Original Article

Postprocedural Outcomes and Risk Factors for Arrhythmias Following Transcatheter Closure of Congenital Perimembranous Ventricular Septal Defect: A Single-center Retrospective Study

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Abstract

Background: Currently, transcatheter closure of perimembranous ventricular septal defect (pmVSD) is a widely accepted therapeutic modality. However, arrhythmias, especially postprocedural heart blocks, are a concern and outcomes are not very clear. This study explored the outcomes and risk factors of arrhythmias associated with transcatheter device closure of pmVSD.

Methods: A total of 395 patients diagnosed with pmVSD who successfully underwent transcatheter intervention between January 2010 and December 2015 in our center were retrospectively reviewed. Electrocardiographic data before and after the procedure were collected and analyzed. We first evaluated the potential risk factors including gender, age, weight, inlet and outlet diameters of defect, subaortic rim length, occluder size, corrected occluder size into body surface area, fluoroscopy time, presence of aneurysm, and deployment position. We compared the potential risk factors between arrhythmia and nonarrhythmia groups using univariate analysis, followed by logistic analysis for independent risk factors.

Results: Various arrhythmias were detected in 95 cases (24.1%) following transcatheter closure procedure. Logistic regression analysis revealed that eccentric (odds ratio [*OR*] 2.9, 95% confidence interval [*CI*]: 1.2–7.2) and large occluders (*OR* 2.0, 95% *CI*: 1.6–2.5), as well as long fluoroscopy time (*OR* 1.1, 95% *CI*: 1.1–1.2), were correlated with postprocedural arrhythmia. During 35.5 months (range: 9–80 months) of follow-up, most of the patients (74 out of 95) reverted to normal heart rhythm.

Conclusions: The mid-term outcome of patients with arrhythmias after transcatheter closure of pmVSD was satisfactory as most of the patients recovered normal rhythm. Eccentric, large device and long fluoroscopy time increase the risk of arrhythmias after transcatheter closure of pmVSD.

Key words: Arrhythmia; Occluder; Outcomes; Percutaneous Closure; Perimembranous Ventricular Septal Defect; Risk Factors

Introduction

Congenital ventricular septal defect (VSD) is one of the most common congenital heart anomalies. It accounts for approximately 40% of all congenital heart diseases.[1] Perimembranous VSDs (pmVSDs) are the most common type of VSDs, accounting for about 80% of all VSDs.[2] Transcatheter device closure of congenital muscular VSDs was first carried out in 1998 and used in the treatment of pmVSD since 2002.[3,4] The advantages of the technique include minimal invasiveness, rapid recovery, and absence of skin scar. Currently, percutaneous closure of pmVSD is an accepted alternative to surgical closure in selected cases. However, arrhythmias which are associated with the interventional procedure occur frequently and lead to heart block.[5-7] As arrhythmia cannot be prevented completely, it is important to investigate the associated risk factors to decrease the incidence rates significantly. Although several

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studies involving arrhythmia-related risk factors have been reported, the risk factors and long-term outcomes of arrhythmia after transcatheter closure of pmVSD are not very clear. Hence, this study investigated the outcomes and identified the risk factors associated with arrhythmias postprocedure.

Methods

Study population

Clinical data of patients with congenital VSD who underwent transcatheter device closure in the Department of Pediatric Cardiology, Shandong Provincial Hospital Affiliated to Shandong University (China), were retrospectively reviewed between January 2010 and December 2015.

Inclusion criteria were: (1) patients who successfully underwent transcatheter closure; (2) anatomy of pmVSD, as determined by transthoracic echocardiogram (TTE); and (3) patients who were implanted with domestic membranous ventricular septal occluders including symmetric, eccentric, or small-waist large-disc devices. Exclusion criteria were patients who had preprocedural arrhythmias.

Technique

Indications for intervention in pmVSD include: (1) recurrent respiratory tract infections; (2) significant hemodynamic changes such as left chamber enlargement; (3) heart failure and developmental delay; (4) patient's weight >10 kg and age >2 years; (5) uncomplicated but significant pulmonary hypertension; and (6) absence of concomitant heart abnormalities warranting surgical repair concurrently.

The study was approved by the Ethics Committee of Shandong Provincial Hospital Affiliated to Shandong University (No. 2017-03). A written informed consent was obtained from parents or guardians of the patients before procedure. Transcatheter closure was performed as previously described.[8,9] Occluders included domestic symmetric, domestic eccentric, or small-waist, large-disc membranous ventricular septal occluder (LifeTech Scientific Corporation, China).

