Transthoracic device closure of ventricular septal defects without cardiopulmonary bypass: experience in infants weighting less than 8 kg

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Abstract

Objective: Both surgical and percutaneous device closure of ventricular septal defect (VSD) have drawbacks and limitations in infants. We report our experiences and midterm results of transthoracic device closure of VSDs (TDCVs) without cardiopulmonary bypass (CPB) in infants.

Methods: Between September 2007 and September 2009, 32 patients, with a mean age of 7.2 ± 4.7 months, body weight of 6.8 ± 2.8 kg, underwent this procedure. The procedure was performed in the operating room. A small subxiphoid incision was made. A purse-string suture was placed on the right ventricular free wall. The free wall was punctured using a trocar, then a guide wire was inserted and advanced to cross the VSD into the left ventricle under transesophageal echocardiographic guidance. A modified delivery sheath was then introduced over the guide wire. The device was delivered and deployed in position along the sheath to close the defect.

Results: A total of 30 cases (94%) were successfully closed, and the remaining two cases (6%) were converted to open heart repair. No patients received transfusion. There was no perioperative mortality, or any major complication. The mean size of the devices was 7.6 ± 3.4 mm. The total operative time was less than 60 min, and the mean time for device implantation was 18.3 ± 9.4 min. All patients were extubated within 2 h, and were discharged within 5 days after operation. The follow-up period ranged from 6 to 31 months (18.3 ± 9.6 months). There was no late major complication detected.

Conclusion: Minimally invasive TDCV without CPB is a safe and effective alternative to the conventional operation in low-body-weight infants.

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Keywords: Ventricular septal defect; Device closure; Minimally invasive surgery; Off-pump; Infant

1. Introduction

Since the first time when ventricular septal defect (VSD) was surgically closed by Lillehei et al. in 1954 [1], surgical closure has been regarded as the gold standard for treatment. However, this method has been challenged for the past 10 years by percutaneous trans-catheter device closure. A growing number of VSD patients received this new kind of treatment without cardiopulmonary bypass (CPB) and related risks, residual surgical scar and psychological complication [2]. However, trans-catheter closure is only indicated for a limited group of VSD patients, and several aspects of drawbacks should also be concerned, such as being difficult to manipulate, which increases cardiac catheterization time, radiation, risk of arrhythmia, interference with aortic (AVs) and tricuspid valves, and quite frequent significant residual shunting. When encountering in small infants or patients with poor vascular access, catheter closure also remains being challenged [3,4]. Recently, off-pump transthoracic device closure of VSDs (TDCVs) in perimembranous VSDs (pVSDs) and muscular VSDs under echocardiographic guidance is being increasingly performed with excellent midterm results [5–8]. Having mastered the learning curve of TDCV since September 2007, we began to use this technique in infants. In this communication, we describe our experience of TDCV on beating heart without CPB in 32 infants with body weight less than 8 kg.

2. Patients and methods

We chose the patients according to the surgical indications for isolated VSDs: refractory heart failure with medications; repeated respiratory infection; tardiness of body development; evidence of left-heart volume overload; and history of previous endocarditis. Exclusion criteria: non-restrictive or malaligned VSDs; those with inlet extension of the VSD; VSD with significant aortic prolapse; newborn or young infants with large VSD and severe pulmonary hypertension; and those who could not be followed up.

Between September 2007 and September 2009, 32 patients with VSDs underwent TDCV without CPB, aided by a newly designed delivery system. The patients’ general...
characteristics are listed in Table 1. Transthoracic echocardiography (TTE) also demonstrated that nine patients with pmVSDs and one patient with muscular VSD had trace or mild preoperative tricuspid regurgitation (TR). Two patients were detected with trace-to-mild aortic regurgitation (AR) before operation. Second-degree atrioventricular block (AVB) was preoperative recorded in one patient.

The study was approved by the institutional ethics committee. The nature, advantages and disadvantages of this new technique were fully explained to each patient’s family, compared with conventional open heart repair with CPB and percutaneous trans-catheter closure. Individual informed consents were obtained from the patients’ guardians.

