Received: 29 November 2017 | Revised: 28 July 2018 | Accepted: 4 August 2018

DOI: 10.1002/ccd.27851

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ORIGINAL STUDIES

Feasibility and 1-year outcome of transcatheter closure of perimembranous ventricular septal defects with different devices

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Abstract

Objective: To analyze feasibility of closing perimembranous ventricular septal defect (pmVSD) with different devices by percutaneous approach and determining initial 1-year outcome of the procedure.

Background: Transcatheter closure of pmVSD remains controversial due to a previous higher incidence of complete heart block (CHB), especially with the Amplatzer pmVSD occluder. Recently, several devices have been used to minimize the procedure-related complications.

Methods and materials: A retrospective longitudinal cohort study of 133 patients who underwent transcatheter closure of pmVSD from September 2009 to March 2015. The median age and weight at intervention were 7.1 years (ranging from 9 months to 28 years) and 21.2 kg (ranging from 6.4 to 93 kg).

Results: Transcatheter pmVSD closure was successfully performed in 129 cases (97%) using 13 different devices. There were two new onset severe aortic regurgitation (AR) (1.5%), one new onset severe tricuspid regurgitation (0.7%), and one CHB (0.7%). Immediately after procedure, 41 patients (30.8%) had mild to moderate residual shunt and 27 patients (20.8%) had trivial to mild AR. At 1 year, there was no CHB and 10 patients (9.6%) had tiny to mild residual shunt and 10 patients (9.6%) had trivial AR.

Conclusion: With proper case selection, good expertise, and judicious use of various devices with respect to anatomic details of pmVSD, transcatheter closure is feasible with satisfactory early outcome.

KEYWORDS

complete heart block, device, perimembranous ventricular septal defect, transcatheter closure

1 | INTRODUCTION

Transcatheter closure of perimembranous ventricular septal defect (pmVSD) is an emerging alternative modality to surgical closure. This procedure can avoid cardiopulmonary bypass, midline sternotomy, and post-procedural ICU stay hence decreasing overall cost whilst considerably improving quality of life of the patient.[1] Although performed in some eminent cardiac centers, transcatheter pmVSD closure is yet to be accepted globally particularly due to its effect on the conduction pathway and its risk of post procedure and late onset heart blocks.[2–6]

Currently, various devices and techniques have been employed in order to maximize the efficacy and minimize the complications of transcatheter pmVSD closure. This study aims to analyze the feasibility and to determine the initial 1-year outcome of percutaneous closure of pmVSD in two major cardiac centers in Thailand.

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2 | METHODS AND MATERIALS

A retrospective longitudinal cohort study was conducted between September 2009 and March 2015. Database of all consecutive patients who underwent transcatheter closure of VSD at Queen Sirikit National Institute of Child Health (QSNICH) and Songklanagarind hospital during the study period were reviewed and enrolled in the study. Clinical records, electrocardiograms, echocardiograms, procedural details including angiogram, and follow-up information were reviewed. For transparent and secure data recording of both institutions, online database was created (URL: http://simanh.psu.ac.th/vsd/) with unique username and password login. Ethical committee of both hospitals approved the study.

2.1 | Patient selection

Patients were eligible for transcatheter pmVSD closure if one or more of the following: (1) evidence of the left heart enlargement from transthoracic echocardiogram (TTE), (2) pulmonary-to-systemic blood flow (Qp/Qs) ratio greater than 1.5 demonstrated by hemodynamic assessment in cath lab, and (3) history of endocarditis. Patients were excluded from the procedure if: (1) the body weight was less than 6 kg, (2) size of pmVSD was larger than 10 mm, (3) VSD-aortic valve rim distance was less than 1 mm, (4) distance of VSD to septal leaflet of tricuspid valve (TV) was less than 2 mm, (5) presence of significant aortic valve prolapse or aortic regurgitation (AR), (6) pulmonary vascular resistance index of greater than 6 WU m^2, and (7) additional lesions requiring surgical intervention.

The pmVSD is the defect at interventricular septum in the position that has continuation between TV and aortic valve leaflets.[7] It was classified into four types depending on the appearance on TTE and left ventriculogram (Figure 1). The conical type pmVSD is a defect that becomes narrower at the RV exit. The aneurysmal type pmVSD is a defect that has been partially covered by tissue from TV. The window type pmVSD is a short defect with the length less than 5 mm. The tubular type pmVSD is a conduit-like defect with the length ≥5 mm.

