd week, 3rd month, 6th month, 1st year, 2nd year and 3rd year. The follow-up rates at the 2nd week, 3rd month, 6th month, 1st year, 2nd year and 3rd year were 100, 98, 97, 91, 85 and 80%, respectively. No severe adverse events (embolism, complete atroventricular block, valve injury, or death or left or right ventricular outlet stenosis) were noted during the period of 3–36 months (median, 12 months). The trivial residual shunt disappeared at the 3rd postoperative month, and the new trivial regurgitation disappeared at the 3rd postoperative year.

DISCUSSION

With the development of technology, many simple CHDs, such as ASD, VSD, PDA and PS, can all be treated by transcatheter intervention. Based on our literature review, most reports on the transcatheter intervention for multiple CHDs were for adults, with a few for children [8–11]. Song et al. [8] reported that 36 patients, aged 17.20 ± 10.52 years, underwent a simultaneous transcatheter intervention. Hamid et al. [9] reported only a few cases in adults. Atiq et al. [11] performed simultaneous transcatheter interventions on 10 patients, aged 4.4 ± 2.6 years. There are two reasons that explain this phenomenon. First, children, especially infants with small blood vessels, cannot undergo transcatheter intervention because of vessel wall lesions. Second, radiation damage is still a disturbing problem.

Percardiac intervention not only avoids the above problems, but also greatly shortens the operation time, reduces surgical trauma and accelerates postoperative recovery. In contrast to open-heart surgery, this method does not require a blood transfusion. Percardiac intervention for single VSD, ASD and PDA has been well tested for its technological feasibility [2–6]. However, for multiple CHDs, there are no simple combinations of percardiac intervention that are used in single CHDs. Additionally, the applicability and safety of simultaneous percardiac intervention technology is still a hot and controversial topic in clinical practice. In this study, except for 2 patients (1 with a slight crevice shunt and 1 with trivial regurgitation after the procedure, both of which disappeared in the follow-up period) all the other patients were treated without any complications.

Our case series clearly emphasizes the success of applying percardiac interventional techniques to treat more than one defect at the same time without much added risk. However, its applicability and safety are still unclear because the sample size and length of follow-up appear too limited to ensure these positive results. More experience and long-term follow-up are mandatory.

The patients’ multiple CHDs and the smaller incision required by this technique increased the difficulty of the operation. Nevertheless, it has shown the advantages of aesthetics and operation standardization. Maintaining a strict order is crucial to ensuring the safety and effectiveness of percardiac intervention in treating multiple CHDs. Therefore, we recommend the procedure sequence of occlusion being VSD → ASD → PDA → PS. We recommend this order for the following reasons: (i) the VSD occlusion encountered the most complications and (ii) the failure incidences of CHD followed the order of VSD → ASD → PDA → PS from highest to lowest. Thus, the simple principle is ‘The difficult first, then the easy; or the complex first, then the simple’.

CONCLUSION

Treating patients who have multiple CHDs with percardiac intervention is quite feasible, and the results should be satisfactory. However, more experience and long-term follow-up are mandatory to assess the safety and effectiveness of these procedures as alternatives to conventional therapy.

ETHICAL STANDARDS

The authors assert that all procedures contributing to this work comply with the ethical standards of the Helsinki Declaration of 1975, as revised in 2008, and has been approved by the Committee on Clinical Trials at the Second Xiangya Hospital.

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Conflict of interest: none declared.

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