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Original Article

The Comparison of Perventricular Device Closure with Transcatheter Device Closure and the Surgical Repair via Median Sternotomy for Perimembranous Ventricular Septal Defect

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Background: Perventricular and transcatheter device closures are performed for perimembranous ventricular septal defect (pmVSD) to reduce the surgical trauma of conventional surgical repair via median sternotomy. Few comparative studies have been conducted among these three procedures.
Methods: From June 2015 to May 2016, 247 patients with isolated pmVSD who had undergone perventricular or transcatheter device closure or conventional surgical repair were reviewed to compare these three procedures.
Results: The procedure success rate was similar in these three groups. There were a statistically significant difference in operative time, aortic cross-clamping time, duration of cardiopulmonary bypass (CPB), blood transfusion amount, and medical cost in these three groups. Meanwhile, postoperative mechanical ventilation time, duration of intensive care, and length of hospital stay were longer in surgical group than the other two groups. The surgical group required the longest incision. No significant difference was noted in major adverse events. There were different advantages and disadvantages in these three kinds of procedures.
Conclusions: Device closure may be alternative to conventional surgical repair for patients with isolated pmVSD. Perventricular device closure was the preferred procedure because it showed more maneuverable than transcatheter procedure with the same clinical result.

Keywords: congenital heart diseases, ventricular septal defect, surgery, perventricular devices occlusions, transcatheter

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Introduction

Ventricular septal defect (VSD) is one of the most common congenital cardiac defects, taking up 20% of all forms of congenital cardiac malformations, and 80% of VSDs are perimembranous ventricular septal defects (pmVSD).[1–3] Surgical repair with cardiopulmonary bypass (CPB) and median sternotomy for the VSD has been the golden standard treatment. However, conventional surgical repair is limited by potential risk of neurologic sequelae, morbidity, complete atrioventricular block (cAVB), surgical scar, and

Table 1 Preoperative data comparison among three groups of patients

Item	Group A	Group B	Group C	P
N	86	90	71	
Age (year)	1.4 ± 1.5	1.6 ± 1.3	2.1 ± 0.8	P >0.05
Gender (M/F)	46/40	48/42	35/36	P >0.05
Weight (kg)	9.5 ± 3.1	10.1 ± 2.3	10.6 ± 2.8	P >0.05
Size of VSD (mm)	5.9 ± 1.05	5.3 ± 1.12	5.1 ± 1.04	P >0.05
Pulmonary Hypertension (mm Hg)	41.3 ± 10.5	35.1 ± 5.2	32.1 ± 4.3	P >0.05
Cardiothoracic ratio	0.51 ± 0.10	0.50 ± 0.09	0.48 ± 0.05	P >0.05

VSD: ventricular septal defect

delayed recovery.[4–7] With the development of various device, transcatheter device closure of VSD has gradually become an alternative to conventional surgical repair, especially in patients with perimembranous and muscular defects with a promising success rate of closure.[8–10] During the same period, perventricular device closure of VSD under guidance of transesophageal or transthoracic echocardiography (TEE/TTE) has been widely and successfully applied in China.[11–14] In our institution, we applied perventricular or transcatheter device closure or conventional surgical repair for patients with isolated pmVSD, and by document retrieval we found that the comparative studies conducted among these three procedures were scared. In this article, we compared the early and mid-term results of these three procedures.

Materials and Methods

The present study was approved by the ethics committee of Fujian Medical University, China and adhered to the tenets of the Declaration of Helsinki. Additionally, written informed consent was obtained from the parents of the patients.

In this study, we reviewed the medical records of 247 patients who had undergone pmVSD closure at our hospital between June 2015 and May 2016. There were 86 patients in group A (surgical repair via median sternotomy), 90 patients in group B (perventricular device occlusion), and 71 patients in group C (transcatheter device occlusion). All of the patients' clinical data are shown in **Table 1**. There were no significant differences in gender, age, and body weight distribution among the three groups. Routine clinical examinations were performed, which included a standard lead electrocardiogram, a chest X-ray examination, and routine blood and biochemical tests. All patients enrolled in this study were diagnosed of VSD and were sufficiently assessed by TTE. The inclusion criteria are as follows: isolated VSD and no other intracardiac malformation, significant left-to-right shunt, and ventricular overload with or without pulmonary hypertension. The exclusion criteria are as follows: age below 6 months, weight below 10 kg, respiratory diseases, history of thorax procedure, severe valvular regurgitation, and right-to-left shunt caused by severe pulmonary hypertension. The successful VSD closure was defined as no large residual shunt (<2 mm) was found by postoperative TTE. All the procedures were performed by the same team of surgeons and cardiologists.

