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Original article

Safety and Efficacy of Percutaneous Transcatheter Closure of Perimembranous Ventricular Septal Defects with Nit Occlud® Lê VSD Coil: A Single Center Experience

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Background: Perimembranous ventricular septal defect (pmVSD) is the most encountered form of VSD. Transcatheter closure of pmVSD in suitable candidates is an appealing alternative to surgical closure with equivalent success and major complications rates; however, with shorter hospital stay and better cosmetic outcome. The Nit Occlud® Lê VSD coil (pfm medical, KÖln, Germany) has been designed for percutaneous VSD closure. **Aim:** The purpose of this study is to evaluate the safety and efficacy of pmVSD closure with Nit Occlud® VSD Lê coil. **Subjects and methods:** Patients diagnosed with pmVSD and eligible for percutaneous closure with Nit Occlud® VSD Lê coil were recruited and followed for 6 months. **Results:** 16 patients (median (IQR) age 6 (3.8-9.1) years, 68.75% females) who underwent percutaneous pmVSD closure with Nit Occlud® VSD Lê coil and completed 6-months follow-up were enrolled in the study. The procedure was successful in all patients with no major complications requiring device retrieval. Median procedure time was 57 minutes and median fluoroscopy time was 24 minutes. The immediate complete occlusion rate was 31.25%, which increased to 75% after 6-months. One patient (6.25%) developed transient 2:1 AV block. One patient (6.25%) developed hemolysis that resolved after the implantations of two vascular plugs. One patient (6.25%) developed mild aortic regurgitation and 2 patients (12.5%) developed mild tricuspid regurgitation **Conclusions:** Percutaneous pmVSD closure using Nit Occlud® Lê VSD coil is feasible, safe and efficacious in selected patients. It may be a suitable alternative for surgical closure in appropriate candidates.

Keywords: Perimembranous ventricular septal defect, Nit Occlud® Lê VSD coil, Percutaneous closure, Congenital heart defect.

Background

Congenital heart disease (CHD) affects 0.8% of new born and is a leading cause of morbidity and mortality despite major advances in management **(1).** Ventricular septal defect (VSD) is the most common congenital heart problem representing about 30% of CHD **(2).** VSD may occur anywhere within the interventricular septum, with 70-80% of defects are in the perimembranous position **(3).**

Early closure of large VSD is warranted specially in the presence of signs of left side chambers overload in order to prevent the development of pulmonary arterial hypertension, left ventricular dysfunction, arrhythmias and aortic regurgitation **(4).**

Surgical VSD closure was performed for the first time in 1954 by Lillehei et al **(5)** and since then it became the gold standard for VSD closure. However, this occurs on the cost of prolonged hospital stay, patient discomfort and unfavorable cosmetic outcome. Percutaneous techniques have been established in order to reduce the impact of such disadvantages of surgery.

Percutaneous VSD closure was first introduced by lock et al in 1988, where they reported transcatheter VSD closure using Rashkind double umbrella device **(6)**. In the following decades several dedicated and non-dedicated devices were used for transcatheter VSD closure. Yet, the use of percutaneous closure for perimembranous VSD was hampered by its proximity to conduction system, tricuspid and aortic valve with increased risk of development of complete atrioventricular block (cAVB) and significant valvular dysfunction **(4).**

The aim of this study is to determine the safety and efficacy of percutaneous transcatheter closure of perimembranous VSD with Nit Occlud® Lê coil device.

Methods

Study population

This prospective cohort, single arm observational study, included patients diagnosed with perimembranous VSD who underwent percutaneous closure with Nit Occlud® Lê coil device and were followed for 6 months post procedure, during the period from June 2015 to February 2017.

Inclusion criteria included: 1) VSD located within the perimembranous septum, 2) ≥ 8 Kg of body weight, 3) Pulmonary vascular resistance < 7 woods unit, 4) Proximity of ventricular septal defect to Aortic valve ≥ 3mm by TTE and 5) Significant Left to right shunt

with pulmonary to systemic blood flow ratio (Qp/Qs) >1.5, supported by the presence of (a) cardiomegaly on CXR (defined as cardiothoracic ratio > 0.5) and/or (b) clinical manifestations as recurrent respiratory infections and / or symptoms of heart failure. Exclusion criteria included: 1) VSD associated with other congenital cardiac abnormalities that require surgical treatment, 2) contraindication to antiplatelet therapy.

