Original Studies

The Results of Transcatheter Closure of VSD Using Amplatzer® Device and Nit Occlud® Lê Coil

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Objective: We retrospectively reviewed the result of patients who underwent transcatheter closure of ventricular septal defect (VSD) using Amplatzer® Perimembranous or Amplatzer® muscular VSD device (the Amplatzer® group) and Nit Occlud® Lê VSD Coil (the Pfm group). **Background:** Perimembranous type (PmVSD) and doubly committed subarterial (DCSA) VSD were the major isolated congenital heart defects in Thai children. Transcatheter device closure technique for both types of VSD has emerged as an alternative treatment to surgery. **Methods:** Retrospectively, data was reviewed between 2003 and 2009. **Results:** 116 patients were enrolled. Device or coil was successfully implanted in 94%. Complete closure at 24 hr is slightly higher in the Amplatzer® group. The average size of VSD in the Amplatzer® group was larger than the Pfm group ($P = 0.001$). The Pfm coil was primarily deployed in DCSA VSD when compared with the Amplatzer® group ($P < 0.01$). At 6 months follow-up the residual shunt was comparable ($P = 0.054$). There was only one transient AV block (AVB) in the Pfm group and 5 AVB in the Amplatzer® group. Four pacemakers were placed in the Amplatzer® group. **Conclusions:** Transcatheter closure of VSD in both Pm VSD and DCSA can be achieved by using either of the device. The Amplatzer® VSD device had the advantage of closure of larger defects with immediate less residual shunt but appeared to have a significant number of 3° AVB, which required pacemaker implantation. The Nit Occlud® Lê VSD Coil had the advantage of closure of both types of defects, in particular DCSA VSD with only small residual shunt.

Key words: outcome; Amplatzer® VSD; Nit Occlud® Lê VSD coil

INTRODUCTION

Transcatheter closure of ventricular septal defect (VSD) is an attractive alternative treatment for closure of perimembranous VSD. Surgical closure had low mortality, but there were certain morbidities from cardiopulmonary bypass. Lock et al. [1] reported series of patients using a Rashkind double umbrella for transcatheter closure of VSD in 1987. Originally, this device was designed for patent ductus arteriosus closure. When this device was used for VSD closure, the success rate and residual shunt were variable. Other devices, such as Amplatzer® duct occluder for PDA, Amplatzer® septal occluder for ASD, and Gianturco coils were used for VSD closure in the first era. In 1998, Arora et al. [2] reported outcome of the patients who underwent muscular type VSD closure with the Rashkind double umbrella and Amplatzer® muscular VSD occluder. None had residual shunt or new aortic regurgitation (AR). Transient complete heart block was

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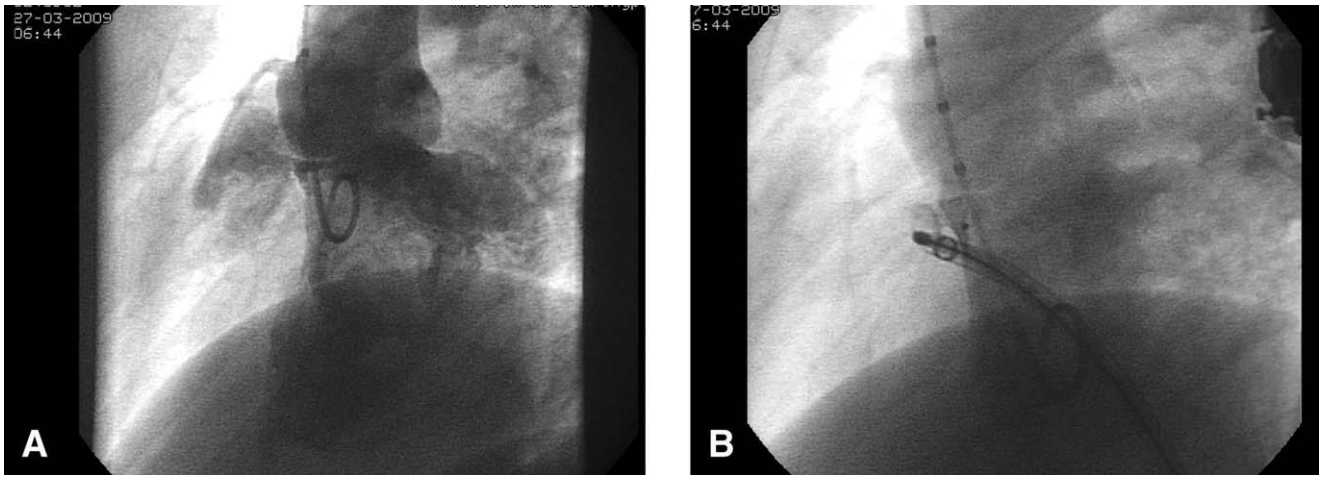

Fig. 1. (A, B) LV angiogram showed pre and post the Amplatzer® perimembranous VSD device was deployed in VSD without aneurysm.

