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Transcatheter closure of a perimembranous ventricular septal defect with Nit-Occlud Lè VSD Coil: a French multicentre study

Fermeture percutanée des communications interventriculaires pérимembraneuses avec le coil Nit-Occlud Lè VSD : données du registre multicentrique français

Abbreviated title: Transcatheter VSD closure with Nit-Occlud Lè VSD coil

Abbreviated title: Fermeture percutanée de CIV avec le coil Nit-Occlud Lè VSD

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Summary

Background. – Transcatheter perimembranous ventricular septal defect (pmVSD) closure remains challenging and is seldom used in France given the risk of atrioventricular block (AVB). pmVSD closure with the Nit-Occlud Lê VSD coil was recently introduced in France as an alternative to occluder devices.

Aims. – To study the safety and feasibility of pmVSD closure with the Nit-Occlud Lê VSD coil.

Methods. – All consecutive cases of pmVSD closure with the Nit-Occlud Lê VSD coil in 20 tertiary French centres were included between January 2015 and December 2018.

Results. – Among 46 procedures in five centres, indications for pmVSD closure were left ventricle overload (76.1%), exertional dyspnoea (17.4%), history of infective endocarditis (4.3%) and mild pulmonary hypertension (2.2%). The median (interquartile [IQR]) age of the patients was 13.9 (5.7–31.8) years. Aneurismal tissue was identified in 91.3% of patients. VSD median (IQR) size was 8 (7–10) mm on the left ventricle side and 5 (4–6) mm on the right ventricle side. Implantation was successful in 40 patients (87.0%; 95% confidence interval [CI] 73.7–95.1%). Severe complications occurred in six patients (13.0%, 95% CI 4.9–26.3%), mainly severe haemolysis (8.7%, 95% CI 2.4–20.8%). One aortic valve lesion required surgical aortic valvuloplasty. Occurrence of severe complications was significantly related to the presence of haemolysis ($P = 0.001$), residual shunt ($P = 0.007$) and multi-exit VSD ($P = 0.005$). Residual shunt was observed in 40% of cases with the implanted device shortly after closure and 15% after a median follow-up of 27 months. No immediate or delayed device embolization or complete AVB was recorded.

Conclusion. – pmVSD closure with the Nit-Occlud Lê VSD Coil is feasible in older children and adults. However, residual shunting (leading to haemolysis) is a dreaded complication that should not be tolerated. pmVSD closure with the Nit-Occlud Lê VSD as a therapeutic strategy remains controversial and is limited to selected patients.

Resumé

Contexte. – La fermeture percutanée des communications interventriculaires peri-membraneuses (CIVpm) demeure un challenge et est peu utilisée en France en raison d'un risque de bloc atrio-ventriculaire (BAV). L'utilisation du coil Nit-Occlud Lê VSD a été récemment débutée en France et représente une alternative aux occludeurs.

Buts. – Etudier la faisabilité et la sécurité d'emploi de la fermeture percutanée de la CIVpm avec le Nit-Occlud Lè VSD.

Méthodes. – Toutes les procédures de fermeture de CIVpm réalisées en France entre janvier 2015 et décembre 2018 dans les vingt centres spécialisés de prise en charge des cardiopathies congénitales complexes (réseau maladies rare M3C) ont été incluses rétrospectivement et analysées.

