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

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INTRODUCTION

Ventricular septal defect (VSD) is the most common congenital heart defect. VSD can be divided into perimembranous (pmVSD) and muscular (MVSD). The complicated anatomy of VSD, the proximity of the aortic or tricuspid valves, and the trajectory of the conduction system make these procedures difficult. The feasibility of percutaneous VSD closure has been previously reported. Our experience related to this subject has also been published previously [1–7]. However, studies describing long-term results remain scarce [8–10].

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

METHODS

We retrospectively reviewed data of 50 subsequent patients who were qualified for device closure of pmVSD, MVSD, and residual post-surgical VSD (RVSD) between 11/2002 and 04/2016 in our Center. The indication for VSD closure was Qp/Qs >1.5. We excluded patients with larger (>10 mm in diameter), postinfarction VSD, and pulmonary hypertension. Both percutaneous and hybrid procedures were included. In all cases, routine right and left heart catheterization was performed before the procedure. A retrograde (in most 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 morphology of the defect, its location, relation to surrounding structures, diameter, and device availability. All procedures were performed by one of the authors (MSz). The following ventricular septal occluders (VSO) were used in the study period: Amplatzer Muscular VSO (AMO), asymmetrical Amplatzer Perimembranous VSO (asVSO), and Amplatzer Duct Occluders: type I (ADOI), type II — (ADOII) and ADOII Additional Sizes (ADOIIAS) — all Abott Comp, US. Moreover, ADOI-like type devices were applied including HeartR (Lifetech Comp, China) and Cardio-O--Fix (Starway Comp, China). AMO was used in the case of MVSD (2002–2016), and also in the case of pmVSD (2002–2007) when the aortic rim was >4 mm. In 5 children with MVSD a hybrid procedure was applied (2009–2013) — surgical debanding of the 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 was applied when the 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, and 12 months after the procedure and thereafter 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 the electrocardiogram was observed. Adverse events that required surgical, transcatheter, or medical treatment were defined as major complications. Complications that did not require special management were

Table 1. Some clinical data of patients who underwent venticular septal defect closure transcatheter in years 2002–2016

	pmVSD	MVSD	RVSD
Age, years	10 (2–40)	2.35 (0.7–46)	2.5 (1.3–31)
Weight, kg	30 (12–101)	11.3 (4.9–89)	13 (8.7–42)
VSD diameter, Echo-mm	4.8 (3–6)	5.75 (4–10)	3 (2.5–6)
Follow-up, years	10.5 (2–20)	8.5 (3–15)	7 (6–12)

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

Abbreviations: MVSD, muscular venrticular septal defect; pmVSD, perimembranous ventricular septal defect; RVSD, residual post suregery venticular septal defect

termed as minor [10]. Early results were defined as those related to the procedure or those that occurred up to one year after the procedure. The late result was the outcome that appeared during the last follow-up. The study design was approved by our institution's scientific board, and study consent was obtained from all participants.

Statistical analysis

Qualitative variables were described as n (%). The McNemar test was used to compare the frequency of major and minor complications in early and late follow-up. Numerical variables were presented as medians (interquartile ranges). Statistica 13.3 was used, and $P < 0.05$ was considered statistically 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 information (data on the procedures and follow-up) is 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%) — similar to that reported by others — 91.8% [8] and 97.9% [10]. The device was withdrawn (after implantation but before release) 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 deaths during the procedure or follow-up. Of 42 patients monitored, the complete closure rate was initially 71.4%, and it subsequently increased to 95.2% in late follow-up (in other follow-ups [9] — 86.2%). All residual shunts were tiny or mild.

During the early postprocedural period, 6 major complications occurred: 2 cases of complete atrioventricular 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 retrieved (Supplementary material, *Table S1*: patients 25, 26, 30) in 2 adult patients with thick intra-ventricular septum and 1 child with complex congenital heart defect [3].

The most dangerous complication after percutaneous closure of VSD is CAVB [1]. It occured in 4.7% of our patients (2/42) — all after asVSO application; in one, it was 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 follows: 5 TI, 1 aortic insufficiency, 3 cases of right bundle branch block, 2 ectopic ventricular activities. In one patient with RVSD (Supplementary material, *Table S1*: patient nr 44) in follow-up, we observed episodes of supraventricular tachycardia treated successfully with Carto ablation (supraventricular tachycardia was related to previous surgery rather than 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 to the procedure, the number of serious complications diminished significantly (to 0%). Even minor complications, such as mild TI, reduced 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 chordea tendineae of tricuspid valve (TV) is generally benign and was also observed by Rahmath et al. [8] as a new onset in 40% of their 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; it occurred 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

is a viable option and was applied in 22.7% of our MVSD patients (5/22).

Probably, patients with RVSD can benefit the most — we had 4 after TOF, 1 after the 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 patients (Supplementary material, *Table S1*: No. 29) prevented the development of pulmonary hypertension and finally was a bridge to successful heart transplantation (performed recently because of increasing heart failure caused by cardiomyopathy) [11].

The quality of life of our patients was generally good — 2 of them were sportsmen and 3 women have given birth to 5 babies so far.

In conclusion, nowadays an ideal device for percutaneous closure of VSD does not exist. Development of new more flexible devices (like ADOIIAS) may be potentially useful.

Supplementary material

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

Article information

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