reported in one patient. The Amplatzer® perimembranous VSD occluder was developed for closure of the perimembranous VSD with an excellent closure rate. Later on, complete heart block was reported with a rate that varied from 3.8% to 22% [3,4]. Transcatheter closure of perimembranous VSD at Siriraj hospital was first attempted in 2003 using the Amplatzer® perimembranous VSD [5]. We also used this device for closure of some infundibular outflow VSD. In 2006, in conjunction with Dr. Trong Phi Lê, Nit Occlud® Lê VSD coil was used in our hospital for transcatheter closure of both perimembranous and some doubly committed subarterial (DCSA) VSDs. Our objective was to demonstrate the results of transcatheter closure of VSD using disc device, either Amplatzer® perimembranous or Amplatzer® muscular VSD device (the Amplatzer® group) and Nit Occlud® Lê VSD coil (the Pfm group).

METHODS

We retrospectively reviewed our data for results of transcatheter closure of VSD using both devices between 2003 and 2009. The indications of transcatheter closure of VSDs were one of the following (1) hemodynamic data significant of left to right shunt by echocardiography or cardiac catheterization (Qp:Qs > 1.5); (2) clinical signs and symptoms of heart failure; (3) evidence of left side chamber enlargement by echocardiography; (4) prolapsed coronary cusp with AR; (5) prolapsed coronary cusp with imbalance index >1.3 or deformity index >0.3 [6]; and (6) size of the defects was not larger than the available devices.

Procedure

All procedures were done under general anesthesia. Prophylactic antibiotics were administered before and 24 hr after the procedure. The patients were heparinized to keep an activated clotting time of 200–250 msec. Transesophageal echocardiography (TEE) was done to estimate the defect size and surrounding structures, especially the distance from tricuspid and aortic valves, tricuspid valve aneurysm, and presence of aortic valve regurgitation. Femoral vessels were accessed. Right and left heart catheterizations were performed to estimate degree of shunt, pulmonary artery pressure, and pulmonary vascular resistance. Left ventricular angiogram was done to define location and size of the defect. The prebent Judkins Right catheter or Benston catheter were used for VSD engagement. An exchange length 0.035" soft J tipped noodle guidewire (Noodle wire from AGA, MN) was advanced through the catheter to pulmonary artery. The noodle guidewire was snared and exteriorized out through the femoral vein. A complete arteriovenous loop was performed. The delivery sheath (Torque Vue™ sheath, AGA, MN) was inserted through the femoral vein and advanced along the wire to the Judkins Right catheter in right atrium. The size of delivery sheath used for all Amplatzer® VSD device (perimembranous and muscular) was according to AGA recommendation. The sized of delivery sheath for Nit Occlud® Lê VSD Coil was 7 French. The system was moved together until the delivery sheath reached the ascending aorta. The Judkins Right catheter was replaced by pigtail catheter. The device was slowly pushed out under angiogram and echocardiogram. LV angiogram was performed to check the location of device and residual shunt before the device was deployed (as shown in Figs. 1–4).

Brief Device Description

The Amplatzer® muscular VSD device (Fig. 5A) and Amplatzer® perimembranous VSD device (Fig. 5B) (AGA Medical, Golden Valley, MN) [7] are made of

