Perventricular device closure of ventricular septal defects: results in patients less than 1 year of age

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Abstract

OBJECTIVES: To present and share our experience in perventricular device closure of ventricular septal defects in patients less than 1 year old.

METHODS: From 2012–2014, 51 patients less than 1 year old with ventricular septal defects were operated on with minimally invasive trans-thoracic device closure under the guidance of transoesophageal echocardiography (TOE) without cardiopulmonary bypass (CBP). The median age at operation was 8.0 ± 2.5 months and the mean body weight was 7.9 ± 3.4 kg; 7.3% (5) of patients had a weight less than 5 kg. The Qp/Qs ratio was 1.9 ± 0.4. The ventricular septal defect size ranged from 3 to 9 mm; the mean diameter was 5.7 ± 1.6 mm; 27.4% (14) of defects were subaortic, 66.7% (34) perimembranous and 5.9% (3) were muscular. For defect closure, we used a ventricular septal defect occlusion device (Lepu Medical Technology Co., Ltd, Beijing, China) through a 3-cm skin incision in the lower third of the sternum.

RESULTS: The procedural success rate was 96.1% and there were 2 patients who were converted to open-heart surgery (3.9%) during procedures. The operation time ‘skin to skin’ was 55.9 ± 41.0 (40) min; 48.8% of cases were less than 40 min. Intensive care unit stay was 16.5 ± 9.4 (18) h; ventilation time was 3.2 ± 3.5 (2) h; all patients did not require inotropic support, blood transfusion and analgesia. Of the total, 7.8% (4) of patients had residual shunt of not more than 1 mm; there were no atrioventricular blocks, rhythm disturbances or other types of major complications in the early postoperative period. Length of hospital stay was 5.6 ± 3.2 days. The mean follow-up was 18.7 ± 10.1. Residual shunts, conduction disturbances or valve complications were not observed in any patients.

CONCLUSIONS: Perventricular device closure of ventricular septal defects showed safety and high efficiency in patients less than 1 year of age, compared with conventional surgical repair with cardiopulmonary bypass, and provided a short period of rehabilitation and excellent cosmetic result.

Keywords: Perventricular • Ventricular septal defect • Infants

INTRODUCTION

Following the first surgery to close a ventricular septal defect (VSD) by Lillehei et al. in 1954 [1], surgical closure has been regarded as the gold standard for treatment. To reduce the impact of such drawbacks of open-heart surgery such as cardiopulmonary bypass (CPB), aortic cross-clamping and surgical trauma, percutaneous techniques have been developed [2, 3]. However, this technique has several undesirable aspects that cause concern, including an increase in cardiac catheterization time, the use of radiation, an increased risk of atrioventricular (AV) block, interference with the aortic and tricuspid valve, and, of course, is limited by the vascular access in small patients [4, 5]. A new off-pump perventricular device closure (PVDC) of VSDs (Fig. 1) under transoesophageal echocardiographic (TOE) guidance has been described and is being increasingly performed with excellent results [6–8]. Our group has performed PVDC on a series of more than 130 patients since June 2012 [9]. Recent reports indicate that a PVDC can be a safe and effective alternative to the standard surgical closure of VSD even in small babies [10, 11]. However, the safety and effectiveness of this procedure in patients younger than 1 year is unclear due to lack of data. In this study, we report our results of using PVDC to repair VSD in patients less than 1 year of age.

MATERIALS AND METHODS

Between June 2012 and June 2014, 51 consecutive patients underwent PVDC. The median age was 8.0 ± 2.5 months, the median weight was 7.9 ± 3.4 kg and 5 patients (7.3%) had a body
mass less than 5 kg. Patient characteristics are presented in Table 1. There was no evidence of aortic or tricuspid regurgitation; 8 (15.7%) patients had patent foramen ovale with haemodynamically insignificant flow. No patient had previously undergone an open-heart surgery. The preoperative protocol included trans-thoracic echocardiographic screening and TOE evaluation of the defect (location, size, shape and distance from the tricuspid and aortic valves). Contraindications included large inlet defects with no sub-tricuspid rim and doubly committed subaortic VSDs. There were no limitations concerning the weight of the patient.