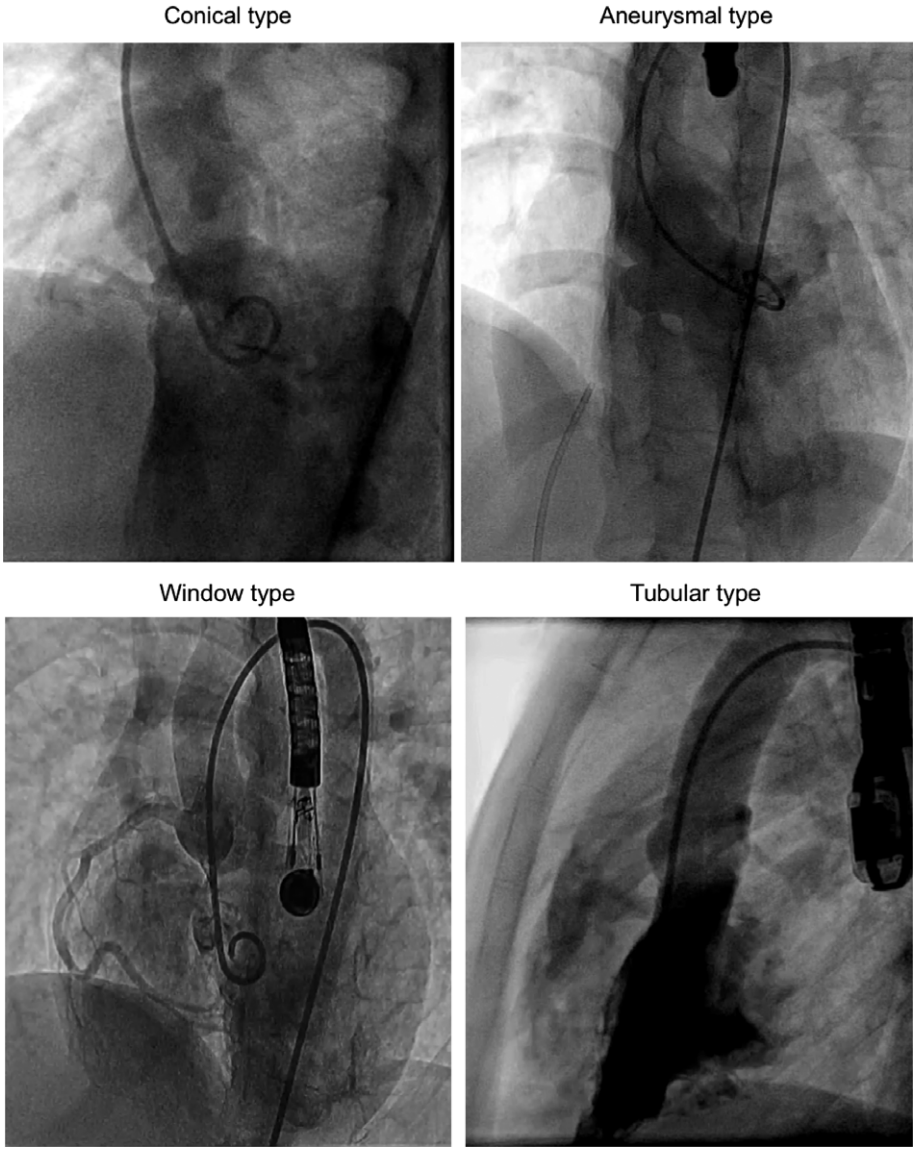

FIGURE 1 Angiographic appearances in four types of perimembranous VSD

2.2 | Devices

Many devices have been used for transcatheter closure of pmVSD. Devices are made from nitinol wire mesh with self-expanding properties. Broadly the devices can be categorized into: (I) Double-disc devices having two discs linked together by a connecting waist corresponding to the defect including the Amplatzer Duct Occluder II (ADO II; St Jude Medical, MN, USA), the Amplatzer Muscular VSD Occluder (AMVO; St Jude Medical, MN, USA), the Cocoon VSD Occluder (Vascular Innovations, Nonthaburi, Thailand), and the Cera VSD Occluder (Lifetech Scientific, Shenzhen, China); (II) single-disc devices including the Amplatzer Duct Occluder (ADO; St Jude Medical, MN, USA), the Cocoon duct occluder (CDO; Vascular Innovations, Nonthaburi, Thailand), the Cera PDA Occluder (LPDAO; Lifetech Scientific, Shenzhen, China), and the Lifetech Multifunctional Occluder (LMFO; Lifetech Scientific, Shenzhen, China); (III) The Nit-Occlud Lê VSD coil (PFM coil; Produkte für die Medizin AG, Köln, Germany) having a double coil layer one inside the other at its proximal portion to fill the VSD with sufficient material.

