Percutaneous closure of perimembranous and postsurgical ventricular septal defects with Amplatzer Duct Occluder II Additional Sizes in paediatric patients – case series

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Adv Interv Cardiol 2018; 14, 4 (54): 429–432
DOI: https://doi.org/10.5114/aic.2018.79874

Introduction

Perimembranous ventricular septal defect (pmVSD), one of the most frequent congenital heart defects, requires surgical (gold standard) or transcatheter closure in a considerable number of children. In general, the results of surgical correction are excellent; however, in 2.5% of patients residual postsurgical VSDs (psVSD) are reported [1]. There have been numerous attempts to close pmVSD with various devices, with different efficacy and safety rates [2]. The percutaneous closure of psVSD, sometimes of atypical anatomy, was also reported in the literature [3]. The transcatheter treatment of pmVSD remains a controversial problem. The main issues are the risk of embolization, early and late conduction disturbances, damage to the tricuspid valve apparatus or aortic insufficiency [4]. Numerous devices have been proposed for percutaneous pmVSD closure, including the off-label use of Amplatzer muscular VSD occluders, Amplatzer duct occluders type I and II (ADO I, II) or ADOII Additional Sizes (ADO II AS) [2, 5–7]. To the best of our knowledge, there have been only two previous publications from this and the previous year regarding this application of ADO II AS in children – 1 case report [6] and 1 presentation of a series of 4 cases [7].

Aim

To present our preliminary experience with ADO II AS used for the transcatheter closure of 4 pmVSDs and 2 psVSDs.

Material and methods

All patients were qualified for percutaneous VSD closure by a team of paediatric cardiologists and cardiac surgeons based on clinical symptoms of increased pulmonary flow (chest X-ray) and/or echocardiographic signs of LV volume overload. All patients had a Qp/Qs ratio > 1.5. Written informed consent was obtained from the parents prior to the procedures.

Device

ADO II AS (St. Jude Medical, Inc., USA) is a device originally designed for arterial duct closure. Briefly, it is a symmetrical, self-expanding, single mesh layer Nitinol occluder. There are three different waist-disc diameters available (3 mm – 4 mm, 4 mm – 5.25 mm, 5 mm – 6.5 mm), each available with three different waist lengths (2, 4 and 6 mm). A dedicated Amplatzer TorqVue LP 4 French catheter is recommended for the deployment procedure. ADO II AS and its dedicated delivery catheter are characterized by soft construction – this feature is of special importance due to procedural manoeuvres carried out in the proximity of the conduction system and tricuspid valve apparatus. The device should be 1–2 mm bigger than the VSD diameter (as for patent ductus arteriosus cases).

Procedure

All procedures were carried out under general anaesthesia with elective intubation, fluoroscopy and direct transoesophageal echocardiography. Both venous and arterial femoral (4 Fr) access was obtained. Standard diagnostic catheterization was performed in all patients. The VSD was crossed from the LV in all cases with direct implantation of the ADO II AS from the LV in 3 children and from the RV – after arterio-venous loop creation – in

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Received: 16.08.2018, **accepted:** 4.09.2018.

Table I. Some clinical and procedural data of patients in whom VSD was closed with the Amplatzer duct occluder Additional Sizes (ADO II AS)

No.	Gender	Age [years]	Weight [kg]	VSD type	VSD TTE [mm]	Closure from:	ADO II AS size [mm]	Fluoro [min]	Follow-up [month]	Follow-up observ.
1	F	2.7	13.5	pmVSD	3.0	LV	5/2	36	12	RBBB + LPFB
2	F	2.4	12.0	pmVSD	3.0	LV	4/4	22	1	–
3	M	1.3	9.4	psVSD	3.2	LV	5/2	36	13	Rest VSD
4	M	1.8	8.7	psVSD	2.5	RV a-v l	5/2	9	21	Rest VSD
5	F	5.7	20.0	pmVSD	3.0	RV a-v l	5/4	9	9	–
6	F	8.8	30.0	pmVSD	2.5	RV a-v l	5/2	29	1	Short VT
Median		2.5	12.8		3			25	10.5	
Range		1.3–8.8	8.7–30		2.5–3.2			9–36	1–21	

