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ORIGINAL ARTICLE

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Nit-Occlud Lê VSD coil versus Duct Occluders for percutaneous perimembranous ventricular septal defect closure

Hieu Lan Nguyen MD, PhD[1,2] | Quang Tan Phan MD[3,4] | Linh Huynh Dinh MD, PhD[2] | Hieu Ba Tran MD[2] | Hoyoun Won MD, PhD[4] | Julian Johny Thottian MD, PhD[4,5] | Dung Doan Duc MD[1] | Truong Nguyen Quang MD[3] | Sang Wook Kim MD, PhD[4]

[1]Intervention Center, Hanoi Medical University Hospital, Hanoi, Vietnam

[2]Intervention Center, Vietnam National Heart Institute, Hanoi, Vietnam

[3]Intervention Center, Quang Nam Central General Hospital, Quang Nam, Vietnam

[4]Intervention Center, Chung-Ang University Hospital, Seoul, South Korea

[5]Westfort Group Hospital, Intervention Center, Kerala, India

Correspondence
Phan Tan Quang, Address: Intervention Center, Quang Nam Central General Hospital, Quang Nam 562314, Vietnam.
Email: quangft@gmail.com

Abstract

Objective: To evaluate the efficacy and safety of Nit-Occlud Lê VSD Coil versus Duct Occluders for percutaneous closure of perimembranous ventricular septal defect (pmVSD).

Introduction: VSD closure using conventional pmVSD occluders has been largely abandoned because of an unacceptable high rate of complete heart block (CHB). The advantages of Duct Occluders and VSD Coil are supposed to reduce the drawbacks of previous devices, especially CHB complications.

Method: Patients underwent percutaneous pmVSD closure were divided into Coil group (using VSD Coil, $n = 71$) and DO group (using Duct Occluders, $n = 315$). Patient demographics, clinical presentations, echocardiography measurements, procedure details and follow-up data were collected.

Result: The procedure success rate was high in both DO group (95.6%) and Coil group (97.2%, $P = .53$). The closure rate immediately after procedure in the DO group was higher than that in the Coil group (76.8% vs. 58.0%, $P < .01$). After 6 months, the closure rate was not significantly different between the 2 groups (DO group 91.3% vs. Coil group 84.1%, $P = .07$). The mean follow-up time was 61.4 ± 24.1 months. The major complication rate was low in both groups (DO group 1.9% vs. Coil group 1.4%, $P = .78$). Two patients (0.7%) in the DO group and one patient (1.4%) in the Coil group with CHB needed permanent pacemaker ($P = .5$). Device embolization (3 patients, 1.0%) and endocarditis (1 patient, 0.3%) occurred only in the DO group. There was no death, disability or other major complications detected in either group.

Conclusion: Percutaneous pmVSD closure using either Nit-Occlud Lê VSD Coil or Duct Occluders is feasible, safe and efficacious in selected patients. The main problems of Duct Occluders are unsuitable defect anatomy and device embolization while VSD Coil disadvantages are residual shunt and hemolysis.

KEYWORDS

congenital heart disease, duct occluders, Nit-Occlud Lê VSD Coil, percutaneous closure, perimembranous ventricular septal defect

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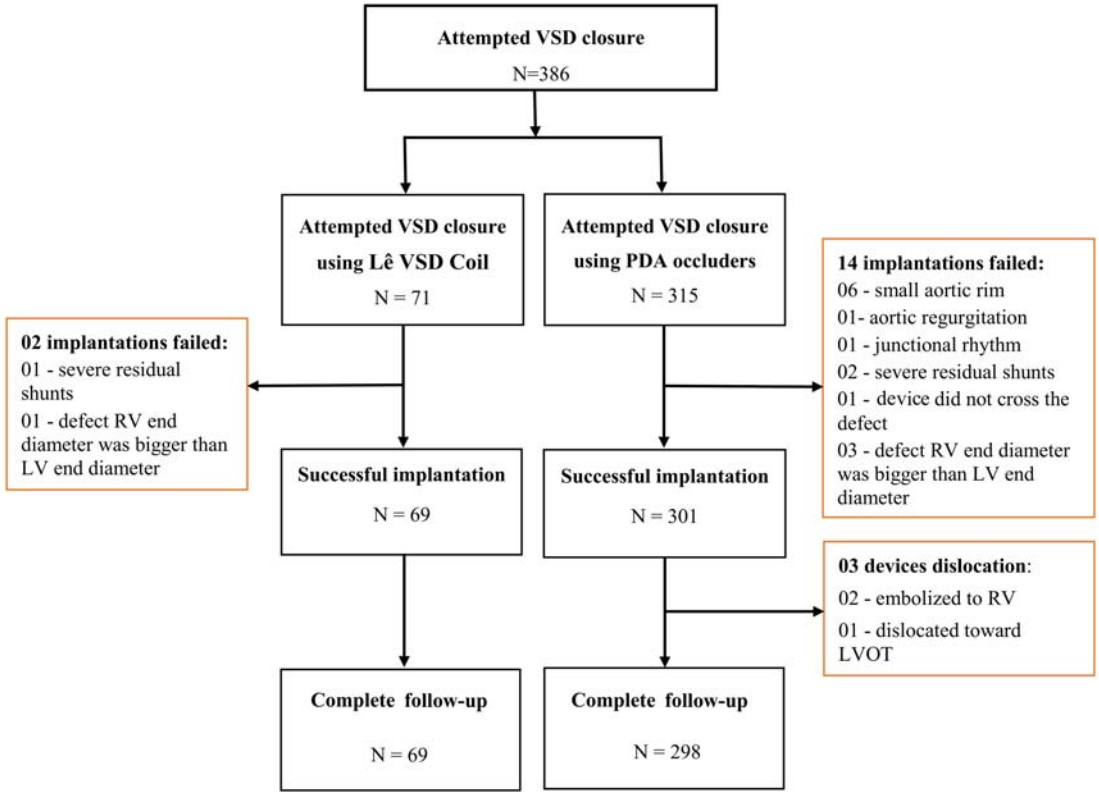

