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ARTICLE

Transcatheter Closure of Perimembranous Ventricular Septal Defect Using the Amplatzer Duct Occluder II

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ABSTRACT

Objective: To evaluate the efficacy of Amplatzer duct occluder II (ADO II) in the treatment of perimembranous ventricular septal defect (pmVSD) in children. **Methods:** Between June 2017 and June 2020, 13 patients with pmVSD had attempted transcatheter closure using ADO II, seven of patients were used antegrade approach and six of them were used retrograde approach. **Results:** There were 8 males and 5 females, age from 1 to 7 years, weight from 10.5 to 31.0 kg, and VSD size from 2.0 to 4.0 mm. Procedure was successful in all cases with the outer diameter of the occluders ranging from 4 to 6 mm. No aortic, tricuspid regurgitation or residual shunt was found in the immediate ultrasound assessment. No arrhythmia was observed in the Holter monitoring 3 days after the intervention. Discharge echocardiography indicated complete shunt closure. No evidence of occluder prolapse, malignant arrhythmia, or intensed valve regurgitation was seen on a median follow-up of 18 months (range, 6 to 36 months). **Conclusions:** Based on our experience, ADO II showed good efficacy in the early and middle stages of pediatric pmVSD closures.

KEYWORDS

Ventricular septal defect; transcatheter closure; Amplatzer duct occluder; children

1 Introduction

Perimembranous ventricular septal defect (pmVSD) is a very common congenital heart disease (CHD) [1]. Traditional surgical repair requires cardiopulmonary bypass support. In recent years, with the emergence of various percutaneous occlusion systems, transcatheter closure for VSD has become widely accepted [2,3]. Traditional transcatheter VSD occlusion requires simultaneous puncture of the femoral artery and femoral vein, and delivery of the occluder via the femoral vein. During orbital construction, tricuspid chordae tendineae, aortic valve, and other anatomical structures may be injured and caused arteriovenous puncture (AVP) loop associated complication. The above situation can lead to longer procedure higher irradiation and even failure of the operation [4]. Besides, high incidences of complete atrioventricular block (CAVB) also limit the use of traditional VSD occluder [5–7]. Haddad [8] compared the effectiveness of three different occluders in 51 pmVSD patients and concluded that Amplatzer duct occluder II (ADO II) has significant advantages in device softness, flexibility, and faster implantation process. They also used KONAR multifunctional occluder to close restrictive-type pmVSD and achieved good results [9]. All this two occluders can be used in retrograde approach. Retrograde approach can avoid the establishment of

AVP loop, reduce the difficulty of treatment, and reduce the incidence of tricuspid chordae tendineae and aortic valve injuries. Therefore, we decided to evaluate our 3 years' experience of pediatric pmVSD closure using the ADO II.

2 Patients and Methods

2.1 Study Population

This is a retrospective observational study on the transcatheter closure of VSD using the ADO II in Qingdao Women and Children's Hospital, Qingdao University from June 2017 to June 2020.

All the patients were diagnosed by transthoracic echocardiography (TTE) before cardiac catheterization by an experienced doctor, with a Phillips IE 33 machine including M mode, two-dimensional, and Doppler examination.

Inclusion criteria: Defect diameter ≤5.5 mm with significant left-to-right shunt. Significant shunt was diagnosed base on the presence of at least one of the following clinical manifestations: (1) Increased cardiothoracic ratio > 0.5 on chest X-ray; (2) Increased diameter of left atrium and left ventricle at the end of diastolic period; (3) Ratio of pulmonary to systemic blood flow (Qp/Qs) > 1.5; (4) History of infective endocarditis related to VSD; and (5) Symptoms, including recurrent respiratory infections and growth retardation.

Exclusion criteria: (1) Diameter of VSD > 5.5 mm; (2) Distance between the upper margin of VSD and aortic valve < 4 mm; (3) Aortic valve prolapse with mild or more reflux; (4) Severe pulmonary artery hypertension and a right-to-left shunt or pulmonary vascular resistance (PVR) > 8 Wood units; (5) Presence of any other associated CHD unrepairable percutaneously; and (6) Body weight < 8 kg.

