Intraoperative device closure of perimembranous ventricular septal defects: another safe and feasible alternative to surgical repair in infants

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Received 19 September 2011; received in revised form 20 December 2011; accepted 30 December 2011

Abstract

OBJECTIVES: Conventional surgical closure has been considered the gold standard for the treatment of perimembranous ventricular septal defects (PVSDs) in infants for many years, but it requires a cardiopulmonary bypass and midline sternotomy which can lead to both physical and psychological trauma in the future. An intraoperative device closure can be performed with the advantages of reduced invasion, faster recovery and so on. We evaluate the safety and feasibility of intraoperative device closure of PVSDs in infants in comparison with surgical closure.

METHODS: One hundred eighty-six infants with a PVSD were enrolled in our study. Among them, 97 patients were treated by surgical closure and 89 were treated by intraoperative device closure. The success rates, complications, length of hospital stay and costs were measured.

RESULTS: The success rate was similar (P = 0.228) in the two groups: 87/89 patients (97.8%) in the device group versus 97/97 patients (100%) in the surgical group. Complication needs management was required in one patient of the device group (1.1%) and in two patients of the surgical group (2.0%) (P = 1.000). Minor complications were observed in 7/87 patients (8.0%) of the device group versus 15/99 patients (15.2%) of the surgical group (P < 0.001). Both groups were similarly effective in reducing the left ventricular end-diastolic dimension, pulmonary arterial pressure and cardiothoracic rate. The procedure time, inpatient stay and intensive care unit stay are shorter in the device group; the total cost was similar for both groups.

CONCLUSIONS: Intraoperative device closure of PVSDs under real-time transoesophageal echocardiography guidance is safe and feasible without CPB. Under the right conditions, intraoperative device closure can be a good alternative to surgical closure for the treatment of PVSDs in infants.

Keywords: Congenital heart disease • Ventricular septal defect • Surgical repair • Infant

INTRODUCTION

Isolated ventricular septal defect (VSD) is one of the most commonly recognized forms of cardiac malformation and constitutes over 20% of all incidences of congenital cardiac disease [1]. Perimembranous ventricular septal defects (PVSDs) account for nearly 80% of isolated VSDs, and are located in the membranous septum and the adjacent muscular septum. Conventional surgical closure has been considered the gold standard for the treatment of PVSDs for many years [2], but it requires a cardiopulmonary bypass (CPB) and midline sternotomy, which can lead to both physical and psychological discomfort in the future [3, 4]. Recently, transcatheter device closure has become another standard treatment for VSDs, especially for perimembranous defects and muscular defects. The transcatheter closure technique has advantages such as reduced trauma, faster recovery and shorter hospital stay, but cannot always be used in infants due to the small diameter of their vessels. Use of the transcatheter technique presents additional challenges in Third World nations because it requires more advanced equipment and is significantly more expensive than conventional surgical closure. We present a technique that uses an intraoperative closure device with a minimally invasive surgical technique under the guidance of transoesophageal echocardiography (TEE), which does not require CPB or sternotomy and has better cosmetic results than open cardiac surgery [5, 6]. This technique is easy to learn and the costs are acceptable for Third World nations.

The purpose of this study is to determine whether intraoperative device closure using our technique is safe and feasible for treating PVSDs in infants by comparing it with surgical closure with regard to safety, effectiveness, complications, hospital stay and cost. The results are encouraging.
MATERIALS AND METHODS

The study was approved by the ethics committee of our hospital and complied with the tenets of the WMA Declaration of Helsinki. Written informed consent was obtained from the parents of patients.

Devices

The intraoperative device closure system consists of a trocar, guidewire, expander, delivery sheath, loading sheath and SHSMA occluder (Shanghai Xingzhuangjiyi Alloy Material Co., Ltd., China) (Fig. 1) [7]. Asymmetric and symmetric occluders are available, both of which are self-expandable, shape-memory functional, double-disc devices made from an alloy of nickel and titanium. The occluder can be divided into three parts: a left ventricular disc, a right ventricular disc and a waist connecting the two discs. The only difference between the occluders is the shape of the left ventricular disc. On the asymmetric occluder, the left ventricular disc is eccentric, with the aortic side of the disc 1 mm wider than the waist to prevent impingement of the aortic valve, and the apical side 5 mm wider than the waist to prevent the occluder from getting displaced. The apical side has a platinum marker that is used to guide device orientation. On the symmetric occluder, both discs are circular and are 2 mm wider than the waist. The occluder is sized according to the waist diameter, which ranges from 4 to 18 mm.