History taking, general and cardiac examination and growth assessment (weight, height, body surface area (BSA) and body mass index (BMI)) were taken from all enrolled patients. A 12 lead electrocardiogram was done before and immediately post procedure and at 1- , 3-and 6- months post procedure to detect any rhythm and/or conduction abnormalities .

A detailed and informed written consent was obtained from all the eligible patients or parents. The study was approved by the institutional review board and local ethical Committee.

Device Description

The Nit-Occlud Lê VSD coil (pfm medical, KÖln, Germany) frame is made of nitinol wires with polyester fibers added to the left-sided parts of the loops. The device has a distal coil representing the larger left-sided cone and a smaller right sided proximal cone **(Fig.1)**.

The device is available in different sizes: 8/6, 10/6, 12/6, 12/8, 14/8, and 16/8mm; the first and the second number represents the diameter of the device at the left and right ventricular sides, respectively. Coils are premounted on their delivery catheter **(7).**

Procedure:

Percutaneous closure of VSD was performed under general anesthesia in all patients. All percutaneous VSD closures were guided by trans-thoracic echocardiography and/or trans-esophageal echocardiography and fluoroscopy. All patients received intravenous heparin (100 units/kg) and Amoxicillin (50–100 mg/kg, IV) 30–60 minutes prior to the procedure. A 6F right-sided femoral venous access and a 4F left-sided femoral arterial access were obtained. Right and left heart catheterization was preformed through percutaneous trans-femoral route. Assessment of the defect was performed in multiple views. The angiographic view that best profiled the defect was used as a reference for closure **(Fig. 2A)**. In most cases modified left anterior oblique 60° cranial 20° and left anterior oblique 45° cranial 45° were used. Measurements of the defect size from left and right ventricular sides and its distance from the aortic and tricuspid valve were confirmed

using angiography and echocardiography. The size of the Nit Occlud® Lê coil selected was 1-2 mm more than angiographic measurement of the left ventricular side of the defect and double the right ventricular side of the defect.

A 0.035 in Terumo wire (Terumo Corporation, Tokyo, Japan) was passed through the defect from the right side in a multipurpose or cut pig tail catheter according to the anatomy of the defect and was snared using a 10–15 mm goose neck snare (Ev3 Endovascular, Inc., Plymouth, MN, USA) in either the pulmonary artery or right ventricle or inferior vena cava. The wire was snared and exteriorized out the right femoral vein. This established an arteriovenous wire loop (AV loop) which had to be straight without any incorporation to any of the tricuspid tissue indicted by any kink or resistance ((**Fig. 2B)**. The delivery sheath was inserted through the femoral vein and advanced to the ascending aorta through the defect **(Fig. 2C)**. The size of delivery sheath for Nit Occlud® Lê c oil was chosen according to the coil size. The first loops were opened in the ascending aorta, and then the device was slowly withdrawn into the left ventricle and into the VSD pouch **(Fig. 2D)**. Confirmation of position was performed by LV angiography. Following this, the next loops were opened in the left ventricle, and the latter device was slowly pulled back into the last part of the loops opened in the defect. Thereafter, the final loops were deployed at the right side of the defect **(Fig. 2E)**. A left ventricular angiogram and echocardiography was performed to assess the location of the device, tricuspid valve, aortic valve and residual shunt before the device was deployed in its final position **(Fig. 2F).**

Patients were prescribed antiplatelet therapy in the form of oral aspirin 5mg/kg/day for 6 months. Infective endocarditis prophylaxis was prescribed for 6 months and continued beyond 6 months in cases with persistent residual shunt **(8).**

Follow-up

Patients were subjected to standardized follow-up protocol at day 1 post procedure, 1-, 3- and 6- months post VSD closure. The protocol included transthoracic echocardiographic study, 12 leads electrocardiogram (ECG), clinical examination to detect any new murmur and urine analysis to detect hemolysis.

