Results of two different approaches to closure of subaortic ventricular septal defects in children

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Abstract

OBJECTIVES: Percardiac device closure of ventricular septal defects (VSDs) is considered as an alternative to surgical repair in certain patients; however, the safety and validity of this technique in subaortic VSD are unproven.

METHODS: A total of 463 patients with subaortic VSD underwent two different operative procedures. The clinical data were collected and a retrospective analysis was performed.

RESULTS: A total of 145 (90.06%) cases were successfully occluded in Group A, and 16 (9.94%) patients were converted to open-heart surgery after occlusion procedure failure. A total of 302 patients in Group B underwent open-heart surgery. Multivariable analysis showed that a diameter of <5 mm in doubly committed subarterial VSD was the sole predictor of device closure failure. There were statistically significant differences (P < 0.05) between the two groups in operation time, postoperative mechanical ventilation time, cardiac intensive care unit duration, postoperative hospitalization time and blood transfusion requirement. Patients were followed up with clinical examination, echocardiography (ECG) and transthoracic ECG during the period of 3–36 months (median, 12.6 months) at second week, third month, sixth month, first year, second year and third year after the operation. No acute complications or severe adverse events (death, valve injury, complete atrioventricular block and embolism) occurred either in the early period or during the follow-up.

CONCLUSIONS: Percardiac device occlusion is a safe, effective and efficient option for treating subaortic VSD in selected patients.

Keywords: Subaortic ventricular septal defect • Children • Transoesophageal echocardiographic guidance • Surgical repair • Percardiac device

INTRODUCTION

Open-heart repair via cardiopulmonary bypass is the most accepted classic procedure for closing ventricular septal defects (VSDs). With the rapid development of the interventional technology, more patients choose percutaneous interventional therapy instead of traditional surgical procedures because it leaves no scar and avoids the complications of cardiopulmonary bypass [1, 2]. The presence of a ≤2 mm rim of tissue between the aortic valve and the defect is considered a prerequisite for percutaneous device closure [3]. A new technique, percardiac device closure of VSD, is considered an alternative to surgical repair [4–7] in certain patients. However, its safety and validity in patients with subaortic VSD is unproven. In this paper, we compare the percardiac interventional procedure with open-heart surgery and report the short- and medium-term outcomes of two different approaches for treating subaortic VSDs.

MATERIALS AND METHODS

Subaortic ventricular septal defect

Among VSDs, those immediately below the aortic valve are a special subgroup because of their propensity to aortic valve prolapse. These VSDs include some perimembranous VSDs and doubly committed subarterial VSDs. Considering the specific prognosis and common haemodynamics, we consequently defined subaortic VSDs as those with a <2 mm rim of tissue between the aortic valve and the defect.

Clinic material

From April 2010 to July 2013, 463 patients with isolated subaortic VSD were enrolled in this study. Patient selection criteria were the following: (i) clinically indicated device closure, (ii) maximum diameter of the doubly committed subarterial VSD ≤10 mm, (iii) aortic valve prolapse had occurred but no more than mild regurgitation of the aortic valve was present, (iv) no more than moderate regurgitation of the atriointerventricular valve was present and (v) no other malformations needed repair except for patent foramen ovale (<≤ mm). These patients were divided into two groups according to the parents’ choice. In Group A, 161 patients underwent an initial attempt at percardiac device closure. In Group B, 302 patients underwent a repair procedure under cardiopulmonary bypass. Chest roentgenography demonstrated increased pulmonary blood flow and cardiomegaly in all patients. Echocardiography (ECG) showed left or bilateral ventricular hypertrophy in all patients.
Detailed patient profiles are given in Table 1. There were no statistically significant differences in the clinical data between the two groups \((P > 0.05)\). Informed consent was obtained from the parents of all of the participants, and the study was approved by the Committee on Clinical Trials at the Second Xiangya Hospital.

**Procedure**

**Group A.** All patients underwent general anaesthesia. Two venous access lines were established to provide convenience for conversion to open-heart surgery if needed. Transoesophageal ECG (Vivid 7 Dimension; GE, USA) was performed before surgery to further determine the patient's suitability for the pericardial device closure procedure and identify previously undiagnosed but important cardiac abnormalities. The device (Fig. 1) and the delivery systems (Shanghai Shape Memory Alloy Co., Ltd) used in this cohort were specially designed for this procedure and approved by the Food and Drug Administration of China. The device size was selected to be 1–2 mm larger than the VSD diameter. The device is fixed onto a 0.035-in. delivery cable made of stainless steel by a microscrew system and attached by a 4–0 Prolene suture (Ethicon, Inc., Somerville, NJ, USA), called a safe wire in the case of detachment of the occluder from the delivery leader, that is sewn onto the right side of the disc for retrieval should occluder dislocation occur and is cut and removed after the procedure. The occluder is then immersed in saline in and out of the loading sheath to remove the air.

