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# Transcatheter closure of congenital and acquired Gerbode defects with Nit-Occlud Lê VSD (PFM)-Coil. Immediate and mid-term results

## Wyniki przezskórnego zamknięcia ubytku typu Gerbode z zastosowaniem Nit-Occlud Lê VSD (PFM)-Coil

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## Abstract

**Introduction.** Left ventricle-to-right atrial (LV-RA) communications termed Gerbode defects are a special and very rare type of ventricular septal defect. Transcatheter closure using Nit-Occlud Lê VSD-Coils is a new and not well-known alternative to cardiac surgery in selected cases. This study aimed to describe results and experience with interventional closure of Gerbode defects using Nit-Occlud Lê VSD-Coil.

**Material and methods.** The procedures were performed between October 2014 and October 2018. Patients were selected based on detailed transthoracic echocardiography (TTE). The diameter of the defects based on the TTE study was verified and comparable to values found in the angiocardiography. Despite the fluoroscopy guidance the intraprocedural transoesophageal echocardiography was carried out in every case. Finally, the effectiveness of the procedure and the occurrence of complications during the observation were assessed in each case.

**Results.** The study involved eight children, including an infant with native Gerbode defect and seven older children with acquired post-operative LV-RA shunts. Age ranged from 8 months to 17.8 years, bodyweight from 7.4 kg to 56 kg, bodyweight from 7.4 kg to 56 kg, 5/8 females. The diameter mean of the defects in the angiocardiography was 3.86 ± 0.82 mm and it was comparable to values from TTE. All procedures were successful. The coils ranged from 8 × 6 mm to 12 × 6 mm. Early complications after the procedure: one case of transient haemolysis which required blood transfusion and steroids, one case of temporary arrhythmia. The follow-up period ranged 2–36 months, with only one case of a permanent small residual shunt was observed.

**Conclusions.** The interventional treatment of very rare Gerbode defects seems to be a safe alternative to surgery in selected cases. This study is one of the largest suchlike published.

Key words: Gerbode defect, congenital heart disease, interventional cardiology, ventricular septal defect, Nit-Occlud Lê VSD-Coil

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## Introduction

Left ventricle-to-right atrial (LV-RA) shunts represent an unusual type of ventricular septal defect (VSD) often called "Gerbode defect" since the report by Gerbode et al. in 1958 [1]. They may be congenital or acquired [2–5]. The direct and indirect type was suggested by Riemenschneider and Moss, depending on defect location above or below the insertion of the septal leaflet of the tricuspid valve [6]. Sakakibara and Konno [7] introduced differentiation of these defects into three types, in which type I and II corresponded to Riemenschneider classification and the third was a combination of both types. Direct congenital LV-RA communication (the so-called true Gerbode defect) is very rare. Kelle et al. reported 6 patients with this type of defect among over 400 subjects with various types of VSD, operated on at Children's Memorial Hospital Chicago IL between 1990 and 2008 [8]. Congenital indirect type is more common, in which perimembranous ventricular septal defect (pmVSD) coexists with various anomalies of the septal leaflet of the tricuspid valve (malformation, perforation, widened commissure, clefts) [9]. Nowadays the most common are acquired LV-RA defects due to various reasons for example (e.g.): the complication of surgical treatment of pmVSD, atrioventricular septal defects, implantation of the mitral or aortic valve, as a consequence of infective endocarditis, myocardial infarction or even chest trauma [2–5]. Regardless of their type and origin, the LV-RA defects were previously the domain of cardio-surgical treatment. Progress in interventional cardiology has recently made it possible to employ transcatheter methods in selected cases. So far, the most widespread type of used devices has been the Amplatzer Duct Occluder (ADO) II occluders [10, 11].

The objective of this study was to present the authors' experience with still not a well-described method of transcatheter closure of Gerbode defects using Nit-Occlud Lê VSD-Coil (PFM: Produkte für die Medizin AG, Cologne, Germany).

## Material and methods

The study material consisted of children with LV-RA shunts selected by detailed transthoracic echocardiography (TTE) (showing enlarged RA, presence of high-velocity shunt and direction of jet flow in the colour Doppler between LV and RA, Qp/Qs ratio ≥ 1.5:1), verified with the transoesophageal echocardiography (TEE) in four cases of the oldest children. The detailed assessment included the location and dimension of the defect and its structural relationship with nearby valvular structures. The parents were informed about the benefits and risks of transcatheter closure of the defect and that the final decision will be taken during cardiac catheterization. All of them gave informed consent to the procedure and participation in the study. The study protocol complies with local applicable ethical requirements.