Patients

From January 2009 to July 2010, we prospectively collected data from 186 patients with isolated PVSDs who were treated at our institution. Patients were enrolled if they had significant clinical symptoms (frequent respiratory infections, failure to thrive or repeated heart failure) or had a haemodynamically significant left-to-right shunt, significant heart enlargement or mild-to-moderate pulmonary hypertension. Exclusion criteria were: (i) non-restrictive or malaligned PVSD; (ii) moderate-to-severe aortic valve prolap or aortic regurgitation; (iii) right-to-left shunt; (iv) New York Heart Association functional class IV; (v) pulmonary arterial pressure (PAP) ≥ 75 mmHg or pulmonary vascular resistance >8.0 Wood units/m² with vasodilatation; (vi) PVSD diameter < 3 mm or > 12 mm; (vii) other coexisting cardiac anomalies; and (viii) infective endocarditis. Patients with suitable margins on transthoracic echocardiography (TTE) were offered the intraoperative device closure. The device closure group included 89 patients (42 males and 47 females), in the age range of 5 to 24 months (8.7 ± 3.1 months) and weighing 6.9 to 15.5 kg (9.8 ± 1.8 kg). The surgical closure was performed in patients with deficient margins on TTE, patients in whom attempted non-surgical closure had failed and patients who had defects suitable for the non-surgical closure but whose parents opted for surgery. The surgical closure group included 97 patients (48 males and 49 females), ranging in age from 3 to 24 months (6.1 ± 2.9 months) and weighing 5.6 to 14.7 kg (7.7 ± 1.9 kg). Full TTE was performed on all patients using a GE Vivid7 ultrasound system to confirm the diagnosis of PVSD and assess the margins for closure, especially the aortic valve edge. All patients underwent routine clinical examination, chest X-rays, electrocardiography (ECG) and blood tests. Of all the patients, six had trivial-to-mild tricuspid regurgitation, 67 had mild pulmonary hypertension (pulmonary artery systolic pressure 30–45 mmHg on TTE) and 8 patients had moderate pulmonary hypertension (pulmonary artery systolic pressure 45–75 mmHg).

Intraoperative device closure

Patients were placed in the supine position under general anaesthesia. The VSD shape and size, and its relationship with the aortic valve and the adjacent structures were reassessed by TEE before the operation [8]. An asymmetric occluder was used if the distance between the VSD and the aortic valve was less than 2 mm; otherwise a symmetric occluder was used. The occluder size was chosen according to the largest diameter of the PVSD, with the size of the waist 1–2 mm larger than the diameter of the defect. A 3 cm inferior median sternotomy incision was made 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. The activated clotting time was maintained at >250 s. To determine the puncture site, the free RV wall was palpated lightly to locate the area of maximal thrill corresponding to the PVSD location. An 8-mm diameter purse string suture was placed at the puncture site. A short trocar was punctured into the right ventricle through the purse string suture, and a guidewire was passed through the trocar and the PVSD under TEE guidance. An expander was passed over the guidewire to enlarge the puncture spot slightly. A delivery sheath was advanced over the guidewire into the left ventricle, establishing the delivery pathway (Fig. 2). The guidewire was then removed and the delivery sheath was filled with blood, ensuring that there was no air entrapment. The occluder was screwed onto the delivery cable and loaded into the loading sheath, which was introduced into the delivery sheath. The delivery sheath was pulled back slowly, and the left ventricular disc was deployed when the tip of the loading sheath was in the left ventricle and at the correct distance from the aortic valve (Fig. 3). If an asymmetrical occluder was used, it was rotated slightly until the platinum marker on the apical side pointed downwards, and then the waist and the right ventricular disc were deployed (Fig. 4). A to-and-fro motion of the sheath was performed to ensure its secure position across the defect. If TEE confirmed the absence of the significant residual shunt, the absence of the moderate-to-severe aortic, pulmonary or tricuspid regurgitation and the absence of left or right ventricular outflow tract obstruction, the occluder was released by rotating the delivery cable counterclockwise. The sheath and the delivery cable were withdrawn and the suture was tied snugly. The chest was closed routinely and a drainage tube was placed. Oral aspirin was given for 3 months as an anticoagulant.
Surgical closure was performed by two cardiothoracic surgeons under general anaesthesia in 97 patients using standard CPB techniques and an autologous pericardial patch as described in the literature [9]. A standard median sternotomy was used in all patients.

