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Transcatheter Closure of Peri Membranous VSD Using the Nit-Occlud® Lê VSD Coil (PFM Coil), Midterm Outcome

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Abstract

Objective: This study aims to show the feasibility, safety, and efficacy of the Nit-Occlud® Lê VSD (PFM coil) in the treatment of peri membranous ventricular septal defects.

Background: Most ventricular septal defects are closed surgically, while less invasive transcatheter treatment using closure devices is an alternative. Device-based closure is reported to be associated with the risk of complete atrioventricular block and impingement on the tricuspid valve. However, the PFM coil represents a less invasive alternative to surgical closure, offering fewer complications for closing peri membranous defects.

Methods: This is a single-center, retrospective study which included all patients diagnosed with peri membranous ventricular septal defects who underwent transcatheter closure using the Nit-Occlud® Lê VSD (PFM coil) from January 2015 to December 2020, at Prince Sultan Cardiac Center (PSCC) Riyadh, Kingdom of Saudi Arabia.

Results: Transcatheter VSD closure with PFM coil was performed in 11 patients. The mean age was 10.27±5.50 years and body mass index was18.30±6.32 kg/m2. Eight cases had a small residual VSD at the 3-month after procedure, and only two of these patients (20% of the total) had residual VSD after 5 years. Five patients had mild tricuspid valve regurgitation (TR) at 3 months which improved in 2 of them at 5 years. One patient had moderate TR before closure, which improved to a mild degree. No complications occurred.

Conclusion: The Nit-Occlud® Lê VSD coil offers the possibility of an effective and safe treatment approach for patients with peri membranous ventricular septal defects. The potential for TR improvement with this procedure needs to be tested with larger prospective studies. The uneventful completion of the procedure in this cohort is promising and encouraging for future use.

Keywords: Ventricular septal defect · Interventional therapy · PFM coil · Residual shunt. Tricuspid valve regurgitation.

Introduction

Ventricular septal defect (VSD) is the most common congenital heart defect with an incidence of 3.5 per 100 births, with a neonatal rate of more than 50% of all congenital heart defects in some studies. [1,2] Surgery was the only available treatment for VSD closure till 1988 when the percutaneous closure was first described by Lock et al [3]. Since then, interventionists have been trying to develop new devices and techniques to close VSD less invasively. Transcatheter closure became the modality of choice to close all muscular Ventricular defects. In contrast the device closure of peri membranous VSD (pmVSD) has been associated with high rate of heart block and impingement of tricuspid valve.

[4,5,6] Therefore surgical closure of pmVSD was considered the better choice for treatment, which is also associated with potential risks of complete heart block, wound infection, longer recovery and cardiopulmonary bypass complications. The Nit-Occlud Lê VSD coil (pfm medical, KÖln, Germany) has been one of the specially manufactured devices for closing pmVSD. A well-formed aneurysmal tissue around a VSD represents an excellent site for device implantation which places the coil away from conductive tissue and the aortic valve. There is relatively lower risk of heart block, aortic valve regurgitation but with possibility of residual shunt. [7,8,9,10]. The PFM coil has been used for more than a decade in Prince sultan cardiac center (PSCC) pediatric catheterization laboratory, but there is no published report on the follow-up from the center till date. We want to study the mid-term outcomes of using PFM coil to close pmVSD in PSCC.