Complications

A major complication was defined as an event that lead to death, required immediate surgery, persistent cAVB requiring permanent pacemaker insertion, ongoing hemolysis requiring blood transfusion, and new onset or increased valvular regurgitation requiring device retrieval. Other complications that were

transient, self-limited or required only medical treatment were classified as mild **(4).**

Definition of outcomes

Procedural success

Procedural success was defined by device implantation in the appropriate position without significant residual shunt or valve regurgitation requiring device removal or surgery **(4).**

Residual shunt

The diagnosis of residual shunt was given, if transthoracic echocardiographic study detected left to right shunt across the IVS by color flow mapping. It was classified as trivial, small, moderate and large if the color jet width was <1 mm, 1-2 mm, >2-4 mm and > 4 mm, respectively **(4).**

Statistical Analysis:

Statistical analysis was carried out using IBMSPSS Statistics for Windows. Version 20.0. Armonk NY: IBM Corp Numerical data was presented as number and percentages, while categorical data was presented as median and interquartile range (IQR).

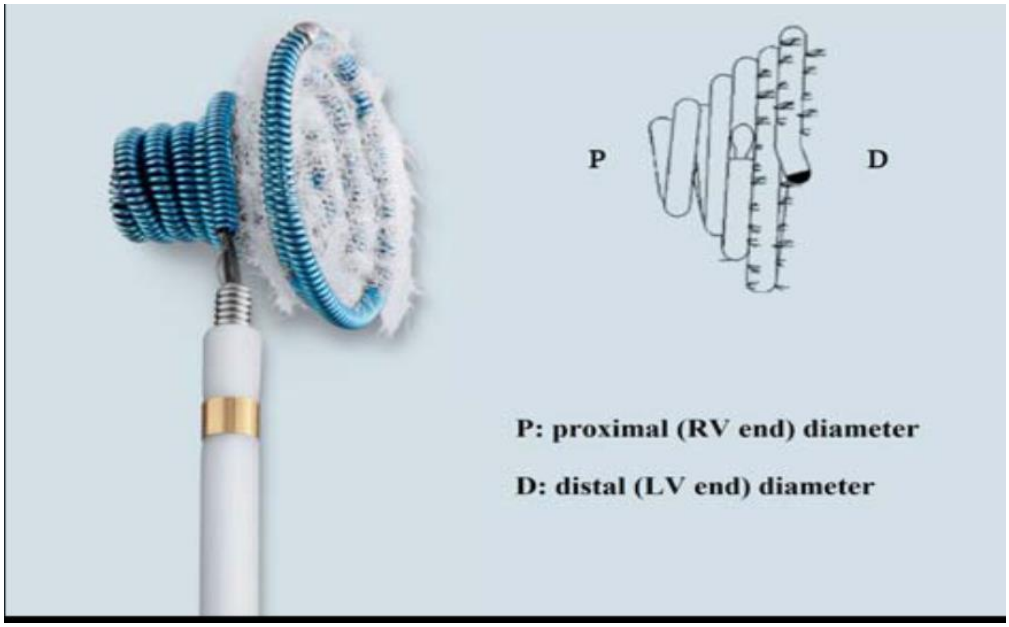

Fig. 1. The Nit-Occlud Lê VSD coil