FIGURE 1 Study flowchart [Color figure can be viewed at wileyonlinelibrary.com]

1 | INTRODUCTION

Percutaneous pmVSD closure using conventional pmVSD occluders, such as Amplatzer Membranous VSD Occluder or Occlutech pmVSD Occluder, has been limited due to an unacceptable high CHB rate, which has been documented in the literature.[1–6] This complication may be related to significant direct mechanical trauma caused by the delivery system or device deployment during the procedure or later fibrosis formation, radial compression or inflammatory reaction of the conduction system.[4,7] The conventional pmVSD Occluders have a high tendency to cause damage to the ventricular septum and other adjacent structures because of their big delivery system needed for the large profile devices, high clamping force caused by double disc design and high radial stress due to high device stiffness.[8] Other devices with a low profile and ease of implantation may reduce the trauma, clamp force and radial stress to the ventricular septum and thereby decrease the CHB complication rate.[8,9] Among available devices, Nit-Occlud Lê VSD Coil and Duct Occluders have these characteristics and offer a promising alternative to conventional VSD occluders with a better outcome.

2 | METHODS

2.1 | Patient selection

From January 2009 to October 2016, 386 patients who underwent attempted percutaneous closure of pmVSD using either Duct Occluders or Nit-Occlud Lê VSD Coil at Vietnam National Heart Institute ($n = 254$), Hanoi Medical University Hospital ($n = 85$), Hanoi Heart Institute ($n = 31$) and Quang Nam Central General Hospital ($n = 16$) were retrospectively included in this study. Criteria for pmVSD closure were $Qp/Qs \geq 1.5$ and at least one of the following: dilation of the left ventricle or left atrium observed on two-dimensional echocardiography, symptoms of heart failure, failure to thrive or cardiomegaly observed on chest radiography. Patients with concomitant lesions requiring cardiac surgery, contraindication to aspirin, pulmonary vascular resistance >8 Wood units, significant aortic regurgitation, aortic valve prolapse and right-to-left shunt were excluded from percutaneous pmVSD closure.

The participants were divided into 2 groups as follows: The Coil group included patients who underwent attempted VSD closure using the Nit-Occlud Lê VSD Coil, and the DO group included patients who underwent attempted VSD closure using Duct Occluders. The study flow chart is demonstrated in Figure 1.

This study was approved by the Institutional Review Board of Quang Nam Central General Hospital and was conducted in accordance with the Declaration of Helsinki. An informed written consent was obtained from all patients or their guardians before intervention.

2.2 | Device selection

There were 4 device types used in this study, including 97 Amplatzer Duct Occluders (St. Jude Medical Inc., St. Paul, Minnesota, USA), 149 Cocoon Duct Occluders (Vascular Innovations Co. Ltd., Nonthaburi,

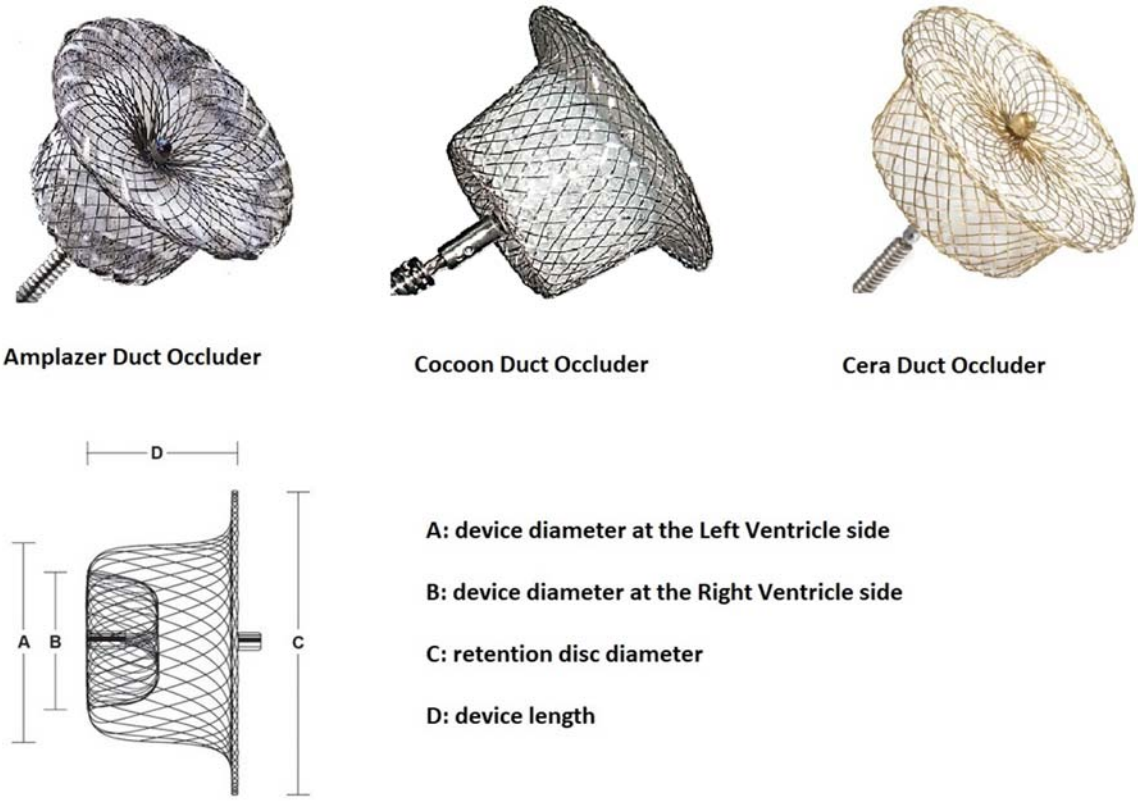

FIGURE 2 PDA occluders [Color figure can be viewed at wileyonlinelibrary.com]

Thailand), 69 Cera PDA Occluders (Lifetech Scientific Co. Ltd., Shenzhen, China) and 71 Nit-Occlud Lê VSD Coils (PFM Medical AG., Cologne, Germany).