Preoperative routine examination including blood test, chest X-ray, standard 12 leads electrocardiogram, Holter monitoring, and TTE were performed on all patients.

2.2 Occluder Selection

The ADO II from AGA Corporation were used in all the patients in this procedure. The ADO II is a self-expanding double-disc Nitinol wire mesh and consists of three parts, two equally large disk-shaped structures and a waist connecting the two disk-shaped structures. The waist diameter has 4 kinds of specifications: 3, 4, 5 and 6 mm, and the waist length has 3 kinds of specifications: 4, 5 and 6 mm.The unique structure enables the occluder to be released either in the antegrade approach or the retrograde approach, with better flexibility in operation. The device is soft and has no polyester fiber inside. The required delivery sheath is small (4F and 5F), so the peripheral vessels are less damaged.

In non-aneurysmal type defects, defect diameter should be <5 mm with a sub-aortic rim (SAR) larger than 3 mm. In aneurysmal type, the right ventricular exit should be <5.5 mm with a lift ventricular entry <12 mm but large enough to accept the left disk in the aneurysm especially when the SAR <3 mm. The diameter of the device waist in ADO II was chosen to be 1 mm greater than the smallest VSD diameter.

2.3 Technique

TTE was used to evaluate the relationship between VSD and aortic valve, whether aortic valve prolapse or regurgitation was present before the operation. All patients underwent general anesthesia, followed by routine puncture of femoral artery and vein, the left and right cardiac catheterization. After the TTE, left and right cardiac catheterization, appropriate ADO II was selected. According to the size and type of VSD, choosing the antegrade approach or retrograde approach [8].

Antegrade approach. Using the scissored cut pigtail catheter (Cordis, USA) and 0.035-inch guide-wire (Terumo, USA) to send the catheter from the left ventricle to the right ventricle through the defect. Then sending the guide-wire to the pulmonary artery or superior vena cava. The guide-wire was drawn from

the femoral vein with the snare (Abbott, USA) to form an arteriovenous (AV) loop. Through this wire, choosing a proper delivery sheath (Abbott, USA) across the VSD until the sheath arrived at the ascending aorta from femoral vein. At the same time, the guide-wire and the coronary catheter are rapidly sent forward to send the sheath to the left ventricle and lower the head toward the apex of the heart. The pre-equipped occluder was sent to the left ventricle along the delivery sheath and using the standard method to release the occluder. After that, using the angiography and TTE to confirm the position and the shape of the occluder.

Retrograde approach. Using the same technique above to send the catheter from the left ventricle to the right ventricle through the defect. Then sending the guide-wire to the pulmonary artery. Sending the delivery sheath to the left ventricle along the guide-wire, entering the right ventricular outflow tract through the VSD. The pre-equipped occluder was sent to the right ventricle along the delivery sheath and the open the right disc surface. Using the same technique to release the whole occluder after the absence of tricuspid regurgitation related to the right disc was confirmed by TTE. Using the angiography and TTE to confirm the position and the shape of the occluder.

All patients took aspirin orally 6 months after operation, and antibiotics were administered to prevent infection for 1 day. Holter monitoring was used to assess the presence of arrhythmias. Blood routine, electrocardiogram, and TTE were repeated 3 days after operation, then 1, 3, 6, 12 months thereafter annually.

3 Results

A total of 13 children with VSD were included in the study, including 8 males and 5 females. Age from 1 to 7 years (mean, 3.54 ± 1.81). Weight from 10.5 to 31.0 kg (mean, 17.62 ± 6.11). VSD size from 2.0 to 4.0 mm (mean, 2.92 ± 0.79). All the cases were perimembranous VSD (Tab. 1).