The free wall of the right ventricle (RV) was exposed via a 3-cm incision in the inferior sternum for closure of the perimembranous VSD or the left second intercostal 1–2-cm incision for occlusion of doubly committed subarterial VSDs. Patients were systemically heparinized by intravenous heparin sodium (1 mg/kg), and an additional dose (0.5 mg/kg) was given every 30 min. The puncture site is usually located on the cardiac surface by palpation of a heart maker pointing towards the apex (to avoid interference with aortic valve), and the occluder was retracted against the septum. The delivery sheath was pulled back again, and the waist and right side of the disc were subsequently released. Transoesophageal ECG was performed to ensure that there were no residual shunts or aortic regurgitation. If no complications were found, both the loader sheath and the cable were withdrawn and the purse-string wire was tied. The chest was closed with drainage tube placement. A prophylactic antibiotic was given during the procedure and the day after. Aspirin (3 mg/kg/day) was routinely given for 6 months.

Upon occlusion failure, the patients’ incision in the inferior sternum was lengthened or the left second intercostal incision was closed and a median sternotomy was made. The patients then underwent the same surgical procedure as in Group B (Fig. 2).

**Group B.** All patients underwent open-heart surgery. The perimembranous VSD was repaired from the right atrium and the doubly committed subarterial VSD was repaired from the pulmonary artery. The VSDs were closed using patch or interrupted mattress sutures reinforced with small pledgets.

**Statistical analysis**

Data are expressed as percentage for nominal variables and mean ± standard deviation for continuous variables. SPSS for Windows, version 17.0 (IBM, Armonk, NY, USA) was used for the statistical analysis. Closure failure was analysed as a dependent outcome variable. Gender, age, weight, VSD diameter, aortic valve prolapse, tricuspid

<table>
<thead>
<tr>
<th><strong>Table 1:</strong> Patient characteristics</th>
<th>Group A</th>
<th>Group B</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number</td>
<td>161</td>
<td>302</td>
<td>-</td>
</tr>
<tr>
<td>Male/female</td>
<td>84/77</td>
<td>156/146</td>
<td>0.915</td>
</tr>
<tr>
<td>Mean age (months)</td>
<td>44.4 ± 27.7 (5–168)</td>
<td>45.8 ± 29.1 (6–168)</td>
<td>0.606</td>
</tr>
<tr>
<td>Mean weight (kg)</td>
<td>16.70 ± 7.46 (6–51)</td>
<td>15.6 ± 5.0 (5–47)</td>
<td>0.055</td>
</tr>
<tr>
<td>Type of VSD</td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>pmVSD</td>
<td>119</td>
<td>152</td>
<td></td>
</tr>
<tr>
<td>dcsVSD</td>
<td>42</td>
<td>150</td>
<td></td>
</tr>
<tr>
<td>Diameter of VSD (mm)</td>
<td>6.95 ± 1.90</td>
<td>6.81 ± 2.13</td>
<td>0.470</td>
</tr>
<tr>
<td>Distance from the rim of VSD to AV (mm)</td>
<td>1.35 ± 0.17</td>
<td>1.37 ± 0.31</td>
<td>0.371</td>
</tr>
<tr>
<td>Incomplete right bundle branch block</td>
<td>3</td>
<td>5</td>
<td>0.870</td>
</tr>
<tr>
<td>Aortic valve prolapse</td>
<td>12</td>
<td>28</td>
<td>0.507</td>
</tr>
<tr>
<td>Aortic valve regurgitation</td>
<td>0</td>
<td>12</td>
<td>0.012</td>
</tr>
<tr>
<td>Mitral valve regurgitation</td>
<td>5</td>
<td>17</td>
<td>0.279</td>
</tr>
<tr>
<td>Tricuspid valve regurgitation</td>
<td>10</td>
<td>9</td>
<td>0.095</td>
</tr>
</tbody>
</table>

Values are mean ± standard deviation.

pmVSD: perimembranous ventricular septal defect; dcsVSD: doubly committed subarterial ventricular septal defect; VSD: ventricular septal defect; AV: aortic valve.
regurgitation, mitral regurgitation and VSD type (perimembranous VSD or doubly committed subarterial VSD) were analysed as independent variables. Independent variables with $P$-values <0.05 on univariate analysis were included in the multivariable analysis. The odds ratio and its 95% confidence interval were calculated.

RESULTS

There were no acute procedural complications or severe adverse events (death, valve injury, complete atrioventricular block or embolism).

Group A had much lower values of operative time, postoperative mechanical ventilation time, cardiac intensive care unit duration, postoperative hospitalization time and need for blood transfusion than Group B (Table 2).