Duct Occluders (Amplatzer Duct Occluder, Cocoon Duct Occluder and Cera PDA Occluder) have a similar self-expanding and self-centering nitinol wire mesh design with a small single retention disk and a cylindrical main body.[10] The polyester membranes sewn inside the device promote quick thrombosis formation to close the communication between the left ventricle (LV) and right ventricle (RV). The smaller RV end of the device fits in the RV side of the pmVSD, while the bigger LV end and retention disc provide secure positioning in the LV ampulla of the defect. The available sizes of the Amplatzer™ Duct Occluder are 6/4, 8/6, 10/8, 12/10, 14/12 and 16/14 mm, where the first number refers to the LV end diameter and the second number indicates the RV end diameter of the device (Figure 2). The largest size of the Cocoon Duct Occluder is 20/18 mm and the Cera PDA Occluder is up to 24/22 mm. The device size (the RV end diameter) was chosen to be 2 mm larger than the smallest pmVSD diameter measured on echocardiography and left ventriculogram. The device was deployed through a small delivery catheter (6–8 French).

The Nit-Occlud Lê VSD Coil is a modification of the Nit-Occlud PDA (PFM Medical AG.) with securely attached polyester fibers for the closure of perimembranous and muscular VSD. The coil design allows it to easily adapt to various shapes and sizes of pmVSD, especially in those with an aneurysm. The Nit-Occlud Lê VSD Coil is available in sizes 8 × 6, 10 × 6, 12 × 6, 14 × 8, and 16 × 8 mm corresponding to the LV end diameter and RV end diameter (Figure 3). The RV end of the coil will secure the RV side of the pmVSD, while the bigger LV end will fit in the LV ampulla of the defect. A coil with an LV end diameter at least twice the minimal diameter of the pmVSD and 2 mm greater than the LV ampulla diameter of the defect was selected. A small delivery catheter (6–7 French) was used to deploy this device.

2.3 | Procedure

The procedure was performed under general anesthesia in small children or local anesthesia in older patients. The right femoral vein and

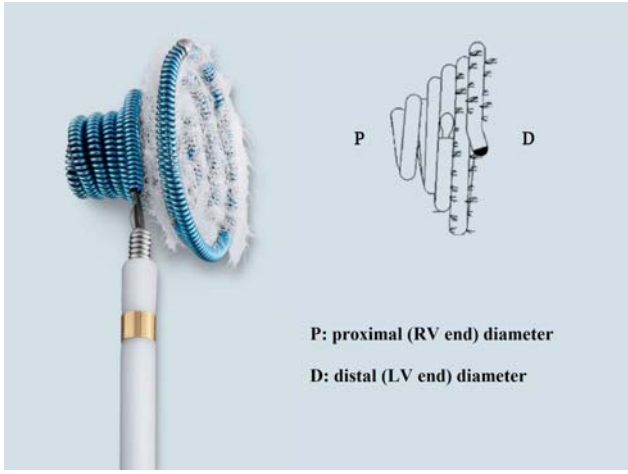

FIGURE 3 Nit-Occlud Lê VSD Coil [Color figure can be viewed at wileyonlinelibrary.com]