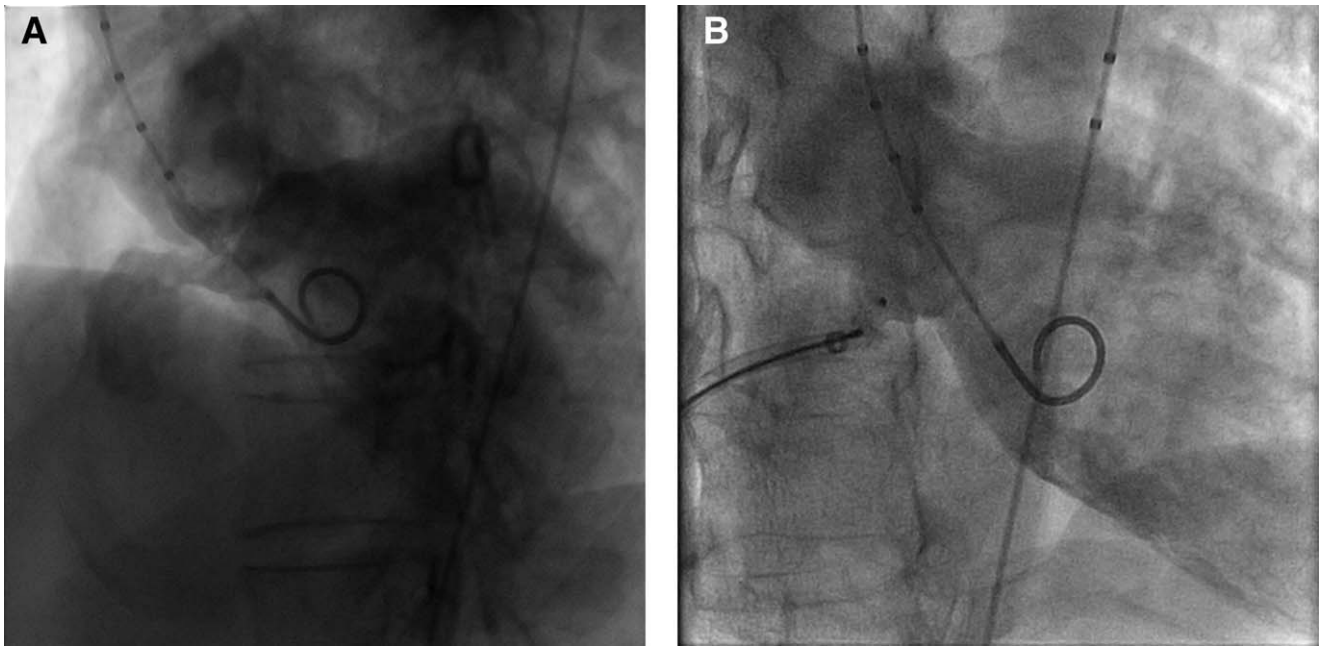

Fig. 2. (A, B) LV angiogram showed pre and post the Amplatzer® muscular VSD device was deployed in VSD with aneurysm.

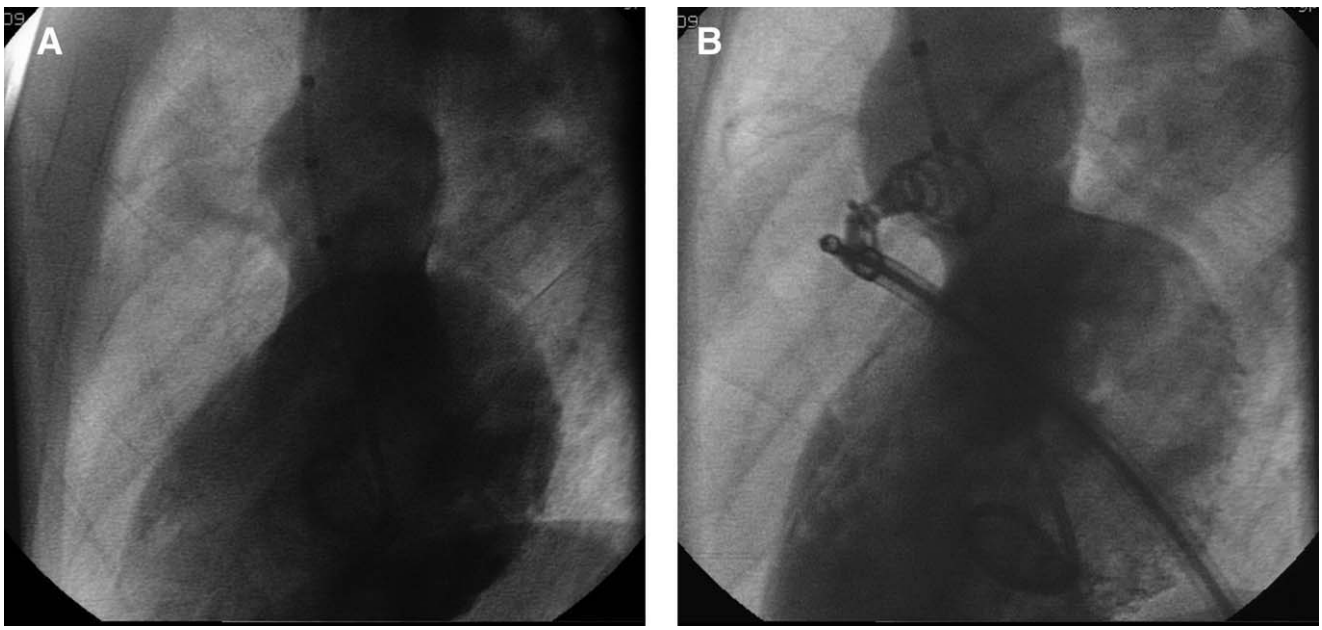

Fig. 3. (A, B) LV angiogram showed the Nit Occlud® Lê VSD Coil was deployed in outlet VSD.