Of the various devices available, PFM coil can be employed in conical and aneurysmal type defects that has RV exit less than 4 mm. Single-disc occluders can be employed in tubular, window, and conical type defects with the waist (narrowest diameter) ≥4 mm. The ADO II and dedicated double-disc VSD devices are options for aneurysmal and window type defects.

Procedural success was defined as the pmVSD being successfully closed with the device(s) at the appropriate position with residual shunt not more than moderate degree and without the need for surgery. Residual shunt was considered to be present if color Doppler flow mapping showed a left-to-right shunt across the interventricular septum. It was classified as follows: trivial (<1 mm color jet width), small (1–2 mm color jet width), moderate (2–4 mm color jet width), or large (>4 mm color jet width).[6] Major complication included procedure related death, complete heart block (CHB) requiring pacemaker implantation, new onset of AR or TR requiring surgical repair, hemolysis requiring blood transfusion, neurovascular events requiring surgery, and infective endocarditis.

All subjects underwent clinical examination, electrocardiography, chest X-rays, and TTE at 24 hr after the procedure, 1 month,

TABLE 1 Baseline characteristics

Variables	Results
Male (n)	67 (50.4%)
Age (years) (median with range)	7.1 (9 months-28 years)
Weight (kg) (median with range)	21.2 (6.4-93)
Height (cm) (median with range)	119 (66-178)
NYHA Functional Class (n)	
I	118 (88.7%)
II	12 (9.0%)
III	0 (0%)
IV	3 (2.3%)
Cardio-thoracic ratio (median with range)	0.55 (0.45-0.63)
Left Ventricle Dimension by TTE (m-mode) (n = 116)	
LVEDD (median with range) (mm)	42 (29.6 – 58)
LVEDD z-score (mean ± SD)	2.1 ± 0.6
Diameter of pmVSD (mm) by TEE (median with range)*	
LV entry (n=133)	6.7 (2.5-18.0)
RV exit (n=129)	3.8 (2.0-10.0)
Length of VSD (n=130)	6.0 (2.9-13.5)
AO-VSD distance (n=119)	4.0 (1.0-5.0)
TV-VSD distance (n=112)	3.0 (2.0-5.0)
VSD Morphology (n=133)	
Conical	48 (36.1%)
Aneurysmal	56 (42.1%)
Window	4 (3.0%)
Tubular	25 (18.8%)
Number of RV exit (n)	
Single	107 (80.5%)
Double	17 (12.8%)
Multiple	9 (6.8%)
Hemodynamic data (mean ± SD)	
Systolic PA pressure (n=125) (mmHg)	26.9 ± 6.5
Mean PA pressure (n=127) (mmHg)	18.9 ± 4.5
Qp/Qs (n=125)	1.5 ± 0.6
PVR (n=126) (WU.m^2)	1.3 ± 0.7
Rp/Rs (n=126)	0.1 ± 0.07

*In patients weighing less than 10 kg, transthoracic echocardiogram was used for procedure guidance. NYHA: New York Heart Association; TTE: Transthoracic echocardiogram; LVEDD: Left ventricle end diastolic dimension; pmVSD: perimembranous ventricular septal defect; TEE: Transesophageal echocardiogram; LV: left ventricle; RV: right ventricle AO: aorta; TV: tricuspid valve; PA: pulmonary artery; Qp/Qs: ratio of pulmonary and systemic blood flow; PVR: pulmonary vascular resistance; Rp/Rs: ratio of pulmonary and systemic vascular resistance

TABLE 2 Procedural characteristics

Variables	Results*
Procedure time (n=131) (min) (median with range)	69 (30-260)
Fluoroscopy time (n=133) (min) (median with range)	22 (4.8- 77.1)
Procedural success (n)	129 (97.0%)
Hospital stay (days) (median with range)	2 (2-14)
Type of implanted device	
PFM coil	59 (44.4%)
ADO	22 (16.5%)
ADO II	20 (15.0%)
CVO-ME	6 (4.5%)
CDO	5 (3.8%)
LMFO	5 (3.8%)
LVO-MS	6 (4.5%)
LPDAO	3 (2.3%)
CVO-MU	2 (1.5%)
LVO-MU	2 (1.5%)
LVO-MA	1 (0.7%)
CVO-A	1 (0.7%)
AMVO	1 (0.7%)