**Table 1**: Patient characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
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<tbody>
<tr>
<td>Number of patients</td>
<td>51</td>
</tr>
<tr>
<td>Sex (m/f)</td>
<td>26/25</td>
</tr>
<tr>
<td>Age (months)</td>
<td>8.0 ± 2.5 (3–12)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>7.9 ± 3.4 (4–25)</td>
</tr>
<tr>
<td>Pulmonary artery pressure (mmHg)</td>
<td>40.3 ± 13.1 (38)</td>
</tr>
<tr>
<td>Pulmonary hypertension &gt;1 grade</td>
<td>31.3% (16)</td>
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<tr>
<td>VSD size on TOE (mm)</td>
<td>5.7 ± 1.6 (5)</td>
</tr>
<tr>
<td>Perimembranous VSDs with good upper rim</td>
<td>66.7% (34)</td>
</tr>
<tr>
<td>Perimembranous VSDs with no upper rim</td>
<td>27.4% (14)</td>
</tr>
<tr>
<td>Muscular VSDs</td>
<td>5.9% (3)</td>
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TOE: transoesophageal echocardiography; VSD: ventricular septal defect.

Technique

During the procedure, all patients were placed in the supine position. A TOE probe was inserted routinely throughout the whole procedure. Using general anaesthesia, a 3-cm skin incision was made in the lower third of the sternum, the processus xiphoideus was divided and a small rib spreader was used to open the incision. The pericardium was opened and suspended to expose the right ventricle, and systemic heparin (1 mg/kg) was administered. To determine the puncture site, the free right ventricular (RV) wall was palpated lightly to locate the area of maximal thrill, corresponding to the VSD location. A purse-string suture was placed on the RV free wall at the point of maximal thrill (Fig. 2). A guidewire was inserted through a needle within that suture into the left ventricle via the VSD under echocardiographic guidance (Figs 3 and 4) and the delivery sheath was passed into the defect. A second sheath with the VSD occlusion device (MemoPart VSD Occlusion Device; Lepu Medical Technology, Shanghai Shape Memory Alloy Co., Ltd, Shanghai, China) was screwed into it and pulled back until both disks were completely open (Fig. 5). The device chosen for closure was ‘oversized’ only 1–2 mm. In the majority of cases (64.7%), we used a symmetrical device; in 12 patients (23.5%) with a subaortic defect, an asymmetrical device was implanted. The position of the device, residual shunt, aortic and tricuspid insufficiency were checked by TOE. The chest wall was closed in a routine manner. Oral aspirin was administered for 3 months in all patients.
RESULTS

There were no hospital deaths. Device implantation was successful in 96.1% patients. In 2 cases (3.9%), the procedure failed due to device dislocation just after the implantation. The main reason was an inadequate occluder size chosen. In both cases, conversions to open-heart closure were done. The procedural data are summarized in Table 2. Intraoperative aortic, tricuspid and mitral regurgitation did not exceed trivial grade, without no appearance of new ones during the procedure. No inotropic support or blood infusion was needed in all cases. Four patients (7.8%) had small (<1 mm) residual shunts. There were no rhythm or AV conduction disorders. The postoperative data are presented in Table 3. Follow-up data were available for all patients. The follow-up period was 14.3 ± 6.7 months (range, 2–24 months). There were no deaths during this period. No residual or new shunts, endocarditis or rhythm disorders were observed. No obstruction of the left or right outflow tract, or device dislocation was detected. No sternum or rib deformation was observed, and the small skin incision gave an excellent cosmetic result.

