Short- and long-term outcomes of transcatheter ventricular septal defect closure using different devices: A single center experience in pediatric and adult patients

Authors: Jacek Białkowski, Roland Fiszer, Mateusz Knop, Jan Głowacki, Szymon Pawlak, Małgorzata Szkutnik

Article type: Short communication

Received: February 14, 2024

Accepted: July 1, 2024

Early publication date: July 5, 2024
Short- and long-term outcomes of transcatheter ventricular septal defect closure using different devices: A single center experience in pediatric and adult patients

Short title: Transcatheter closure of ventricular septal defect

Jacek Białkowski1, Roland Fiszer1, Mateusz Knop1, Jan Glowacki2, Szymon Pawlak3, Małgorzata Szkutnik1

1Department of Pediatric Cardiology and Congenital Heart Defects, Faculty of Medical Sciences in Zabrze, Medical University of Silesia, Silesian Center for Heart Diseases, Zabrze, Poland
2Department of Radiology, Faculty of Medical Sciences in Zabrze, Medical University of Silesia, Silesian Center for Heart Diseases, Zabrze, Poland
3Department of Pediatric Cardiac Surgery, Faculty of Medical Sciences in Zabrze, Medical University of Silesia, Silesian Center for Heart Diseases, Zabrze, Poland

Correspondence to:
Prof Jacek Białkowski, MD, PhD,
Department of Pediatric Cardiology and Congenital Heart Defects,
Silesian Center for Heart Diseases,
Curie-Skłodowskiej 9, 41–800 Zabrze, Poland
phone: +48 32 271 34 01,
e-mail: jabi_med@poczta.onet.pl

INTRODUCTION
Ventricular septal defect (VSD) is the most common congenital heart defect. VSD can be divided into perimembranous (pmVSD) and muscular (MVSD). Complicated anatomy of VSD proximity of aortic or tricuspid valve and trajectory of conduction system makes these procedures difficult. The feasibility of percutaneous VSD closure has been previously proven. Our experience related with this subject has been published previously [1–7]. However studies describing long term results remains scare [8–10].

We aimed to present our institutional experience with transcatheter VSD closure and evaluate short and long term (till 20 years) follow-up of this procedures.
METHODS

We retrospectively reviewed data of 50 subsequent patients who were qualified for device closure of pmVSD, MVSD and residual postsurgical VSD (RVSD) between 11/2002 and 04/2016 in Our Center. Indications for VSD closure was Qp/Qs >1.5. We excluded patients with larger (>10 mm in diameter), postinfarction VSD and with pulmonary hypertension. Both percutaneous and hybrid procedures were included. In all cases routine right and left heart catheterization was performed before the procedure. Retrograde (in the majority of patients) or anterograde approach was used for VSD percutaneous closure according to the descriptions published elsewhere [2–6]. In all cases different types of nitinol mesh occluders were used. Device selection depended on the defect morphology, location, relation to surrounding structures, diameter of the defect and device availability in the armamentarium. All procedures were performed by one of the authors (MSz). Following ventricular septal occluders (VSO) were used in the study period: Amplatzer Muscular VSO (AMO), asymmetrical Amplatzer Perimembranous VSO (asVSO) and Amplatzer Duct Ocluders: type I (ADOI), type II — (ADOII) and ADOII Additional Sizes (ADOIIAS) — all now Abbott Comp, US. Moreover ADOI-like type devices were applied including HeartR (Lifetech Comp, China) and Cardio-O-Fix (Starway Comp, China). AMO were used in case of MVSD (2002–2016), and also in case of pmVSD (2002–2007) when aortic rim was >4 mm. In 5 children with MVSD hybrid procedure was applied (2009–2013) — surgical debanding of pulmonary artery and transcatheter MVSD closure in 4 of them and primary treatment in 1 patient because of low body weight (4.9 kg). AsVSO were applied when aortic rim of pmVSD was absent or small (in the period 2003–2008). ADOI, II, IIAS or ADO-like occluders were used in selected cases with RVSD or pmVSD (2011–2016).

Follow-up evaluation was performed one day before discharge and 3, 6, 12 months after the procedure and thereafter was planned every 12 months. Device position, VSD residual shunt and valvular condition were evaluated by transthoracic echocardiography and Holter monitoring was performed when an abnormality in electrocardiogram was observed. Adverse events which required surgical, transcatheter or medical treatment were defined as major complications. Complications which did not require special management were termed as minor [10]. Early results were defined those related to the procedure or those which occurred till one year after the procedure. Late result was this which appeared during last follow up. Study design was approved by our institution scientific board and study consent was achieved from all participants.
**Statistical analysis**

Qualitative variables were described as n (%). McNemar test was used to compare frequency of major and minor complications in early and late follow-up. Numerical variables were present as median (interquartile range). Statistica 13.3 was used, $P < 0.05$ was considered as statistical significant.

**RESULTS AND DISCUSSION**

There were 50 patients: pmVSD (n = 21), MVSD (n = 22) and RVSD (n = 7) — 39 children and 11 adults. Table 1 illustrates some clinical data. Detailed informations (data of the procedures and follow-up) are included in Supplementary material, Table S1.

Among these 50 patients 54 VSD procedures of percutaneous closure were made [double procedures were conducted in 4 patients with multiple MVSD (Supplementary material, Table S1: patients 24, 29, 36, 37)].