Résultats. – 46 procédures ont été réalisées dans cinq centres. Les indications de fermeture étaient la surcharge diastolique du ventricule gauche (76%), une dyspnée à l'effort (17.4), un antécédent d'endocardite (4.3) et une hypertension artérielle pulmonaire modérée (2.2%). L'âge médian (interquartile) était de 13.9 (5.7-31.8) ans. Un anévrysme du septum interventriculaire a été observé dans 91.3% des cas. La taille médiane (interquartile) des CIV était de 8 (7-10) mm sur le versant ventriculaire gauche et 5 (4-6) mm sur le versant ventriculaire droit. Le taux de réussite d'implantation de la prothèse était de 87.0 % (IC 95 %, 73.7–95.1 %). Des complications sévères ont été observées chez six patients (13.0 %, IC 95 %, 4.9–26.3 %). L'hémolyse persistante était la complication sévère la plus fréquente (8.7 %, IC 95 % 2.4–20.8 %). Une lésion de la valve aortique a nécessité une valvuloplastie aortique chirurgicale. La survenue de complications est liée à la présence de l'hémolyse ($P = 0.001$) d'un shunt résiduel ($P = 0.007$) et la présence de CIV avec anévrysme multi-perforée ($P = 0.005$). Un shunt résiduel a été documenté dans 40 % des cas juste après l'intervention et 15 % durant le suivi (durée médiane de suivi de 27 mois). Aucun cas de migration de prothèse ni de bloc atrioventriculaire de haut grade n'a été rapporté

Conclusion. – La fermeture percutanée de CIVpm avec le coil Nit-Occlud Lè VSD est réalisable chez les grands enfants et les adultes. La présence d'un shunt résiduel important provoquant une hémolyse parfois sévère est une complication redoutable et ne doit pas être tolérée. La place de cette prothèse dans l'algorithme de prise en charge des CIVpm reste controversée. être toléré.

KEYWORDS

Ventricular septal defect;

Nit-Occlud Lè VSD;

Catheterization;

Left ventricle overload;

Shunt closure

MOTS CLÉS

Communication interventriculaire ;

Nit-Occlud Lê VSD ;

Cathétérisme ;

Dilatation ventriculaire gauche ;

Fermeture de shunt

Abbreviations: AVB, atrioventricular block; CI, confidence interval; IQR, interquartile range; LV, left ventricle; LVEDD, left ventricular end diastolic diameter; pmVSD, perimembraneous ventricular septal defect; RV, right ventricle; TOE, transoesophageal echography; VSD, ventricular septal defect.

Background

Percutaneous perimembranous ventricular septal defect (pmVSD) closure is technically challenging [1]. Others shunt closure techniques, particularly of atrial septal defects and ductus arteriosus, have improved over the last two decades, with the transcatheter method being the preferred option [2,3]. However, catheter closure of pmVSD remains controversial. The risk of immediate or delayed complete atrioventricular block (AVB) observed with previous devices has limited the development of this technique [4-7]. With its low rate of complications, surgical closure is still the preferred approach in France when pmVSD closure is indicated [8]. Previously, most pmVSD in patients without heart failure or pulmonary hypertension (type I and type IIa) were not closed to avoid surgery. In recent years, some studies have shown that adults with these defects have a higher risk of endocarditis, left ventricular diastolic dysfunction, supraventricular arrhythmia and pulmonary hypertension [9-12]. In the same timeframe, other devices have appeared as alternatives to the historic Amplatzer device to close pmVSD, e.g. Amplatzer Duct Occluder 1, Amplatzer Duct Occluder II, Amplatzer Vascular Plug II (Abbott, Chicago, USA), Nit-Occlud Lê VSD Coil (PFM, Köln, Germany) and Cera duct occluder (Lifetech, Shenzhen, China) [13-19].

Currently, surgery remains the preferred technique for pmVSD closure in small children < 1 year old who present with heart failure, and results are excellent. A percutaneous technique may be an alternative in older patients. The Nit-Occlud Lê VSD Coil may be an interesting device for pmVSD closure as it has several advantages: low profile, retrievable device and small introducing sheath. Some reports, including a multicentre European study, have suggested that it is effective and safe for pmVSD closure, without causing complete AVB [13-16]. However, some cases of haemolysis were reported with this coil [15,16]. Indications and effectiveness of pmVSD closure with the Nit-Occlud Lê VSD Coil remain controversial among the French paediatric cardiology community. We aimed to study the results and outcomes of consecutive cases performed in France to evaluate its feasibility and safety.