Nitinol, an alloy of 55% nickel and 45% titanium that has superelastic properties. This device is a double disc device. The thickness of the Nitinol wire is 0.004" for devices 10 mm and smaller and 0.005" for larger devices. The Amplatzer® muscular VSD device has two same diameter discs linked together by short waist corresponding to the size of the VSD. The length of connecting waist is 7 mm. The Amplatzer® Perimembranous VSD device is eccentric double disc device. The leading retention disc is 4 mm larger, and the proximal disc is 3 mm larger than the diameter of the waist. The two discs are connected by a short cylindrical waist, which corresponds with the device size. An eccentric device has been designed to avoid interference with

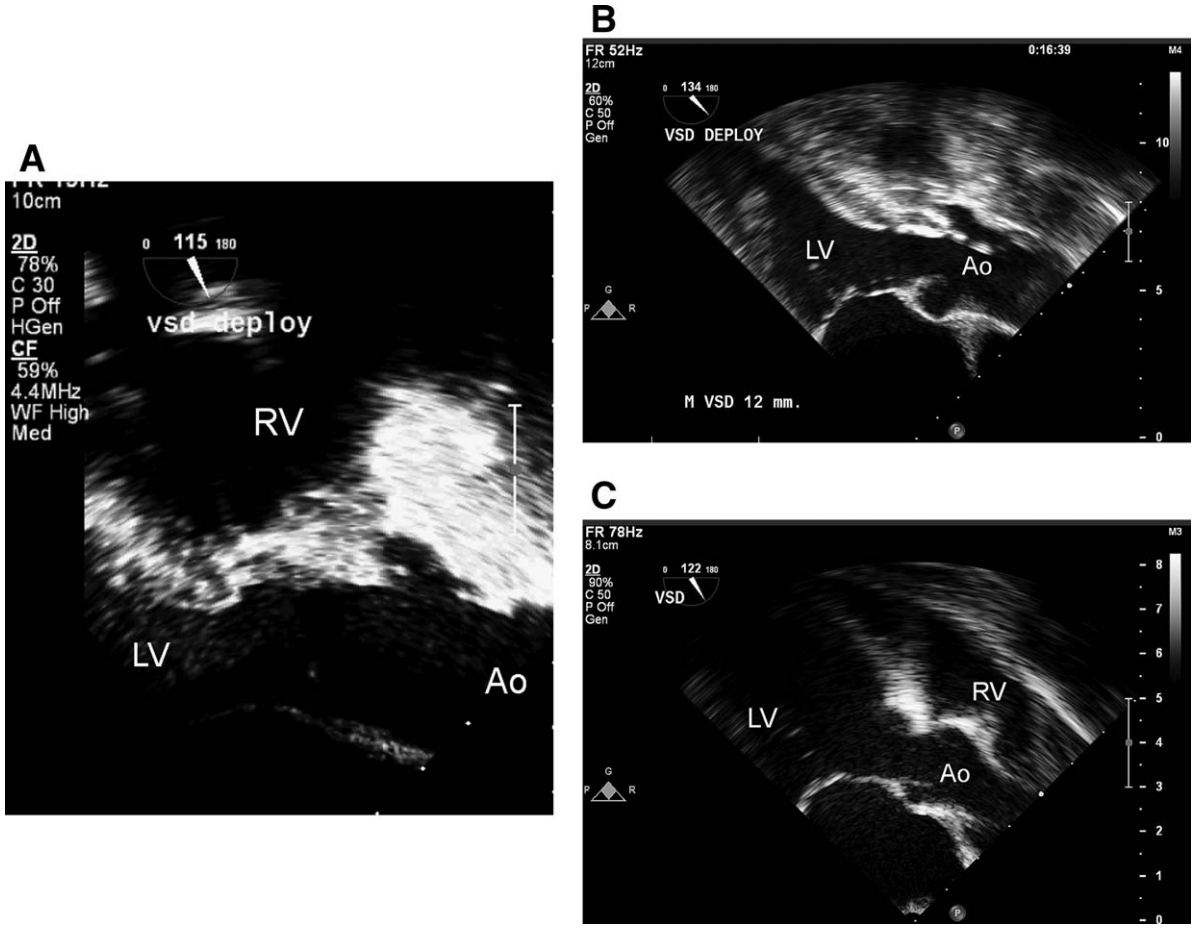

Fig. 4. TEE demonstrated (A) the Amplatzer® perimembranous VSD device on the position of VSD without aneurysm, (B) TEE demonstrated the Amplatzer® muscular VSD device on the position of VSD with aneurysm, and (C) TEE demonstrated the Nit Occlud® Lê VSD Coil on the position of outlet VSD.

the aortic and atrioventricular valves. So, the difference between the Amplatzer® muscular VSD device and the Amplatzer® perimembranous VSD device is the shape of left ventricular disc that lies within eccentric configuration. To achieve immediate complete closure, three Dacron polyester patches are sewn securely with polyester thread into the two discs and the waist of the device. The device size corresponds to the diameter of the waist. The size varies from 4 to 18 mm (1 mm increment). We selected the device using both measurements from echocardiography and angiographic methods. The device size was calculated from square root of longest diameter multiplied with shortest diameter.