VSD occluder

The occluder is self-expandable and double-disk (China-made occluder, Shan Dong Visee Medical Apparatus Co. Ltd. of China and Amplatzer VSD occluder, AGA Medical, Corporation, Plymouth, Minn). Two type of occluders were supplied, asymmetric and symmetric occluder. Asymmetric one, on the left ventricular side of the device, the aortic end of the disk is 1 mm wider than the waist so as to avoid impingement on the aortic valve. The other part on the left ventricular is positioned to be 5–6 mm wider than the waist. A platinum marker on this side was designed to guide device orientation. Symmetric one, both side of the disk is 2 mm wider than the waist. Asymmetric occluder was allowed for a margin of 0–2 mm from the aortic valve, whereas symmetric one was used for a margin of more man 2 mm from the aortic valve. The device is available based on the waist diameter ranging from 6 to 14 mm in 1 mm increments.

Operative technique

In group A, conventional surgical repair was conducted through median sternotomy approach under CPB. Pericardial patch was used in all patients.

In group B, perventricular device closure was performed under general anesthesia in the operating room.

Table 2 Perioperative and postoperative data comparison among three groups of patients

Item	Group A	Group B	Group C	P
Operative time (min)	120.5 ± 18.2	30.6 ± 15.2	73.1 ± 24.6	P >0.05
Aortic occlusion clamping time (min)	39.1 ± 12.3	0	0	P >0.05
Cardiopulmonary bypassing time (min)	56.6 ± 13.5	0	0	P >0.05
Mechanical ventilation time (h)	15.8 ± 4.8	10.5 ± 2.8*	0	P <0.05
Intensive care unit time (h)	22.6 ± 5.8	13.7 ± 2.5*	0	P <0.05
Drainage (mL)	65.4 ± 25.6	28.3 ± 18.8*	0	P <0.05
Blood transfusion volume (mL)	345.1 ± 75.5	45.2 ± 16.6*	0	P <0.05
The incision length (cm)	11.8 ± 2.1	3.1 ± 1.2*	0	P <0.05
Postoperative hospital stay (d)	8.5 ± 3.4	4.2 ± 1.6*	3.9 ± 2.2*	P <0.05
Hospital costs (10000 RMB)	5.53 ± 0.82	3.12 ± 0.25*	3.22 ± 0.43*	P <0.05

*Compared with group A, P <0.05. RMB: Renminbi

Patients were placed in spine position with entire chest exposure. Intraoperative TEE/TTE was used to assess the VSD position, and the circumferential margins, especially its relationship with the aortic valve and tricuspid valve. Minimally incision was made through a lower inferior median sternotomy. The pericardium was opened and cradled to expose right ventricle. Heparin was administered at 1 mg/kg body weight, and it was mandatory to monitor activated clotting time until longer than 250 sec. The location of the right ventricle was punctured within the suture and a floppy wire was inserted and aimed toward the defect under TTE/TEE guidance. The guidewire was slowly advanced through the VSD into the left ventricle, then the dilator was removed, and a selected delivery sheath was introduced through the guidewire into the left ventricle to establish a delivery pathway. The wire and the inner dilator were removed. The occluder was loaded into the delivery sheath with the help of a loading cable. Then, the occluder was advanced to the tip of the sheath and the left disc was deployed. The sheath was pulled back slowly until the left disc approximated the ventricular septum and the right disc was deployed in turn. During deployment of asymmetric device, the occluder was gently rotated to make sure that the platinum marker of the distal disk pointing to heart apex and thus it can avoid the interaction with the aortic valve. Oral dipyridamole or aspirin was administered for 3–6 months as an anticoagulation.

In group C, transcatheter device occlusions were performed under general anesthesia with orotracheal intubation which has been previously described in many paper.

Follow-up assessments were conducted at the 3rd and 12th months after the VSD closure. Assessments included clinical examination, ECG, chest X-rays, and TTE.

Statistical analysis

Continuous variables were expressed as x ± s, t-test or analysis of variances were applied for continuous variables and the χ^2 or Fisher's test for categorical variables. We defined P value <0.05 as statistical significance.

Results

The three groups had similar VSD size, pulmonary hypertension, and cardiothoracic ratio. In group A, conventional surgical repair was attempted in 86 patients and was successful in all patients according to our definition. In group B, perventricular device closure was attempted in 90 patients, and 87 patients had a successful occlusion. In the other three patients who convert to surgical repair, one patient for the significant residual shunt, one patient for the significant aortic valve regurgitation, and one patient for newly cAVB. We did not count them into the surgical repair group. In group C, transcatheter device closure was attempted in 71 patients and was successful in 67 patients. Deployment of the occluder failed or was terminated in four patients because of the following factors: large residual shunt in one patient, newly cAVB in one patient, and aortic valve regurgitation in two patients. In these four patients, surgical repair was done and got the successful result, who also not been counted into the surgical group.