*Results are expressed in frequency (%) and median (range) PFM coil: Nit-Occlud® Lê VSD coil; ADO: Amplatzer duct occluder; ADO II: Amplatzer duct occluder II; CVO-ME: Cocoon VSD occluder-membranous; CDO: Cocoon duct occluder; LMFO: Lifetech multifunctional occluder; LVO-MS: Lifetech VSD occluder-membranous symmetrical; LPDAO: Lifetech PDA occluder; CVO-MU: Cocoon VSD occluder-muscular; LVO-MU: Lifetech VSD occluder-muscular; LVO-MA: Lifetech VSD occluder-membranous asymmetrical; CVO-A: Cocoon VSD occluder-aneurysm; AMVO: Amplatzer muscular VSD occluder.

TABLE 3 List of procedural complications

	Number (%)
Major complications	**4 (3.0)**
Complete Heart Block	1 (0.7)
New onset of severe AR	2 (1.5)
New onset of severe TR	1 (0.7)
Minor complications	**12 (9.0)**
Transient RBBB	5 (3.7)
Groin hematoma	1 (0.7)
Hematuria	1 (0.7)
Intra-procedural atrial flutter	1 (0.7)
Transient 1st degree AV block	1 (0.7)
Transient junctional rhythm and infrequent PVCs	1 (0.7)
Transient hematuria with transient LBBB and frequent PVCs	1 (0.7)
Diminished femoral artery pulse	1 (0.7)

AR: aortic regurgitation; TR: tricuspid regurgitation; RBBB: right bundle branch block; AV: Atrio-ventricular; PVCs: premature ventricular complexes; LBBB: left bundle branch block;

6 months, and 1 year. Aspirin 5 mg/kg/day was routinely prescribed and continued at least for 6 months. However, if there was a residual shunt more than moderate degree, aspirin would be withheld.

All the collected data were entered in the statistical software SPSS version 20 for windows (SPSS, Inc, Chicago, IL). Continuous variables were expressed as mean ± SD or median with range as appropriate and discrete variables were presented as frequencies and/or percentages. For the categorical variable, Chi-square test was used and *P* value less than 0.05 was considered significant.

3 | RESULTS

One hundred and thirty-three pmVSDs were enrolled in the study. Baseline characteristics of patients and characteristics of pmVSD with measurements at different sites and hemodynamic status are shown in Table 1. There was a male to female ratio of 1.01:1. The median age and weight of patients at the time of closure were 7.1 years (ranging from 9 months to 28 years) and 21.2 kg (ranging from 6.4 to 93 kg), respectively. Aneurysmal type pmVSD was the most common type (42.1%) and most of pmVSD had single exit (80.5%).

Of the 133 pmVSD patients, in whom transcatheter closure was attempted, 129 patients (97%) were successfully treated. Various devices were used to occlude pmVSD (Table 2). The PFM coil was the commonest implanted device (44.4%). In the majority of the cases (96.9%), pmVSD was occluded with single device. Two devices were used in 2.3% of the cases. One patient (0.7%) with aneurysmal type defect with multiple exits was successfully closed with three PFM coils. The median hospital stay was 2 days (ranging from 2 to 14 days). One 9-month-old baby with a body weight of 6.4 kg and 5 mm tubular type pmVSD with torrential left-to-right shunt underwent transcatheter closure due to persistent pneumonia and inability to wean from ventilator. Ventilator support was successfully discontinued 4 days after VSD closure and she was discharged home after 10 days.

Four patients (3%) had major complications during the procedure (Tables 3 and 4). Two of these (1.5%) developed new onset of severe AR from impingement of the LV disc of the device to the aortic valve cusp and one of these (0.7%) had new onset of severe TR due to encroachment of the device to the septal leaflet of the TV. One patient (0.7%) developed CHB a week after the procedure. Surgical explantation of the device followed by patch repair of the VSD was performed in patients complicated with severe AR and CHB. The latter patient regained normal sinus rhythm 5 days after surgery. The patient with severe TR was closely monitored with consideration of removing the device within first few weeks if he developed progressive enlargement of the right heart or signs of congestive heart failure. During 1 month, 6 months, and 12 months follow-up, the patient remained clinically and hemodynamically stable after the procedure although TR remained in severe degree. Hence, the device was not removed.