Table 1: Demographic data

Patient No.	Age (years)	Weight (kg)	Height (m)	BSA (kg/m^2)	CTR	Sex	VSD size (mm)
1	2	13.5	0.90	0.57	0.52	Male	3.0
2	4	17.0	1.05	0.70	0.50	Male	3.0
3	7	21.5	1.27	0.86	0.40	Female	2.0
4	2	10.5	0.85	0.49	0.57	Female	3.0
5	5	16.0	1.11	0.73	0.52	Male	3.5
6	3	14.5	1.00	0.49	0.55	Male	4.0
7	4	17.0	1.09	0.73	0.51	Female	2.0
8	2	14.5	0.94	0.60	0.49	Male	3.0
9	3	17.5	0.98	0.67	0.51	Male	4.0
10	2	14.0	0.92	0.59	0.51	Male	4.0
11	6	31.0	1.32	1.07	0.55	Female	2.0
12	1	13.0	0.88	0.55	0.49	Female	2.0
13	5	29.0	1.20	0.97	0.50	Male	2.5

Note: VSD, Ventricular septal defect; BSA, Body surface area; CTR, Cardiothoracic ratio.

All the 13 cases were successfully implanted into the ADO II, seven of patients were used antegrade approach and six of them were used retrograde approach. the size of the device used ranged from 3 to 6 mm. 3 mm in one patient, 4 mm in seven patients, 5 mm in three patients, and 6 mm in two patients. During the operation, the operation data was showed in Tab. 2.

Table 2: Operation data

Patient No.	PAP (mmHg) S/D/E	VP (mmHg) S/D/E	Qp (L/min)	Qs (L/min)	Qp/Qs	PVR (Wood units)
1	32/10/22	84/0/14	7.21	7.21	1.68	2.22
2	21/12/16	86/-2/12	6.60	6.60	1.15	1.52
3	32/6/19	83/2/10	8.51	8.51	1.30	1.52
4	33/15/24	87/0/18	10.07	10.07	1.16	1.69
5	32/9/21	90/12/15	8.62	8.62	1.49	1.62
6	27/14/17	86/2/14	14.82	14.82	1.39	1.27
7	27/11/19	83/5/12	8.51	8.51	1.30	1.52
8	19/9/13	77/5/7	9.97	9.97	1.07	1.52
9	26/14/20	81/2/13	9.05	9.05	1.40	1.33
10	28/12/20	84/11/14	8.09	8.09	1.23	1.25
11	25/9/17	90/5/12	7.03	7.03	1.74	1.42
12	25/9/17	73/9/12	3.65	3.65	1.00	1.32
13	22/14/16	79/13/3	8.51	8.51	1.30	1.52

Note: PAP, pulmonary artery pressure; VP, ventricular pressure; S/D/E, systolic/diastolic/end-diastolic; Qp, pulmonary flow; Qs, systemic flow; PVR, pulmonary vascular resistance.

No aortic, tricuspid regurgitation, or residual shunt was found in the immediate postoperative echocardiography assessment. 3 days after the operation, no arrhythmia was observed in the Holter monitoring, TTE indicated that the position and the shape of the occluder were good, and no residual shunt was observed. All the children were followed up regularly for 6 to 36 months, showed that occluders in 13 patients was placed well, had normal morphology, without malignant arrhythmia, or intensed valve regurgitation.

4 Discussion

ADO II is an occluder for the treatment of PDA. Unlike conventional VSD occluders, ADO II has no filling polyester fiber, make its outline a smaller, softer, even can be incomed in 4F delivery sheath, significantly reduced in patients with vascular injury.

Traditional percutaneous VSD occlusion requires AV loop creation [4]. Such operation is not only complicated but may damage the tricuspid chordae tendineae, aortic valve, and other anatomical structures in the process of setting up the orbital, resulting in tricuspid regurgitation and tricuspid regurgitation, leading to operation elongation or even failure. However, the ADO II delivery sheath is thinner, softer and more flexible, and can simply close VSD through femoral artery approach. Based on the reasons above, using ADO II can shorten the operation time and X-ray fluoroscopy time [10].

Based on the reasons above, scholars have successively applied ADO II to block VSD in recent years. Many kinds of special VSD patients, such as patient with multiple VSD, dextrocardia patient with pmVSD, pmVSD patient with septal aneurysm and patient with iatrogenic pmVSD [11–14]. The above cases demonstrate the universality of ADO II in the treatment of VSD.