The procedures were performed between October 2014 and October 2018. Right and left heart catheterizations were performed to estimate the diameter of the defect, pulmonary artery pressure and Qp/Qs ratio. The device description and technique used to close the Gerbode defects in the study patients has been similar to the EUROVECO-Registry by Haas et al. [12]. All procedures were performed under general anaesthesia with antibiotics as prophylactic. Every patient received a heparin bolus appropriate for body weight. Despite the fluoroscopy guidance an intraprocedural TEE was carried out in every case. In the beginning, the right femoral venous (RFV) and right femoral arterial (RFA) accesses were obtained. Furthermore, left ventriculography was performed to confirm the size and the localization of the defect in each case. The size of the used coils was selected after final evaluation and ranged from 8 × 6 mm to 12 × 6 mm. The LV-RA defect was crossed with Berenstain 4F catheter in a retrograde fashion from RFA access through the aorta, LV to RA. The guidewire was snared at the superior or inferior vena cava and withdrawn through the femoral venous sheath (femoral arteriovenous loop was made). By RFV access the long delivery sheath was advanced into the ascending aorta and the Nit-Occlud Lê VSD (PFM)-Coil was passed through it. The first loops of the device were released in the aorta and then retracted into LV and the defect area. After confirming the correct position of the device and closure effect in control angiography, the device was slowly pulled back into the defect and final loops were deployed in RA. Another control angiography was performed and providing that the effect was satisfactory the device was released. Finally, the TTE and TEE control examinations were performed. The follow-up consists of regular ambulatory visits with detailed physical examination and TTE. The results are presented as mean ± standard deviation (SD).

## Results

The total number of patients enrolled in the present study was eight children (5 females, 3 males). The group consisted of one infant with native and seven children with acquired post-operative LV-RA shunts: one after correction of atrial septal defect type 1 (ASD I) and presented with mitral regurgitation due to significant anterior mitral valve cleft and in six children after a closure of pmVSD [coexisting in five infants with other congenital heart defects: coarctation of the aorta (CoAo) — in two, interrupted aortic arch (IAA) type B — in another two and double outlet right ventricle (DORV) — in one patient]. The age of patients who underwent a surgical correction of a congenital heart defect was highly heterogeneous due to a personalized approach to the treatment of various heart malalignments and ranged

**Table 1.** Selected data including echocardiography of patients with left ventricle-to-right atrial (LV-RA) defects before the transcatheter treatment

| Pts | Gender F/M | Age at the procedure (years) | Weight [kg] | Diagnosis | Selected echocardiographic data | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | Shunt Ø at the LV side [mm] | TVR* | RA enlargement | RV enlargement | Qp/Qs |
| 1. GM | F | 0.7 | 7.4 | Native, direct LV--RA shunt | 5 | II/III° | Moderate | Moderate | 2.2:1 |
| 2. PK | F | 14.7 | 50 | Direct LV-RA-shunt (post-operative: ASD I, with a cleft in the AMVL) | 6 | ≤ I° | Moderate | Moderate | 1.7:1 |
| 3. RM | M | 17.8 | 56 | Indirect LV-RA shunt (post-operative: pmVSD, subAS, CoAo with Ao arch hypoplasia) | 4 | III° | Severe | Moderate | 1.5:1 |
| 4. CK | F | 7.5 | 24 | Indirect LV-RA shunt (post-operative: IAA type B, bicuspid Ao-valve, pmVSD), Di George S | 2.5 | ≤ II° | Mild | Mild | 1.2:1 |
| 5. KA | F | 14.5 | 52 | Indirect LV-RA shunt (post--operative: DORV, pmVSD) | 4.5 | ≤ II° | Moderate | Moderate | 1.7:1 |
| 6. KA | M | 9 | 3 | Indirect LV-RA shunt (post-operative: pmVSD, CoAo with Ao arch hypoplasia) | 3.5 | ≤ II° | Mild | None | 1.7:1 |
| 7. MM | M | 7 | 28 | Indirect LV-RA shunt (post-operative: IAA type B, pmVSD) | 4 | < II° | Moderate | Moderate | 2:1 |
| 8. PZ | F | 12.5 | 40 | Indirect LV-RA shunt (post-operative: pmVSD, PDA) | 4.5 | < II° | Moderate | None | 1.6:1 |
| Total | 5F<br>3M | 10.46 ± 5.5 | 35.55 ± 20.3 | 1 — native true Gerbde defect<br>7 — acquired, post--cardiac surgery | 4.25 ± 1 | 6 — ≤ II°<br>1 — II/III°<br>1 — III° | 2 — mild<br>5 — moderate<br>1 — severe | 5 — moderate<br>1 — mild<br>1 — none | 1.7 ± 0.3 |