Twelve patients (9%) developed minor complications. Most of those resolved spontaneously. One patient had first degree atrioventricular (AV) block at 1-month follow-up, which reverted to normal after 5 days of prednisolone. There was no substantial change in PR interval and QRS duration in any patient at 1-year follow-up. No patient developed CHB at 1-month, 6-month, and 1-year follow-up.

Forty-one patients (30.8%) had residual shunt immediate after the procedure. Most of the leaks were trivial to mild degree. One patient with aneurysmal type pmVSD, with two RV exits, closed using two devices (PFM coil and Cocoon VSD occlude-membranous [CVO-ME]), had moderate residual leakage immediately after device closure, which decreased to trivial degree at 1 month follow-up. Over the period of 1 year, the number of patients with residual shunt decreased from 29 (22.8%) to 16 (13.2%) to 10 cases (9.6%) at 1-month, 6-month, and 1-year follow-up, respectively (Table 5).

TABLE 4 Summary of patients having major procedural complication

Age/Gender	Weight (kg)	LV/RV Site (mm)	VSD morphology	Device (size)	Complication
3.1 years/F	9.6	9/4	Aneurysmal	PFM coil (8/6)	New onset of severe AR
4.5 years/F	16.4	6/4	Tubular	ADO (8/6)	New onset of severe AR
12.3 years/F	31	8/7	Window	ADO (12/10) CDO	CHB
2.6 years/M	11	6/4	Aneurysmal	CDO(8/10)	New onset of severe TR

LV : left ventricle; RV: right ventricle; VSD: ventricular septal defect; F: female; M: male; PFM coil: Nit-Occlud® Lê VSD coil; AR: aortic regurgitation; ADO: Amplatzer duct occluder; CDO: Cocoon duct occluder; CHB: complete heart block; TR: tricuspid regurgitation.

TABLE 5 Follow-up characteristics

		Pre-procedure (n= 133)	24 hour post procedure (n=130)	1 month follow-up (n=127)	6 month follow-up (n=121)	1 year follow-up (n=104)
Electrocardiogram						
PR interval (msec)* (mean ± SD)		-	138.7 ± 26.3	138.5 ± 23.9	141.1 ± 21.3	143.3 ± 22.2
QRS duration (msec)* (mean ± SD)		-	85.5 ± 15.4	86.9 ± 17.8	86.7 ± 14.9	88.1 ± 15.5
RBBB (n)		19 (14.3%)	24 (18.5%)	24 (18.3%)	24 (19.8%)	12 (11.5%)
LBBB (n)		6 (4.5%)	6 (4.5%)	7 (5.3%)	6 (4.9%)	3 (2.8%)
Residual shunt (n)	Tiny	-	21 (16.2%)	22 (17.3%)	8 (6.6%)	7 (6.7%)
	Mild	-	19 (14.6%)	7 (5.5%)	8 (6.6%)	3 (2.8%)
	Moderate	-	1 (0.7%)	0	0	0
	Total	-	41 (30.8%)	29 (22.8%)	16 (13.2%)	10 (9.6%)
TR (n)	Trivial	86 (64.7%)	85 (65.4%)	83 (65.3%)	92 (76.0%)	64 (61.5%)
	Mild	18 (13.5%)	20 (15.4%)	21 (16.5%)	11 (9.0%)	15 (14.4%)
	Moderate	2 (1.5%)	2 (1.5%)	2 (1.5%)	1 (0.8%)	1 ((0.9%)
	Severe	-	1 (0.7%)	1 (0.8%)	1 (0.8%)	1 (0.9%)
AR (n)	Trivial	3 (2.3%)	23 (17.7%)	16 (12.5%)	16 (13.2%)	10 (9.6%)
	Mild	-	4 (3.1%)	2 (1.5%)	2 (1.6%)	0
	Moderate	-	0	0	0	0
	Severe	-	0	0	0	0

*No pre-procedure data Percentages (%) were calculated according to number (n) of patients during follow up RBBB: right bundle branch block; LBBB: left bundle branch block; TR: tricuspid regurgitation; AR: aortic regurgitation.

Twenty-three patients (17.7%) and four patients (3.1%) had trivial AR and mild AR respectively immediately after the procedure. At 1-month, 6-month, and 1-year follow up, number of patients with trivial AR and mild AR were 16 (12.5%) and 2 (1.5%), 16 (13.2%) and 2 (1.6%), and 10 (9.6%) and 0, respectively (Table 5).