Methods

We designed an observational, multicentre, nationwide cohort study. We retrospectively included all cases of percutaneous closure of pmVSD with or without aneurismal tissue using the Nit-Occlud Lê VSD Coil performed in France over the first 3 years of device availability (January 2015 to December

2018) among 20 catheterization laboratories of paediatric and adult congenital cardiology centres. Selection of patients for pmVSD closure was according to each centre's protocol. We ensured inclusion of all cases by cross-checking with data from the manufacturer.

Written informed consent was obtained from patients or their legal guardians. Demographic data, clinical information and non-cardiac comorbidities were collected.

All patients were examined in a paediatric and congenital cardiology tertiary centre (M3C network for complex congenital heart diseases). Using echocardiography, left ventricle size was measured in a parasternal long-axis view and an apical four-chamber view. Left ventricular end diastolic diameter (LVEDD) Z-score was calculated using the Detroit Formula [20]. Left ventricle overload was considered significant when the LVEDD Z-score was ≥ 2 . Pulmonary pressures were estimated by pulmonary regurgitation, ventricular septal shape and Doppler gradient through the ventricular septal defect (VSD), and then directly during catheterization. The indication for closure was determined by local practitioners.

Percutaneous pmVSD closure with the Nit-Occlud L^ê VSD coil was undertaken using a standard method, as has been previously reported [15,16]. To assess the appropriate device size, left- and right-sided opening of the VSD, aneurysm length and distance to the aortic rim were measured in two- and three-dimensional transthoracic echography and transoesophageal echography (TOE) views, with the largest measurement being recorded. All procedures were performed under general anaesthesia and two- or three-dimensional TOE guidance. Some cases were guided by fusion between echocardiography and fluoroscopy (Echonavigator software®, Phillips) [21]. All procedures were performed by experienced operators and/or with the support of highly trained operators for pmVSD closure.

Short 5F and 6F sheaths were introduced in the femoral artery and femoral vein, respectively. Intravenous heparin (50–100 IU/kg according to the institutional protocol) was given. An angiogram was performed in the left lateral view to measure the VSD. The defect was crossed retrogradely from the arterial route using a multipurpose catheter or a cut pigtail and an exchange guidewire, which was snared in the right side (pulmonary artery or superior vena cava) to create an arteriovenous loop. The device left-side size was selected as at least twice the minimal diameter of the VSD (on the right ventricular side) as measured by echocardiography and angiogram, and equal to or 1–2 mm greater than the diameter of the VSD at the left ventricular opening. The device right-side diameter should be

greater than the minimal size. The delivery sheath was introduced from the venous route into the ascending aorta and a Nit-Occlud L^ê VSD Coil was usually implanted into the aneurysm under TOE and angiographic control (Fig. 1). In patients without aneurysmal tissue, the left side of the coil was implanted in the left side of the ventricular septum and the right side was positioned in the right ventricle. Post-procedure evaluation and follow-up were performed according to local institutional protocols. Generally, clinical, electrocardiographic and echocardiographic assessments were performed within 24 hours, at 1, 6 and 12 months, and yearly thereafter. Complications were classified as minor (category 1 or 2) or severe (category 3 or more) [22]. Medium-term clinical success was defined as successful pmVSD closure without residual shunt, severe complication or device-related aortic or tricuspid valve lesion.

Statistical analysis

Statistical analyses were carried out using SPSS version 23 (IBM, New York, USA) and Stata software version 11.2 (StataCorp, College Station, Texas, USA). Non-normally distributed quantitative variables are shown as medians (interquartile ranges [IQRs]). Clinical and procedural data were compared between patients with and without severe complications using the Mann-Whitney test and the exact Fischer test. Alpha risk was set at 5%.