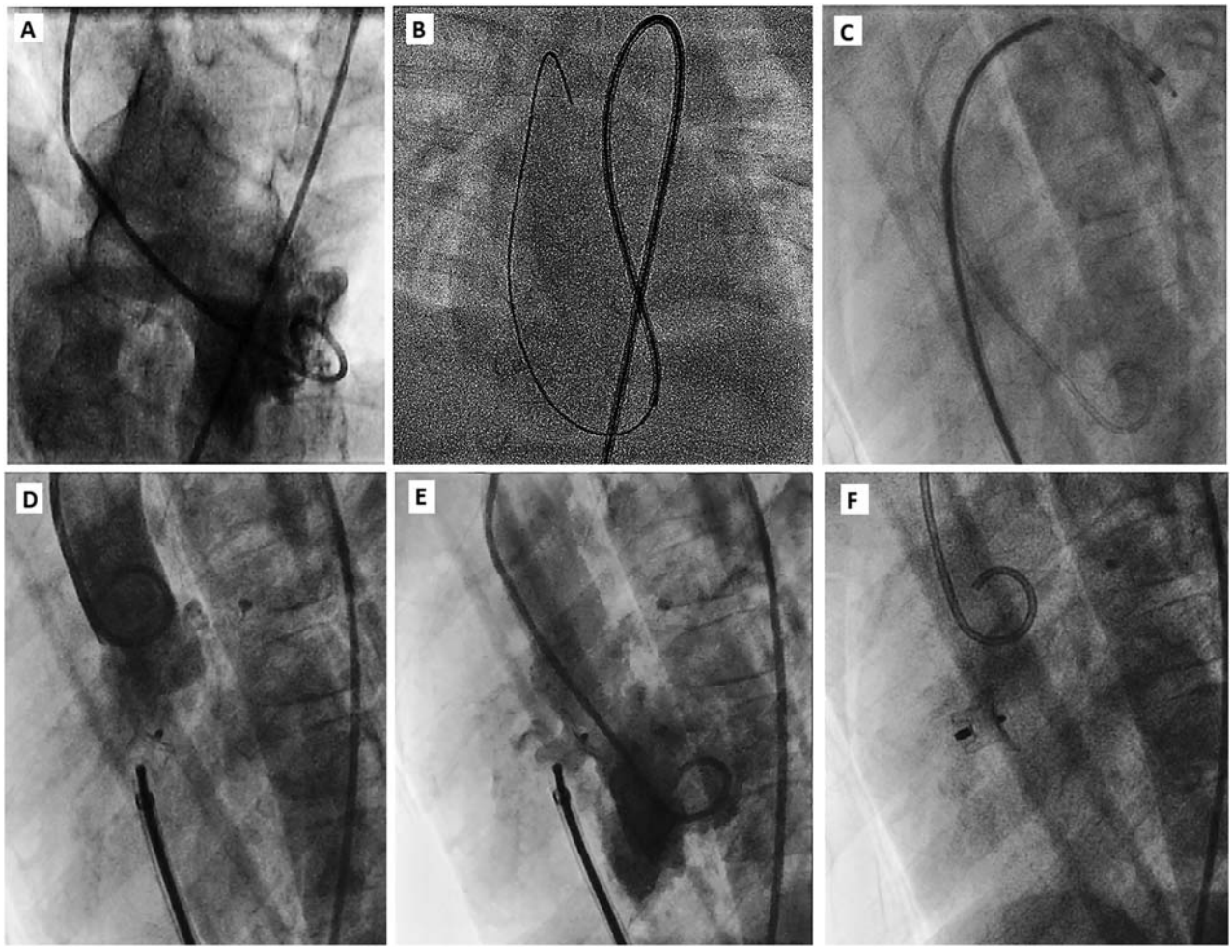

FIGURE 4 (A) A large pmVSD on left ventriculography; (B) Through the defect, a guidewire was introduced from left ventricle to right ventricle and then to superior vena cava; (C) The delivery catheter was introduced from venous access to ascending aorta and the Duct Occluder was introduced inside the delivery catheter; (D) Aortography showed the device was in good position and no aortic regurgitation; (E) Left ventriculography showed the device was in good position and minimal residual shunt through the defect; (F) The final position of device after release

right femoral artery were used for the access. Before standard catheterization, 100 IU/kg intravenous heparin and prophylactic antibiotic were administered. Left ventriculography at left anterior oblique 55° and cranial 30° projection was used to profile the defect (Figures 4A and 5A). The location, size of the VSD and its relationship with the aortic valve were assessed. The VSD size was the smallest diameter of the defect, usually located on the RV side, and the VSD ampulla size was the largest diameter of the defect, usually located on the LV side.

For the pmVSD closure using PDA occluders, a 0.35-inch Terumo guidewire (Terumo Corporation, Yamanashi, Japan) was introduced through the defect from LV to RV, then to the right atrium and superior vena cava (Figure 4B). This guidewire was then captured by a snare advancing from the femoral vein to make an arteriovenous loop. Through this loop, the delivery catheter was introduced from the venous access to the RV, then to the LV and to the ascending aorta. The closure device was connected to the cable, advanced to the defect through the delivery catheter and then deployed under fluoroscopic and echocardiographic guidance (Figure 4C–H). Similar steps were used for percutaneous pmVSD closure using Nit-Occlud Lê VSD Coil (Figure 5). Left ventriculogram, aortogram and echocardiography were performed before the device release to confirm an appropriate device position.

2.4 | Follow-up

Strict follow-up examinations were applied after percutaneous pmVSD closure according to the institutions' protocol. During the first 24 hours after the procedure, continuous ECG monitoring was used to detect arrhythmias. Echocardiography was performed to check for acute complications and residual shunt immediately and 24 hours after the procedure. Urine was analyzed the next day to detect hemolysis. Aspirin was administered at 5mg/kg per day for 6 months in all patients. The follow-up echocardiography, ECG and clinical examination were scheduled at 1month, 6 months, and every 12 months after the procedure. All follow-up data were available until October 2017.

2.5 | Data collection and definitions

The patient demographic information, clinical presentations, echocardiography measurements, procedure details and complications were