Occlusion

The average occluded VSD diameter was $6.39 \pm 1.99$ mm and the average occluder diameter was $8.36 \pm 2.12$ mm. In Group A, 145 (90.06%) patients were successfully occluded, whereas 16 (9.94%) patients were converted to open-heart surgery after occlusion.
failure. There was no statistically significant difference (P = 0.09) in closure failure between the two VSD types. Nine patients with perimembranous VSD were converted to open-heart surgery; 5 with tricuspid regurgitation, 3 with residual shunt and 1 with occluder displacement. Seven patients with doubly committed subarterial VSD were converted to open-heart surgery because of aortic regurgitation (4 patients) and residual shunt (3 patients). All of these complications were resolved by occluder removal and the performance of repair surgery.

Multivariable analysis showed that a diameter ≥ 5 mm of a doubly committed subarterial VSD was the predictor for percardiac device closure failure (odds ratio, 4.125; 95% confidence interval, 4.69–36.72; P < 0.001). Five of the patients with a doubly committed subarterial VSD ≥ 5 mm were converted to open-heart surgery; of these, only 2 were successfully occluded. None of the other indexes (gender, age, weight, aortic valve prolapse, tricuspid regurgitation or mitral regurgitation) showed statistically significant differences in closure failure rates.

Surgery repair

The average diameter of VSD in surgery repair was 6.45 ± 1.72 mm. All doubly committed subarterial VSDs were closed by patching. Patch repair was adopted for perimembranous VSDs with diameters ≥ 5 mm, whereas interrupted mattress sutures were used for the other VSDs.

Complications

Arrhythmia. During the procedures in Group A, 10 younger patients had a short, well-tolerated episode of junctional rhythm that spontaneously converted back to sinus rhythm. No complete atrioventricular blocks were detected, while incomplete right bundle branch block were noted in 6 (3.73%) patients upon discharge.

In Group B, 16 patients had a short, well-tolerated episode of junctional rhythm that spontaneously converted back to sinus rhythm. No complete atrioventricular blocks were detected, whereas incomplete right bundle branch block was seen in 21 (6.95%) patients upon discharge.

Atrioventricular regurgitation. In Group A, mitral regurgitation decreased in 3 patients. Tricuspid regurgitation decreased in 7 patients, whereas new trivial to mild tricuspid regurgitation was detected in 5 other patients. In Group B, mitral regurgitation decreased in 4 cases. Tricuspid regurgitation decreased in 6 cases; however, new trivial to mild tricuspid regurgitation was detected in another 15 cases. Aortic regurgitation decreased in 8 patients but occurred in 3 patients.

Residual shunt. In Group A, a trivial residual shunt (width, 1–2 mm; flow rate < 3.0 m/s) was detected in 3 patients upon discharge. In Group B, a trivial residual shunt was observed in 7 patients after the operation.

Other. Pericardial effusion occurred in 2 patients in Group A in 1 week. No complications such as device dislocation or drop-off, thrombosis or obstruction of the left or right ventricular outflow tract were seen in Group A.

Eleven in Group B occurred after surgery and 2 cases of Group B occurred 1–2 weeks after surgery. Nonetheless, no other complications occurred in Group B (Table 3).

Follow-up

The patients were followed up by clinical examination, ECG and transthoracic ECG at the second week, third month, sixth month, first year, second year and third year. No deaths were noted during the period of 3–36 months (median, 12.6 months). The follow-up rates at the second week, third month, sixth month, first year, second year and third year were 100, 98.70, 96.07, 91.02, 83.67 and 79.63%, respectively. No new complications or severe adverse events (death, valve injury, complete atrioventricular block, embolism or left or right ventricular outlet stenosis) occurred during the follow-up period.

The incomplete right bundle branch block disappeared in 1 case in Group A and 3 cases in Group B in the follow-up period.

New trivial aortic regurgitation was observed in 1 patient at 14 months and disappeared at the second postoperative year in Group A. Tricuspid valve regurgitation decreased in 2 cases at the
first and second postoperative years in Group A. Neither worse nor better other valve regurgitation was detected during the follow-up period. The shunt disappeared in 2 patients in Group A at the sixth postoperative month and in 5 patients in Group B at the third and sixth postoperative months during the follow-up period (Table 2).

**DISCUSSION**

Aortic valve prolapse and even aortic regurgitation can occur in perimembranous VSD (towards the outflow tract) and doubly committed subarterial VSD. All of these defects have a common anatomical characteristic of partial or complete lack of subaortic septal tissues. They also share the haemodynamic property of the propensity to aortic valve prolapse. Based on these profiles, it is reasonable to define these defects as subaortic VSD. Some reports revealed that aortic regurgitation develops easily and quickly when aortic valve prolapse occurs in subaortic VSDs [8, 9]. Therefore, early closure should be recommended to prevent further aortic valve complications before aortic valve prolapse develops [10].