DISCUSSION

Surgical on-pump closure of a VSD has become routine since its first use in 1954. However, there have been perceptible changes in the surgical strategy. It has shifted from a two-stage approach with pulmonary artery banding to decrease blood flow to the lungs followed by the surgical closure of the defect, to a single-stage approach with radical surgery performed at an early age. The strategy of perfusion has also changed from a total circulatory arrest with cooling to 18°C to normothermia and standard CPB [12]. Nevertheless, CPB remains a non-physiological technique with severe haemodilution, acute inflammatory response, macro- and microthrombosis, and multiple organ dysfunctions. Additionally, in small children, this alone can lead to excessive perioperative blood loss and require a large volume of transfusion [13].
Another serious complication of the open-heart VSD surgery is the risk of a complete heart block. The conduction system is almost always located along the margins of the defect, and therefore can easily be compromised with surgical stitches and traction or tension. Complete atrioventricular block occurring during or after the procedure demanded a pacemaker implantation, with partial sternotomy or on some occasions even full resternotomy, with insertion of epicardial pacemaker electrodes [12].

Transcatheter device closure has become another standard treatment for VSD. This technique avoids using CPB and is associated with advantages such as reduced trauma, faster recovery and shorter hospital stay. However, the percutaneous approach can be difficult in patients with low weight and poor vascular access. In small infants, the passage of large delivery catheters may result in rhythm disturbances and haemodynamic compromise [14]. Data from the European Registry clearly have showed limitations and drawbacks of transcatheter VSD closure [3]. Patient’s weight, device type and VSD location are possible risk factors for a successful closure, as well as for complete heart block development [3, 15]. The results of PVDC of VSDs using TOE guidance have been encouraging. Recent reports indicate that PVDC can be a safe and effective alternative to standard surgical closure of VSD, even in small babies [10, 11]. The advantages of this technique include a simple delivery mechanism, a small delivery system for deployment, and a self-expandable and easily retrievable device [14]. Compared with the conventional method of VSD repair, the unequivocal advantage of PVDC lies in the avoidance of CPB. It is important to note that PVDC results in very low complete heart block rates [8]. Comparing with previously used percutaneous techniques, it does not require a guidewire loop creation through the heart and the VSD. In the perventricular approach, neither guidewires nor sheaths need to pass through the VSD at an angle, with ultimately no push and pull on VSD margins. The inferior partial sternotomy also results in an improved cosmetic result and allows for swift patient recovery. There are a few reports in the literature on device-assisted closure of the VSD in infants less than 1 year of age [14]. A multicentre study by Bacha et al. [16] reported on seven infants less than 1 year of age who underwent the perventricular approach with good results. In our report, PVDC was used in 51 cases of infants under 1 year of age. Our series demonstrates excellent results with high (96.1%) closure rates and low morbidity. We emphasize that the PVDC technique is not limited by the patient’s age or weight and the key to achieving good results is a precise assessment of VSD size and location. Patients required a shorter intensive care unit stay and a decreased postoperative hospital stay, indicating that the small incision, less severe myocardial trauma and absence of CPB led to a much faster recovery.

**CONCLUSION**

Off-pump PVDC of a VSD under TOE guidance is safe and feasible in infants under 1 year of age. We believe that PVDC of the VSD will become the procedure of choice for small children in experienced hands. However, more follow-up results are needed to assess the long-term safety and efficacy of this technique.

**Conflict of interest:** None declared.

**REFERENCES**


### Table 3: Postoperative data

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean ± SD (range)</th>
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<tbody>
<tr>
<td>Ventilation time in ICU (h)</td>
<td>3.2 ± 3.5 (range, 0–15)</td>
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<tr>
<td>Blood loss postoperatively (ml)</td>
<td>26.9 ± 21.5 (range, 5–100)</td>
</tr>
<tr>
<td>ICU stay (h)</td>
<td>16.5 ± 9.4</td>
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<tr>
<td>Mean postoperative hospital stay (days)</td>
<td>3.9 ± 2.2</td>
</tr>
<tr>
<td>Total hospital stay (days)</td>
<td>5.6 ± 3.2</td>
</tr>
<tr>
<td>Pulmonary artery pressure at discharge (mmHg)</td>
<td>243 ± 3.9</td>
</tr>
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</table>

ICU: intensive care unit.

### Table 3: Postoperative data