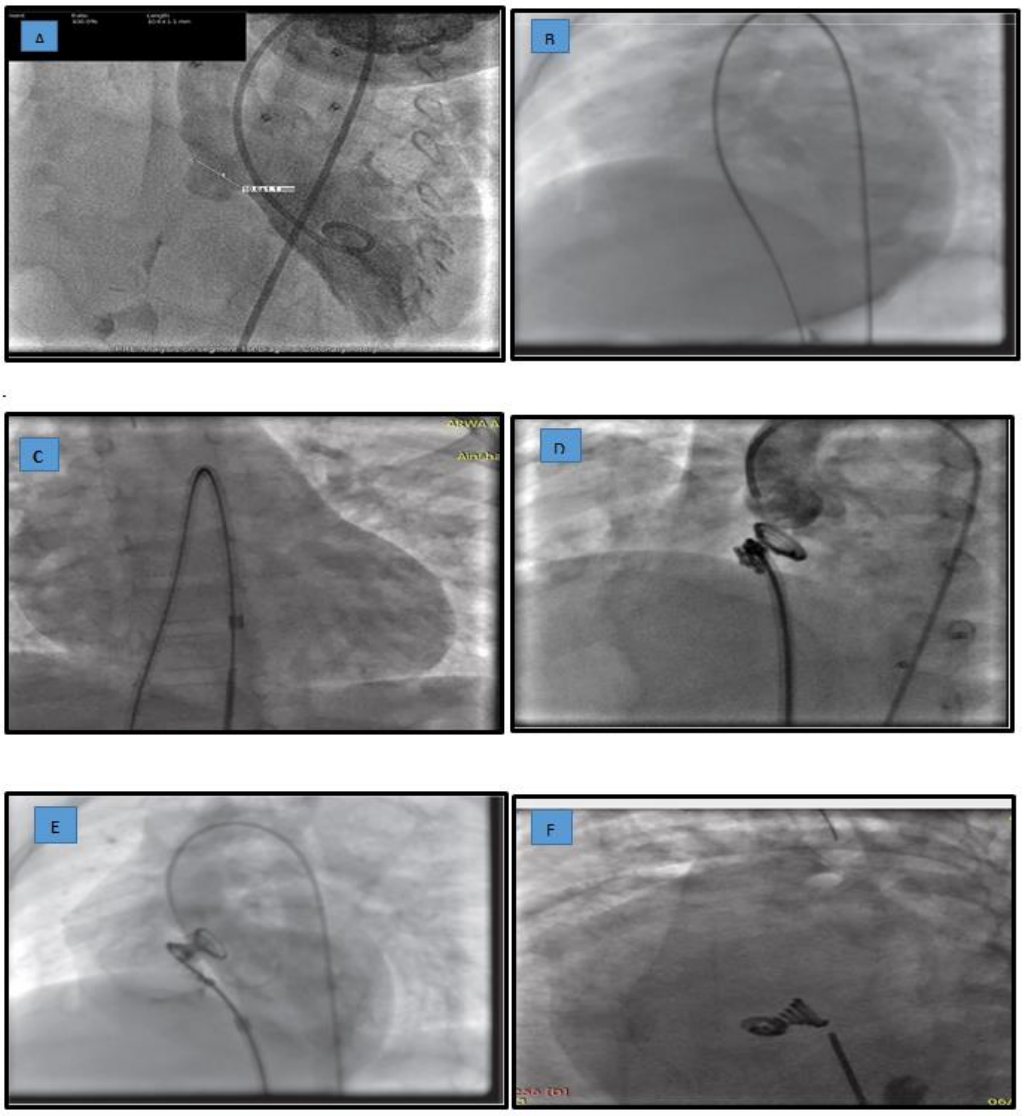

Fig. 2. The procedure of VSD closure

Results

Patient's characteristics

This study included 16 patients who underwent percutaneous closure of pmVSD with Nit-Occlud Lê VSD coil from June 2015 to February 2017 and completed follow-up period. The demographic characteristics of the patients are demonstrated in Table (1).

Median age of the patients was 6 years (IQR 3.8- 9.1years) and females represented 68.75% of patients.

Baseline echocardiographic data

Baseline echocardiographic characteristics are demonstrated in Table (2)

Procedural data

The Nit Occlud® Lê coil device was successfully implanted in 16 patients (100 %). Procedural characteristics and device sizes are demonstrated in Table (3).

Percutaneous closure outcome

No patients experienced major complications that needed device retrieval during follow-up. Six patients (37.5%) developed complications demonstrated in Table (4).

Hemolysis

One patient (6.25%) developed hemolysis post procedure that was associated with large residual shunt. The condition was associated with 4 gm/dl hemoglobin drop (from 12.5 gm/dl to 8.5 gm/dl) and elevated reticulocytic count. Patient received 2 units of packed red blood cells and implantation of 2 vascular plugs was done with complete resolution of hemolysis after few days.