Results

pmVSD percutaneous closure was attempted in 46 patients in five centres (CHRU Lille [$n = 17$]; CHU Bordeaux [$n = 14$]; CHU Toulouse [$n = 8$]; CHU Marseille [$n = 5$]; CHU Reims [$n = 2$]). Patient and VSD characteristics are detailed in Table 1. The median (IQR) age was 13.9 (5.7–31.8) years, although patients aged 0.7–60.4 years were included. Closure indications were left ventricular overload in 35 patients (76.1%), exertional dyspnoea in eight patients (17.4%), infective endocarditis history in two patients (4.3%), and mild pulmonary hypertension with significant left-to-right shunt in one patient (2.2%; mean pulmonary artery pressure 31 mmHg; left-to-right output ratio 3.4; LVEDD 27 mm; Z-score +4.7).

Aneurysmal tissue was identified in 42 patients (91.3%). Median (IQR) VSD size was 8 (7–10) mm on the left side and 5 (7–10) mm on the right side. The median (IQR) distance to the aortic annulus was 5 (4-6) mm. Multiple-exit pmVSD was described in four cases (8.7%). The median (IQR)

LVEDD Z-score was 2.6 (2.0–3.3).

In 45 patients (97.8%), one coil was implanted. In eight of these cases, closure was attempted using more than one device (three devices in four patients, two devices in four patients). In two cases, two devices were implanted to close multifenestrated pmVSD.

In one patient, the coil got stuck in the aortic valve before positioning, inducing aortic valve regurgitation, and was retrieved. In five patients, the coil was positioned, but not released, and was removed due to aortic valve regurgitation ($n = 1$), severe tricuspid regurgitation related to the device ($n = 1$), significant residual shunt ($n = 2$) or instability of the device ($n = 1$).

Overall successful coil implantation was achieved in 40 patients (87.0%, 95% confidence interval [CI] 73.7–95.1%). Procedural characteristics and device sizes are detailed in [Table 2](#). Residual shunt on angiogram or day 0 echocardiography was identified in 16 patients (40.0% of patients with implanted devices).

Periprocedural complications occurred in 16 cases (34.8%, 95% CI 21.4–50.3%), of which six (13.0%, 95% CI 4.9–26.3%) were severe (mainly severe haemolysis [8.7%, 95% CI 2.4–20.8%]). The most common complication was mechanical haemolysis ($n = 8$); residual shunt was present in all of these cases. Haemolysis was transient and self-limiting in four patients. In the other four patients, it required blood transfusion and an additional invasive procedure (residual shunt closure with an Amplatzer duct Occluder II in one patient ([Fig. 2](#)) and removal of the device and surgical VSD closure in three patients). In one of the surgical VSD closure cases, the device was trapped in the tricuspid valve, which required additional tricuspid valvuloplasty ([Fig. 3](#)). The second most common complication was aortic valve regurgitation ($n = 5$: two minor cases, which disappeared during follow-up; two resolved by immediate device retrieval; one needing surgical management due to aortic valve perforation when the device passed through the valve). The other complications were minor groin haematoma ($n = 2$), tricuspid valve regurgitation ($n = 1$; resolved by device retrieval), grade 1 AVB ($n = 1$) and haemodynamic instability with sinus bradycardia ($n = 1$; resolved rapidly under anaesthesiologist support and pmVSD closure was then completed).

The occurrence of severe complications was significantly related to the presence of haemolysis ($P = 0.001$), residual shunt ($P = 0.007$), multiple-exit VSD ($P = 0.005$) and higher LVEDD Z-score ($P = 0.03$). Age, weight, VSD size and absence of aneurysm were not significantly associated with severe complications ([Table 1](#)), nor was centre intervention volume. There was a non-significant

trend towards a lower rate of severe complications in the last 23 patients compared to the first 23 ($n = 4$ [17.4%] and $n = 2$ [8.7%], $P = 0.7$). Rate of severe complications by centre varied from 0% to 25% (Fig. 4).