Nit Occlud® Lê VSD Coil [8] (Fig. 6A and B) (pfm: Produkte für die Medizin AG, Köln, Germany) is made of Nitinol coils and has cone-in-cone configuration, which means that the proximal cone is reversed. The device has reinforced distal coil loops to be placed on the left ventricular side of the defect. The proximal cone is more flexible and to be partially deployed on the left ventricular side of the defect. Only the last two proximal coil loops are placed on the right ventricular side [9,10]. The current coil used were the third generation with polyester fibers added to the left ventricular cone. The mechanism of closure involves filling-up the defect by the device without real stenting effect. The flow reduction leads to obstruction of the defect and subsequent endothelialization. The device nomenclature refers to the sizes of the largest diameter left ventricular coil, followed by the largest diameter right ventricular coil. The 14×8 device has a maximum left ventricular coil diameter of 14 mm and a maximum right ventricular coil diameter of 8 mm. The distal diameter of the coil should be at least twice the diameter of VSD at right ventricular side and equal or 1–2 mm more than the diameter of VSD at left ventricle side. The devices come in size from 8×6, 10×6, 12×6, 14×8, and 16×8 mm.

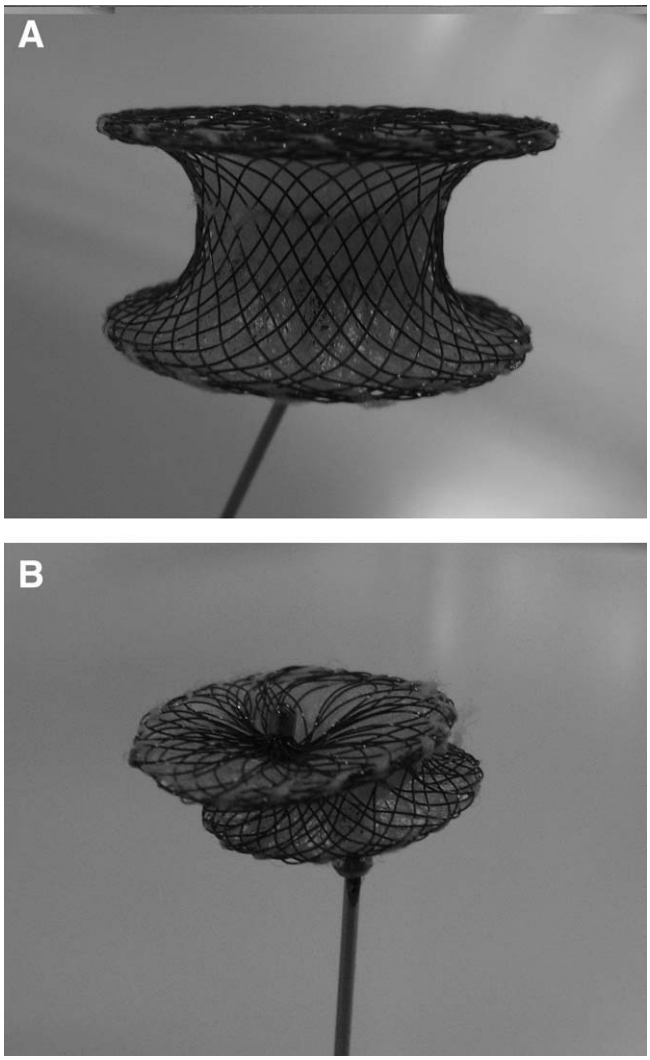

Fig. 5. (A) The Amplatzer® muscular VSD device and (B) the Amplatzer® perimembranous VSD device.

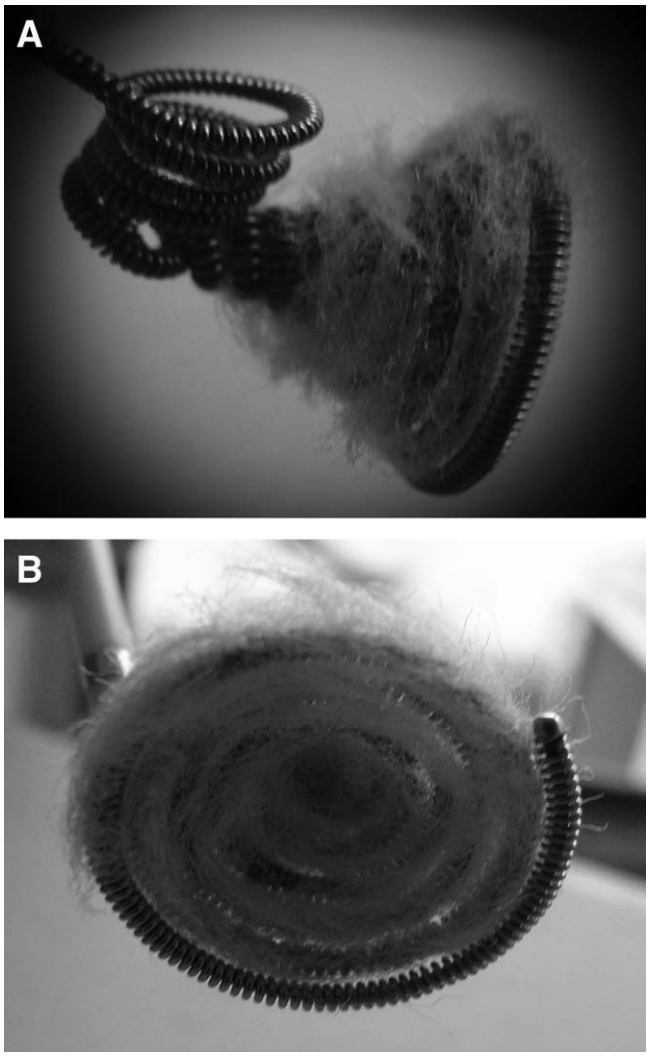

Fig. 6. (A, B) The Nit Occlud Lê VSD Coil.