Statistical analysis

All data were processed using SPSS version 11.5. Continuous variables are presented as mean ± standard deviation, and comparisons of continuous variables between groups use the independent sample t-test. Comparisons of categorical variables between groups use Fisher’s exact test. A P-value < 0.05 was considered significant.

RESULTS

Clinical data

Table 1 shows comparisons of the basic patient characteristics between the two groups, which differed demographically and anatomically.

Procedure success and complication rates

There were no deaths in either group. Occlusion was successful in 87 of 89 patients (97.8%) in the device closure group, which involved the use of 61 symmetric devices and 26 asymmetric devices. Device placement failed in the remaining two patients (2.2%) because of one case of transient complete atrioventricular block (AVB) and one case of moderate residual shunt. The AVB developed when the left disc was deployed, and quickly resolved after the disc was retrieved. The other patient experienced residual shunt after complete release of both discs. Both these patients underwent surgical closure and were moved to the surgical closure group. Among the 87 patients with a successful closure, the immediate complete closure rate was 74.7% (65/87), with a tiny smoke-like residual flow was detected immediately after the procedure in 22 patients.

One major complication was observed in the device closure group, which was a case of complete AVB which developed on the fifth day after surgery. This patient regained sinus rhythm after a 3-day course of corticosteroid therapy, and no temporary or permanent pacemaker implantation was required. Minor complications were observed in 7 of 87 patients (8.0%) in the device closure group before discharge, including three cases of new-onset trivial or mild tricuspid regurgitation, two cases of transient incomplete left bundle branch block and two cases of atrial premature beats. All four cases of arrhythmia recovered spontaneously or with a short course of anti-arrhythmic drug therapy. No increase in regurgitation was observed in those with preoperative tricuspid regurgitation. Blood transfusion was required in the first eight cases due to loss of blood, however, with the recent experience of the surgeons, the remaining patients did not require transfusion. There were no episodes of pleural effusion, endocarditis, thromboembolism, aortic regurgitation or permanent rhythm disturbance.

Occlusion was successful in all 97 patients in the surgical closure group. Two major complications were observed before discharge, including one case of global pericardial effusion (250 ml in the first 24 h) and one case of Mobitz type II AVB. The patient with pericardial effusion underwent surgical drainage and pericardial sclerosis. The patient who developed Mobitz type II AVB regained sinus rhythm after a 2-day course of corticosteroid therapy. Minor complications were observed in 15 of 99 patients.
(15.2%) in the surgical closure group before discharge, including two cases of atrial premature beats, three cases of transient incomplete right bundle branch block, two cases of mild pericardial effusion, seven cases of pneumonia and one case of mild residual shunt at 1 week after surgery. The residual shunt was successfully occluded by the intraoperative device closure. All five cases of transient arrhythmia recovered spontaneously or with a short course of anti-arrhythmic drug therapy. All patients in the surgical closure group needed blood transfusion. There were no episodes of pneumothorax, pleural effusion, endocarditis, thromboembolism, permanent rhythm disturbance or new-onset aortic or tricuspid regurgitation.

**Non-invasive follow-up**

We established a standard follow-up protocol. All patients were asked to return to our institution for review every month for the first 3 months, and then once every 3 months. Routine follow-up included chest X-ray, ECG, TTE and urine test. TEE was used to determine the position of the occluder, tricuspid and aortic valve motion, residual shunt, left ventricular end-diastolic diameter (LVEDD) and PAP. ECG was used to detect arrhythmia, chest X-ray was used to determine the cardiothoracic ratio and the urine test was used to detect haemolysis.