2.1. Devices and delivery system

The occluder used in our group was modified from the Amplatzer (AGA Medical Corporation, Plymouth, MN, USA) atrial septal defect and membranous VSD occluder, made by Shanghai Shape Memory Alloy Co., Ltd., Shanghai, China and Lifetech Scientific (Shenzhen) Co., Ltd., Shenzhen, China. It is a self-centering and repositionable device, consisting of two disks and a connecting waist with a polyester mesh inside. A female screw is welded in the center of the right disk for attachment to the delivery cable. The size of the device corresponds to the waist dimension of the device. Four types of occluders were supplied in this cohort: concentric (symmetrical) and eccentric (asymmetrical) occluders for pmVSDs closure and regular muscular and patent ductus arteriosus (PDA) occluders for muscular VSDs closure, which were similar to that in our previous studies [6,8] (Fig. 1). We recommended a device with a waist size 1—2 mm larger than the VSD diameter, an eccentric occluder for pmVSDs with the margin less than 2 mm from the AV, a concentric occluder for other kinds of pmVSDs, and a regular muscular or PDA occluder for the muscular VSDs.

The entire delivery system was modified by Dr Quansheng Xing, including an 18-gauge trocar, a flexible guide wire, a dilator, a delivery sheath, a delivery cable, and a loading sheath (Fig. 2). The total length of the device delivery system ranged from 20 to 30 cm. The device is available in sizes ranging from 4 to 18 mm, with 1-mm increment. The size of the selected delivery sheath is dependent on the device size and ranges from 5F to 9F.

2.2. Implantation technique

TDCV was performed in the operating room under general anesthesia and transesophageal echocardiography (TEE) guidance in the operating room. The VSD shape, size, and adjacent structures, especially its relationship with the AV, was reassessed with TEE before operation. Access was through a small incision of 3—4 cm, subxiphoid or inferior sternotomy. A small pericardiotomy was performed and the pericardium was cradled to expose the free wall of the right ventricle (RV) (Fig. 3).

Under continuous TEE monitoring, the RV free wall was gently pressed with the index finger of the surgeon. This

![Fig. 1](image1.png)

![Fig. 2](image2.png)
could be clearly visualized by TEE. By repeated probing, a puncture site was chosen, which is away from coronary arteries and papillary muscles. Then, a purse-string suture of 5/0 Prolene (Ethicon Inc, Somerville, NJ, USA) was placed at the site. After systemic heparinization (1 mg per kilogram of body weight), an 18-gauge trocar was punctured into the RV cavity within the purse-string suture, and a 0.035-in. flexible guide wire was passed through the trocar and advanced toward the shunt orifice in RV under TEE guidance, crossing the defect into the left ventricle (LV) cavity (Fig. 4(A)). Then, a dilator sheath was fed over the wire and carefully advanced into the LV cavity to establish the delivery pathway (Fig. 4(B)). The wire and dilator were removed and a loading sheath with an appropriate occluder in it was connected to the delivery sheath. The LV disk of the occluder was deployed by gently pushing the cable along the delivery sheath, making sure it was not engaged in the tension apparatus of the mitral valves (Fig. 4(C)). The entire system was then pulled back onto the LV surface of the defect, and the sheath was pulled back, allowing the occluder’s waist and RV disk to open (Fig. 4(D)). If an eccentric device was used, the device would be rotated gently to align the marker on the opposite side of the AV (Fig. 4(C) and (D)).

The device could be easily retracted into the sheath and redeployed in case of inappropriate position of the occluder causing valvular regurgitation or other abnormalities. We can also shift to another puncture site on the RV free wall, if necessary. After multiplane TEE assessing, if anything more than mild residual shunt, new aortic insufficiency, or more than mild TR were identified, the patient would be converted to conventional repair with CPB. If none of the above was found, the device was completely released by rotating the cable anticlockwise. The pericardium was left open and a chest tube was placed in the mediastinum. The rest of the wound closure was routine.