Materials and methods

This is a single center, retrospective study. All patients with diagnosis of peri membranous ventricular septal defects who underwent trans catheter closure with PFM coil from August 2015- till December 2020 were enrolled. Study design included reviewing electronic records of patient's files to record demographic data, clinical presentations and findings of the relevant investigations: electrocardiography (ECG), echocardiography (Echo), and cardiac catheterization with angiography. Hemodynamic profiles from the echocardiography and the cardiac catheterization were analyzed prior, post trans-catheter device closure and follow up echocardiography at primary end point 3 months and at secondary end point at 5 years after closure were recorded. The general aim of our study is to demonstrate feasibility, efficacy and safety as well as early and mid-term outcome of VSD closure with the (PFM coil). Complications including residual shunts, heart block, survival and need for re-intervention were recorded. Nevertheless, Echo parameters including presence and severity of tricuspid valve regurgitation at pre interventions stage were compared with the findings at each follow up. Inclusion criteria: All patients with peri membranous ventricular septal defect who underwent trans catheter PFM coil closure from August 2015- till December 2020. We excluded: all Patients with ventricular septal defects other than peri membranous type, patients with incomplete medical record and patients who did not complete at least one follow up post procedure. The indications for VSD closure were as follows: significant clinical symptoms of left-to-right shunt (e.g., recurrent lower respiratory tract infections and failure to thrive despite adequate medical treatment and/or echocardiographic evidence of significant left-to-right shunt. The study was approved by the research department in Prince Sultan cardiac center with the identifier R21012.

The Device:

TheNit-Occlud Lê VSD coil (pfm medical, KÖln,Germany) is made of nitinol wires with polyester fibers added to the left side of the loops. It consists of a distal coil representing the larger left-sided cone and a proximally smaller right-sided cone. The device is available in different sizes: 8/6, 10/6, 12/6, 12/8, 14/8, and 16/8 mm; the first number represents the diameter of the distal coil (left ventricle side) and the second number represents the diameter of the proximal one (Right ventricle side). Coils are pre-mounted on their delivery catheter. [8]

Procedure:

After explaining the benefits and the risks of the procedure and obtaining informed consent from legal guardians, all procedures were performed under general anesthesia; under fluoroscopic monitoring and transesophageal echocardiography (TEE) guidance. All patients received prophylactic dose of antibiotic (cefazolin 20 mg/kg/ dose) before procedure and then another dose after 8 hours. Under complete aseptic conditions femoral vein and femoral artery were accessed with 6FR and 5FR sheaths respectively according to patient's size. All patients received IV heparin 50–100 international unit/kg at the beginning of procedure to maintain an activated clotting time of 200–250 milli seconds. Transesophageal echocardiography (TEE) was done to estimate the defect size and evaluate the adjacent structures using 2D images and 3D images -when possible (figure 1 A & B, figure 3 A). Right and left heart diagnostic catheterizations were performed to estimate the degree of shunt, pulmonary artery pressure, and to calculate the ratio of the volume of pulmonary flow to systemic flow (QP:QS) , and pulmonary vascular

resistance (PVRi).The left ventricular angiogram was done to define the location and size of the defect Judkin's right coronary or cut-pigtail catheter was used to cross VSD. An exchange 0.035 in. hydrophilic guidewire was advanced through the catheter to the pulmonary artery then snared and exteriorized out through the femoral vein, to make a complete arteriovenous loop. The delivery sheath was inserted through the femoral vein and advanced to the ascending aorta through the defect. The size of the device was decided based on TEE findings and angiography. First four windings of coil were released in the ascending aorta then the complete system was pulled back via the aortic valve to the left ventricle outflow tract then the device was positioned in the defect. Simultaneously, the last two windings were released on the RV side. Left ventricular angiogram was done to assure proper position of the device and any residual shunt, before complete deployment of the device (Figure 2 A&B). Post closure Echo using 2D and 3D were done at end of procedure (figure 1 C&D, figure 3 B&C).

Statistical analysis:

Data were checked for completeness and correctness. Categorical variables were presented as frequencies and percentages. Continuous variables were presented as mean ± standard deviation. The numeric data were checked for normality using Shapiro-Wilk test. The relationship between patients' characteristics and presence or absence of residual shunt was assessed by Mann-Whitney U test. The analysis was performed in 95% confidence interval using the Statistical Package for Social Science (SPSS), version 23.0 (IBM, Armonk, NY, USA).