The basic principles of device selection and deployment are as follows: (1) VSD without aneurysm is usually treated by closing the inlet orifice (left ventricular side). A symmetric occluder is selected if the subaortic rim was ≥2 mm, otherwise, an eccentric occluder is preferred. (2) A symmetric occluder and outlet orifice (right ventricular side) closure are desirable for VSD with large aneurysm (usually larger than 8 mm in diameter) and small single exit or centralized exits. Small-waist, large-disc devices are preferred for large aneurysms with dispersed multiple exits. (3) If aneurysm is not very large (usually <8 mm), inlet occlusion is considered, and the strategy and device type selection are as indicated in the first principle. If inlet deployment is indicated, the occluder size is usually 1 to 2 mm larger than the inlet diameter in the symmetric device and 2 to 4 mm larger in the eccentric device. If outlet closure is indicated (usually for large aneurysm with multi-exits), the left disc diameter of device is usually equal or slightly larger than the inlet diameter to facilitate insertion into the aneurysm sac. If significant residual shunts still exist, which warrant larger device replacement, a 2 mm increment is indicated.

Arrhythmia follow-up and classification

Electrocardiogram (ECG) examination was performed before procedure, and routine ECG monitoring was performed for 24 h after procedure. Subsequently, ECG examination was performed every day until discharge. The ECG was recorded at 1, 3, 6, and 12 months after procedure and every year thereafter. The ECG findings at each visit were collected and fed into an electronic database by specially trained persons. The patients were regularly followed up at the outpatient department. Very few patients failed to return to the clinic on time, and their follow-up data were collected by fax or mail.

According to the postprocedural incidence or absence of arrhythmia, all the patients were divided into arrhythmic and nonarrhythmic groups. Based on the duration, arrhythmia was divided into early (<1 month) and late phases (1 month later).[10] According to the degree of severity and symptoms, arrhythmia was divided into minor groups such as junctional tachycardia and bundle branch block without symptoms, obviating the need for further treatment. Severe group involved significant hemodynamic changes or associated symptoms such as dizziness, palpitations, and seizures. In this study, severe arrhythmia includes complete atrioventricular block (CAVB), complete left bundle branch block (CLBBB), ventricular tachycardia (VT), and complete right bundle branch block (CRBBB), which is accompanied with left anterior bundle branch block (LABBB).

Statistical analysis

Continuous variables were expressed as median and quartile, and Mann-Whitney *U*-test was used to test the statistical difference. Categorical variables were reported as count and percentage, and the difference was tested with Chi-square test. Logistic analysis was performed to identify independent risk factors of postoperative arrhythmias. The β coefficient, odds ratio (*OR*), and the corresponding 95% confidence interval (*CI*) were calculated at the same time. A two-sided $P < 0.05$ was considered to indicate statistical significance. All tests were performed by the IBM SPSS Statistics Version 19 statistical software package (SPSS Inc., Chicago, Illinois, USA).

Results

Baseline and procedural characteristics

A total of 395 patients (199 males) with pmVSD who fulfilled the inclusion criteria were enrolled in this retrospective study. The median age was 4 years and the median body weight was 17 kg. Complex abnormalities were detected in 11 cases, which included patent ductus arteriosus in four, atrial septal defect in five, and pulmonary stenosis in two, which were

closed simultaneously. Detailed baseline and procedural data comparing arrhythmia and nonarrhythmia groups are listed in Table 1.

Incidence of postprocedural arrhythmia

Various arrhythmias developed in 95 patients (24.1%) following the procedure. The incidence rates and types of arrhythmias are listed in Table 2.

Bundle branch block and nonparoxysmal junctional tachycardia (NPJT) were the most common types of arrhythmia postprocedurally, with an incidence rate of 16.5% and 2.3%, respectively. Among the patients with bundle branch block, the right bundle branch block was the most frequently observed, followed by the left anterior branch block. In contrast, left bundle branch block was relatively rare in incidence. Only one patient developed transient complete atrioventricular conduction block whereas 14 patients were classified as severe arrhythmia including transient CAVB in one, CLBBB in 11, CRBBB accompanied with LABBB in one, and VT in one patient. No deaths occurred, and no temporary or permanent pacemaker implantation was needed.

Most of the arrhythmias occurred in early phase, especially between days 2 and 7 after the procedure. Late-onset arrhythmias were observed only in one patient who developed CLBBB at 6 months postprocedure.