In 2011, Koneti [15] reported by using ADO II close 13 cases of children with VSD, including 11 cases (84.6%) of successful operation, follow-up without arrhythmia, and related complications. Polat [16] reported that in 26 VSD patients by using ADO II, the complete VSD closure rate was 93%, and no

device embolization and atrioventricular block happened. Zhao [10] compared 51 patients with conventional VSD occluders and 51 patients with ADO II and found no statistically significant differences in the incidence of complications and length of hospital stay between the two groups. But, the ADO II group was cost-effective and required less fluoroscopy time. Haddad [8] compared the effectiveness of three different occluders in 51 pmVSD patients and concluded that because of the softness, flexibility, and faster implantation process of ADO II, the ADO II group showed more advantages compared with ADO group and Amplatzer Muscular VSD occluder (AMO) group. Studies have shown that ADO II applied to close the VSD, in general, is safe and effective, less complications [17–20].

In our study, all patients completed the operation without complications such as arrhythmia and intensed regurgitation on a median follow-up of 18 months (range, 6 to 36 months). Our results are the same as those of Ghaderian [21]. The incidence of CAVB is low by using ADO II [8,21,22], which is related to the structure. Nitinol wire mesh is a thin and soft structure, and depending on the waist support of the occluder, rather than the discs, reduced the pressure of the bundle on the ventricular septum. In addition, efficient retrograde approach is also one of its advantage. ADO II can convey by smaller sheath (4F or 5F), reduced the damage to tissue and vascular, at the same time it can avoid repeatedly damage for a long time to the bundle.

PmVSD is close to the tricuspid valve and aortic valve. The treatment of transcatheter occlusion may affect valve function, and aortic regurgitation is another main complication [13]. Because ADO II umbrella plate of 4 mm larger than the waist, repeated evaluation by TTE is necessary before release. Accurate evaluation of the VSD and selection of a suitable size occluder are important factors in reducing the aortic regurgitation [8].

As mentioned above, ADO II can be used both in antegrade approach and a retrograde approach. Koneti [15,23,24] used retrograde approach to release ADO II, which they believe avoids the need to build an arteriovenous loop, reduces fluoroscopy time, makes it easier to perform the procedure, and prevents damage to the tricuspid and aortic valves. Haddad [8] also used ADO II to close pmVSD for 27 by retrograde approach and achieve good result. In our study, the retrograde approach was adopted for six patients whose orbits were difficult to be established and cannot release the occluder through the antegrade approach. All these six patients obtained good results. However, there are some technical difficulties with the retrograde approach. Here, we will share our own experience. (1) The delivery sheath through the aorta is not as smooth as imagined. When the delivery sheath cannot pass through the aortic valve smoothly, we should avoid pushing forward. We need to rotate the sheath tube, adjust the angle, and move it gently forward to avoid damaging aortic valve. (2) When it is difficult to control the guide-wire through the VSD, we should try to adjust the angle and switch to a harder guide-wire if necessary. (3) Releasing the occluder is a critical step. If the sheath enters the right ventricle too deep, it is easy to squeeze the tricuspid valve and cause tricuspid valve injury. If it enters too shallow, the occluder will retreat from the VSD, causing the release to failure. Therefore, we should pay attention to the depth of the sheath into the right ventricle.

Limitation: This was a single-center retrospective study with a limited number of cases. Large prospective cohort study is necessary. Our study can provide direction and reference for the large sample study in the future.

5 Conclusion

Because of its good profile and flexible release approach, transcatheter closure of pediatric pmVSD by using ADO II showed its advantages in reducing the incidence of the CAVB and aortic regurgitation in early and middle stages. It seems the best choice to close pmVSD. However, due to the limitation of the size, only VSD with small diameter can be closed. Meanwhile, CAVB is still the most serious complication in

a long-term. If the ADO II is to be used as a conventional instrument for the treatment of VSD, a large number of and long-term clinical studies is necessary.

Availability of Data and Materials: Not available.

Ethical Approval: The study was approved by the ethical committees of Qingdao Women and Children's Hospital (No. QFELL-KY-2019-64).

Contributions: All authors contributed to the design or implementation of the study and approved the final manuscript as submitted. HXS drafted the manuscript. GL participated in the operation. ZHD and ZXJ had primary responsibility for patient screening, enrollment, outcome assessment. SLP participated in the operation and was responsible for study conception and design.

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Conflicts of Interest: The authors declare that they have no conflicts of interest to report regarding the present study.

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