Criteria for Device Selection

The Amplatzer® perimembranous VSD device was used primarily for perimembranous VSD and outlet VSD (with or without aneurysm) in all cases (as Fig. 1). The Amplatzer® muscular VSD was used for muscular VSD defect. After several AV block (AVB) were reported in the patients who had Amplatzer® perimembranous VSD device deploy straddle the interventricular septum (IVS). Because of its small waist, it has potential encroaching into IVS and injury part of AV node. We decide to use Amplatzer® muscular VSD, which had a larger waist to deploy straddle IVS for patients who had perimembranous VSD without aneurysm. For patients who had perimembranous VSD with aneurysm, we still can use Amplatzer® perimembranous VSD device to deploy inside the aneurysm. In 2006, the Nit occlud Lê VSD Coil was introduced to our hospital. This device was used for the patient who had perimembranous VSD with aneurysm and opening less than 6–8 mm. After 2008, the Nit occlud® Lê VSD Coil was also chosen for DSCA VSD as well (as shown in Fig. 3).

Postimplantation Care

Catheter-related complication was observed during postoperative period. The patients were evaluated by electrocardiography and echocardiography at 24 hr, at 1 week, 1 month, 6 months, or by decision of the physician during follow-up. Infective endocarditis prophylaxis and antiplatelet dosage of aspirin were given for at least 6 months after the procedure was successful or until the defect was completely occluded.

Statistical Analysis

Data were reported as a frequency or percentage for nominal variables. The continuous variables were

TABLE I. Demographic Data, Hemodynamic, and Immediate Procedural Data

	Amplatzer® VSD ($n = 76$)	Nit Occlud® Lê VSD Coil ($n = 33$)	P value
Age (year)	18.6 ± 14.2 (1–59)	9.8 ± 7.1 (1–29)	0.001
Weight (kg)	44.4 ± 21.9 (10.1–93.7)	34.5 ± 21.2 (10.1–83.2)	0.016
VSD diameter by TEE at LV side (mm)	7.8 ± 2.8 (3.1–15)	4.7 ± 1.4 (2.5–8)	0.001
Type VSD			
–Pm VSD	42/76 (55.3%)	6/33 (18.0%)	0.001
–PmVSD with inlet	20/76 (26.3%)	5/33 (15.2%)	0.001
–Outlet and DCSA VSD	14/76 (18.4%)	22/33 (66.7%)	0.001
Preprocedure AR			
no	65/76 (85.5%)	24/33(72.7%)	0.11
trivial/mild AR	11/76 (14.5%)	8/33 (24.3%)	
moderate AR	0/76	1/33 (3%)	
*Q*p:*Q*s	1.9 ± 0.8 (1–6.3)	1.56 ± 0.7 (1–4.6)	0.05
PA systolic pressure (mm Hg)	29.7 ± 8 (16–67)	26.2 ± 4.1 (20–35)	0.03
LVEDP (mm Hg)	14.1 ± 3.3 (5–25)	13.8 ± 3 (1–19)	0.69
Device size	8.4 ± 2.5 (4–14)	10.3 ± 1.1 (8–12)	0.001
Device size/VSD size	0.9 ± 0.3 (0.2–2.1)	0.5 ± 0.1 (0.3–0.8)	0.001
Flu time (min)	25.1 ± 12.1(2.7–51)	21.9 ± 3.0 (8.2–75.1)	0.17
Procedure time (min)	98.1 ± 30.2 (60–210)	88.2 ± 27.5 (60–150)	0.110

Pm: perimembranous VSD; DCSA VSD: Doubly committed subarterial VSD; AR: aortic valve regurgitation; *Q*p:*Q*s: pulmonary blood flow: systemic blood flow; PAP: pulmonary artery pressure; PVR: pulmonary vascular resistance; LVEDP: left ventricular end diastolic pressure; VSD size: square root (long-axis diameter × short axis diameter).

shown in median and at range. Risk factors of complete heart block were analyzed using version 17.0 SPSS program. Chi-square, Independent T-test, and Mann-Whitney U test were used. A probability value of $P < 0.05$ was considered to be statistically significant.