VSD – ventricular septal defect, pmVSD – perimembranous VSD, psVSD – postsurgical VSD, F – female, M – male, VSD TTE – VSD diameter in transthoracic echocardiography, LV – left ventricle, RV – right ventricle, a-v l – arterio-venous loop, Fluoro – fluoroscopy time in minutes, follow-up – follow-up period, RBBB – right bundle branch block, LPFB – left posterior fascicular block, rest VSD – insignificant residual VSD, short VT – short, transient episode of ventricular tachycardia.

another 3 patients. A dedicated Amplatzer 4 Fr delivery catheter was used in all cases.

Follow-up

All patients underwent Holter ECG monitoring and transthoracic echocardiography (TTE) on days 1 and 3 after the procedure. Antibiotic prophylaxis of endocarditis prophylaxis was continued for 6 months and extended if warranted by the presence of a residual shunt. Physical examination, ECG and TTE were performed 3, 6 and 12 months after VSD closure and yearly thereafter. The median follow-up was 10.5 months (range: 1–21 months).

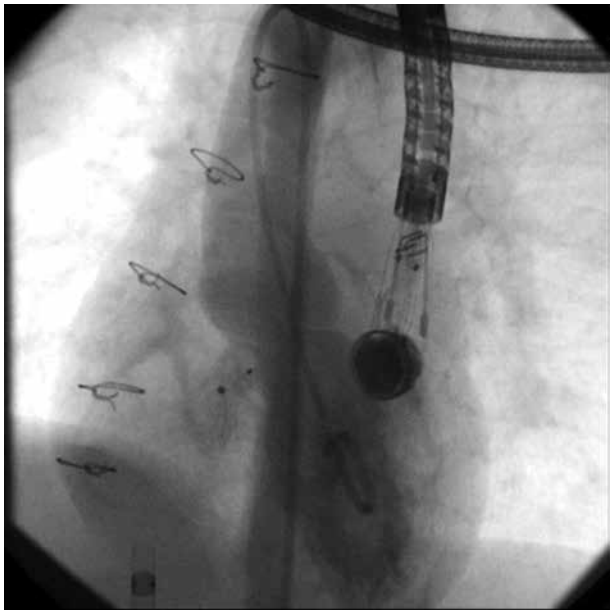

Figure 1. LAO 30 projection. Left ventriculography. Gerbode-like post-surgical VSD closed with ADO II AS. Still visible foam of radiographic contrast from left ventricle to right atrium

Results

Six patients (2 males) were included in our analysis. Some clinical and procedural data of the treated patients are presented in Table I. The median age was 2.5 years (range: 1.3–8.8 years) and the median weight was 12.8 kg (range: 8.7–30 kg). Four children had an isolated pmVSD with a small aneurysm, the defect size ranging from 2.5 to 3.2 mm. Two patients with residual VSD previously underwent surgical correction of tetralogy of Fallot at the ages of 5 and 7 months and had a residual VSD of 3.2 mm (outflow type, patient 3) and 2.5 mm (Gerbode type, patient 4), respectively (Figure 1). In the first psVSD case an unsuccessful attempt to close the outflow VSD with the Amplatzer Duct Occluder II (a precursor of ADO II AS) was made 4 months before the final successful closure with ADO II AS. The pulmonary pressure was within normal limits in all patients.

There were no major adverse events in the periprocedural period, but we observed two transient moderate events. Soon after one of the procedures, we noted conduction disturbances with the progression of a partial right bundle branch block (RBBB) to complete RBBB with a new-onset left posterior fascicular block that resolved after a short course of steroid therapy (patient 1). Another patient with pmVSD (patient 6) had short-lasting, asymptomatic ventricular tachycardia (5 QRS complexes, 120/min) on the second day after the procedure. After device implantation, we did not observe any progression of tricuspid insufficiency or more than trivial aortic insufficiency. Two patients with psVSD had an insignificant residual shunt after the procedure that remained stable during further follow-up. No persistent or late-onset conduction abnormalities were observed.