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Fig. 3. (A) 3 cm inferior sternal incision and inferior median sternotomy, an 18-gauge trocar has already been punctured into the right ventricle through the free wall, and the guide wire was inserted. (B) The incision was sutured after the procedure.

Fig. 4. Schematic and transesophageal echocardiography (TEE) picture illustrating the steps involved in deployment of asymmetrical device through the right ventricular free wall: (A) An 18-gauge trocar was punctured into the right ventricle through the free wall and a 0.035-in. flexible guide wire was advanced through the trocar to pass the defect. (B) The dilator and delivery sheath were advanced over the guide wire through the defect into the left ventricle. (C) The guide wire and the dilator were removed, then the loading sheath was introduced into the delivery sheath, and the device was advanced to the tip of the sheath. Left disk was deployed in the left ventricle, and adjusted by the platinum mark on the left disk, to make the hyperechoed mark rightly deviate from aortic valve and face to the apex. (D) Device and sheath were pulled to approximate ventricular septum. Right disk was deployed. After completely TEE assessing for absence of residual shunting, left and right ventricular outlet tracts obstruction, valve interference and arrhythmia, the device was released.
2.3. Follow-up

All subjects were monitored in the intensive care unit (ICU) until extubation, and urinalysis was performed daily to exclude hemolysis for 3 days. Antiocoagulation therapy with aspirin 3 mg kg⁻¹ day⁻¹ p.o. was prescribed for 3–6 months. Electrocardiography (ECG), and TTE were performed before discharge. Outpatient follow-up was at 1 month, 3 months, 6 months, 1 year, and then yearly, respectively, with clinical examination, ECG, and TTE.

All the patients were strictly followed up according to a standard protocol, by two doctors who are specially appointed. Follow-up data were established for each patient, and the follow-up rate was 100%.

2.4. Data analysis

All continuous variables are expressed as mean ± standard deviation (SD) with range, and nominal variables are presented as percentages.

3. Results

3.1. Intra-operative and early postoperative results

Device implantation was successful in 30 patients (93.8%). Two (6.2%) patients failed the attempt and then were converted to traditional intracardiac repair because of moderate device-related AR in one and arrhythmia after repeated attempts in the other. The procedural data are summarized in Table 2. No patients received transfusion. Two patients with pmVSDs were detected with trace and mild residual shunt after device closure, respectively. None of the nine pre-existing TRs worsened after the closure; in fact, five of them diminished from mild to trace immediately after the closure. Three patients with pmVSDs developed new trace or mild TR, and one patient developed incomplete right bundle branch block after the procedure. The two patients with pre-existing trace-to-mild AR and one patient with second-degree AVB remained the same as before. There was no incidence of device embolization or complete AVB.

The total operative time was 45.2 ± 16.1 min (range, 35–58 min). The intubation time in the ICU room was 50.8 ± 36.6 min (range, 28–120 min), except three patients who were extubated in the operating room. The ICU stay was 12.7 ± 13.1 h (range, 3–48 h). Total drainage was 4.5 ± 2.1 ml kg⁻¹ (range, 3–6 ml kg⁻¹), and the drainage tube was removed 1–2 days after the operation. The mean postoperative hospital stay was 3.7 ± 1.1 days (range, 3–5 days).

3.2. Follow-up results

Follow-up data were available for all patients. The follow-up period was 18.3 ± 9.6 months (range, 6–31 months). No deaths or cases of endocarditis occurred. Patients with frequent respiratory infections had no significant recurrences. The cardiac function was New York Heart Association (NYHA) class I in all subjects. Mild residual shunt in one patient diminished to trace at the latest follow-up, 6 months after the operation, and the other residual shunt remained trace at the latest 3-month follow-up, the same as just after the operation. During the entire follow-up period, no complete AVB, new or aggravating AR or TR, obstruction of left or right outflow tract, or device dislocation has been detected. There was also no thrombosis or hemolysis. The two pre-existing ARs remained trace to mild as before. The lower sternal incisions caused minimal cosmetic concern.