*≤ II° — mild, II/III° — moderate, III° significant type I — above the tricuspid valve, type II — below tricuspid valve; pts — patients; F — female; M — male; LV — left ventricle; TVR — tricuspid valve regurgitation; RA — right atrium; RV — right ventricle; ASD I — atrial septal defect type 1; AMVL — anterior mitral valve leaflet; pmVSD — perimembranous ventricular septal defect; subAS — membranous subaortic stenosis; CoAo — coarctation of the aorta; Ao — aorta; IAA — interrupted aortic arch; DORV — double outlet right ventricle; PDA — patent ductus arteriosus

from 3 weeks to 13.5 years (2.4 ± 4.95 years). Selected data of patients qualified for the procedure are presented in Table 1. The LV-RA shunt was properly diagnosed in the first postoperative TTE study in five children. In three patients, the initial assessment was incorrect: in one — residual VSD with the tricuspid regurgitation and in the rest (after ASD I and mitral valve repair) only the tricuspid regurgitation were suggested. All patients included in this study were not initially qualified for re-operation. Instead, the children were recommended to continue ambulatory visits and undergo

**Table 2.** The results of interventional transcatheter closure of left ventricle-to-right atrial shunt with Nit-Occlud Lê VSD (PFM)-Coil

| Pts | Shunt Ø (on angiogiography at LV side) in mm | Device size [mm × mm] | Procedure time [min] | Fluoro-scopy-time [min] | Residual shunt directly after the procedure | Significant complication | Time of hospitalization (days) | Follow-up (months)/ /residual shunt (±) |
|---|---|---|---|---|---|---|---|---|
| 1. GM | 4.5 | 8 × 6 | 40 | 14 | Mild | Haemolysis | 12 | 19 (–) |
| 2. PK | 3.8 | 10 × 6 | 65 | 19 | Trivial* | No | 3 | 36 (+) |
| 3. RM | 4.2 | 12 × 6 | 65 | 18 | Trivial* | No | 4 | 2 (–) |
| 4. CK | 3.5 | 8 × 6 | 50 | 15 | No | No | 3 | 25 (–) |
| 5. KA | 4.5 | 10 × 6 | 60 | 14 | Trivial* | No | 3 | 26 (–) |
| 6. KA | 4.2 | 10 × 6 | 55 | 16 | No | No | 4 | 13 (–) |
| 7. MM | 4.2 | 10 × 6 | 40 | 7 | Trivial* | No | 3 | 24 (–) |
| 8. PZ | 2.0 | 8 × 6 | 45 | 16 | Trivial* | No | 5 | 17 (–) |
| Total | 3.86 ± 0.82 | | 52.5 ± 10.4 | 14.9 ± 3.6 | 1 – mild**<br>5 – trivial*<br>2 – none | 1/8 (12.5%) | 4.6 ± 3.1 (3–12) | 20.3 ± 10.1 |

*Trivial: < 1 mm in diameter; **mild: 1–2 mm in diameter; pts – patients; LV – left ventricle