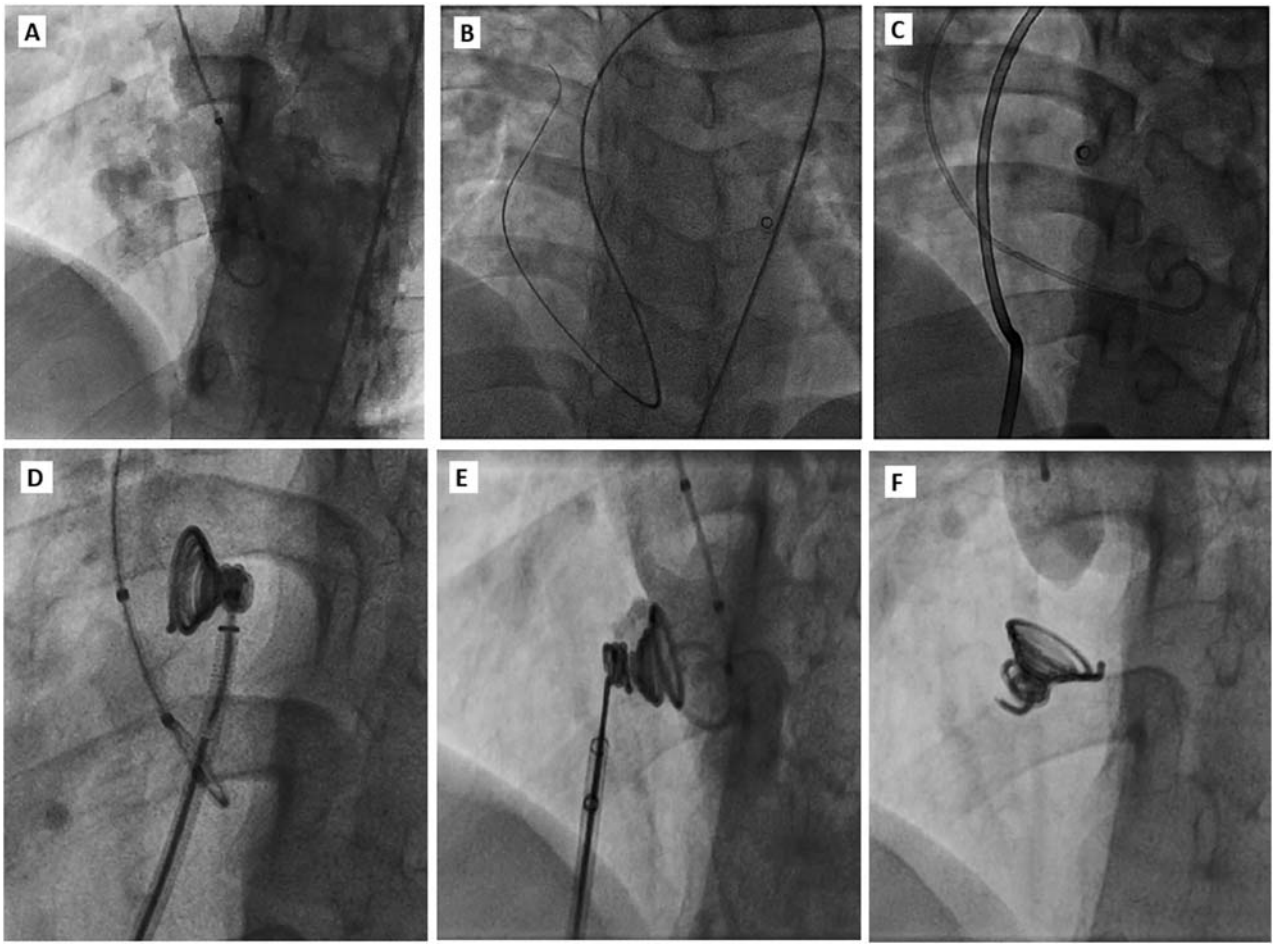

FIGURE 5 (A) A pmVSD with a large aneurysm on left ventriculography; (B) Through the defect, guidewire was introduced from left ventricle to right ventricle and then to superior vena cava; (C) The delivery catheter was introduced from venous access to ascending aorta; (D) The VSD Coil was partly released and pulled back from aorta to the defect; (E) Left ventriculography showed the VSD coil was in good position with minimal residual shunt; (F) Aortography after release showed good device position and no aortic regurgitation

collected. Echocardiographic data included the defect size, LV ejection fraction (EF), LV diastolic diameter (LVDd), left atrial (LA) diameter, pulmonary systolic pressure, sub aortic rim length, and the pressure gradient through the defect. Procedural details consisted of procedure time, fluoroscopy time, pulmonary pressure, Qp/Qs ratio, defect size, and the type and size of devices used. Additionally, the reasons for aborted procedures or failed implantations were recorded.

Heart failure was diagnosed using the Framingham criteria. Failure to thrive in children was defined by weight less than the 5th percentile for age and sex. On echocardiography, LA enlargement was defined as an LA to aortic ratio >1.5 in the long-axis parasternal view. LV enlargement was defined as LVDd ≥ 2 standard deviations for the body surface area. A residual shunt was considered to be present if color-Doppler echocardiography showed a left-to-right jet across the VSD. It was classified as small (jet $\leq$1 mm), moderate (jet 2–4 mm), or large (jet $\geq$4 mm).

Major complications were defined as procedure-related death, life-threatening adverse events or complications that needed surgery such as device embolism, myocardial or vessel rupture, severe residual shunt, severe hemolysis or valvular injury that required surgery, complete heart block that needed permanent pacemaker, endocarditis and stroke. Complications categorized as minor were nonfatal complications that regressed spontaneously or with medication such as access-site hematoma, hemolysis requiring only medication, blood transfusion because of blood loss, transient complete heart block, junctional rhythm, bundle branch block, fascicular block, first degree or Mobitz I type AV block, rash, fever, etc. Total complication was the sum of minor and major complications.

Procedure success was defined by the appropriate position of implanted device determined using echocardiography and the absence of major complications 24 hours after the procedure.

2.6 | Statistical analysis

Statistical analysis was performed using SPSS Statistics 23.0 (IBM Corp., Armonk, New York, USA). Continuous variables were expressed as mean $\pm$ standard deviations. Categorical data were presented as frequencies and percentages. The chi-square test was used to compare categorical variables and the independent samples *t*-test was used to compare continuous variables. A probability value of $P < .05$ was considered statistically significant.

TABLE 1 Baseline characteristics

Variable	DO group ($n = 315$)	Coil group ($n = 71$)	P
Age (years)	15.1 ± 12.6	16.8 ± 14.4	.31
Age groups, *n* (%)			
<6 years	127 (40.3%)	28 (39.4%)	.89
6–16 years	57 (18.1%)	11 (15.5%)	.60
>16 years	131 (41.6%)	32 (45.1%)	.59
Male, *n* (%)	139 (44.1%)	31 (43.7%)	.94
Weight (kg)	32.1 ± 20.5	31.0 ± 18.7	.68
Clinical presentation			
Heart failure, *n* (%)	71 (22.5%)	14 (19.7%)	.60
Recurrent pneumonia, *n* (%)	85 (27.0%)	14 (19.7%)	.21
Failure to thrive, *n* (%)	101 (32.1%)	18 (25.4%)	.27
Dyspnea, *n* (%)	89 (28.3%)	21 (29.6%)	.82
Asymptomatic, *n* (%)	60 (19.0%)	18 (25.4%)	.23
Echocardiography			
VSD size (mm)	4.4 ± 1.3	4.1 ± 1.5	.12
VSD ampulla size (mm)	7.0 ± 2.5	7.3 ± 3.2	.42
VSD length (mm)	6.0 ± 1.6	6.3 ± 1.8	.13
Systolic gradient* (mm Hg)	89.4 ± 19.0	90.0 ± 18.0	.79
Sub aortic rim (mm)	3.5 ± 1.4	3.7 ± 2.9	.39
PAPs (mm Hg)	35.9 ± 8.9	34.8 ± 6.6	.30
EF (%)	66.3 ± 6.2	66.8 ± 8.0	.56
LVDd (mm)	43.3 ± 8.5	42.1 ± 8.7	.28
Aneurysm, *n* (%)	152 (48.3%)	47 (66.2%)	.01
Concomitant ASD, *n*	2	0	
Concomitant PDA, *n*	2	1	
Cardiomegaly on chest X-ray	71 (22.5%)	12 (16.9%)	.30

Abbreviations: VSD, ventricular septal defect; PAPs, pulmonary artery systolic pressure; EF, left ventricular ejection fraction; LVDd, left ventricular end diastolic dimension; LVDs, left ventricular end systolic dimension; *, pressure gradient through the defect; ASD, atrial septal defect; PDA, patent ductus arteriosus.