Result:

Data were collected on 11 patients; five males and six females, who underwent transcatheter VSD closure. The mean age and BMI were 10.27 ± 5.50 years and 18.30 ± 6.32 kg/m^2 respectively. The procedure was successful in all cases and none of the cases had any complications. Eight cases had mild TR, two cases had mild MR, (Table 1, 2)

The sizes of the implanted devices were 14X8 (3 cases), 16X8 (3 cases), 12X8 (3 cases), and 10X6 (2 cases). The mean LV and RV defect size was 10.00 ± 3.10 mm and 5.45 ± 1.13 mm respectively. The mean Qp:Qs was 1.27 ± 0.60 and the mean procedure time was 107.82 ± 28.58 minutes. (Table 3).

Eight cases had small residual VSD at month 3, and 2 of them still had residual VSD by 5 years. Five patients had mild TR at 3-month follow-up: whereas the TR improved in 2 patients while three patients still had mild TR on year 5 follow-up. (Table 3).

Discussion:

Transcatheter closure of isolated muscular VSD became the standard, when possible, but pmVSD closure data initially showed less encouraging results about heart block and aortic valve injury due to anatomical proximity. Traditionally, Amplatzer devices were used to close these defects, but due to increasing reports of significant number of complete heart blocks requiring permanent pacemaker insertion, transcatheter closure became less attractive option in comparison with surgical closure. Carminati et al reported in a large European registry data of 430 patients after device closure, the incidence of AV block in 12 of 250 peri membranous VSDs (4.8%) [5]. Similar outcome was reported in multiple studies. [13]. For that reason, the manufacturers and interventionists felt the need for safer catheter-based alternatives. Some tried Amplatzer duct occluder device which reduced the incidence of complete heart block but was associated with high risk for device embolization [14].

The Nit-Occlud Lê VSD coil came to provide more encouraging alternative to close pm VSD with less heart block (0 % - 2%) due its unique design [8,11,12]. Several papers did compare Amplatzer membranous device and PFM coil and showed significantly less heart block in the PFM coil group. Ali Houeijeh et al in multicenter French study reported no heart block in all 46 patients [15]. Chungsomprasong et al reported permanent pacemaker insertion in (5.2% of 76 patients with membranous defect closed by Amplatzer membranous device vs none in 33 patients whom their defects closed by The Nit-Occlud Lê VSD coil.[11] In our study we did not experience any heart block in all our 11 patients.

Residual VSD shunt was reported in multiple papers with PFM coil ranging from 5-40% [7,12,14]. We reported 20% residual VSD shunt throughout the follow-up period.

Intravascular hemolysis is another well-known complication but none of our patients developed

it. Interestingly 1 patient had severe TR prior to intervention which became only mild post intervention.

Conclusion:

The Nit-Occlud Lê VSD coil can be used safely and in a very efficient way for the transcatheter closure of VSD with excellent mid-term follow-up results. The additional benefit of improving pre-existing TR needs to be evaluated with further prospective large randomized clinical trials.

Limitations:

This is a retrospective, single center experience with small sample size. Larger, prospective, and perhaps randomized multicenter studies are needed.

Table 1: Baseline characteristics of the patients who underwent the transcatheter procedure

Pt. No.	Age	Sex	Weight	Height	BMI	BSA	Aortic Rim size	LV VSD size	RV VSD size	Associated defect
1	5	F	5	1.04	4.62	0.41	4	8	6	Mild TR
2	12	F	59	1.57	23.94	1.59	8	11	7	Mild TR
3	10	F	29	1.36	15.68	1.06	6	5	3	None
4	9	F	25	1.3	14.79	0.96	3	9	5	Upper muscular VSD + Mild TR
5	17	M	49	1.61	18.9	1.5	0	14	10	Mild MR
6	18	F	64	1.48	29.22	1.6	0	7	4	MILD TR + Down syndrome
7	17	M	62	1.65	22.77	1.7	8	7	5	Severe TR
8	7	F	33	1.24	21.46	1.07	10	9	5	PFO, Mild TR
9	3	M	13	0.88	16.79	0.55	5	8	3	Mild TR + Mild MR
10	3	M	14	0.96	15.19	0.6	3	7	5	Sub-aortic mem
11	12	M	42	1.53	17.94	1.36	10	10	6	Mild TR + Coronary fistula to MPA