The perioperative and postoperative data of these three groups are shown in **Table 2**. The group A required the longest of mechanical ventilation time, operative time, the longest time of hospitalization, and intensive care unit (ICU) stay (P <0.05). Meanwhile, they had the largest volume of blood transfusion (P <0.05). Only surgical group required CPB and aortic cross-clamping and the longest incision. Major complications occurred in some cases after the procedure in groups B and C.

Table 3 Postoperative complications comparison among three groups of patients

Item	Group A	Group B	Group C	P
Small residual shunt	3	3	2	
Significant residual shunt	0	1	1	
Large residual shunt requiring re-operation	0	0	0	
Severe arrhythmia				
Complete AVB	0	1	1	
Mobitz type II AVB	0	1	0	
Low cardiac output syndrome	0	0	0	
Newly mild AR		2	2	
Newly moderate-severe AR		1	2	
Cerebrovascular accident	0	0	0	
Pulmonary infection	9	6	1*	P <0.05
Surgical wound bad healing	4	1	0	
Pneumothorax	1	0	0	
Thoracic deformity	4	0	0	
Pericardial effusion	1	1	0	
Pleural effusion	2	0	0	

*Different from groups A and B (P <0.05). AR: aortic valve regurgitation; AVB: atrioventricular block

In group B, Mobitz type II atrioventricular block (AVB) occurred in one case during the procedure. After treated by glucocorticoid, it changed to Mobitz type I AVB quickly. No further medical intervention was needed except closed observation. Surgical repair was performed for one case for the newly occurred cAVB in intraoperative period. In group C, there was also one patient with the newly occurred cAVB who was converted to surgical repair. Newly mild aortic valve regurgitation was occurred in four patients in both device groups, closed medical observation was applied for these patients. Surgical repair was performed for those patients with newly moderate-severe aortic valve regurgitation in both device groups. The relevant data are shown in **Table 3**.

The median follow-up was 1.1 years, during the follow-up period, no late-onset cAVB was occurred in both device groups. Those four patients with newly mild aortic valve regurgitation had been followed-up for 12 and 16 months, with no further progress. None of the three groups had any other serious complications or mortality, such as cerebral embolism, cardiac perforation, cardiac valve distortion, endocarditis, newly moderate-severe aortic valve regurgitation, or malignant arrhythmia.

Discussion

The conventional surgical repair via median sternotomy approach is the golden standard treatment for pmVSD.[15–17] Considering its visible mid-sternotomy scar and potential risk of CPB, transcatheter and perventricular device closure for pmVSD are performed to reduce the invasiveness of conventional surgical repair, especially in children, teenager, and female people. In the last decade, transcatheter device closure of pmVSD performed widely with a promising early and mid-term follow-up in many reports.[8–10,18–20] Yang and his colleagues reported a series of 848 patients with pmVSD undergoing transcatheter device closure with a successful rate 98.1%, and there were only two cases of cAVB requiring pacemaker implantation during follow-up. They concluded transcatheter pmVSD closure can be performed safely and successfully with low morbidity and mortality.[20] In the recent period, perventricular device closure of pmVSD had also been a great advance in China. Xing et al. reported a series of 458 patients undergoing minimally invasive transthoracic device closure of VSD and showed a successful closure rate 96.29%. During the follow-up period, there were no severe complications and death. They concluded transthoracic device closure is a safe and effective alternative to conventional treatments.[21] Xu and his colleagues reported 235 young children undergoing perventricular device closure of VSD with a successful closure rate 94.90%, and concluded that perventricular device occlusion of VSD was a safe modality with an acceptable mild early complication rate and a less severe late complication rate.[22] However, comparative studies conducted among these three procedures were scared. In this study, we found that compared with the surgical group, the device groups including transcatheter and perventricular device closure groups performed a similar success rate and comparable rates of adverse events, faster recovery in terms of postoperative hospital and ICU stay, and less invasiveness

of operative time and mechanical ventilation time, incision length, and no need of CPB.

Surgical repair for pmVSD still has its irreplaceable. In this study, total seven patients in device groups were converted to surgical repair, two patients for newly occurred cAVB, three patients for newly moderate-severe aortic valve regurgitation, and two patients for the significant residual shunt. Surgical repair for pmVSD almost suitable to all patients without limitation of patients' age and VSD size, in addition, there is no need for anticoagulant therapy. However, cosmetic results should be taken into consideration while comparing these three procedures. Patients in group A leaved a visible surgical scar, whereas patients in group B leaved a much smaller scar, and patients in group C even only leaved a punch point, thus making transcatheter procedure more acceptable to patients, especially for female and children. Compared with transcatheter method, perventricular device closure for pmVSD has no limitation of peripheral vascular condition, and the age limitation was relatively small. In addition, if perventricular procedure attempts fail, it could be converted to conventional surgical repair immediately because the whole process is performed by surgeons in the operating room. Surgeons just need to extend the original incision and do surgical repair. Meanwhile, the surgeons and patients could escape from X-ray exposure because the whole process of perventricular device closure is guided by TEE/TTE.