Risk factors for postprocedural arrhythmia

Univariate analysis was carried out between arrhythmia and nonarrhythmia groups. Variables including age, weight, gender, size and type of occluders, defect size (inlet and outlet diameters using TTE and angiography), corrected device diameter into the body surface area, whether or not accompanied with septal aneurysm, deployment position, and fluoroscopy time were compared between the two groups. The results revealed that the occluder diameter ($P < 0.01$), occluder type ($P < 0.01$), inlet diameter of defects measured with TTE ($P < 0.05$), inlet diameter of defects based on angiography ($P < 0.01$), outlet diameter of defects determined angiographically ($P < 0.01$), corrected device diameter in the body surface area ($P < 0.01$), and fluoroscopy time ($P < 0.01$) in the two groups showed statistically significant differences [Table 1].

Logistic regression analysis was conducted to further determine the risk factors for arrhythmia associated with transcatheter closure of pmVSD. Arrhythmia was used as the dependent variable. Significant variables in univariate analysis including occluder size, occluder type, inlet diameter of defects determined by TTE and angiography, outlet diameter of defects measured using angiography, corrected device diameter, and fluoroscopy time were introduced into the logistic model. Binary logistic regression analysis revealed that large occluder (*OR* 2.0, 95% *CI*: 1.6–2.5), eccentric occluder (*OR* 2.9, 95% *CI*: 1.2–7.2), and long fluoroscopy time (*OR* 1.1, 95% *CI*: 1.1–1.2) were independent risk factors for postprocedural arrhythmia [Table 3].

Outcomes of arrhythmia

All the patients were followed up over a median time of 35.5 months (range: 9–80 months). NPJT was detected in 25 cases within 5 days after the procedure, who recovered

Table 1: Baseline and procedural characteristics of patients with congenital ventricular septal defect who underwent transcatheter device closure in both arrhythmia and nonarrhythmia groups

Variables	Arrhythmia group ($n = 95$)	Nonarrhythmia group ($n = 300$)	Stathistical values	*P*
Male, *n* (%)	49 (51.6)	150 (50.0)	0.072*	0.789
Age (years)	4 (3–6)	4 (3–6)	–0.347†	0.728
Weight (kg)	17 (15–23)	17 (15–22)	–0.201†	0.841
TTE findings				
Inlet diameter of VSD (mm)	8.0 (6.0–11.0)	7.0 (4.8–9.2)	–3.246†	0.001
Outlet diameter of VSD (mm)	3.1 (2.7–4.0)	3.0 (2.5–3.8)	–1.071†	0.284
Subaortic rim (mm)	1.5 (0–2.4)	2.0 (0–2.9)	–1.741†	0.082
Septal aneurysm, *n* (%)	60 (63.2)	174 (58.0)	0.795*	0.373
Angiography findings				
Inlet diameter of VSD (mm)	8.4 (6.0–11.0)	7.4 (5.1–9.2)	–2.927†	0.003
Outlet diameter of VSD (mm)	3.0 (2.3–4.3)	2.8 (2.0–3.3)	–3.062†	0.002
Subaortic rim (mm)	2.0 (0–2.8)	2.0 (0–3.0)	–0.180†	0.857
Septal aneurysm, *n* (%)	59 (62.1)	171 (57.0)	0.773*	0.379
Occluder size (mm)	8 (7–10)	6 (5–7)	–9.815†	<0.001
Corrected occluder size (mm/m^2)	10.5 (8.1–14.0)	8.0 (6.0–10.0)	–5.870†	<0.001
Fluoroscopy time (min)	21.5 (14.3–32.5)	12.0 (8.0–17.5)	–8.250†	<0.001
Deployment position (inlet), *n* (%)	69 (72.6)	234 (78.0)	1.164*	0.281
Occluder type, *n* (%)			42.685*	<0.001
Symmetric occluder	54 (17.9)	351 (81.4)		
Eccentric occluder	29 (61.7)	18 (38.3)		
Small-waist occluder	12 (25.5)	35 (74.5)		

Data are expressed as *n* (%) or median (quartile). *χ^2 values; †*Z* values. TTE: Transthoracic echocardiogram; VSD: Ventricular septal defect.

Table 2: Incidence of various types of arrhythmias during transcatheter closure of pmVSD in 395 cases

Arrhythmia classification	Incidence
CAVB	1 (0.3)
Bundle branch block	65 (16.5)
CRBBB	13 (3.3)
ICRBBB	19 (4.8)
CLBBB	11 (2.8)
ICLBB	1 (0.3)
LABB	13 (3.3)
CRBBB + LABB	1 (0.3)
NPJT	25 (6.3)
Complex arrhythmia	9 (2.3)
ICRBBB + NPJT	4 (1.0)
CRBBB + NPJT	1 (0.3)
CLBBB + NPJT	1 (0.3)
LABBB + NPJT	1 (0.3)
ICRBBB + PVC	1 (0.3)
VT	1 (0.3)
Total	95 (24.1)

Data are expressed as *n* (%). CAVB: Complete atrioventricular block; CRBBB: Complete right bundle branch block; IRCBBB: Incomplete right bundle branch block; CLBBB: Complete left bundle branch block; ICBBB: Incomplete left bundle branch block; LABB: Left anterior branch block; NPJT: Nonparoxysmal junctional tachycardia; PVC: Premature ventricular contraction; PJC: Premature junctional contraction; VT: Ventricular tachycardia; pmVSD: Perimembranous ventricular septal defect.