periodic TTE control. In follow-up, the decision was changed and closure of shunt was suggested. In five children, including an infant with true Gerbode defect, enalapril and/or spironolactone were administered due to presentation of congestive heart failure symptoms (e.g., *tachypnoe*, excessive perspiration, early fatigability *etc.*). The age of patients at the time of procedure ranged from 8 months to 17.8 years (10.46 ± 5.5 years), body weight was from 7.4 kg to 56 kg (35.55 ± 20.3 kg). The angiocardiographic study revealed the defect located above the tricuspid valve in three patients (type I) and below in five patients (type II). The diameter of defects based on the TTE was verified and comparable to values found in the angiocardiographic study (4.2 ± 1 mm vs. 3.86 ± 0.82 mm), Qp/Qs ratio was 1.7 ± 0.3. The implantation of a coil was successful in all patients. The procedure time extended from 40 to 65 min (52.5 ± 10.4 min). A procedure of Gerbode defect closure is shown in Figures 1–2. Immediately after the procedure, a residual shunt was observed in six patients: one mild (case of congenital LV-RA shunt) and nonsignificant in five others. In two children the defect was completely closed. The follow-up period was 2–36 months (20.3 ± 10 months). Control TTE studies revealed no residual shunt in seven patients. In one, with the longest follow-up, the residual shunt was still present (≤ 2 mm in diameter, below the implant). In two patients, significant tricuspid regurgitation co-existing with LV-RA defect decreased to benign: in an infant immediately, in the teenager – 2 months after the procedure. The results of transcatheter treatment are shown in Table 2.

In an infant with true Gerbode defect, soon after the procedure haemolysis was observed with a decreased level of haemoglobin – 9.1 g/dL, haematocrit – 27.7% and proteinuria (++). After a blood transfusion and an administration of steroids and propranolol, haematological parameters normalized and proteinuria regressed within 10 days. In another child with pre-existing benign ventricular ectopy, the arrhythmia temporarily worsened immediately after the procedure, but afterwards, it spontaneously relieved in a few following days.

## Discussion

LV-RA shunts are an unusual form of VSD. The term "Gerbode defect" was assigned to the anomaly after Gerbode's et al. publication of successful surgical repair in five patients. In their material only one patient had direct and the others – tetralogy of Fallot (TOF) indirect types of LV-RA defects [1]. The very first description of this anomaly was given by Thurnam in 1838 [13], followed by Buhl in 1857 [14]. The first successful surgical closure of LV-RA shunt was performed by Kirby et al. in 1956 [15]. Until recently, the LV-RA defects, regardless of their nature and location have been the domain of cardiac surgical treatment. Progress in interventional transcatheter methods has recently made it possible to close those defects using different types of occluders. The first who performed successful transcatheter treatment of acquired RA-LV shunt (post pmVSD repair) by the Amplatzer ventricular septal occluder was Trehan et al. in 2006 [16]. Moreover, Dangol