The follow-up rate was 100%. The total follow-up period was in the range of 13–32 months (20.5 ± 3.2 months). All occluders remained in a stable position with an optimal shape. All residual shunts disappeared during the first 3 months after surgery, and the closure rate remained 100% at the 3-month follow-up. All patients had normal sinus rhythm and a normal PR interval, with no late-onset AVB or other arrhythmias detected. In one of the three patients with new-onset trivial or mild tricuspid regurgitation the regurgitation decreased, and in the other two patients the regurgitation remained stable. No worsening regurgitation was observed in those with preoperative tricuspid regurgitation, and no new-onset tricuspid regurgitation or aortic regurgitation was found during follow-up. Reductions in the LVEDD, cardiothoracic ratio and PAP were expressed as a percentage change relative to preoperative measurements. Compared with pretreatment values, both groups had a significant reduction in the LVEDD, PAP, right ventricular systolic pressure and cardiothoracic ratio. The reduction in the right ventricular systolic pressure at the 1-month follow-up and the reductions in the PAP, cardiothoracic ratio and LVEDD at the 12-month follow-up were similar in both groups.

**DISCUSSION**

PVSD is one of the most commonly recognized forms of congenital heart disease and accounts for over 80% of all VSDs. Some infants with PVSD are asymptomatic and can be treated when they are older. However, some infants who suffer from congestive heart failure, frequent respiratory infections, failure to thrive, significant heart enlargement or progressive mild-to-moderate pulmonary hypertension need early medical treatment. Open-heart repair with midline sternotomy and CPB has been considered the gold standard for the PVSD closure for many years. Surgery has been proved safe and effective, but operative trauma, postoperative discomfort, scar formation, adverse effects of CPB, long hospital stay and the potential risks associated with blood transfusion are inevitable. With the recent development of minimally invasive techniques, the transcatheter device closure has become another standard treatment for PVSD [10], but cannot be used in some infants because of the small diameter of their vessels. Many hospitals in Third World nations are also not able to meet the high costs of the equipment required for the transcatheter closure. Our technique combines intraoperative device closure with minimally invasive

<p>| <strong>Table 1:</strong> Characteristics and outcomes of patients according to the treatment |
|---------------------------------|-----------------|-----------------|-----------------|</p>
<table>
<thead>
<tr>
<th><strong>Device group</strong></th>
<th><strong>Surgical group</strong></th>
<th><strong>P-value</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>89</td>
<td>97</td>
</tr>
<tr>
<td>Gender (male/female)</td>
<td>42/47</td>
<td>48/49</td>
</tr>
<tr>
<td>Average age (months)</td>
<td>8.7 ± 3.1</td>
<td>6.1 ± 2.9</td>
</tr>
<tr>
<td>Average weight (kg)</td>
<td>9.8 ± 1.8</td>
<td>7.7 ± 1.9</td>
</tr>
<tr>
<td>Average VSD size (mm)</td>
<td>5.1 ± 1.5</td>
<td>6.4 ± 1.7</td>
</tr>
<tr>
<td>Procedure success</td>
<td>87/89</td>
<td>97/97</td>
</tr>
<tr>
<td>Procedure time (min)</td>
<td>36.3 ± 7.4</td>
<td>108.7 ± 19.5</td>
</tr>
<tr>
<td>Complication rate</td>
<td>8/87</td>
<td>17/99</td>
</tr>
<tr>
<td>Complication need management</td>
<td>1/87</td>
<td>2/99</td>
</tr>
<tr>
<td>Pressure gradients across PVSD (mmHg)</td>
<td>51.7 ± 17.1</td>
<td>49.1 ± 16.5</td>
</tr>
<tr>
<td>RVSP preoperation (mmHg)</td>
<td>14.1 ± 4.2</td>
<td>13.3 ± 3.8</td>
</tr>
<tr>
<td>RVSP at 1-month follow-up (mmHg)</td>
<td>11.8 ± 3.6</td>
<td>11.2 ± 3.2</td>
</tr>
<tr>
<td>Decrease in LVEDD at 12 months (%)</td>
<td>10.4 ± 5.7</td>
<td>9.5 ± 4.4</td>
</tr>
<tr>
<td>Decrease in CT rate at 12 months (%)</td>
<td>7.2 ± 2.3</td>
<td>7.8 ± 1.9</td>
</tr>
<tr>
<td>Decrease in PAP at 12 months (%)</td>
<td>25.1 ± 7.1</td>
<td>24.2 ± 8.6</td>
</tr>
<tr>
<td>Average ICU stay (days)</td>
<td>0.8 ± 0.3</td>
<td>2.5 ± 1.1</td>
</tr>
<tr>
<td>Average inpatient stay (days)</td>
<td>9.1 ± 3.1</td>
<td>14.3 ± 3.3</td>
</tr>
<tr>
<td>Total cost (RMB)</td>
<td>27 778.6 ± 2,160.5</td>
<td>26,939.7 ± 2,644.9</td>
</tr>
</tbody>
</table>