The use of various devices in relation to the morphology of pmVSD was further analyzed (Figure 2). The PFM coil was mostly implanted in patients with aneurysmal type pmVSD (64.4%). Single disc devices were used in all types of pmVSD, maximum in conical type pmVSD (43.3%) and double disc devices were used in all types except window type pmVSD (Figure 3). Among four patients with window type pmVSD, three were occluded with single disc devices. Comparing between the single and the double disc device groups, the usage of the device in relation to the VSD morphology has no statistical significance ($P = 0.07$).

Patients with residual shunt and AR at 1-year follow-up were further analyzed with respect to the device usage to close the VSD and the VSD morphology (Tables 5–7). The PFM coil was found to be used in most cases having residual shunt and AR. However, due to remarkable heterogeneity of type and frequency of device employed in the study, the association of PFM coil with residual shunt ($P = 0.14$) and

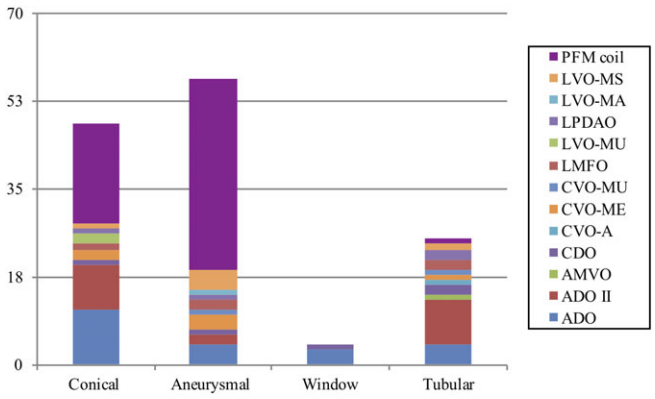

FIGURE 2 Variety of the implanted devices in relation to the morphology of pmVSD. PFM coil: Nit-Occlud Lê VSD coil; LVO-MS: Lifetech VSD occluder-membranous symmetrical; LVO-MA: Lifetech VSD occluder-membranous asymmetrical; LPDAO: Lifetech PDA occluder; LVO-MU: Lifetech VSD occluder-muscular; LMFO: Lifetech multifunctional occluder; CVO-MU: Cocoon VSD occluder-muscular; CVO-ME: Cocoon VSD occluder-membranous; CVO-A: Cocoon VSD occluder-aneurysm; CDO: Cocoon duct occluder; AMVO: Amplatzer muscular VSD occluder; ADO II: Amplatzer duct occluder II; ADO: Amplatzer duct occluder

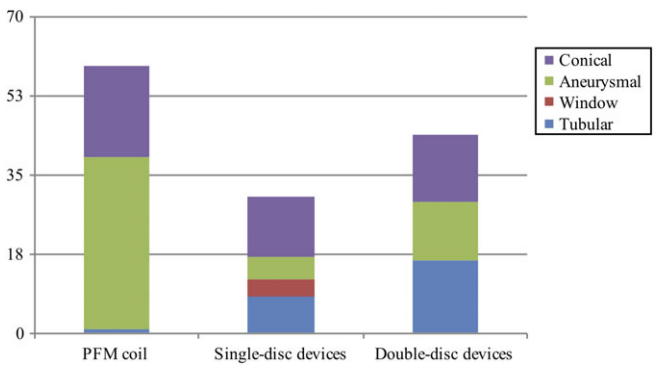

FIGURE 3 Distribution of types of device in relation to VSD morphology. PFM coil: Nit-Occlud Lê VSD coil

TABLE 6 VSD morphology and types of implanted device with residual shunt at one year follow-up (n=11)

	Frequency
VSD Morphology*	
Aneurysmal	8
Tubular	1
Conical	1
Types of implanted device	
PFM coil	9
LVO-MA	1
CDO	1

*No record of VSD morphology in 1 patient. VSD: ventricular septal defect; PFM coil: Nit-Occlud® Lê VSD coil; LVO-MA: Lifetech VSD occluder-membranous asymmetric; CDO: Cocoon duct occluder.

AR (P = 0.14) was not statistically significant. Similarly, aneurysmal type VSD has shown a higher number of patients with residual shunt.