After a median follow-up of 27 months (range 2–50 months), median LVEDD Z-score was 1.3 (IQR 0.9, 2.0). A tiny residual shunt was observed in six patients (15.0% of patients with implanted coil; 37.5% of patients with immediate post procedure residual shunt). No delayed severe complications were reported (in particular, no endocarditis, haemolysis, aortic valve lesions, tricuspid valve lesions, AVB or embolization). The medium-term clinical success (pmVSD closure without residual shunt or complications) rate was 65.2%.

Discussion

We report the initial French experience with pmVSD closure using Nit-Occlud Lê VSD Coils during the first 4 years after its introduction in France. The main observations of this study are: (1) the number of procedures was low; 2) there was a high feasibility of transcatheter closure of pmVSD using this device and 3) there was a high rate of complications.

The number of procedures remains limited, at only 46 patients over 4 years in France. Despite a retrospective study design, we are certain that no procedure was missed, having cross-checked with data from the manufacturer. Several reasons may have led to the low rate. Firstly, in France, symptomatic infants with pmVSD and significant left ventricle overload are often referred for surgery within the first year of life. Asymptomatic patients with restrictive pmVSD with or without mild left ventricle overload are not referred for closure as their long-term outcome is excellent [23]. Thus, there are a very limited number of patients that are candidates for this percutaneous technique. It may mainly be considered in adults and children aged over 1 year with pmVSD and a history of endocarditis and/or significant LV overload. The second explanation for the low number of procedures may be related to practitioner's caution. Among more than 20 congenital cardiac catheterization centres in France, only five started a program of pmVSD closure with the Nit-Occlud Lê VSD Coil. The coil was considered to be an interesting alternative, given its profile, the lack of material on the rim of the VSD and the absence of AVB reported in the first studies [13-16]. Good feasibility and outcomes were observed in a European multicentre study [13]. However, in the low-risk population of patients that are candidates for percutaneous pmVSD closure, any severe complication is unacceptable.

Previous experiences with Amplatzer pmVSD occluder devices with early, as well as delayed, complete AVB, had cooled the enthusiasm of specialists [4,5]. Several practitioners were already concerned by the risk of residual shunting after coil positioning and haemolysis, which was described in some cases (15). To maximise the rate of success and decrease the potential learning curve impact in the current study, all procedures were performed by very experienced specialists of paediatric catheterization, assisted by the technical support of international specialists experienced with coil handling.

In our study, the feasibility of the procedure was confirmed. Positioning of the coil was achieved in > 95% of patients, as has been previously reported [13-16]. In one case, a coil got stuck in the aortic valve. After discussing the case with experienced colleagues, it seems that the coil could have been freed from the aortic valve by pushing the device rather than by withdrawing it. The latter manoeuvre leads to a severe aortic valve lesion that requires surgery. However, the rate of coil deployment and release was lower than expected given that, in some cases, the coil was retrieved due to residual shunting or associated lesions of the tricuspid or aortic valves. The handling of this device is more difficult than for other coils in other indications or for self-expandable nitinol devices. Manipulating the coil, the guide catheter and the sheath at the same time in the tricky area within the aortic, tricuspid and mitral valves, and the conduction tissues is challenging. The coil is partially released before positioning with limited control of its position and rotation. The training of echocardiographers is also a key issue to extensively describe the shape and geometry of the VSD in order to select suitable candidates and help to select appropriate devices.

The efficacy of the device was confirmed after mid-term follow-up by normalization of left ventricle size, as has been reported by others [14].

The complication rate was higher in this study compared to previous ones [13-16]. The main complication was mechanical haemolysis. Haemolytic anaemia related to intracardiac prosthetic material is a well-known condition. Gu et al. documented haemolysis in 9% of patients after implantation of Amplatzer pmVSD devices [24], whereas the incidence was 2% with the ADO1 device [14]. In the two aforementioned series, haemolysis was transient and resolved by medical therapy alone. Mechanical haemolysis is also observed in patients with paravalvular leak, and can even occur after percutaneous closure [25]. Mechanical haemolysis seems to be more frequent after Nit-Occlud L^ê VSD positioning due to a tendency of more residual shunt. Odemis et al. documented haemolysis