3 | RESULTS

Of 386 patients who underwent attempted percutaneous pmVSD closure in this study, 315 were in the DO group, and 71 were in the Coil group. The baseline characteristics of participants are showed in Table 1. The mean age was 15.1 ± 12.6 years in the DO group and 16.8 ± 14.4 years in the Coil group ($P = .31$). The mean defect size measured on echocardiography was 4.4 ± 1.3 mm in the DO group and 4.1 ± 1.5 mm in the Coil group ($P = .12$). There was no statistically significant difference between the 2 groups in weight, gender, clinical presentations, LV size, systolic function, pulmonary arterial pressure and cardiomegaly ratio. On echocardiography, pmVSD with aneurysm was more commonly seen in the Coil group than in the DO group (66.2% vs. 48.3%, $P = .01$).

The procedure-related data are presented in Table 2. There was no significant difference between the 2 groups in procedure time, pulmonary arterial pressure, Qp/Qs ratio, defect size and aortic rim on ventriculography. Although the device RV end diameter in the DO group was larger than that in the Coil group (8.2 ± 3.2 mm vs. 6.6 ± 1.5 mm, $P < .01$), the device LV end diameter was not significantly different between the 2 groups (10.2 ± 3.1 mm in the DO group vs. 10.9 ± 2.7 mm in the Coil group, $P = .09$). There was no severe residual shunt after the procedure in either group. However, the Coil group had higher rate of mild and moderate residual shunt than the DO group (36.2% vs. 22.1%, $P = .02$ and 5.8% vs. 1.0%, $P = .03$, respectively).

The procedure success and closure rate are presented in Table 3. The procedure success rate was high in both groups (95.6% in the DO group vs. 97.2% in the Coil group, $P = .53$). The main reasons for procedure failure in the DO group were unsuitable defect anatomy (6 cases with inadequate aortic rim, 3 cases with unsuitable defect shape) and severe residual shunt before device release (2 cases). Two procedures were unsuccessful in the Coil group because of unsuitable defect anatomy and severe residual shunt. The closure rate immediately and 24 hours after the procedure was higher in the DO group than that in the Coil group (76.8% vs. 58.0%, $P < .01$ and 85.2% vs. 73.9%, $P = .02$, respectively). However, the closure rate was not significantly different between the DO group and Coil group 6 months, 1 year and 2 years after the procedure (91.3% vs. 84.1%, $P = .07$; 96.6% vs. 94.2%, $P = .34$ and 99.0% vs. 98.6%, $P = .75$, respectively).

The adverse events are presented in Table 4. The mean follow-up time was 61.4 ± 24.1 months (62.1 ± 24.7 months in the DO group and 57.2 ± 21.3 months in the Coil group, $P = .12$). There was no significant difference between the 2 groups in the total complication rate (14.3% in DO group vs. 17.4% in Coil group, $P = .48$). Most of the complications were categorized as minor (12.1% in the DO group vs. 14.5% in the Coil group, $P = .43$). The major complication rate was low and not significantly different between the 2 groups (1.9% in the DO group and 1.4% in the

TABLE 2 Procedure-related data

Variable	DO group ($n = 315$)	Coil group ($n = 71$)	P
Procedure time (minute)	89.8 ± 36.9	92.7 ± 36.5	.83
Fluoroscopy time (minute)	26.3 ± 11.9	27.1 ± 12.4	.19
Catheterization			
PA systolic pressure (mm Hg)	34.3 ± 9.5	32.5 ± 7.3	.12
PA diastolic pressure (mm Hg)	16.5 ± 4.6	15.6 ± 3.5	.13
PA mean pressure (mm Hg)	22.5 ± 6.2	21.2 ± 4.8	.10
Qp/Qs ratio	2.2 ± 0.7	2.1 ± 0.7	.33
Left ventriculography			
VSD size (mm)	4.7 ± 2.0	4.4 ± 1.7	.27
VSD ampulla size (mm)	7.7 ± 2.8	7.9 ± 2.8	.62
VSD length (mm)	6.0 ± 1.6	6.2 ± 1.8	.34
Sub aortic rim (mm)	3.3 ± 1.1	3.1 ± 0.9	.15
Device used			
RV end (mm)	8.2 ± 3.2	6.6 ± 1.5	<.01
LV end (mm)	10.2 ± 3.1	10.9 ± 2.7	.09
Residual shunt after procedure			
All type	69 (23.1%)	29 (42.0%)	<.01
Mild	66 (22.1%)	25 (36.2%)	.02
Moderate	3 (1.0%)	4 (5.8%)	.03
Severe	0	0	

Abbreviations: PA, pulmonary artery; Qp, pulmonary blood flow; Qs, systemic blood; flow; LV, left ventricle, RV, right ventricle; *, diameter of the defect on the right ventricular side was much bigger than the left one.

TABLE 3 Procedure success and closure rate

Variable	DO group	Coil group	*P*
Procedure success, *n* (%)	301 (95.6%)	69 (97.2%)	.53
Procedure failure, *n*	14 (4.4%)	02 (2.8%)	.53
Inadequate aortic rim, *n*	6	0	
Aortic valve compromised*, *n*	1	0	
Severe arrhythmia*, *n*	1	0	
Severe residual shunt*, *n*	2	1	
Devices could not pass the defect, *n*	1	0	
Unsuitable anatomy@, *n*	3	1	
Closure rate (on echocardiography)			
Immediate closure, *n* (%)	229 (76.8%)	40 (58.0%)	<.01
After 24 hours, *n* (%)	254 (85.2%)	51 (73.9%)	.02
After 6 months, *n* (%)	272 (91.3%)	58 (84.1%)	.07
After 1 year, *n* (%)	288 (96.6%)	65 (94.2%)	.34
After 2 years, *n* (%)	295 (99.0%)	68 (98.6%)	.75

Abbreviations: PA, pulmonary artery; Qp, pulmonary blood flow; Qs, systemic blood; flow; LV, left ventricle, RV, right ventricle; *, before release the device; @, diameter of the defect on the right ventricular side was much bigger than the left one.