4 | DISCUSSION

From QSNICH hospital database in the past 10 years, 8 out of 82 (10.9%) infective endocarditis cases were associated with small to moderate size VSDs. As a result, for endocarditis prevention in Thailand, VSD with isolated LV volume overload in the absence of a clinical significant shunt is one of the reasonable considerations for closure. Although surgical closure is the standard of care when indicated, for small to moderate size pmVSDs, transcatheter closure is an attractive alternative modality. Various reports have shown satisfactory results with percutaneous closure by dedicated pmVSD devices.[8–14] However, during the past years, off-label usage of various devices for pmVSD closure is becoming an emerging practice with high global success rate and encouraging early outcomes.[15,16] The present study reports using 13 different brands of the device for percutaneous pmVSD closure with a high success rate of 97%.

PFM coil was the most frequently used occluder (44.4%) in our study similar to various authors.[13,14] Due to flexible characteristic of the coil and the ability to adapt itself inside the VSD pocket with less radial and clamping force to the aortic valve and the conduction system, it is reasonably safe in aneurysmal (64.4%) and conical defects (33.8%). Nonetheless due to its dubious stability it is not preferred for window type defect (Figures 2 and 3). Though there were reported higher incidence of residual shunt with PFM coil,[13,14] our study showed statistically non-significant (P = 0.14). Residual shunt in these groups of the patients may relate to a unique character of aneurysmal type defect that may have multiple exits and the character of PFM coil with delicate polyester fibers that may not complete obliterate the flow promptly. Since this study overlaps five and half years of practice in two centers, we compared the use of device between first and second half of study period (i.e., before and after 2013) (Figure 4). We found only four different devices were used before 2013 and all 13 different devices were used after 2013. PFM coil was the first dedicated device for pmVSD in Thailand. Therefore it was used in majority (75%) of the cases during initial period. Recently, availability of many devices making us options to choose more appropriate one.

TABLE 7 Types of implanted device with aortic regurgitation one year follow-up (n=10)

	Frequency
PFM coil	6
ADO II	1
LVO-MA	1
LVO-MS	1
LMFO	1

PFM: Nit-Occlud® Lê VSD coil; ADO II: Amplatzer duct occluder II ; CDO: Cocoon duct occluder; LVO-MA: Lifetech VSD occluder-membranous asymmetric; LVO-MS: Lifetech VSD occluder-membranous symmetric; LMFO: Lifetech multifunctional occluder

Originally designed for PDA devices, the single-disc devices (ADO, CDO, LPDAO), can be employed for closure of the pmVSD with morphology similar to PDA (Figure 3). The double-disc devices (ADO II, AMVO, CVO, LVO, LMFO) can be employed in most type of pmVSDs with retrograde deployment of the device without the AV loop creation being its major advantage. The ADO II was the most preferred double disc occluder (15%) implanted in tubular (45%), conical (45%) and aneurysmal type defect (10%). Although this study shows tendency of device selection in relation to VSD morphology, significant correlation between type of the device and type of the defect cannot be statistically demonstrated due to a disproportionate distribution of the usage of the device and the VSD morphology in the study group. Nonetheless, it is recommended that interventionists should select the device based on their experience by looking in every aspect regarding size/morphology of the pmVSD, relationship of the defect to adjacent structures and availability of the device.

Major complications of transcatheter pmVSD closure are usually related to the surrounding structures: the aortic valve, the TV, and the conduction system. An oversized device may unnecessarily compress the vital structures and lead to unacceptable complications whereas undersized device has a risk of embolization. In this report, the selected device diameter was 1–2 mm larger than measured VSD

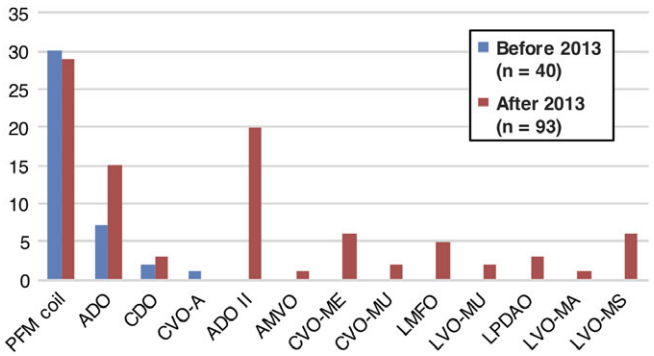

FIGURE 4 Comparison of devices used before and after 2013. PFM coil: Nit-Occlud Lê VSD coil; ADO: Amplatzer duct occluder; CDO: Cocoon duct occluder; CVO-A: Cocoon VSD occluder-aneurysm; ADO II: Amplatzer duct occluder II; AMVO: Amplatzer muscular VSD occluder; CVO-ME: Cocoon VSD occluder-membranous; CVO-MU: Cocoon VSD occluder-muscular; LMFO: Lifetech multifunctional occluder; LVO-MU: Lifetech VSD occluder-muscular; LPDAO: Lifetech PDA occluder; LVO-MA: Lifetech VSD occluder-membranous asymmetrical; LVO-MS: Lifetech VSD occluder-membranous symmetrical