in 3/18 patients with the Nit-Occlud Lê VSD coil and surgical removal of the device was necessary in one of them [15]. In our study, haemolysis was observed in half of the patients with residual shunt while no case of haemolysis was reported after complete shunt closure. Shunt suppression is mandatory to avoid or cure persistent haemolysis. Haemolysis was significantly related to the presence of residual shunt and multiple-exit VSD. Details about the type of residual shunt (para-versus intra-prosthetic leaks) were not available in all patients. The fact that haemolysis was associated with multiple-exit VSD and resolved by additional device implantation suggests that residual para-prosthetic leak is the main mechanism. Several strategies could be attempted before surgery to abolish persistent haemolysis: implanting another coil, implanting another device (e.g. ADO II), as reported in our study and by others [15,26]. During the procedure, in case of residual shunt, it may be recommended to implant another device or withdraw the device before release to avoid the high risk of foreseeable persistent haemolysis, as was done in three cases in this study in the centre with the lowest rate of severe complications. The absence of a self-expandable characteristic leading to a 'stent' effect into the defect could explain the tendency of higher rate of residual shunt with this device, mainly shortly after the procedure. The rate of residual shunt decreased during follow-up, probably by the coagulating effect of the polyester fibres included in the device [13-15]. However, nearly half of the patients with residual shunt after the procedure still had a tiny residual shunt at the end of follow-up.

The second main issue in this study was the rate of aortic and tricuspid valve lesions, which were transient, resolved by device withdrawal or definitive (needing surgical valvuloplasty in a few cases). A learning curve impact may have affected this result and attention should be focused on the valves by echocardiographers during the procedure. The multiple steps required to implant the coil may have contributed to this complication. Firstly, an arteriovenous loop is necessary. A 'butter wire' effect on the valves may be prevented by the 'kissing technique'. Secondly, the sheath has to be advanced from the right ventricular side through the pmVSD into the aorta. Thirdly, the coil is partially released in the aorta and then has to be very gently moved back through the aortic valve. Finally, when the coil is positioned and deployed, it can trap tricuspid chordae.

In our study, it is noteworthy to mention the absence of complete AVB, although there was one case of transient grade 1 AVB. Complete AVB is rare with this device and can be resolved by surgical removal [14]. However, long-term outcomes should be reported to confirm this finding. Similarly, no

cases of endocarditis or embolization were reported.

Finally, the trend towards a lower rate of complications at the end of the study suggests a learning curve bias despite the presence of an experienced operator and proctor for all interventions. Meticulous patient selection should be done, with exclusion of multiple-exit pmVSD. Further, during procedure, residual shunting should not be tolerated. To date, only two French centres continue to perform pmVSD closure with Nit-Occlud Lê VSD. Some other centres have moved to pmVSD occlusion using alternative devices.

Limitations

The number of procedures was low. We cannot exclude that a learning curve effect and lack of experience affected our results, despite the precautions taken by specialists. Indeed, results tended to be better in the second part of the study, particularly with strategies to prevent residual shunt and attention focused on the valves. The follow-up period is also relatively short, so we cannot confirm the absence of late complications, especially complete AVB. A more prolonged follow-up will be mandatory, in particular to know the effect of residual shunt on the occurrence of endocarditis.

Perspectives: This study demonstrates the complexity of the management of pmVSD with significant left-to-right shunt in older children and adults. Both surgical and percutaneous techniques have risks. New devices for this indication are under investigation and will need to be carefully assessed. The optimal therapeutic strategy in this selected population remains to be determined in the modern arena. Therefore, the French heart association started the FRANCISCO study (Observatoire français des Communications Interventriculaires périmembraneuses Congénitales avec hyper débit pulmonaire, NCT03363932) to investigate the long-term outcome of these patients according to therapeutic strategy and assess anatomic predictors of complications.