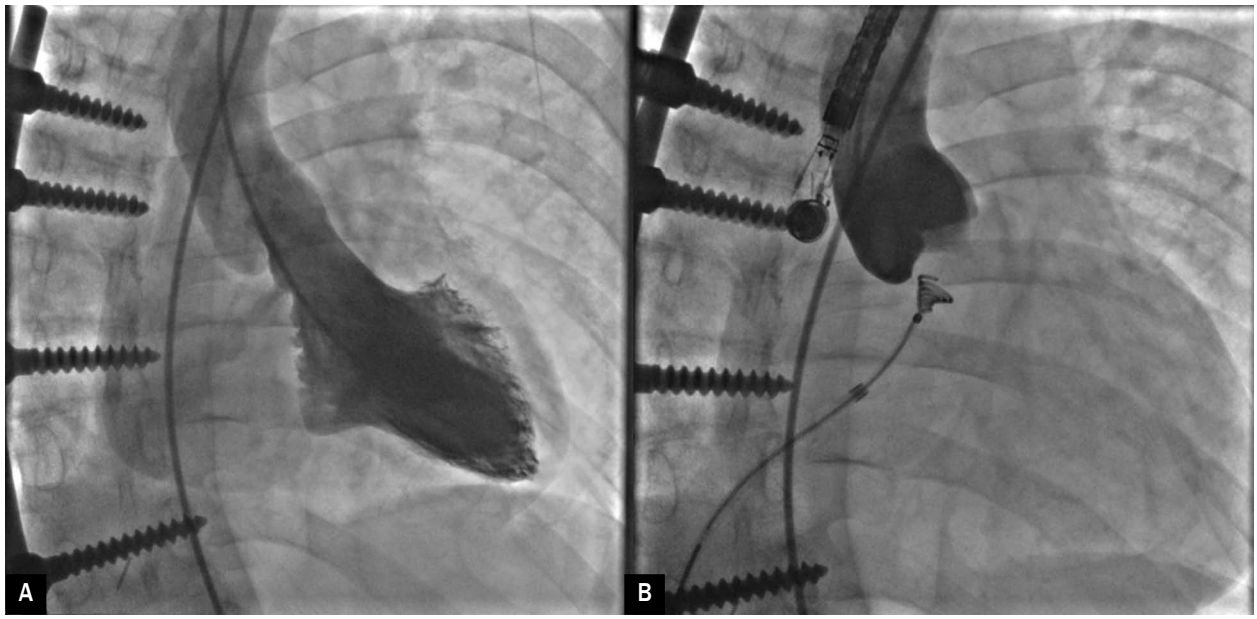


**Figure 1.** Angiocardiographic image of acquired left ventricle-to-right atrial shunt (type I) before and after closing by Nit-Occlud Lê VSD-Coil: **A.** Left ventriculography (LAO projection) in patient 2 showing the shunt flow to the right atrium; **B.** The same projection illustrating the occluder closing the defect (Nit-Occlud Lê VSD-Coil) at the place of the shunt; VSD — ventricular septal defect

et al. in 2012 described closure of acquired LV-RA shunt in an infant post-TOF repair with the use of ADO occluder [17]. In the group of devices used in the treatment of various types of VSD a specific type of nickel-titanium spiral coil (Nit-Occlud Lê VSD-Coil) became available in August 2010 [12]. This system was applied for the first time by Lê et al. [18] in the population of adult patients. The significant data regarding this device in closing various types of VSD except for Gerbode type defects was presented by Haas et al. [12]. The advantages of that device are its plasticity and that it is fully retrievable. In the case of any complications or incorrect configuration, the device can be removed and implanted again or another size of the device can be used [9, 12]. Moreover, it has low-risk trauma to the conduction system [12].

Clinical symptoms of LV-RA defect are similar to those found in other VSD and depend on the size of the shunt. The key to diagnosis is accurate TTE, especially using parasternal long-axis and apical five-chamber views. However, the LV-RA shunt in TTE may sometimes be misdiagnosed as tricuspid regurgitation. In doubtful and demanding diagnostic cases TEE is necessary and decisive.

In the present material, Gerbode defects closure was successful in all enrolled patients. After the procedure, one case of intravascular haemolysis was observed. This complication has already been described after the use of Nit-Occlud Coils in transcatheter treatment of various types of VSD [12]. Odemis et al. [19] reported a similar frequency (3/20) of this complication among patients who underwent transcatheter closure of pmVSD with Nit-Occlud Lê VSD-Coil. Saygı et al. [20] reported management of intractable haemolysis after the closure of pmVSD with this system in two children. Re-intervention with the use of another coil in one patient was not successful and the child required cardiac surgery with removal of implants. In another case, the residual shunt was successfully closed with the ADO II occluder [20]. Severe haemolysis may require a blood transfusion as in one patient. Propranolol and steroids are also helpful in the treatment of it. In this patient, haemolysis resolved after three days of such combined therapy. Low doses of steroids were administered as prophylaxis for the subsequent several days. However, in very serious cases or if a condition deteriorates despite the treatment, surgical removal of the occluder may be necessary [19, 20]. Haemolysis may also occur when other types of occluders are used in the transcatheter treatment of PDA, ASD or VSD [21, 22]. However, it was suggested that the Nit-Occlud Lê VSD-Coils may have a higher risk of this complication [12, 19, 20].

In mid-term follow-up (17 months after the procedure) non-significant residual shunt was shown in TTE in only one patient. Noteworthily, no conduction disturbances immediately after the procedure and in the follow-up were observed in the study patients. The risk of this complication is probably low due to the flexibility and plasticity of the occluder.

The procedure of LV-RA shunt closure with occluder is demanding and requires a lot of experience. In infants