Table 3: Logistic regression analysis of risk factors for arrhythmias after transcatheter closure

Variables	β	*OR*	95% *CI*	*P*
Occluder size	0.682	1.978	1.559–2.511	0.000
Corrected occluder size	−0.002	0.998	0.893–1.115	0.969
Fluoroscopy time	0.114	1.121	1.081–1.161	<0.001
Symmetric occluder	–	1	–	–
Eccentric occluder	1.068	2.909	1.180–7.170	0.02
Small-waist occluder	−0.335	0.715	0.232–2.183	0.556
Inlet diameter (TTE)	−0.035	0.966	0.847–1.101	0.600
Inlet diameter (angiography)	0.009	1.009	0.868–1.173	0.908
Outlet diameter (angiography)	−0.118	0.889	0.653–1.211	0.456

β: Logistic correlation coefficient; *OR*: Odds ratio; 95% *CI*: 95% confidence interval; TTE: Transthoracic echocardiogram. –: Not applicable.

in 1 week without any recurrence during the follow-up. More than half of the patients with various bundle branch blocks were automatically eliminated at 1-month follow-up. None of them developed severe arrhythmias. Late-onset arrhythmias occurred only in one patient who developed CLBBB at the 6-month visit. The patient was hospitalized and treated unsuccessfully with a high dose of intravenous corticosteroid combined with immunoglobulin therapy. The patient had no symptoms and refused to remove the device surgically. The ECG readings remained unchanged after 1 year of follow-up.

Discussion

The incidence rate of arrhythmia after transcatheter closure of pmVSD is approximately 25.4% to 37.7%. The estimated incidence of severe arrhythmias ranges from 2.1% to 6.4% in previous studies.[11,12] CAVB is the most severe complication of transcatheter device closure, with an incidence rate of 0.3–6.4%.[13-16] The rate of total arrhythmia was 24.1% and that of severe arrhythmia was 3.5% in our series, which are consistent with previous studies.[11-15] A high incidence of postprocedural arrhythmias was observed, and most of them presented a benign course, which were resolved spontaneously. Permanent pacemaker requirement was very rare. In our series, only 21 (22.1%) of 95 cases remained unchanged until this writing. One patient (0.3%) developed transient CAVB 2 days after the procedure and rapidly and effectively treated with steroid therapy. Compared with traditional open surgery with an estimated 1.1% CAVB complication rate, percutaneous device closure showed no significant differences in CAVB complications according to a recent meta-analysis of 3134 cases of VSD.[17,18] Conversely, transcatheter closure is superior to surgery in terms of need for blood transfusion and hospitalization days. Although a large number of studies investigated arrhythmias following transcatheter closure of VSD, no definitive conclusions are available. Our study indicated that eccentric and large devices as well as long fluoroscopy time were related to postprocedural arrhythmias.

Outcomes of various types of postprocedural arrhythmias

Bundle branch block including right bundle branch block and left anterior branch block are quite common, probably due to the delicate and fragile features that increase the risk of injury. However, they are just occasionally associated with adverse hemodynamic outcomes. Complete left branch block is relatively rare. In our series, a total of 11 patients developed CLBBB postprocedurally with an incidence rate of 2.8%. Ten patients with these defects were detected in a week and were resolved quickly following corticosteroid therapy. CLBBB is usually not symptomatic, but can cause ventricular contractile dys-synchrony, which may lead to chamber enlargement and heart failure.[19,20] Death associated with postprocedural heart failure due to CLBBB was reported previously.[10] Therefore, CLBBB may be regarded as severe arrhythmia. The mechanism probably involves mechanical stimulation and compression of occluders in the conduction system. Notably, nine of the 11 patients developed complications associated with CLBBB. They carried large device implants (over 8 mm), suggesting that large devices might be associated with postprocedural CLBBB.