4. Discussion

In the past 20 years, cardiac surgeons and cardiologists have been trying their best to modify the interventions of VSDs to minimize the drawbacks for both surgical repair and trans-catheter closure. The main directions are minimally invasive congenital cardiac surgery with the aim of less trauma, and modifying occluders or the delivery system for percutaneous trans-catheter intervention. However, the results are not very satisfactory. Neither systemic inflammatory reactions from CPB, intra-operative cardiac arrest, and blood products’ transfusion for cardiac surgery, nor limitation due to thin peripheral vessels in low-weight infants and X-ray exposure for trans-catheter intervention were completely avoided. For infants with low body weight, catheters are difficult to manipulate, leading to increasing cardiac catheterization time and radiation, creating significant aortic or tricuspid insufficiency and injuring the conductive system or the peripheral vessels [9]. Most of the published literature indicated that the patients with VSDs weighted less than 8–10 kg are not suitable for transcatheter closure [9–15].

Consequently, many scholars have sought to integrate the two methods as a hybridization, which is called TDCV, to avoid potential complications from the traditional cardiac surgery and percutaneous intervention. This technique simplifies VSD closure, requiring excellent collaboration between the echocardiographer and the cardiac surgeon. The whole process can be monitored and guided by TEE in the operating room. Once a patient is considered not suitable for such a procedure or the procedure is not smooth, the surgeon can easily extend the incision, partly or completely open the sternum, and convert to traditional surgical repair in the same setting. It avoids additional incision or transferring the patient from the catheterization laboratory to the operating room, ensuring the safety of the procedure. The potential
complications of CPB, cardioplegic arrest, cardiac catheterization, and fluoroscopy are all eliminated. In addition, the procedure is performed on beating heart. Thereafter, the closure rate and the integrity of the AV and tricuspid valve are evaluated in real time during the whole procedure. The procedure time will be shortened and the potential complications decrease.

At the beginning of our experience, we were afraid that, for infants, the disks protruding into the outflow tract might result in RV or LV outflow tract obstruction. However, in our group, the lowest weight was 4 kg, and the infant was implanted an 8-mm occluder. The occluder looked too large relative to the heart size from the echocardiographic views, but blood flow in the two outflow tracts was normal, as shown in the figures. Predescu et al. [16] sought to close large pmVSDs with Amplatzer membranous VSD occluders in several small children. Despite an unacceptably high rate of complete AVB (22%), there were excellent results for immediate closure, and no outflow obstruction was observed during the follow-up of a median 23.1 months (range, 1–37.8 months). However, in the long term, it should be further evaluated if heart function is affected with a relatively larger device in it.

New aortic incompetence is a serious complication and has occasionally occurred in trans-catheter closure of pmVSDs even though using the Amplatzer pmVSD device [9–15]. Unlike muscular VSDs, pmVSDs lie much closer to the AV, and there is potential for injuring the valve with the delivery sheath, catheter, or device. In our group, there was no evidence of AV insufficiency on the basis of follow-up data. In addition to selecting appropriate eccentric occluders, it might be due to the fact that the newly designed delivery system we used is very short (only 20–30 cm long), which can be easily held in one hand without rapid turning of the catheter inside the heart. Hence, one operator can perform the whole procedure. For precise positioning of the device, with the flat side toward the AV, we can rotate the entire delivery assembly much easier clockwise or anticlockwise than in the percutaneous approach from the groin [9]. The guide wire and sheath also can be easily kept away from the AV to avoid damaging it. As for TR, the procedure has no need to establish an arteriovenous circuit crossing the tricuspid valve as in the percutaneous technique. This might be the real reason why we have not seen obvious injury to the tricuspid valve, although the possibility exists. If there is any new aortic or significant tricuspid incompetence developing during the procedure, we can convert to conventional CPB repair. In the operating room, it is relatively easier [7,8,12].