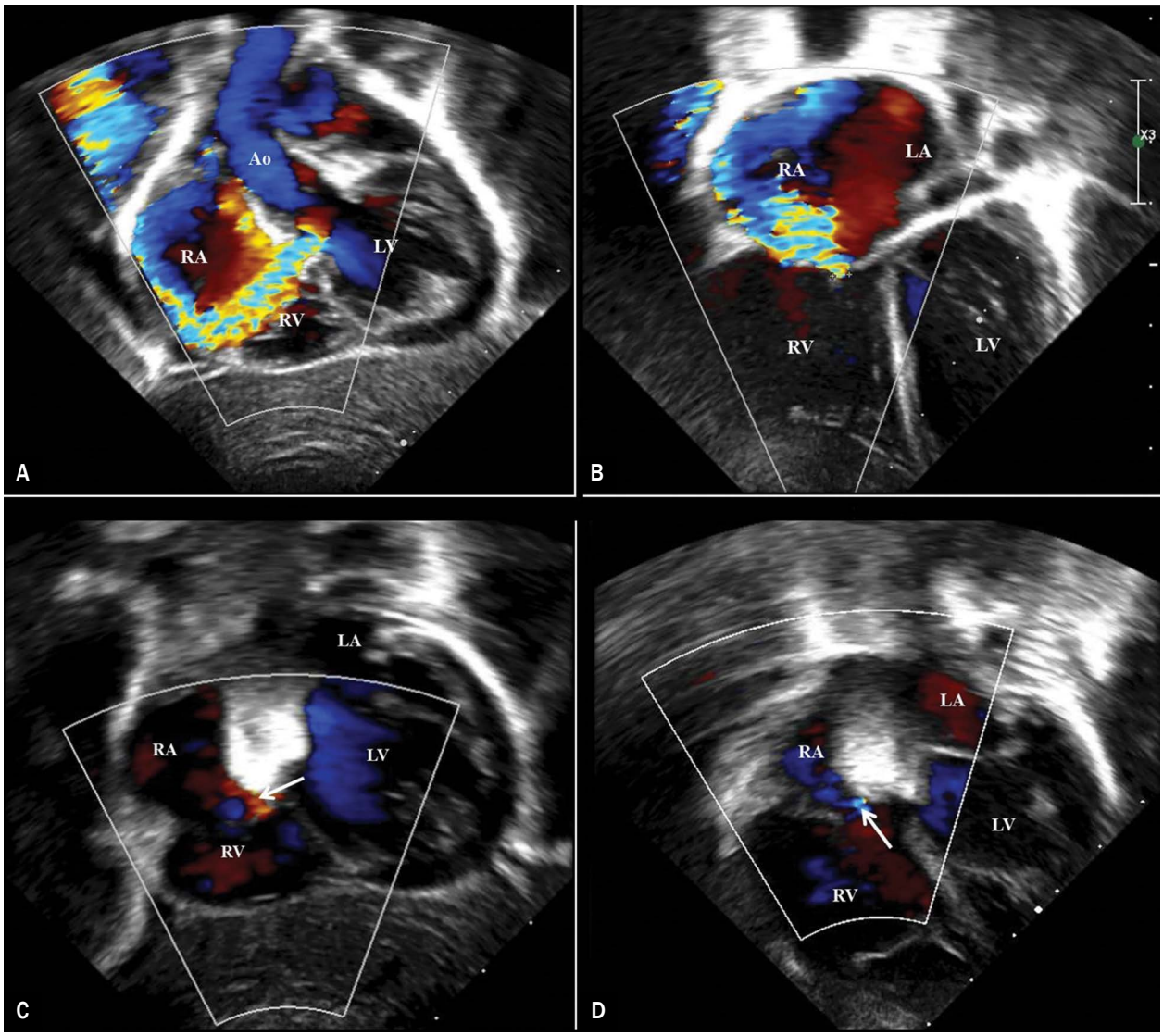


**Figure 2A**, **B.** Transthoracic echocardiography image of native, true Gerbode shunt coexisting with significant tricuspid regurgitation in an infant before; **C, D.** After closure with Nit-Occlud Lê VSD device. **A.** A subxiphoid view of the congenital, direct left ventricle-to-right atrial shunt in an 8-month-old infant before the procedure; **B.** Four-chamber view of the same patient showing regurgitation of the tricuspid valve, due to prolapsing of the septal leaflet. No shunts below the septal leaflet of the tricuspid valve were seen; **C.** A subxiphoid transthoracic echocardiography projection demonstrating mild, residual shunt (white arrow) after the closure of true Gerbode defect with Lê VSD-Coil (a bright hourglass-like shadow); **D.** A four-chamber view showing trivial retrograde flow across the tricuspid valve after the procedure in this patient; VSD — ventricular septal defect

a diameter of the ascending aorta evaluation is crucial for the proper formation of the device left loops and their safe movement through the aortic valve. Due to the specific anatomy of the Gerbode type defects (longer and more torturous than muscular or membranous VSD), ADOs and especially Nit-Occlud Lê VSD-Coils seem more suitable to close such defects than other VSD occluders. An additional benefit was decreasing coexisting tricuspid regurgitation in two of the patients. Two mechanisms might explain that phenomenon. In the infant, the length of the Nit Occlud device was sufficient to counteract and stabilize the prolapsing septal leaflet of the tricuspid valve. In the other patient, it was a residual pmVSD jet elimination that improved TV function. Such observations were also presented by Kerst et al. [9].