cAVB is one of the most serious complications of transcatheter occlusion of pmVSD. Butera[23] and his colleagues reported a cAVB rate incidence ranging from 1 to 8%, and Predescu[24] and his colleagues even reported a cAVB incidence up to 22%. Although no significant difference of cAVB was found between perventricular and transcatheter group in this study. cAVB was occurred in only one patient and transient Mobitz type II AVB was occurred in one patient in perventricular device closure group during the procedure. And similar probability was found in another device group. No late-onset cAVB was found in the follow-up period in both device groups. Compared with the traditional operation, the occurrence of cAVB in patients with device occlusion is unpredictable. Zhou[25] and colleagues contributed the occurrence of cAVB during the procedure to mechanical injury caused by catheter or occluder itself. It can be recovered by surgical removal of the occluder in those patients with the newly occurred cAVB. According to previous study and our clinical experience, we speculated that the occurrence of cAVB during the procedure may be the result of mechanical injury caused by catheter or occluder itself, which may be minimized by shorter delivery system in perventricular procedure. There is no need to go through tricuspid annuls in such procedure, which can reduce the compression of atrioventricular node. In our institution, we paid attention to the procedure details to avoid occurrence of cAVB during the perventricular device closure. It is advisable not to apply an oversized occluder because progressive device flattening may be a mechanism for the development of cAVB according to Butera's hypothesis.[22] Thus, we chose occluder according to TEE/TTE assessment of VSD size, and after placement of occluder we checked by TEE/TTE again to determine whether there was residual shunt or not. In case of residual shunt, the diameter of occluder size should be increased 1–2 mm gradually. Cooperation between surgeons and ultrasound doctor during the procedure were the basis of successful closure of VSD. And most of patients in this study only used one occluder to achieve a successful attempt, and we contributed these to a short pathway and an easily controllable set and good cooperation between ultrasound doctor and surgeon. Unfortunately, once late-onset cAVB occurred, it is really difficult to cure other than permanent pacemaker.[26,27]

Aortic valve regurgitation is another severe complication of pmVSD device closure due to the short subaortic rim of pmVSDs and close proximity between the device and the aortic valves. No moderate-severe aortic valve regurgitation occurred in the surgical group. In perventricular procedure, it is easy for operators to manipulate the eccentric side of the occluder to face the heart apex and thus avoid the risk of aortic valve regurgitation in those VSDs that are closer to the aortic valve. Compared with transcatheter method, the shorter delivery pathway can be ease to handle the controllable set, and to allow the operators to advance the delivery system to the septal defect directly and accurately deliver the device. In transcatheter procedure, it is relatively more difficult to deploy the device because of the long delivery pathway and obscure position from an indefinite radiologic angle difference related to the variation of the VSD position. In addition, we chose those patients with a subarterial rim more than 2 mm in device groups to avoid interference with aortic valvular structures in our institution.[28]

Both perventricular and transcatheter device closure are less invasive procedures compared with surgical repair for VSD, and both of them showed a promising early and mid-term results. Medical service is closely associated with economic situation. Up to date, there are

no study available to compare the effectiveness and costs among these three procedures. However, medical sources are limited in low-income countries, cost-effectiveness information are in great need. There was a clear statistical difference between the two device groups and the conventional surgical group in medical cost. We contributed these to less blood transfusion and faster recovery and the relatively short hospital stay. Technical promotion respect should be taken into consideration while comparing two procedures. We preferred perventricular procedure for some supportive reasons. First, perventricular procedure is guided by TEE/TTE during whole procedure in operating room, and there is no need for expensive X-ray machine. Second, for experienced surgeons who are familiar with cardiac anatomy, learning curve of perventricular procedure is short for such procedure providing a quite short and easily controlled delivery system. The learning curve for surgeons is about 20–30 times in our experiences, and the importance of cooperation between with ultrasound doctors should be emphasized. Third, there is no need of X-ray exposure for surgeons and patients, especially for adolescents and some patients who are not suitable for X-ray exposure. Thus, we recommended the perventricular device occlusion for isolated pmVSD for those low-income countries and regions or in medical aid.

This study was not a randomized trial and also associates with following limited factors. First, this study was single institution, and multi-center cooperation is needed for further study. Second, the follow-up is very short, although the mid-term results of device closure of pmVSD were promising, longer follow-up is still needed in future study to observe the probability of late-onset cAVB, and we emphasized that conventional surgical repair is still irreplaceable in many situations.

Conclusion

Device closure may be an alternative to conventional surgical repair in selected patients with pmVSD, and perventricular device closure was the preferred approach for it showed large advantage in technical promotion, especially for developing countries and regions.

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Disclosure Statements

The authors declare that they have no competing interests.

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