The occurrence of complete heart block has to be regarded as the most important complication in percutaneous closure of pmVSDs [2,4,9,10,16–20]. However, similar to our results reported previously [6,8,10,15], there was no acute- or late-onset complete AVB in our series, which is favorable when compared with the reported incidence of complete AVB after trans-catheter device closure [9,16]. As is mentioned above, TDCVs need only a short pathway and an easily controllable set. The guide wire and sheath need less than 5 cm advancement from the RV free wall to the left-ventricular cavity, vertically crossing the VSD as opposed to the percutaneous approach with arteriovenous circuit crossing tricuspid valves and oblique angle. Therefore, the modified delivery system may reduce ribbing and compressing the tissues near the conductive bundles around the VSD. This may be one important reason why there was no immediate serious complete AVB in our patients.

As for the late-onset complete AVB, the current occurrence rate of complete AVB after pmVSD closure by interventional cardiologists is 1–5%, according to the data published [2,4,9,17–20]. Recently, Predescu et al. [16] reported the occurrence rate is 22%, much higher than all other published studies.

We present a discussion about no late complete AVB in our patients.

The pmVSDs shape and the occluder shape: The simple anatomic classification of a VSD in the perimembranous region belies wide variability of its shape. This begs the question whether one device shape can fit all kinds of pmVSDs, and, more prudently, whether such a device can avoid damaging the conducting tissue [16]. In most centers, only one type of device, the Amplatzer eccentric occluder, was used for pmVSD closure [2,4,16–20]. Eccentric devices for closing pmVSDs have provided excellent rates of closure, but the occurrence of complete AVB remains a concern [9,16]. In our cohort, we used two kinds of device for pmVSDs, the concentric one for those having more than 2-mm distance between the superior rim of the defect and the AV, and the eccentric one for those with no or less than 2-mm rim distance. We estimate the larger left disk of the eccentric device maybe an important cause resulting in complete AVB because it is just beneath the apex of the Koch triangle through which the conductive tissue passes to divide branches.

The device sizing: Progressive device flattening of an originally oversized device has been hypothesized as a mechanism for the development of complete AVB [9]. The occluders we used were often no more than 1 mm, rarely 2 mm larger than the VSD diameter, and almost no oversized occluder was used. Furthermore, with the easily controllable delivery set, we often initially choose a smaller device; if inappropriate, we can change a second or third one by 1-mm increments, which avoids an oversized device.

In addition, compared with cardiologists, the cardiac surgeon may be more familiar with the anatomy of VSD and its’ surrounding tissue because they almost encounter the real and live heart every day. In our series, we strive to choose the device according to the VSD location, shape, size, and surrounding structure.

As for the muscular VSDs, although most of them are relatively far from the AV, conventional surgical repair and trans-catheter closure are known to have undesirable limitations. Owing to the unique locations of some of the muscular VSDs, especially those in the apical or anterior region of the ventricular septum, direct surgical repair with CPB and cardioplegic arrest can present significant difficulties. In 2000, clinical experience with percutaneous trans-catheter closure of single muscular VSDs with the Amplatzer occluder (AGA Medical Corporation, Plymouth, MN, USA) was first described [21]. However, this approach has a major limitation in younger children due to the disparity between the sizes of the sheaths and the patients’ access vessels. TDCV of muscular VSDs was first described in 1998 [22], and was refined in 2003 after a consecutive series of six patients, with encouraging results [23]. Compared with percutaneous approaches, this technique has no weight and vascular access.
limitations. In 2003, Bacha et al. [23] reported a 17-day-old, 3-kg neonate with a large anterior muscular VSD, who was easily successfully closed with a 12-mm device via a minimally invasive subxiphoid incision. More recently, good early- and midterm results have been reported by us and another center [7]. We suggest an individual treatment strategy according to the location, number, and size of the defect. For apical muscular VSDs, we should consider which kind of device is more appropriate, a regular muscular VSDs occluder or a PDA-like one? Our initial experience also suggested that PDA occluders can be effectively used to close apical muscular VSDs because the geography of the apex makes it difficult or impossible to deploy the regular right disk of the occluder. For multiple muscular VSDs, we should comprehensively consider which is more appropriate, using a larger device or using two or more relatively small ones to occlude the whole muscular VSDs? We sometimes have attempted to try different devices or methods until optimal results were achieved. As mentioned above, the new technique makes it possible to easily establish the pathway and retrieve and redeploy different devices during the procedure. In our group, even for pmVSDs, it may be one of the most important reasons why no major early or later complication was detected during follow-up.