Bradyarrhythmias

Immediately post closure 2 patients (12.5%) developed bradyarrhythmia; one patient suffered 2:1 heart block that resolved spontaneously after 3 days with steroid therapy and another patient developed sinus bradycardia with a heart rate of 58 beats/ minute which resolved spontaneously. At 1 month follow up, a patient (6.25%) developed 1st degree AVB with PR interval =240 msc which was not associated with symptomatic bradycardia or progressed to higher grade of AVB as assessed by 24- hours Holter ECG study. The 1st degree AVB did not resolve during follow up period.

Valve regurgitation and residual shunt

Complete VSD closure was achieved in 5 patients (31.25%) at the procedure and reached 12 patients (75%) after 6 months follow-up. Residual shunt was detected in 11 patients (68.75 %); 7 patients (63.6%) had mild, 3 patients (27.3%) had moderate and 1 patient (9.1%) had large residual shunt. At 6 months follow-up only 4 patients (25%) had mild residual shunts. Significant valvular affection was recorded in 3 patients (18.75%); one patient developed mild aortic regurgitation (AR) and 2 patients developed mild tricuspid regurgitation (TR).

Table (1) Demographic characteristics of the patients

Parameters	Median (IQR)
Female (No. (%))	11 (68.75%)
Age (year)	6 (3.8-9.1)
Weight (Kg)	22 (13.75-25.75)
Height (cm)	112 (97-126)
BSA (m^2)	0.84 (0.6-0.93)
BMI (kg/ m^2)	18 ((16.6-21)

BMI: Body mass index, BSA: Body surface area, IQR: Interquartile range

Table (2) Baseline Echocardiographic characteristics

Measurements		Baseline (median (IQR)
Qp/Qs		2 (1.9-2.4)
VSD – AV distance		5 (4-6)
AV prolapse		0(0%)
VSD size LV (mm)		10.5 (9-13)
VSD size RV (mm)		6 (4.6-6.6)
Aneurysmal tissue (no (%))	Yes	14 (87.5%)
	No	2 (12.5%)
Gradient across defect (mmHg)		87.5 (75-87)
Mitral regurgitation, no (%)		0 (0 %)
Aortic regurgitation, no (%)		0 (0.0%)
Tricuspid regurgitation, no (%)		9 (56.25%)

AV: Aortic valve, LV: Left ventricle, Qp/Qs: Ratio of pulmonary blood flow to systemic blood flow, RV: right ventricle, VSD: ventricular septal defect.

Table (3) Procedural characteristics and device sizes.

General anesthesia	16 (100%)
Procedure time (minutes)	57 (22-120)
Fluoroscopy time (minutes)	24 (10-50)
Implanted device size	
8x6	2 (12.5)
10x6	3 (18.7)
12x6	3 (18.75)
14x8	6 (37.5)
16x8	2 (12.5)

Data are expressed as median (range) or number (%).

Table (4) Procedural complications.

Implantation success	16/16 (100%)
Total complications	6/16 (37.5%)
Severe complications	1/16 (6.25%) 0 death 0 embolization 1 hemolysis (Blood transfusion ± second device) 0 permanent high grade AV block 0 severe valvular affection
Transient complications	2/16 (12.5%) 0 hemolysis (spontaneous remission) 2 Bradyarrhythmias
Mild complications	3/16 (18.75%) 0 New conduction defect 1 mild aortic regurge 2 mild tricuspd regurge

Data are expressed as number (%)

Discussion

Our study demonstrated that percutaneous closure of perimembranous VSD with Nit-Occlud Lê VSD coil is safe and effective with favorable short term outcome.

Percutaneous closure of perimembranous VSD is a technically demanding procedure that may be associated with serious complications mainly cAVB and significant valvular regurgitation. However, with the improved design, materials used and lower profile of current VSD occludes widely used, it became a very good alternative for surgical closure with no significant difference regarding success and acceptable complications rate **(2).** The ideal VSD closure device should maintain certain characteristics; low profile, introduced via small sheath, fits all types of VSD with complete defect closure within an acceptable time frame, reconfigurable and retrievable and doesn't cause permanent damage or change in the anatomy of the surrounding structures **(7)**