Table 2: Mean and Standard deviation of age, weight, height, BMI, BSA, aortic rim size, LV VSD size, and RV VSD size

Variables	Mean	SD
Age in year	10.27	5.50
Weight in kg	35.91	20.85
Height in meter	1.33	.27
BMI in kg/m^2	18.30	6.32
BSA in sq meter	1.13	.46
Aortic rim in mm	5.18	3.57
LV VSD size in mm	8.64	2.42
RV VSD size in mm	5.36	1.96

Table 3: Patients' data and devices used

Pt. No.	LV defect size	RV defect size	Q_p:Q_s	Device size	Procedure time
1	12	4	1:1	14*8	175
2	13	7	3:1	16*8	70
3	6	4	1:1	12*8	100
4	9	7	1:1	16*8	110
5	6	5	1:1	12*8	115
6	14	5	1:1	14*8	120
7	15	7	1:1	16*8	99
8	9	5	1.2:1	10*6	110

9	8	5	1:1	12*8	120
10	8	5	1.2:1	10*6	100
11	10	6	1.6:1	14*8	67
Mean ± SD	10.00 ± 3.10	5.45 ± 1.13	1.27 ± .60	-	107.82 ± 28.58

Table 4: Three months and five years in complications (none), VSD residual, TR gradient

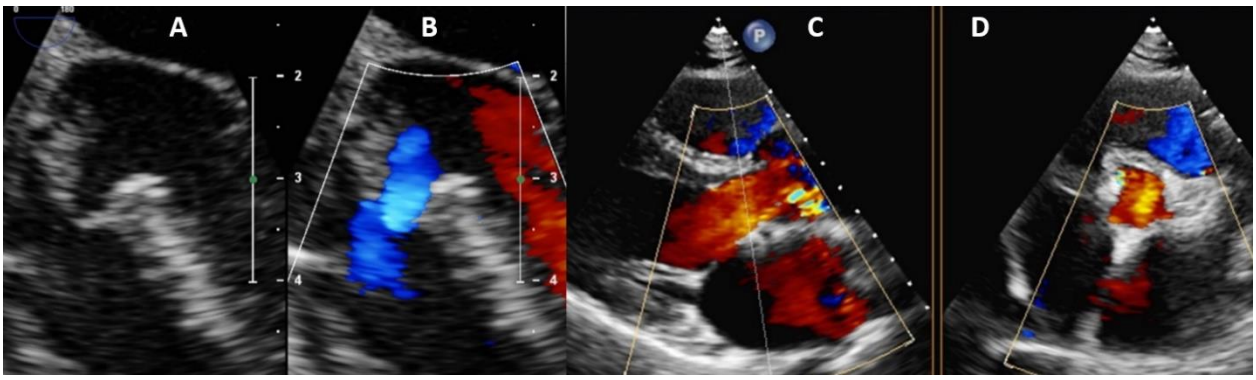
Pt. No.	3 months residual VSD	3 months degree of TR (0-3)	5 years residual VSD	5 years degree of TR (0-3)
1	Small	Mild	None	Mild
2	Small	Mild	None	No TR
3	Small	Mild	Small	Mild
4	None	No TR	None	No TR
5	Small	No TR	Small	No TR
6	Small	Mild	None	No TR
7	Small	Mild	None	Mild
8	Small	No TR	None	No TR
9	None	No TR	None	No TR
10	None	No TR	None	No TR
11	Small	No TR	-	-

* None of the cases had complications

Table 5: Comparison of the data of patients with and without residual shunts in 3 months

Variables	No residual shunt		Residual shunt present		p-value
	Mean	Std. Deviation	Mean	Std. Deviation	
Weight	17.33	6.66	42.88	20.12	.085
Height in meter	1.05	.22	1.44	.21	.048
BMI	15.59	1.06	19.32	7.24	.133
BSA	.70	.22	1.29	.43	.085
Aortic rim size mm	3.67	1.15	5.75	4.06	.376
LV VSD size (Angio)	8.33	.58	10.63	3.46	.921
RV VSD. Size (Angio)	5.67	1.15	5.38	1.19	.279
Qp: Qs	1.67	1.15	1.13	0.21	.776