5. Clinical limitations

The present report demonstrates the feasibility of off-pump VSD device closure, through RV free wall puncture under TEE guidance, using a modified occluder and delivery system in very young children. The risk of very long-term problems with the late-onset complete AVB, AVs or tricuspid valves and heart function remains unknown. Large studies and long-term follow-up will be needed to clarify the actual safety and effectiveness of this procedure as an alternative to conventional surgery intervention. Because of the complex geometry of the VSDs and the limited patient number of this study, up to now, we are not able to delineate the definitive indications and contraindications of this technique. In terms of what we have reported about minimally invasive TDCV in very young children, this can be considered as routine in only a few experienced centers of pediatric cardiology. Experiences in a small number of patients have to be discouraged.

6. Conclusions

Nowadays, in experienced hands, minimally invasive TDCV with individual treatment strategy in infants and young children, who would otherwise require cardiac surgery, is a safe and effective procedure. In selected patients, this technique can be considered a real alternative to the standard surgical approach, with the advantage of reduced rate of complications.

References


Appendix A. Conference discussion

Dr B. Kreitmann (Marseille, France): I have no comment or concern about the procedure itself because it is well described, well done, and, in fact, although very new, it is becoming more and more standardized in several centers; in China, of course, more than 3000 patients(!), but in Europe and USA, too.

I do have concerns and questions. I am concerned about the indications. For us and most of the teams, the indication for a hybrid procedure will be a very large non-restrictive VSD in the muscular or in the apical septum far away from the bundle and with pulmonary hypertension in small babies. Above 6 to 7 kg, which is the mean weight of your patients, the trans-catheter approach is used more and more, and is well described with very good results.

In perimembranous defects, well, there are a lot of risks, but the risk of AV block is very high, up to 20% in some series. And that is normal because of the elasticity of the prosthesis.

Now, my two questions are: First, why did you exclude large VSDs with pulmonary hypertension? And in this case, what do you do when you have a patient with a large VSD, and pulmonary hypertension in a small baby?

And the second question is: How do you explain the fact that in this series, in contrast to all other authors, you have absolutely no AV block in perimembranous defects?

Dr Z. Hua (Beijing, China): As I mentioned when I started this presentation, Dr Xing, who is the author of the paper, could not come for some personal reasons. He asked me to do him a favor and make this presentation. I am not involved in their work, and have not even watched their procedures. So I am not that experienced to answer this question, but from reading his paper, I think this procedure has its advantages.

But in terms of indications, I think initially I thought in small babies, you do not have to do this procedure at this early stage. But the procedure time is usually less than 60 minutes and I think the intubation time or ICU stay is so short, that these factors may be the reason why you can treat the baby early.

And your question about the pulmonary hypertension issue. I have to admit that I have no answer for that question. But if I get the chance to do that procedure, I think severe hypertension, pulmonary hypertension with big VSD, is not a contraindication. But I do not know for sure why they did not do this because it is not my procedure.

Regarding AV block, by reading the paper, I understand that because their approach was short, there is direct access to the right ventricle. The needle and the guide wire can be pushed in directly, and the angle and device adjusted very easily, whereas a trans-catheter approach is longer, with lots of manipulations which can sometimes tear the surrounding tissue.

Also, because conversion to conventional repair is possible, the position can be adjusted as many times as are required to ensure there is no leak. That is my understanding.

So I do not know. I am not sure I answered your question or not.

Dr Kreitmann: Well, the problem is that AV block has been described after prosthetic closure of perimembranous defect as long as 3 years after the procedure and sometimes with sudden death or life-threatening AV block.

So it is not a matter of procedure. It is not because you go through directly or through the groin, through the defect. It is because the prosthesis is enlarging and pushing on the bundle.

Dr Hua: Yes, it is very true. And the paper said they did not use oversized VSD closures. They just use 1 mm bigger than the VSD size. So that was their explanation.