Study Population

Between 2003 to 2009, transcatheter closure of VSDs was attempted in 116 patients. From a total of 116 patients, 110 patients had isolated VSD, the others had associated cardiac lesion such as coarctation of aorta (1), secundum atrial septal defect (1), Tetralogy of Fallot (postoperative residual VSD) (2), aortic stenosis (1), and hypertrophic cardiomyopathy (1). The procedures were not attempted in seven patients because of transient atrioventricular block during crossing of VSD in two patients, being unable to engage VSD in one patient, worsening of AR after deployed the Amplatzer® device in two patients, and findings of the defect size were too large in two patients. The total 76 patients in the Amplatzer® group included 62 patients using the Amplatzer® perimembranous device and 14 patients using the Amplatzer® muscular device. The Pfm group included 33 patients using the Nit Occlud® Lê VSD Coil. The average age was 15.5 ± 12.9 (1–59 years). The average weight was 40.3 ± 21.9 (10.1–93.7) kg. Demographic data as well as hemodynamic and immediate procedural data are presented in Table I. The patients in Pfm group were younger (9.8 ± 7.1 vs. 18.6 ± 14.2 years, $P = 0.001$) and smaller with their weight (34.5 kg ± 21.2 vs. 4.4 kg ± 21.9, $P = 0.016$) than patients in the Amplatzer® group. The diameter in VSD (by TEE) is larger in the Amplatzer® group (7.8 ± 2.8 mm vs. 4.7 ± 1.4 mm, $P = 0.001$). There is no statistical significant difference in hemodynamic data during cardiac catheterization between both groups. There were 48 perimembranous VSD, 25 perimembranous with muscular inlet extension and 36 outlet type VSD (both infundibular outflow and DCSA VSD). The majority of patients selected for closure using Amplatzer® device were perimembranous VSD, but the Pfm group were chosen more often for DCSA type VSD (66.7% vs. 18.4%, $P = 0.001$) when compared with the Amplatzer® group. The frequency of preprocedure AR was comparable among both groups (27.3% vs. 14.5%, $P = 0.11$).

Follow-Up Results. The follow-up time ranged from 180 to 2,285 days (median = 242 days). Postoperative complications were observed. Vascular complications requiring heparin intravenously occurred in two patients. No device embolization or hematuria was noted. There were 76 patients in the Amplatzer® group and 33 patients in the Pfm group (as shown in Table II). The immediate residual shunt was marginally higher in the Pfm group when compared with the Amplatzer® group (18.2% vs. 10.6 %, $P = 0.05$). Four patients in the Amplatzer® group had moderate residual shunt size (2–4 mm.)

The residual shunt at 6 months after closure was comparable among both groups (15.2% vs. 10.5%, $P = 0.54$). The frequency of immediate AR after closure VSD appeared to be higher in the Pfm group (39.4% vs. 23.7%, $P = 0.16$). The frequency of AR

TABLE II. Follow-Up Data on Residual Shunt, Complete Atrioventricular Block (3° AVB), and Degree of Aortic Regurgitation (AR)

	Amplatzer® VSD ($n = 76$)	Nit Occlud® Lê VSD Coil ($n = 33$)	P value
Residual shunt at first day postprocedure			
–small < 2 mm	4/76 (5.3%)	6/33 (18.2%)	0.05
–moderate/large <4 mm	4/76 (5.3%)	0/33 (0%)	0.05
Residual shunt at sixth month postprocedure			
–small < 2 mm	7/76 (9.2%)	5/33 (15.2%)	0.54
–moderate/large <4 mm	1/76 (1.3%)	0/33 (0%)	0.54
AR at first day			
–no	58/76 (76.3%)	20/33 (60.6%)	0.16
–trivial/mild	17/76 (22.4%)	13/33 (39.4%)	
–moderate	1/76 (1.3%)	0/33 (0%)	
AR at sixth month			
–no	69/76 (90.8%)	22/33 (66.7%)	0.002
–trivial/mild	7/76 (9.2%)	11/33 (33.3%)	
–moderate	0/76 (0%)	0/33	
3° AVB	5/76 (6.5%)	1/33	
Pacemaker implantation	4/76 (5.2%)	0	

AR: aortic valve regurgitation; 3° AVB: third degree atrioventricular block.

TABLE III. Patients With High-Grade Heart Block (Both Transient and Permanent)

Sex	Age (year)	Weight (kg)	VSD type	Device	Device size/ VSD diameter	Onset after implantation	Treatment	Recovery	Current status
M	30	50	Peri	Am	1.1	Second day	Steroid and TPM	fifth day	NSR
M	3	13	Inlet	Pfm	0.4	Fourth day	Steroid	fifth day	NSR
F	5	22.2	Inlet	Am	1	Fourth day	Steroid and PPM	No	PPM
F	21	49.7	Peri	Am	1.1	Sixth day	PPM(D12)	1 year	PPM
M	42	75.7	Inlet	Am	0.8	Seventh day	PPM	No	PPM
F	2	13.1	Inlet	Am	0.6	1 3/12 years	PPM	No	PPM

M: male; F: female; VSD Peri: perimembranous VSD; Inlet: perimembranous VSD with inlet extension; Am: Amplatzer® VSD device; Pfm: Nit Occlud® Lê VSD Coil; TPM: temporary pacemaker; PPM: permanent pacemaker; NSR: normal sinus rhythm.

preprocedure and 6 months postprocedure for both groups was not statistically different for both groups (the Amplatzer® group 14.5% vs. 9.2%, $P = 0.272$ and the Pfm group 27.3% vs. 33.3%, $P = 0.103$). The left ventricular outflow tract obstruction was not found in our patients.