Successful implantation was initially achieved in 50/54 procedures (92.6%) — similarly to that reported by others — 91.8% [8] and 97.9% [10]. Device was withdrawn (after implantation but before releasing) in 3 cases because of severe rhythm disturbances — after application of asVSO (patients 6, 10) and AMO (patient 34). In 1 patient cannulation of MVSD was impossible (patient 31).

We observed no mortality during either the procedure or follow-up period. Out of 42 patients monitored complete closure rate was initially 71.4%, which subsequently increased to 95.2% in late follow-up (in others observations [9] — 86.2%). All residual shunts were tiny or mild.

During early postprocedural period 6 major complications occurred: 2 cases of complete atrio ventricular block (CAVB) (Supplementary material, Table S1: patients 8, 13) [1, 4] and massive tricuspid insufficiency (TI) (Supplementary material, Table S1: patient 35) [7]. Furthermore 3 early AMO embolizations occurred — all devices were successfully retrived (Supplementary material, Table S1: patients 25, 26, 30): in 2 adult patients with thick intra ventricular septum and one child with complex congenital heart defect [3].

The most dangerous complication after percutaneous closure of VSD is CAVB [1]. It appeared in 4.7% of our patients (2/42) — all after asVSO application: in one resolved with steroid therapy and in another by permanent pacemaker implantation. Other studies showed that CAVB occurred at a rate of 0.1%–6.8% after interventional VSD closure [9, 10] and <2% after surgical VSD closure [10].
Moreover in 15 patients minor complications in early follow-up were observed: 11 mild TI, 2 mild aortic insufficiency and 2 right bundle branch block (RBBB).

At late follow-up no major complications occurred (diminished from 14.3% — 6/42 in early follow-up to 0% 0/42) \((P = 0.04)\), minor complications were present in 26.2% (11/42) and were as follow: 5 TI, 1 aortic insufficiency, 3 right bundle branch block, 2 ectopic ventricular activites. In one patient with RVSD (Supplementary material, Table S1: patient nr 44) in follow up were observed episodes of supraventricular tachycardia treated successfully with Carto ablation (supraventricular tachycardia were related rather to previous surgery than to percutaneous closure of RVSD). Similarly in 2 patients (one after pmVSD closed with asVSO and one with MVSD closed with AMO) sick sinus syndrome was observed in late follow-up (Supplementary material, Table S1: patient 19, 33).

Overall our results showed that transcatheter closure of VSD is a safe method of treatment. We documented that after initial problems related with the procedure numbers of serious complications diminished significantly (to 0%). Even minor complications as mild TI diminished with time (from 26.2% to 11.9%). TI was observed more frequently in patients with pmVSD closed with AMO. The interference of the device with chordae tendineae of TV is generally benign and was observed similarly by Rahmath et al. [8] as new onset in 40% of his patients. The most severe complication we encountered was the impingement of the device on the septal leaflet, resulting in TV destruction (Supplementary material, Table S1: patient 35) — a crucial warning against the percutaneous closure of inlet MVSD [7].

The risk of device embolization presented a notable challenge, occurring in 13.6% of our MVSD patients (3/22). We emphasize the importance of meticulous patient selection in these cases [3, 7]. The hybrid procedure suits as a viable option, applied in 22.7% of our MVSD patients (5/22).

Probably the most beneficient patients are those with RVSD — we had 4 after TOF, 1 after Rastelli operation and 2 after pmVSD closure. In this subgroup we have found especially useful different types of PDA occluders [5, 6]. We can speculate that percutaneous closure of multiple muscular VSD in early childhood in one of our patient (Supplementary material, Table S1: No. 29) protect development of pulmonary hypertension and was finally bridge to successful heart transplantation (realized recently because of increasing heart failure caused by cardiomyopathy) [11].

Quality of life of our patients was generally good — 2 of them were sportsmen and 3 women till now gave birth to 5 babies.
In conclusion nowadays ideal device for percutaneous closure of VSD does not exist. Probably development of new more flexible devices (like ADOIAS) may be potentially useful.

**Supplementary material**

Supplementary material is available at https://journals.viamedica.pl/polish_heart_journal.

**Article information**

**Conflict of interest:** None declared.

**Funding:** None.

**Open access:** This article is available in open access under Creative Common Attribution-Non-Commercial-No Derivatives 4.0 International (CC BY-NC-ND 4.0) license, which allows downloading and sharing articles with others as long as they credit the authors and the publisher, but without permission to change them in any way or use them commercially. For commercial use, please contact the journal office at polishheartjournal@ptkardio.pl

**REFERENCES**


Table 1. Some clinical data of patients in whom Ventricular Septal Defect was closed transcatheterly in years 2002–2016

<table>
<thead>
<tr>
<th></th>
<th>pmVSD</th>
<th>MVSD</th>
<th>RVSD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>10 (7–23)</td>
<td>2.35 (1.5–8)</td>
<td>2.5 (1.5–11)</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>30 (19–51)</td>
<td>11.3 (8.4–25)</td>
<td>13 (9.4–42)</td>
</tr>
<tr>
<td>VSD diameter, Echo-mm</td>
<td>4.5 (4–5)</td>
<td>5.75 (4–7.5)</td>
<td>3 (2.8–3.4)</td>
</tr>
<tr>
<td>Follow-up, years</td>
<td>10 (5–16)</td>
<td>8 (3–11)</td>
<td>7 (7–8)</td>
</tr>
</tbody>
</table>

Data presented as median (interquartile range) and numbers (%)

Abbreviations: MVSD, muscular ventricular septal defect; pmVSD, perimembranous ventricular septal defect; RVSD, residual post surgery ventricular septal defect