The Nit-Occlud_ Leˆ VSD coil (pfm, Cologne, Germany) was proven to be effective for transcatheter closure of different VSD types **(9).** It is implanted transvenously, fully retrievable, allows repositioning with fine

adjustment to the given anatomy at any time during implantation. The primary concept of this malleable device is a soft filling of the mostly funnel shaped defect rather than occluding the defect by a stent-and-clamp mechanism; it doesn't afford radial force within the septum or pressure on adjacent structures. Its distal loop structure and the polyester fibers ensure effective closure and adequate stability **(7).**

Several studies reported that Nit-Occlud Leˆ VSD coil is associated with promising outcome compared to the Amplatzer VSD occluder device, which the most commonly used device in transcatheter VSD closure. Borges et al **(10)** reported close success rate of the Nit-Occlud_ Leˆ VSD coil and the Amplatzer VSD occluder (93.2 % vs.91.3%, respectively). However, the Nit-Occlud_ Leˆ VSD coil was associated with higher residual shunt at follow up (33.9% vs. 14.8%) but without any clinical drawbacks. On the other hand, There was no cases of cAVB documented with the Nit-Occlud_ Leˆ VSD coil while 2 cases (1%) receiving Amplatzer VSD occlude device required permanent pacemaker implantation. Hemolysis rate was comparable between both devices (3.4% Nit – Occlud vs. 2.5 % Amplatzer). Similarly, it was shown that higher residual shunt rate with Nit-Occlud Leˆ VSD coil (15.2% vs. 10.2%) and lower rate of permanent cAVB requiring pacemaker (0% vs. 5.2%) **(9).**

The reported success rate of VSD closure with Nit-Occlud Leˆ VSD coil ranges from 98%-100% **(7, 10).** Our study showed successful implantation of the device without major complications requiring device retrieval in all patients. The high success rate may be attributable to proper evaluation and selection of cases that deemed suitable for closure with Nit-Occlud Leˆ VSD coil.

Percutaneous closure of perimembranous VSD with Amplatzer VSD device was associated with alarming rate of cAVB requiring permanent pacemaker implantation which hindered its wide spread use **(11).** The development of cAVB may be attributed to many factors; direct compression trauma, pressure of radial forces, the clamping forces (i.e., oversized devices), and an inflammatory process.

Similar to our study, the some previous studies (9 & 12) did not report any cases of cAVB after VSD closure with Nit-Occlud Leˆ VSD coil**.** The lower rate of cAVB with Nit-Occlud Leˆ VSD coil may be explained by the less radial forces exerted by the device on adjacent structure due to its softer structure compared to the Amplatzer devise. Our study reported one case of transient 2:1 AV block that resolved

spontaneously after steroids therapy similar to what reported before **(7)** which emphases on the role of tissue inflammation in the pathogenesis of cAVB post device implantation.

Residual shunt is the most commonly described complication post percutaneous VSD closure, with reported incidence of 25.5% and 3.1% of transient and permanent residual shunts, respectively **(2).** The reported incidence of residual shunt immediately post procedure with Nit-Occlud Leˆ VSD coil is higher than the Amplatzer device (18.2-26 % vs. 8-10.6 %) **(9, 10),** which is also persistent at follow-up (33.9% vs. 14.85%) **(9).** The absence of self-expandable characteristic leading to a stent effect into the defect could explain the tendency of higher rate of residual shunt with Nit-Occlud Leˆ VSD coil **(10).**

One of the recent studies done in 2019, reported complete closure rate with no residual shunt of 62% immediately post procedure which increased to 95% after 6 months. They also reported regression of the degree of residual shunt in 33% and 66% of patients after 6-months and 1- year, respectively **(13).** Also, another study **(14)** showed complete closure rate of 60% post procedure which reached 87% at the end of follow-up. Our study showed complete closure rate lower than previously mentioned studies (31.2 % immediately post closure and 75% after 6 months follow-up). However, our study reported regression of residual shunt degree in 60% of patients similar to what was reported by El Shedoudy et al **(13).** The regression of residual shunt degree observed with the Nit-Occlud Leˆ VSD coil at follow-up may be related to the coagulating effect of the polyester fibers included in the device **(10).**