Figure 1: Echocardiographic images -2 Dimensional



Preprocedural transesophageal echo: Mid esophageal left ventricle out flow tract view , A= Arrow indicating Ventricular septal defect(VSD) pouch and B= Color Doppler with Left to right VSD shunt.
Post PFM deployment, transthoracic echo : C= parasternal long axis view in systole showing laminar flow in left ventricular outflow tract with, D = simultaneous orthogonal plan short axis view .

Figure 2: Left ventricle Angiogram
A= PFM coil placed in VSD pouch, still attached with delivery system. B= Left ventricle angiogram after release of PFM coil, no residual shunt.

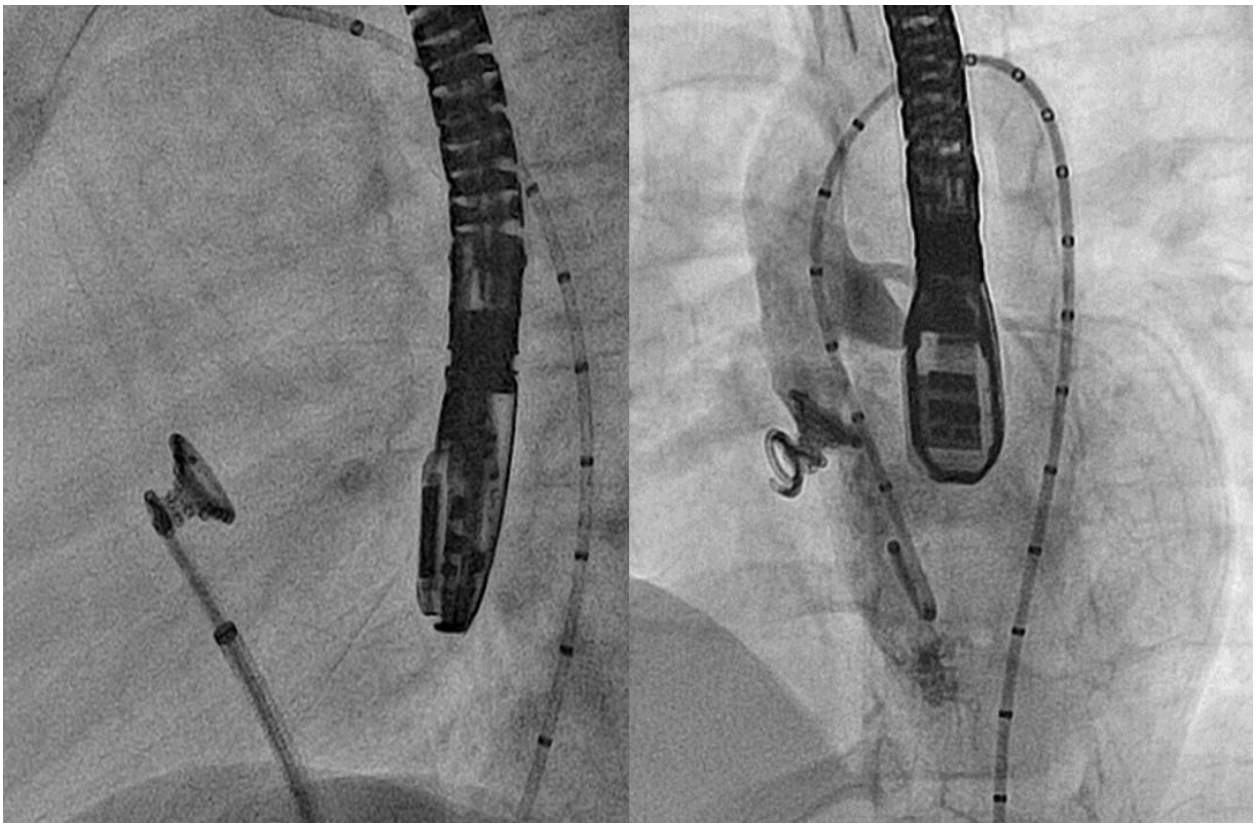
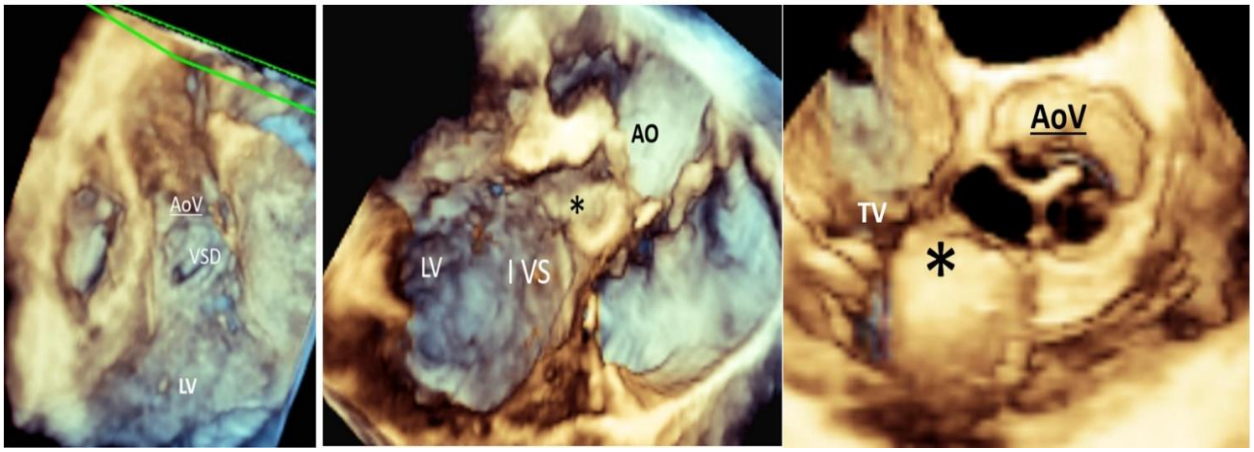