Coil group, $P = .78$). CHB requiring pacemaker occurred in 2 patients (0.7%) in the DO group and 1 patient (1.4%) in the Coil group ($P = .5$). Device embolization requiring surgery occurred in 3 patients (1.0%) in the DO group only. One patient in the DO group acquired subacute endocarditis 8 months after percutaneous VSD closure. There was no death, disability or other major complications detected in either group.

4 | DISCUSSION

Although cardiac surgery has been considered as the standard therapy for pmVSD closure, it is associated with surgical complications, long hospital stays, sternotomy, skin scar and psychosocial impact. Since the first percutaneous closure of VSD performed by Lock,[11] along with the development of many VSD closure devices and deployment techniques, percutaneous VSD closure was commonly followed in many countries.[12–20] However, widespread use of these conventional VSD closure devices has been limited by the unacceptable high rate of CHB.[1,2,5,21] The search for alternative devices that have good performance and reduce the complications of conventional VSD closure devices, especially CHB, is crucial in clinical practice. Both Duct Occluders and VSD Coil have a soft, flexible, low-profile design and can be released, retrieved, or repositioned easily through a small delivery system. Furthermore, the single disc design of Duct Occluders prevents the clamp force and reduces radial stress to the ventricular septum. Similarly, the coil design of the VSD Coil helps to remove the "stenting" mechanism and minimizes compression to the defect wall and conduction system. These advantages are supposed to reduce or even eliminate the drawbacks of conventional VSD closure devices, especially the CHB complication.

The risk of major complications increased significantly in very young and small children during and after the percutaneous VSD closure procedure [4,12,22]. In this study, most of the participants were children, and the patients younger than 6 years of age accounted for 40.3% of the DO group and 39.4% of the Coil group. For percutaneous VSD closure in such small children, the low-profile devices with a small delivery system (6–8 French for the Duct Occluders and 6–7 French for the VSD Coil), ease of implantation and experienced operators were crucial keys to minimize complications.

Defect sizing and device selection also have a great impact on the outcome of percutaneous pmVSD closure.[3,23] While undersized devices increase the risk of device embolization and residual shunt, oversized devices may result in complications such as CHB, ventricular outflow tract obstruction, and aortic valve or tricuspid valve injury. In this study, the size of the Duct Occluder was chosen to be 2 mm larger than the smallest diameter of the defect, usually measured at the right ventricular side. Similarly, a VSD Coil with an LV end diameter at least twice the smallest diameter of the pmVSD and 2 mm larger than the LV ampulla diameter of the defect was selected. This selection approach helped to maintain the necessary force to prevent device embolization to the LV and to minimize compression to the defect wall.[3,25] The larger LV end and retention disc were fixed in the LV ampulla to prevent device embolization to the RV. Device selection was more difficult in patients with a small aortic rim because the implanted device might contact and damage the aortic valve. In such

TABLE 4 Adverse events

Events	DO group *N* = 301	Coil group *N* = 69	*P*
Follow-up (months)	62.1 ± 24.7	57.2 ± 21.3	.12
Total complications, *n* (%)	43 (14.3%)	12 (17.4%)	.48
Major complications, *n* (%)	06 (1.9%)	01 (1.4%)	.78
Procedure and device related death, *n*	0	0	
Complete heart block, needed PM, *n* (%)	02 (0.7%)	01 (1.4%)	.50
Device dislocated, required surgery, *n* (%)	03 (1.0%)	0	
Endocarditis, *n* (%)	01 (0.3%)	0	
Minor complications, *n* (%)	37 (12.1%)	11 (14.5%)	.43
Access site hematoma, *n* (%)	05 (1.6%)	1 (1.4%)	.91
Hemolysis diminished with medication, *n* (%)	06 (2.0%)	5 (7.3%)	.03
Blood transfusion because of blood loss, *n* (%)	02 (0.7%)	0	
New trivial aortic regurgitation, *n* (%)	03 (1.0%)	01 (1.4%)	.50
Transient complete heart block, *n* (%)	04 (1.3%)	01 (1.4%)	.73
Junctional rhythm, *n* (%)	01 (0.3%)	0	
Left bundle branch block, *n* (%)	02 (0.7%)	0	
Left fascicular block, *n* (%)	01 (0.3%)	0	
Right bundle branch block, *n* (%)	01 (0.3%)	0	
Second degree AV II (Mobitz I), *n* (%)	01 (0.3%)	0	
First degree AV I block, *n* (%)	06 (2.0%)	1 (1.4%)	.78
Paroxysmal AF, *n* (%)	01 (0.3%)	0	
Other (rash, fever >38.5°C), *n* (%)	05 (1.6%)	1 (1.4%)	.91

Abbreviations: PM, pacemaker; AV, atrioventricular; AF, atrial fibrillation.

cases, we usually chose smaller devices, and accepted mild to moderate residual shunt, to minimize aortic valve injury. However, we were respectful that surgical closure is still the standard therapy for pmVSD closure and patient safety is the first priority. In the cases of unstable device position, severe residual shunt, significant arrhythmia or compromise of the aortic valve before device release, we discontinued the implantation and recommended cardiac surgery for the patients.

Another important factor that greatly influences the procedure success rate of percutaneous pmVSD closure is the defect shape. A pmVSD with an associated aneurysm represent an anatomically favorable defect for percutaneous closure.[7] The retention disc of Duct Occluders or the LV end of the Coil can be placed entirely within the aneurysm and the RV portion of the devices can be secured in the opening of the aneurysm on the RV side.[22,25,26] Therefore, the device will not contact the aortic valve and create minimum pressure to the ventricular septum. However, because the pmVSD with an aneurysm usually has a small opening at the RV side, the Duct Occluder size selection sometime is difficult because of the fix difference between the LV end and RV end diameter of the device (2 mm). While the LV end and retention disc are suitable for the aneurysm, the RV end may be too big for the RV opening of the defect. In such cases, the VSD Coil with a smaller RV end diameter will be a better choice. This was the reason why the aneurysm was more common in the Coil group compared to the DO group in our study (66.2% vs. 48.3%, $P = .01$). However, in the opposite situation, when the defect LV end diameter was much smaller than the defect RV end diameter, it was impossible for these devices to attain a stable position inside the defect because of their basic smaller RV end design. In such cases, we abandoned the procedure and sent the patients for surgical closure.