To the best of the authors' knowledge, this study enrolled one of the biggest groups of patients with different Gerbode defects who underwent closure with Nit-Occlud Lê VSD-Coils. It is also the first suchlike description in the Polish population.

## Conclusions

LV-RA shunts closure with use Nit-Occlud Lê VSD-Coils seems to be effective and safe. It requires, however, a lot of experience in transcatheter treatment, especially in the group of the youngest patients. It is a great advantage and alternative for surgery, especially for high-risk patients. More studies in a larger group of patients and longer observation are needed for the more accurate evaluation of this method.

## Acknowledgements and Funding

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## Conflict of interest

The authors declared no conflict of interest concerning the authorship and/or publication of this article.

### Streszczenie

**Wstęp.** Ubytki typu Gerbode są szczególnym i rzadkim typem ubytków międzykomorowych (VSD) i umożliwiają przeciek między lewą komorą a prawym przedsionkiem (LV-RA). Często mogą być błędnie interpretowane jako VSD z niedomykalnością zastawki trójdzielnej i znacznym nadciśnieniem płucnym. Do niedawna jedynym wyjściem było leczenie chirurgiczne. Jednakże obecnie ich przezskórne leczenie z zastosowaniem zestawów Nit-Occlud Lê VSD-Coils jest nową, ciekawą alternatywą do klasycznego chirurgicznego postępowania. Celem badania była ocena skuteczności i bezpieczeństwa interwencyjnego leczenia ubytków typu Gerbode z zastosowaniem Nit-Occlud Lê VSD-Coils.

**Materiał i metody.** W przeprowadzonych zabiegach autorzy wykorzystali swoje dotychczasowe doświadczenie w przezskórnym zamykaniu okołobłoniastych VSD. Zabiegi przeprowadzono od października 2014 do października 2018 roku. Dotyczyły pacjentów z ubytkami LV-RA wyselekcjonowanymi na podstawie przezklatkowego badania echokardiograficznego (TTE). Wymiar każdego ubytku ponownie weryfikowano podczas angiografii. W każdym przypadku wykonano również śródoperacyjne przezprzełykowe badanie echokardiograficzne. U wszystkich pacjentów oceniono skuteczność zabiegu i wystąpienie powikłań w czasie obserwacji.

**Wyniki.** Ostatecznie badana grupa składała się z 8 pacjentów pediatrycznych, w tym 1 niemowlęcia z natywnym i 7 starszych dzieci z nabytym, resztkowym ubytkiem typu Gerbode. Wiek badanych wahał się od 8 miesięcy do 17,8 roku, masa ciała od 7,4 kg do 56 kg, 5 spośród 8 było płci żeńskiej. Średni wymiar ubytku w angiografii wynosił 3,86 ± 0,82 mm i był porównywalny z wartością uzyskaną w TTE. Zabieg był skuteczny u wszystkich pacjentów. Wielkość coili wahała się od 8 × 6 mm do 12 × 6 mm. Po zabiegu odnotowano jeden przypadek hemolizy i jeden przypadek przejściowej arytmii. Okres obserwacji wynosił od 2 do 36 miesięcy. W kontrolnym TTE wykazano tylko mały, rezydualny przeciek u tylko jednego pacjenta.

**Wnioski.** W wybranych przypadkach interwencyjne leczenie ubytków typu Gerbode stanowi bezpieczną alternatywę dla korekcji chirurgicznej. Niniejsze opracowanie jest jednym z największych dotychczas opublikowanych na temat tej bardzo rzadkiej wady.

Słowa kluczowe: ubytek typu Gerbode, wrodzona wada serca, kardiologia interwencyjna, wada przegrody międzykomorowej, Nit-Occlud Lê VSD-Coil

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