Discussion

We present our initial data on the efficacy and safety of ADO II AS application in selected perimembranous and

postsurgical VSDs. ADO II AS has several advantages – it has soft construction and its dedicated delivery system is delicate as well as requiring only a 4 Fr sheath. This increases the safety of manoeuvres inside the heart. Moreover, it is important to stress that ADO II AS can be easily implanted from the left side through the arterial access (without the creation of an arterio-venous loop) as it has a symmetrical construction and a relatively small size of retention discs. This was the case in 3 out of our 6 patients presented here and generally simplified the procedure (patients 4 and 5 required only approximately 9 min of fluoroscopy). The construction of ADO II AS ensures safe implantation despite the proximity of tricuspid and aortic valves and is believed not to interfere with the bundle of His. In the late follow-up, we have not observed any rhythm and conduction disturbances, nor aortic or tricuspid regurgitation in any of our cases. ADO II AS was originally designed for the percutaneous closure of patent ductus arteriosus (PDA) in small infants. This implant is particularly useful for the closure of connections less than 4 mm in diameter. We have also published our experience with ADO II AS for PDA closure in adolescents – in our centre this device substitutes coils for such purposes [8]. Champaneri *et al.* [6] have recently described the transcatheter closure of pmVSD in a 1.8 kg infant using ADO II AS (the age was not specified – probably in the second month of life). During the same procedure, residual postsurgical PDA was closed with another ADO II AS [6]. Narin *et al.* [7] presented their experience with percutaneous VSD closure in children under 1 year of age. There were 12 patients – ADOII was applied in 8 patients (complete AV block occurred in 1 of 8 patients after 6 months), while ADO II AS was used in 4 patients (no rhythm disturbances in the follow-up). In the latter group, 2 children had pmVSD, one muscular VSD and one residual postsurgical VSD. Three of these patients were closed from the arterial side (similarly as in our material). A residual shunt was observed in one of these 4 patients in the follow-up. In our material, an insignificant residual shunt was seen in 2 out of 6 children. The reason for this phenomenon may be the lack of patches inside the device. In our series as well as in the cited publications, no complications related to the use of ADO II AS were observed, including death, embolization, malposition, haemolysis, thromboembolism, infective endocarditis or vascular problems.

Iatrogenic complete heart block requiring pacemaker implantation remains the most important issue related to transcatheter pmVSD closure and is caused by the proximity of the bundle of His to the border of the defect [4]. After the initial alarming number of cases requiring pacemaker implantation and the subsequent reports of late-onset advanced heart blocks after VSD closure with Amplatzer Perimembranous VSD Occluders (asymmetric) [9], some new occluders were applied as a potential solution. Szkutnik *et al.* [5] advocated the use of Amplatzer Muscular VSD Occluders in pmVSDs with an aortic rim > 4 mm (length of the skirt of the Muscular VSD Amplatzer Occluder). El Said *et al.* [10] reported successful application of ADO I in 19 of 21 approached patients with aneurysm-type pmVSD, with no complete heart block; however, in 2 patients the procedure was discontinued due to the occurrence of periprocedural block. ADO I has a mushroom shape, can be implanted only from the venous side and requires a bigger delivery system. It can be particularly useful in patients with pmVSD and a coexisting large aneurysm [11, 12]. Other authors also reported a promising safety profile of Amplatzer Duct Occluder II implantation [13, 14]. Based on a retrospective multicenter registry, Haas *et al.* presented short and midterm results of perimembranous (81 patients) and muscular (30 patients) VSD closure with Nit-Occlud, proving its high feasibility and low risk of severe adverse effects [15]. Patients with different anatomical variants of pmVSD and psVSD could benefit from variously constructed occluders. A consensus on optimal device selection has not been achieved so far. ADO II AS, as demonstrated by our evidence, could complement the current armamentarium. The disadvantage of this device is that its application is limited to moderate size VSDs (2–4 mm).

The retrospective character as well as the small number of patients are the main limitations of our study.

Conclusions

In selected patients with perimembranous and post-surgical VSD the transcatheter application of ADO II AS seems to be safe and effective. However, further data on a larger patient population and long-term follow up are necessary.

Conflict of interest

The authors declare no conflict of interest.

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