Percutaneous transcatheter closure is now accepted as an alternative to surgery for certain VSD types [11], and the new occluder from Shanghai Shape Memory Alloy had been proven safe and efficient [12, 13]. However, subaortic VSD had never been considered a type that can be occluded until now. Compared with the percutaneous transcatheter procedure, percardiac intervention can approach VSD in a perpendicular manner (Fig. 3), which is the key to occlusion success [14]. Under transoesophageal ECG guidance, device deployment can be performed both easily and safely.

In this paper, we compared the percardiac device closure using an occluder from Shanghai Shape Memory Alloy with open-heart surgery, the latter of which has been considered the gold standard procedure for treating all kinds of VSD. Our results show that percardiac device closure procedure has the same validity and safety as open-heart surgery (Table 2). Although no statistically significant difference was seen between the two VSD types in this study, a diameter of ≤5 mm in doubly committed subarterial VSD still affects the occlusion success rate. The reason for this is that the actual diameter of the doubly committed subarterial VSD is usually underestimated [14].

<table>
<thead>
<tr>
<th>Groups</th>
<th>n</th>
<th>Complications</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AR</td>
<td>MR</td>
<td>TR</td>
</tr>
<tr>
<td>pmVSD</td>
<td>119</td>
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<td>0</td>
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<tr>
<td>dcsVSD</td>
<td>42</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>pmVSD</td>
<td>152</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>dcsVSD</td>
<td>150</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>P-value 1</td>
<td>0.077</td>
<td>0.657</td>
<td>0.859</td>
</tr>
<tr>
<td>P-value 2</td>
<td>0.356</td>
<td>-</td>
<td>0.652</td>
</tr>
</tbody>
</table>

All complications were newly occurred.

pmVSD: perimembranous ventricular septal defect; dcsVSD: doubly committed subarterial ventricular septal defect; P-value 1: P-value between Group A and Group B of pmVSD; P-value 2: P-value between Group A and Group B of dcsVSD; IRBBB: incomplete right bundle branch block; MR: mitral valve regurgitation; TR: tricuspid valve regurgitation; AR: aortic valve regurgitation; RS: residual shunt; PE: pericardial effusion.

**Figure 3:** The key point to occlusion of the subaortic VSD. (A) The correct manoeuvre for deploying the left side of the disc without interfering with the aortic valve. (B) The incorrect manoeuvre for deploying the left side of the disc and compressing the aortic valve. VSD: ventricular septal defect; AAO: ascending aorta.
The inferior sternum incision is appropriate for closing both kinds of VSDs, but a longer incision is often needed for doubly committed subarterial VSDs. In our experience, the left second intercostal incision is quite suitable for closing doubly committed subarterial VSD.

A complete atrioventricular block is a big problem for occlusion, especially using the Amplatzer occluder [15, 16]. No cases of complete atrioventricular block were detected in this cohort. The lower incidence of malignant arrhythmia that occurred here during occlusion were due to the following reasons: avoiding septal stimulation due to accurate and vertical deployment; occluder waist being 2 mm longer than that of the Amplatzer occluder, which may reduce septal compression on both sides of the umbrella; and the use of a smaller occluder. However, incomplete right bundle branch block occurred often in this study. We speculate that this was related to operating within the RV, which stimulated the right bundle branch block around the VSD.

Since aortic valve regurgitation is the sole contraindication for occlusion, we did not include patients with aortic valve regurgitation in Group A. A total of 12 patients in Group A with aortic valve prolapse were cured by occlusion, while 28 patients in Group B with aortic valve prolapse were cured by VSD repair. We did not operate on the aortic valve because the occluder (Fig. 4) or patch can push the prolapsed aortic cusp back and cure the mild aortic valve regurgitation. One patient in Group A presented with trivial aortic valve regurgitation at the 14th postoperative month that disappeared at the second postoperative year. Mitral valve regurgitation can be reduced after VSD closure, which shrinks the LV. New tricuspid valve regurgitation was reduced further in Group A. A total of 12 patients in Group A with aortic valve prolapse and aortic regurgitation in patients with ventricular septal defect: echocardiographic features and surgical implications. J Am Coll Cardiol 1988;12:1538–46.


Conflict of interest: none declared.

REFERENCES


CONCLUSION

Percardiac device closure can achieve the same validity and safety as surgical repair, but features a more rapid recovery and less trauma than open-heart surgery for treating subaortic VSDs in selected patients. Our study revealed that this new technique may be an alternative to classic surgery. Longer follow-up is needed to determine occlusion safety prior to its general use.

Figure 4: (A) Transoesophageal ECG shows a doubly committed subarterial VSD, prolapsed right coronary valve, enlarged and transformative coronary sinus and no aortic regurgitation. (B) The VSD was successfully occluded by the eccentric occluder without aortic regurgitation. VSD: ventricular septal defect; LA: left atrium; LV: left ventricle; RV: right ventricle; AO: arterial aorta.