In this study, the procedure success rate was high in both groups (95.6% in the DO group vs. 97.2%in the Coil group, $P = .53$) and comparable to other studies using conventional, off-label use or new devices for percutaneous pmVSD closure.[8–14,26–29] In contrast, the closure rate of the Coil group was significantly lower than that of the DO group immediately and 24 hours after the procedure (58.0% vs. 76.8%, $P < .01$ and 73.9% vs. 85.2%, $P = .02$, respectively). This result was accordant with the higher residual shunt rate of the Coil group compared with the DO group (42.0% vs. 23.1%, $P < .01$). These differences could be explained by the differences in design and occlusion mechanism of each device. The self-expanding design with a cylindrical main body helps the Duct Occluders easily create "stenting" inside the defect, while the polyester fabric sewn in the device promotes quick thrombosis formation to close the communication in a short time after device release. In contrast, the coil design of the VSD Coil removes the "stenting" mechanism of the Duct Occluder and replaces it with a single coil inside the defect. Therefore, even with the support of polyester fibers attached to the coil on the LV side, the device may need a longer time to achieve complete closure. The consequence of slower complete closure and a higher residual shunt rate was a higher incidence of hemolysis in the Coil group than that in the DO group (7.3% vs. 2.0%, $P = .03$). However, the hemolysis in all cases in both groups was not severe and diminished with medication. In this study, there was no need to have surgical device removal or blood transfusion in any case with hemolysis after pmVSD closure. Moreover, the closure rate increased gradually during the follow-up period, especially in the Coil group. At 6 months postprocedure, there was no statistically significant difference between the two groups in the closure rate. After 2 years, the complete closure rate was high in both groups, at approximately 99%, and only mild residual shunt still remained without any complication.

Device embolization occurred in 3 cases during the hospital stay and follow-up period in the DO group only. In the first case implanted with a Cera PDA Occluder, the device dislocated to the LV out flow tract 3 days after the procedure. However, there was no LV outflow tract obstruction or aortic regurgitation in this case. In 2 other cases with Cocoon Duct Occluders, the devices embolized to the RV 36 hours and 6 months after deployment. These 3 patients then underwent cardiac surgery for device removal and VSD closure with good recovery. Noticeably, all these cases had multiple risk factors of device embolization, including defect size > 5 mm, aortic rim < 2 mm, age under 6 years old and moderate residual shunt existed before release. Thus, careful patient selection, increase in operator experience, improvement in implantation techniques and careful evaluation before device release may reduce device embolization in percutaneous pmVSD closure.

The most important drawback of percutaneous VSD closure using conventional devices is the unacceptable high rate of CHB. This complication can occur very early or very late after the procedure. It may be transient and reversible with medications or become persistent and require permanent pacemaker insertion.[30–33] Thus, percutaneous VSD closure has been largely abandoned in many countries, and surgical closure is still accepted as the standard therapy for pmVSD. Patients in whom CHB was first detected after percutaneous VSD closure in our centers were treated with intense medication, including corticosteroids, temporary pacemaker and continuously followed for two weeks. After that time, the persistent CHB complication and permanent pacemaker deployment were considered. In this study, 2 patients (0.7%) in the DO group and 1 patient (1.4%) in the Coil group ($P = .5$) developed persistent CHB and needed permanent pacemaker. In the DO group, 2 persistent CHB cases were detected at 15 days and 5 months after the procedure in a 16-year-old girl and a 40-year-old woman, respectively. In the Coil group, persistent CHB was detected in 26-year-old man 3 days after the procedure. Even with intense treatment and close follow-up, the CHB was still persistent in these patients after two weeks. Therefore, all 3 patients were treated with permanent pacemaker, and there was no sign of sinus rhythm recovery during the remainder of the follow-up period. Furthermore, transient CHB occurred in 4 patients (1.3%) in the DO group and 1 patient (1.4%) in the Coil group ($P = .73$). These 5 patients were treated with corticosteroids, temporary pacemaker and converted back to sinus rhythm after 1 to 5 days of treatment. Generally, pmVSD closure using either the Duct Occluders or the VSD Coil does not eliminate the risk of CHB as well as other major complications. However, the rate of this complication in our study was low and comparable to the CHB rate of surgical closure documented in the literate.[34–38]

5 | LIMITATIONS AND STRENGTHS

In this study, the devices were personally selected by the operators based on the preference, availability and familiarity with these devices. Because the operators were experienced in VSD closure (>100 cases) with many types of devices, the outcome of pmVSD closure in this study may not be represented in routine practice. Even though this was a retrospective study, the strict protocol of percutaneous pmVSD closure in each institution before, during and after the procedure allowed for the collected data to be comprehensive and accurate.

6 | CONCLUSION

Percutaneous pmVSD closure using either the Nit-Occlud Lê VSD Coil or Duct Occluders is feasible, safe and efficacious in selected patients. The main drawbacks of Duct Occluders are unsuitable defect anatomy and device embolization, while the disadvantages of the VSD Coil are residual shunt and hemolysis. More improvement in device design, operator experience, implantation technique along with careful patient selection may further reduce these drawbacks and make percutaneous pmVSD closure with suitable devices a good alternative to cardiac surgery in the future.

CONFLICT OF INTEREST

None.

AUTHOR CONTRIBUTIONS

Nguyen LH and Kim SW conceived the concept, supervised the work and gave critical revision; Phan TQ, Nguyen QT, Won H, and Julian JT designed the study, wrote and revised the manuscript; Dinh HL, Tran BH, Duc DD, and Phan TQ collected and analyzed data. All authors discussed the results and commented on the manuscript.

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