Hemolytic anemia is a well-documented complication with intracardiac prosthetic material implantation that has been reported with transcatheter closure of VSD**.** The course e of hemolytic anemia post VSD closure is unpredictable, as it may be a self-limited condition that resolves within days with medical treatment or may be severe enough to require additional device implantation or even device extraction and surgical closure **(12).**

The development of hemolytic anemia is closely related to the presence of significant residual shunt post device closure; thus shunt suppression is obligatory to prevent and/or treat persistent hemolysis **(14).** Hemolytic anemia rate has been reported to be higher with Nit-Occlud Leˆ VSD coil compared to Amplatzer device (3.4% vs. 1.8%), which is expected given the tendency of larger residual shunt with the former **(10).**

Haemolysis was documented in 3/18 (16.7%) patients with the Nit-Occlud Lê VSD coil, one patient required surgical extraction of the device and closure, while the condition resolved spontaneously within few days in the other 2 patients **(12).** Similarly, mechanical hemolysis was reported in 8/46 (17%) patients; the condition was transient and self-limited in 4 patients, an additional device implantation was required in 1 patient and 3 patients required device extraction and surgical VSD closure **(14).** On the other hand, El Shedoudy et al **(13)** did not report any case of hemolytic anemia with Nit-Occlud Lê VSD coil. Our study reported one case of hemolytic anemia that was associated with large residual shunt which resolved few days after the implantation of 2 vascular plugs.

Percutaneous VSD device closure may be associated with injury of the nearby valves namely; aortic and tricuspid valve. The reported rate of secondary valvular dysfunction is 4.9% with permanent defect rate of 2.3% (TR in 1.7% and AR in 2%) **(2).** Nit-Occlud Lê VSD coil is associated with higher rate of AR than the Amplatzer device (33.3% vs. 9.2%, p=0.002) **(9)** but similar to what reported with duct occluders (1.4% vs. 1%, p=0.5) **(15).**

Researchers in 2019 **(14)** reported new onset AR with Nit-Occlud Lê VSD coil in 5/46 (11%) patients which necessitated immediate device retrieval (2 cases) and/or surgical management (1 case). They also reported a case of TR that required device retrieval. In 2017, the development AR and TR with Nit-Occlud Lê VSD coil in 2.9% and 4.9% of patients, respectively, all of which were trivial and required no further interventions was reported (7). On the other hand, El Shedoudy et al **(13)** did not report any case of new onset AR or TR with Nit-Occlud Lê VSD coil. In our study, all cases of new onset AR and TR were mild, didn't progress during follow-up and required no further management.

Valvular injury reported with Nit-Occlud Lê VSD coil may be related to the multiple steps technique required to implant the coil which involve; formation of arteriovenous loop with a 'butter wire' effect on the valves, sheath advancement from the right ventricular side through the VSD into the aorta, partial release of the coil in the aorta with backward withdrawal through the aortic valve and entrapment of tricuspid chordae during coil positioning and deployment (**14).**

Limitations

First, follow-up duration was short and a longer period is required to assure absence of long term device related complications. Second, the number of procedures was low, and this was

related to the fact that surgical closure is still the method of choice for VSD closure especially for symptomatic patients and thus a larger number of patients is needed to confirm the result of our study. Third, this is a single center study and its outcome may be influenced by the experience and learning curve of the operators.

Conclusions

Percutaneous closure of perimembranous VSD with Nit-Occlud Lê VSD coil is an efficient procedure with high success rate.

The device showed to be safe with regard to potential major complications involving the conducting system, aortic and tricuspid valve. Patients should be followed closely for the development of clinically important hemolysis, especially those with residual shunt. Larger studies are required to evaluate the long-term safety and potential future side effects or complications.

List of abbreviations:

AR: Aortic regurgitation

AV: Aortic valve

BMI: Body mass index

BSA: Body surface area

ECG: Electrocardiogram

IQR: Interquartile range

IVS: Interventricular septum

LA: Left atrium

LV: Left ventricle

pmVSD: Perimembranous Ventricular septal defect

Qp/Qs: Ratio of pulmonary blood flow to systemic blood flow

RV: Right ventricle

TR: Tricuspid regurgitation

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