Conclusions

pmVSD closure is feasible with the Nit-Occlud Lê VSD Coil in older children and adults. Residual shunting leading to haemolysis is a dreaded complication. The place of pmVSD closure with the Nit-Occlud Lê VSD in the therapeutic strategy remains controversial and is limited to selected patients. Residual shunting after coil implantation should not be tolerated.

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Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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Figure legends

Figure 1. Step-by-step closure of pmVSD using the Nit-Occlud Lê VSD. A. VSD assessment by left anterior oblique projection angiogram. B. A guidewire was introduced retrogradely through the VSD towards the pulmonary artery and was snared by a lasso introduced from the venous side. C. A 7F sheath was advanced from the venous access to the ascending aorta through the VSD. D. The first loop of the coil was deployed in the ascending aorta. E. The second loop of the coil was deployed, and then the coil pulled back into the VSD aneurysm under TOE and angiographic control. F. Deployment of the third loop into the right ventricle before device release. pmVsd: perimembranous ventricular septal defect; VSD: ventricular septal defect; TOE: transoesophageal echography.

Figure 2. Residual shunt closure using an arterial duct occluder type II device. The device was placed in the VSD residual shunt from the arterial route. VSD: ventricular septal defect.

Figure 3. Nit-Occlud Lê VSD trapped in the tricuspid valve. This patient had moderate tricuspid regurgitation and a residual shunt. During surgical intervention, it became clear that the device had become embedded in the septal leaflet of the tricuspid valve. The patient had surgical VSD closure with tricuspid valvuloplasty with a good result. VSD: ventricular septal defect.

Figure 4. Rates of severe complications at the different centres.

Table 1. Patient and VSD characteristics.

	All patients (<i>n</i> = 46)	No/mild complications (<i>n</i> = 40)	Severe complications (<i>n</i> = 6)	<i>P</i>
Age (years)	13.9 (5.7–31.8)	13.6 (5.7–32.3)	17.8 (5.7–27.3)	0.87
Weight (kg)	36.7 (18–60)	36.7 (18–58.5)	38.5 (15–60)	0.98
Height (cm)	142 (116–170)	141 (118–168.5)	166.5 (109–178)	0.43
Female sex	18 (39.1)	15 (37.5)	3 (50.0)	0.68
VSD LV side size (mm)	8 (7–10)	8 (8–11)	8 (7–9)	0.56
VSD RV side size (mm)	5 (4–6)	5 (4–6)	4.4 (4–6)	0.62
Aortic rim (mm)	5 (4–6)	5 (4–6)	4.5 (3–6)	0.42
LVEDD (mm)	47 (36–55)	47 (36–55)	49 (33–58)	0.87
LVEDD Z-score	2.6 (2.0–3.3)	2.3 (1.7–3.3)	3.6 (3.0–4.9)	0.03
Aneurysm	42 (91.3)	36 (90.0)	6 (100)	1.00
Multiples exits	4 (8.7)	1 (2.5)	3 (50.0)	0.005
Pulmonary hypertension	1 (2.2)	1 (2.5)	0	1.00
Endocarditis history	2 (4.3)	2 (5.0)	0	1.00
Residual shunt	16/40 (40.0)	11 (27.5)	5 (83.3)	0.007
Haemolysis	8	3	5	0.001

Data are expressed as median (interquartile range) or number (%). LV: left ventricle; LVEDD: left ventricular end diastolic diameter; RV: right ventricle; VSD: ventricular septal defect.

Table 2 Procedural characteristics and device sizes.

	All patients (<i>n</i> = 46)
General anaesthesia	46 (100)
TOE guidance	46 (100)
Procedure time (minutes)	88 (8–200)
Fluoroscopy time (minutes)	28 (3–75)
Implanted device size (40 patients)	
8/6	6 (15.0)
10/6	7 (17.5)
10/8	1 (2.5)
12/6	3 (7.5)
12/8	8 (20)
14/8	7 (17.5)
16/8	10 (25)

Data are expressed as median (range) or number (%). TOE: transoesophageal echocardiography.