Figure 3 : Pre and post procedure TEE -3 Dimensional images .



A= Preprocedural TEE mid esophageal LVOT view showing VSD.B= Post PFM coil deployment TEE mid esophageal long axis view showing PFM coil seated well in position. C= Post PFM coil deployment TEE mid esophageal short axis view showing PFM coil seated well in position
TEE= Transesophageal echocardiography, Aov = Aortic valve, * = PFM coil marked *, LV= left ventricle, IVS= interventricular septum from LV side, TV= Tricuspid valve, VSD=Ventricular septal defect.

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References:

1. Hoffman JIE, Kaplan S (2002) The incidence of congenital heart disease. J Am Coll Cardiol 39:1890–1900. https ://doi. org/10.1016/s0735-1097(02)01886-7
2. Lindinger A, Schwedler G, Hense HW (2010) Prevalence of congenital heart defects in newborns in Germany: results of the first registration year of the PAN Study (July 2006 to June 2007). Klin Padiatr 222(321):326. https://doi.org/10.1055/s-0030-1254155
3. Lock JE, Block PC, McKay RG, Baim DS, Keane JF (1988) Transcatheter closure of ventricular septal defects. Circulation 78:361–368
4. Butera G, Massimo C, Mario C (2006) Late complete atriovenous block after percutaneous closure of a perimembranous ventricular septal defect. Catheter Cardio Inte 67:938–941. https ://doi. org/10.1002/ccd.20696
5. Carminati M, Butera G, Chessa M, Giovanni JD, Fisher G, Gewillig M, Peuster M, Piechaud JF, Santoro G, Sievert H, Spadoni I, Walsh K, Registry I of the EV (2007) Transcatheter closure of congenital ventricular septal defects: results of the European Registry. Eur Heart J 28(2361):2368. https ://doi.org/10.1093/eurhe artj/ehm314
6. Holzer R, de Giovanni J, Walsh KP, Tometzki A, Goh T, Hakim F, Zabal C, de Lezo JS, Cao Q-L, Hijazi ZM (2006) Transcatheter closure of perimembranous ventricular septal defects using the amplatzer membranous VSD occluder: immediate and midterm results of an international registry. Catheter Cardiovasc Interv 68(620):628. https://doi.org/10.1002/ccd.20659
7. Shedoudy SE, El-Doklah E (2019) Mid-term results of transcatheter closure of ventricular septal defect using Nit-Occlud Lê ventricular septal defect coil, single-center experience. J Saudi Heart Assoc 31:78–87. https://doi.org/10.1016/j.jsha.2018.11.002
8. Haas NA, Kock L, Bertram H, Boekenkamp R, Wolf DD, Ditkivskyy I, Freund MW, Gewillig M, Happel CM, Herberg U, Karthasyan E, Kozlik-Feldmann R, Kretschmar O, Kuzmenko Y, Milanesi O, Mueller G, Pongiglione G, Schubert S, Tarusinov G, Kampmann C (2017) Interventional VSD-closure with the Nit-Occlud(®) Lê VSD-Coil in 110 patients: early and midterm results of the EUREVECO-Registry. Pediatr Cardiol 38(215):227. https://doi.org/10.1007/s00246-016-1502-8
9. Odemis E, Saygi M, Guzeltas A, Tanidir IC, Ergul Y, Ozyilmaz I, Bakir I (2014) Transcatheter closure of perimembranous ventricular septal defects using Nit-Occlud(®) Lê VSD coil: early and mid-term results. Pediatr Cardiol 35(817):823. https ://doi. org/10.1007/s00246-013-0860-8
10. Rainer Kozlik-Feldmann · Avraham Lorber · Horst Sievert · Peter Ewert · Christian Jux · Götz C. Müller · Robert Dalla Pozza · Mustafa Yigitbasi · Dietmar Schranz · Angelika Lindinger · Omar Galal · Thomas Meinertz Long-term outcome of perimembranous VSD closure using the Nit-Occlud® Lê VSD coil system . Clinical Research in Cardiology (2021) 110:382–390 https://doi.org/10.1007/s00392-020-01750-6
11. Paweena Chungsomprasong,1* MD, Kritvikrom Durongpisitkul,1 MD, Chodchanok Vijarnsorn,1 MD, Jarupim Soongswang,1 MD, and Trong Phi Leˆ,2 MD (wileyonlinelibrary.com) DOI 10.1002/ccd.23084
12. Transcatheter closure of a perimembranous ventricular septal defect with Nit-Occlud Lê VSD Coil: A French multicentre study Ali Houeijeh a,b,c,∗, Franc¸ois Godart a,b, Zakaria Jalal d,e,f, Caroline Ovaert g, Franc¸ois Heitz h,Pierre Mauran i,

Alban-Elouen Baruteau j, Lisa Guirguis k, Khaled Hadeed h, Jean-Benoit Baudelet a,b,c, Xavier Iriart d,e,f, Philippe Aldebert g, Philippe Acar h, Alain Fraisse k, Ender Odemis l, Clément Karsenty h, Jean Benoit Thambo d,e,f, Sébastien Hascoët m archive of cardiovascular diseases https://doi.org/10.1016/j.acvd.2019.11.004

13. Bjørnstad PG, Smevik B, Fischer G (2010) Catheter based closure of VSDs. Scand Cardiovasc J 44:9–14
14. Nguyen HL, Phan QT, Dinh LH, et al. Nit-Occlud L ^e VSD coil versus Duct Occluders for percutaneous perimembranous ventricular septal defect closure. Congenital Heart Disease.2018;00:1 –10. https://doi.org/10.1111/chd.12613
15. A. Houeijeh et al. Transcatheter VSD closure with Nit-Occlud Lê VSD coil Archives of Cardiovascular Disease (2020) 113, 104—112 https://doi.org/10.1016/j.acvd.2019.11.004