LVEDD: left ventricular end-diastolic diameter; RMB: Renminbi (unit of Chinese currency); PAP: pulmonary arterial pressure; RVSP: right ventricle systolic pressure; CT: cardiothoracic.
surgery under TEE guidance, which is less invasive and has better cosmetic results than open cardiac surgery. This method is easy to learn and the cost is acceptable for Third World nations.

Regular open-heart surgical closure needs a midline sternotomy to provide a clear operative view. The intraoperative device closure technique does not require CPB, and only requires a 3.0 cm incision, which leaves a smaller and more cosmetically acceptable scar. It is easy to extend the incision for conversion to regular open-heart surgical closure if intraoperative device closure fails, with no need for additional incisions or for moving from the catheterization laboratory to the operating room. The absence of CPB results in a significantly shorter procedure time, with the skin-to-skin time in our series being 25–50 min. Device placement and residual shunts can be evaluated in the beating heart by TEE during the whole procedure, which enables precise placement of the device, and indicates when a repeat placement is necessary [11].

In our study, we applied the same criteria that cardiologists use to choose PVSDs considered suitable for the intraoperative device closure. The success rate was similar in the two groups ($P = 0.228$), with no deaths in either group. Both surgical and device closures are safe and effective for the treatment of PVSDs. The two patients in the device closure group in whom the procedure failed successfully underwent surgical closure. One patient with a residual shunt after surgical closure successfully underwent an intraoperative device closure. These cases illustrate that both techniques can be used as a backup procedure when the primary procedure fails. Interestingly, we found that the patients in the device closure group were generally older and heavier with smaller PVSDs than patients in the surgical closure group. This is probably the key to achieving good results for device closure. Xunmin et al. [1] also reported these differences when using the Amplatzer device to close PVSDs in 2007. They explained this phenomenon by the selected nature of the groups, with the technical limitations of device closure favouring smaller defects in older patients. We accepted these differences between groups as inevitable in this study.

Accurate assessment of the size and location of the PVSD is important for the success of the intraoperative device closure technique. It is necessary to perform a morphological assessment of the PVSD by TTE to determine the location, size and relationship to the aortic valve. If the distance from the aortic valve to the rim of the PVSD is less than 2 mm, an asymmetric occluder should be selected. During the operation, it is advisable to rotate and move the sheath by hand until the platinum marker on the apical side points downwards and the flat part of the disc is not placed directly adjacent to the aortic valve. This helps avoiding impingement of the aortic valve and aortic regurgitation. No patients in this study developed aortic regurgitation. The size of the occluder was chosen by measuring the largest diameter of the PVSD and adding 1–2 mm to it. An oversized occluder is likely to injure the surrounding tissues, especially the conduction system, and cause arrhythmia. Three patients in the device closure group developed new-onset tricuspid regurgitation, which may have been due to interference of the right ventricular disc with the leaflets of the tricuspid valve. No worsening of regurgitation was observed in patients with preoperative tricuspid regurgitation, and no patients developed tricuspid regurgitation during the follow-up period. However, further follow-up is needed to determine long-term results.