TABLE 8 Comparison with previous studies on percutaneous pmVSD closure

	N	Age at procedure (years)	Devices	Success rate (%)	Major complication (%)	Description
Bass JL, et al. [7]	27	1.25-32	APMVO	93	3.7	Acute AR: 1
Masura J, et al. [8]	186	3-51	APMVO	100	1.07	Transient CHB: 2
Yang J, et al. [9]	832	2-71	APMVO SMVO	98.9	1.08	Death: 1 CHB requiring pacemaker: 1 New-onset AR needs surgical repair: 3 Embolization needs surgical removal: 2 Thrombo-embolism: 1
Wang L, et al. [10]	525	2-12	SMVO	95.6	0.7	Transient CHB: 1 CHB requiring pacemaker : 1 New-onset AR requiring surgical repair: 2
Fu YC, et al. [11]	35	1.2-54.4	APMVO	91	11.4	Early CHB: 1 Late CHB: 1 Peri-hepatic bleeding: 1 Rupture of tricuspid valve Chordae tendinae: 1
Chungsomprasong P, et al. [12]	116	1-59	APMVO AMVO PFM coil	94	5.2 (Amplatzer)	CHB requiring pacemaker: 4 (Amplatzer) Transient AV block: 1 (PFM)
Odemis E, et al.[13]	20	1.3-17	PFM coil	95	5	Hemolysis requiring device retrieval: 1
Present Study	133	0.73-28.2	Various devices	97	3	CHB: 1 New-onset AR requiring surgery: 2 New-onset severe TR: 1

APMVO: Amplatzer pmVSD Occluder; AR: aortic regurgitation; SMVO: Shanghai pmVSD occluder; CHB: complete heart block; AMVO: Amplatzer Muscular VSD occluder; AV: atrio-ventricular; TR: tricuspid regurgitation

diameter at the waist. Similarly, confirmation of the orientation of the wire circuit during loop formation must be made by fluoroscopy to ensure that the chordae tendenae of the TV is not entangled in the circuit. In addition, the right and left ventricular outflow tract velocity, degree of the tricuspid and aortic valve leakage, degree of residual VSD shunt, and the baseline cardiac rhythm must be assessed before releasing the device. Unfortunate may happen and patient can develop CHB after releasing the device as in one of our patient. Hence earlier detection of rhythm disturbance is very important as removing of device early may help in restoring sinus rhythm. Lower body weight, younger age, oversize device and unfavorable surrounding structures are the risk factors for complications of transcatheter closure of pmVSD.[6,10,11] In this study, the complication rate was comparable to the previous reports of surgical and transcatheter treatment (Table 8).[1,6,8–14,17,18] Although this study cannot identify potential risk factors for major complications due to broad diversity of device usage, strict protocol for optimum patient selection is essential to minimize adverse events and maximize success rate.

During 1-year follow-up, there was no new onset rhythm disturbance including AV block. Patients with trace to mild tricuspid and aortic regurgitations had no progression, however, there was no improvement in moderate to severe regurgitation. This could imply that although trivial to mild tricuspid and aortic valve leakage were acceptable, higher grades of valvular regurgitation require immediate consideration regarding reposition, reselection or removal of the device. Regrettably, its statistical significant association cannot be proven in this asymmetrical study population.

This study demonstrated outstanding benefits of transcatheter pmVSD closure with acceptable complication rate, however, there were certain limitations. Being a retrospective study with all records based on hospital database, some of the data were missing. Similarly the 1-year follow-up examination in the study for CHB is also short as its occurrence has been reported as late as 2 years.[18]

5 | CONCLUSION

With requisite case selection, transcatheter closure of small to moderate size pmVSDs can be successfully achieved with variety of the devices. This study has shown satisfying early outcome with minimal procedure-related complications, especially CHB.

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How to cite this article: Shrestha M, Promphan W, Layangool T, et al. Feasibility and 1-year outcome of transcatheter closure of perimembranous ventricular septal defects with different devices. *Catheter Cardiovasc Interv*. 2018;1–8. https://doi.org/10.1002/ccd.27851