Late-onset arrhythmias were observed only in a 2.5-year-old patient who developed CLBBB after 6 months. The patient was implanted with domestic 8 mm small-waist, large-disc symmetric occluders with excellent instantaneous results. ECG was normal until 6 months of follow-up visits. CLBBB remained unchanged after steroid and immunoglobulin therapy. The patient refused surgical removal of the device and remained without any symptom. Late-onset conduction block

might be associated with oversized occluder placement, which compresses the conduction tissue after slow restoration of the original shape. We previously reported a patient who was implanted with one 8-mm small-waist, large-disc occluder and developed CAVB 5 years after the procedure.[21] Early onset of atrioventricular and left branch block after the procedure increases the chances of recovery compared with late onset. Our findings are consistent with previous studies, which showed that late-onset arrhythmias were more difficult to restore than early onset ones.[10,15,22] These potential late-severe heart blocks underscore the need for lifelong follow-up. Surgical removal of the device for severe arrhythmias may facilitate restoration of normal heart rhythm.[23]

NPJT was another common benign arrhythmia observed after surgical procedures. NPJT is not usually associated with harmful hemodynamic changes. In our series, all the 25 cases were transient and disappeared within a week. The mechanism might be associated with increased excitability of junctional area due to stimulation and compression of the occluder. Junctional rhythm was spontaneously restored within several days after edema of myocardial tissue was resolved, which is consistent with a previous study.[10]

Risk factors associated with postprocedural arrhythmias

Our study revealed that the eccentric occluder was associated with a higher risk of postprocedural arrhythmias than the symmetric occluder. Several previous studies also demonstrated that eccentric occluders represented a risk factor for early postprocedural arrhythmia.[10,11] The potential mechanism is 3 fold. First, enlarged left disc of the eccentric occluder increases the risk of compression to the conduction tissue. Second, compared with the symmetric occluder, the eccentric occluder is often oversized to ensure stability when closing defects of similar size. Third, the asymmetric design might lead to mechanical imbalance, which in turn affects the septum and increases the risk of damage to the conduction system.

Our study indicated that large devices were associated with postprocedural arrhythmia, which was consistent with previous studies.[10,14,16,24] Nearly 80% of severe arrhythmia in our series was associated with devices measuring >8 mm. Although univariate analysis showed significant difference in corrected device size based on the body surface area in the arrhythmia and nonarrhythmia groups, subsequent logistic regression analysis failed to confirm it as an independent risk factor. The finding suggested that large, especially oversized, devices increase the risk of damage to the conduction system in both younger and older patients. This finding is inconsistent with previous studies, which indicated that younger patients were more likely to develop postprocedural arrhythmia.[16] Therefore, larger sample size and longer observation studies are needed to validate the relationship between arrhythmia and age or weight.

In addition, procedural stimulation also plays an important role in arrhythmia. We observed that arrhythmias that included premature heart beats and bundle branch block were quite common intraoperatively, which also confirmed that mechanical stimulus might be an important mechanism of arrhythmia. Long fluoroscopy time suggests additional manipulations, especially inside the heart chamber, which also increases the mechanical risk of damage to the conduction system.

According to the deployment position of devices, transcatheter closure can be divided into inlet occlusion (left disc located on the left side of septum) and outlet occlusion (left disc in the aneurysm sac). Previous studies indicated that inlet occlusion increased the risk of LBBB whereas outlet occlusion decreased the associated risks.[24-26] Theoretically, devices that were deployed at the inlet position rather than inner aneurysm might increase the risk of compression of LBB. However, in this study, we compared arrhythmias with different deployment positions and failed to find any relationship between occlusion position and postprocedural arrhythmia. Whether deployment position was related to arrhythmias needs further investigation.

Although several potential risk factors were found, the precise mechanism underlying arrhythmia associated with transcatheter closure of VSD is still not clear. Individual differences in conduction system might also be related to postprocedural arrhythmia. Nevertheless, a comprehensive insight into the outcomes of postprocedural arrhythmia to prevent potential risk factors is imperative. Selection of appropriate device size and skilled manipulation techniques might diminish the risk of arrhythmia.

Limitations

This is only a single-center retrospective study. We also failed to conduct further statistical analysis of the risk factors underlying severe arrhythmia because of limited sample size. Nonetheless, our findings are significant in reducing the incidence of suspected risk factors associated with postprocedural arrhythmias.

In conclusion, arrhythmias following transcatheter closure of pmVSD are very common, but most of them follow a benign course, which resolve spontaneously. Large and eccentric occluders as well as long fluoroscopy time might be related to arrhythmia after transcatheter closure of pmVSD. Therefore, avoiding the use of oversized occluders and skilled manipulation techniques potentially diminishes the risk of arrhythmias associated with transcatheter device closure of pmVSD.

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Conflicts of interest

There are no conflicts of interest.

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