Arrhythmia was the most common complication in both groups, and an AVB was the most serious complication. Some studies have reported a 1–5% incidence of an AVB after transcatheter device closure of PVSDs [12–14]. However, we experienced a lower rate of AVB in our study. Our approach through a smaller and lower sternotomy results in a shorter entrance route and less turns of the catheter inside the heart, making it easier to approach the PVSD perpendicularly and to properly adjust the anchoring of the device. The incidence of conduction system injury from the delivery system or occluder seems to be lower in our series than in other series of the transcatheter device closure. The mechanism causing an AVB is not clear, but we presume that it is related to the proximity of the conduction system to the rim of the PVSD. Three possible explanations for the development of an AVB are: (i) direct traumatic compression of the conduction tissue after the occluder is deployed; (ii) oedema of the tissue adjacent to the conduction system; and (iii) inflammatory reaction or scar formation in the conduction system. An AVB that occurs during the procedure is likely to be due to traumatic compression of the conduction tissue or oedema of the tissue adjacent to the conduction system. Late-onset AVB is more likely to be due to chronic inflammation or fibrosis, and routine follow-up is therefore important. The choice of the correct occluder and administration of intraoperative and postoperative corticosteroids probably reduce the incidence of an AVB. In addition, we found that the incomplete left bundle branch block occurred more often in the device closure group, and the intermittent right bundle branch block occurred more often in the surgical closure group. This is probably because the left bundle branch may be injured during advancement of the guidewire or deployment of the occluder, and the right bundle branch may be injured if surgical closure of the right ventriculotomy injures the right side of the septum.

In patients who underwent a successful device closure procedure, the closure rates were very impressive: 74.7% immediately after device deployment, and 100% at 3-month follow-up. Early shunting is associated with gaps between the occluder and the rim of the defect or in the device itself. Proliferating endotheliocytes eventually cover the occluder, which closes the residual shunt during the weeks following the procedure. Therefore, a trivial or mild residual shunt after the intraoperative device closure is acceptable and can be followed up postoperatively.

Intraoperative device closure and surgical closure were similarly effective in reducing the LVEDD, PAP and cardiothoracic ratio. Data from the 12-month follow-up demonstrate that intraoperative device closure is effective in reducing the PAP, LVEDD and cardiothoracic ratio. This helps to normalize the anomalous haemodynamics and is beneficial for heart structure remodelling. The intraoperative device closure of PVSD also has the advantage of a reduced need for blood products, which reduces the risks associated with blood transfusion such as increased susceptibility to infection.

Patients in the device closure group clearly required a shorter inpatient and intensive care unit stay than the patients in the surgical closure group. This is because of the smaller incision, less severe myocardial trauma and the absence of CPB in the device closure group, leading to much faster recovery than in the surgical closure group. As cost is an important factor influencing the choice of the operation technique in developing countries, we chose a domestically manufactured device to keep medical costs to a minimum. There was no significant difference in the average total cost per patient between groups ($P = 0.396$). The device closure group had a high occluder cost, but had a
lower cost for intensive care and inpatient stay than the surgical closure group, resulting in a similar average total cost in both groups [15–17]. However, this study was conducted in a developing country, and cost-effectiveness calculations in developed countries may be different.

Our study has a limitation. It was conducted in only one institution. A larger, multicentre study is needed to confirm the results.

CONCLUSION

Intraoperative device closure of PVSDs under real-time TEE guidance is safe and feasible without CPB. Under the right conditions, intraoperative device closure can be a good alternative to surgical closure for the treatment of PVSDs in infants.

Conflict of interest: none declared.

REFERENCES


EDITORIAL COMMENT

Know-how transfer from east to west: perventricular closure of perimembranous ventricular septal defects

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Received 17 January 2012; accepted 18 January 2012

Keywords: Ventricular septal defect – Perimembranous – Device – Intervention – Off-pump

Yet another group from China describes their experience on closing perimembranous ventricular septal defects (VSD) in an off-pump fashion through a perventricular approach [1].

Perventricular device closure of a VSD without cardiopulmonary bypass (CPB) under the guidance of epicardial echocardiography was first described in 1998 in an animal model [2]. In humans, perventricular device closures were first reported in 2003, however, limited to patients with a muscular VSD [3]. Device closure of a perimembranous defect, which comprises the largest group of interventricular communications,