Complete AV Block With Pacemaker Placement

Complete heart block after transcatheter VSD closure occurred in six cases. The frequency of complete heart block in our patients was 5.5%. The defects of six patients were completely occluded. Two patients developed complete heart block on second and fourth day, respectively, after VSD closure. After steroid treatment both of their rhythms turned to normal sinus rhythm after 1 and 3 days, respectively. There were four patients who underwent permanent pacemaker implantation. One out of four patients developed late complete heart block at 1 year and three months after follow-up. Data for each patient with AVB is shown in Table III. Three out of 20 patients (15%) in the Amplatzer® group who had perimembranous VSDs with inlet extension developed complete AVB. However, in the Nit Occlud group, only five patients had perimembranous VSDs with inlet extension, since this device was primarily used in outlet and DCSA VSD. Hence, there is a lesser chance of developing complete heart block.

DISCUSSION

Transcatheter VSD closures have been performed at Siriraj hospital since 2003 [5]. The perimembranous defects were occluded using the Amplatzer® membranous VSD Occluder with good results in the early period [5,11,12]. Indication of transcatheter VSD closure should be similar to surgical closure. However, transcatheter closure has limitation to close larger VSD. It can be used in small to moderate size perimembranous VSD with or without aneurysm. In selected cases of DCSA with less than mild AR, it could be considered as an alternative treatment for closure VSD. The only limitation of transcatheter closure of VSD is in a small

size patient (<10 kg) with large VSD [13]. A comparison study between surgical and transcatheter closure of VSD showed that transcatheter closure is less invasive, has a shorter recovery time, and requires less hospital stay time. The complication rates of both methods were comparable. There were also no differences in costs among both methods [14].

Both size and location of VSD were considered as vital information to select type of the device used. It appeared that in large perimembranous VSD, the Amplatzer® devices should be a device of choice. Although 4/7 patients in the Amplatzer® group had moderate shunt, this may be because the Amplatzer® devices were placed in large VSD aneurysm that had more than one opening in right ventricular side. This residual shunt has a tendency to decrease overtime during the follow-up period. On the other hand, the residual shunt in the Pfm group was small but had a tendency to remain at the same degree during the follow-up period. There was a trend toward higher percentage of the preprocedure AR in the Pfm group when compared with the Amplatzer® group. However, this was not statistically significant (27.3% vs. 14.5%, $P = 0.11$). This may be due to higher proportion of DCSA VSD in Pfm group (66.7% vs. 18.4%, $P < 0.001$). After 6 months VSD closure, the frequency of AR was also found to be higher in the Pfm coil group than in the Amplatzer® group (33.3% vs. 9.2%, $P = 0.002$). However, the frequency of AR appeared the same at 24 hr and at 6 months follow-up in the Pfm group. The DCSA VSD was known to have higher risk of progressive AR [15,16]. Thus, closure in DCSA VSD patients was indicated. The degree of AR appeared similarly even after surgical closure of VSD was performed [17]. We believe that our preliminary report showed the Pfm coil was suitable for closure of some type of DCSA VSD with mild AR. It appeared that long term follow-up was needed to determine the fate of AR after transcatheter closure of DCSA VSD using the Nit Occlud® Lê VSD Coil. In theory, the Pfm coil did not have a pressure effect on the aortic cusp as the Amplatzer® device. Furthermore, the Nit Occlud® Lê VSD Coil was used in outlet-type VSD, which has less chance to develop into complete heart block. However, we found one patient who developed complete heart block in the Pfm group. Most of complete heart block patients (four patients from six patients) had perimembranous extension to inlet type that included three patients in the Amplatzer® group and one patient in the Pfm group. Therefore, we suspect that the anatomy of perimembranous VSD with inlet type is the predisposing factor to develop complete heart block. We then selected Amplatzer® muscular VSD for perimembranous extension to inlet type without aneurysm.

In conclusions, transcatheter closure of VSD in selected patients can be achieved using both the devices. The Amplatzer® Perimembranous VSD device had the advantage of closure of larger VSD defects. The number of residual shunts on both devices appeared small and, in particular, improved over time in the Amplatzer® group. The Amplatzer® group appeared to have a significant number of 3°AVB that required pacemaker implantation. Nit Occlud® Lê VSD Coil had the advantage of closure of both perimembranous and selected DCSA VSD (with less than mild AR). The frequency of AR before and at 6 months appeared to be the same during the follow-up period for both device groups.

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