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CONGENITAL

ADO II in Percutaneous VSD Closure in Pediatric Patients

NAZMI NARIN, M.D.,[1] ALI BAYKAN, M.D.,[1] OZGE PAMUKCU, M.D.,[1] MUSTAFA ARGUN, M.D.,[1] ABDULLAH OZYURT, M.D.,[1] TIMUR MESE, M.D.,[2] MURAT MUHTAR YILMAZER, M.D.,[2] ISIN GUNES, M.D.,[3] and UZUM KAZIM, M.D.[1]

From the [1]Erciyes Universıty School of Medıcıne, Division of Pedıatrıc Cardıology, Kayseri, Turkey; [2]Erciyes Universıty School of Medıcıne, Division of Pedıatrıc Anesthesiology, Kayseri, Turkey; and [3]Behcet Uz Children Hospital, Division of Pedıatrıc Cardıology, Izmir, Turkey

***Objectives**: Main aim of our study to show that ADO II device can be used for the small ventricular septal defects successfully and safely with low complication rates in pediatric population.*
***Background**: It is hard to find an ideal device to use for every VSD successfully. If inappropriate device was chosen; complication rate increases, procedure time gets longer that prolongs exposure to ionizing radiation. Therefore interventionalists are in the search for new ideal devices.*
***Material**: Between the dates April 2011–October 2014, 21 VSD closures with ADO-II device. were performed. Twenty patients were included, age ranged between 4 months 18 years. Weight of the patients was between 5–76 kg.*
***Results**: VSD diameter ranges between 2–6 mm (3.75 ± 1.25). VSD types were muscular in 2 patients, rest of them were perimembranous type. Most of the perimembranous defects (19/21) were aneursymatic and tunnel shaped. All the cases were successfully closed, no major complications were reported. There was no incidence of left bundle branch block, P-R prolongation, or complete heart block.*
***Conclusion**: Considering perimembraneous ventricular septal defects as difficult and risky for percutaneous closure because of its proximity to aortic, atrioventricular valves and conduction tissue, we suggest that ADO II device can be safely and effectively used for such defects in particular if an aneurysm formation is present which is also compatible with the literature.* (J Interven Cardiol 2015;28:479–484)

Introduction

Closure of ventricular septal defect(VSD) is required in the children when there is volume overload in left chambers; in order to prevent ventricular dysfunction, arrhythmias, aortic regurgitation, pulmonary arterial hypertension and endocarditis.[1]

Transcatheter VSD closure technique have the advantages like shorter hospital stay, less pain and less discomfort. In experienced hands it is safer than surgery and less complications are seen. Therefore nowadays it has been accepted as an alternative to surgery; but it is technically challenging. Various devices were used for percutaneous VSD closure. It is hard to find an ideal device to use for every defect successfully. It changes according to the size, type and the location of the defect. If inappropriate device was chosen; complication rate increases, procedure time gets longer that means prolonged exposure to ionizing radiation. Therefore interventionalists are in the search for new ideal devices.

In our study we aimed to share our experience and to show that ADO II device can be used for the small VSDs successfully and safely with low complication rates.

Materials and Methods

Patients. Between the dates April 2011–October 2014, 21 VSD closures with ADO-II device (St. Jude Medical, St. Paul, MN) were performed in

Conflict of Interest: The authors have no conflicts of interest to declare.

Address for reprints: Dr. Ozge Pamukcu, Erciyes University School of Medicine, Division of Pediatric Cardiology, Kayseri, Turkey.
Fax: 90-352-4375825; e-mail: ozgepamukcu2002@yahoo.com

Erciyes University Medical Faculty Children Hospital, Pediatric Cardiology Department. Actually there were 20 patients but one of the patient had 2 perimembranous defects which were closed separately. Patients having muscular and perimembranous VSD with hemodynamically significant left to right shunt detected by clinical examination and echocardiography, were included in the study.

Inclusion criteria of the study: 1) patients should have VSD diameter less than 6 mm; cause the waist diameter of ADO II is 6 mm; 2) they should have prominent left to right shunt which was demonstrated with telecardiography (cardiothoracic index >0.5, pulmonary venous congestion), with catheterization ($Qp/Qs > 1.5$) and with echocardiography left atrial and/or left ventricular enlargement.

The study was approved by the local research Ethics Committee. All the parents were informed about the procedure, its complications and written consent were taken from each of them before the procedure.

Procedure. The catheterization procedure was carried out routinely under general anesthesia. Patients were given antibiotics intravenously before the procedure. An electrocardiogram monitor was used throughout the procedure. Heparin (100 IU/kg) was administered intravenously during the procedure. Supplemental heparin treatment was applied when necessary so as to maintain activating clotting time >200 sec. Both femoral venous and arterial routes were accessed. Anatomy, location and size of VSD were defined by left ventriculography in the left anterior oblique view. The procedure was performed with fluoroscopy and transesophageal echocardiography (TEE) guidance. The appropriate device size was chosen to be at least 0.5 to 1 mm larger than the VSD size as measured at the largest diastolic phase by color Doppler TEE or ventriculography. If there is a discrepeancy between 2 measurements, we accept the largest one. (We measured both from right ventricular and left ventricular sides). The VSD was passed through by using a 4 or 5 Fr right Judkins catheter or a partly cut pigtail catheter. A hydrophilic glide wire was passed across the defect into the right ventricle and then into the pulmonary artery or superior vena cava, where it was snared and withdrawn from the femoral vein thus establishing an arteriovenous loop. Subsequently, a long sheath (6 Fr) was advanced to the left ventricle via the arteriovenous circuit. An occluder was advanced into the delivery sheath. Then the occluder was positioned on the VSD. If the device position was good on fluoroscopy and TEE, the device was released. The device closure could be done by arterial route or venous route. After the procedure, occluder position was assessed with TEE and left ventriculography. Cardiac rhythm monitorization was done for all patients during the first 24 h after the procedure. All patients were discharged within 2 days after the procedure. Acetylsalicylic acid (5 mg/kg/daily) was administered for 6 months in all patients. Physical examinations, ECG, and TTE were performed at 1, 3, 6, and 12 months after the procedure and yearly thereafter. Also, 24 h Holter monitoring was performed 3 months after the procedure.

Statistical Analysis. Data are expressed as a frequency or percentage for nominal variables, as the median (range) for categorical variables and as the mean $\pm$ SD for continous variables.

Results

Twenty-one VSD closures were performed. Twenty patients were included. Eight of them were female, 12 were male. Their age were ranged between 4 months 18 years (mean 8.7 ± 4.51). Weight of the patients was between 5–76 kg (33.5 ± 19.9). Associated heart defects were found only in three patients. One had aorta coarctation in newborn period and balloon angioplasty was done previously, 1 had ASD and the other had PDA. The associated lesions were simultaneously closed with atrial septal occluder and ductoccluder in the same sitting.

The diameter of VSDs was between 2–6 mm (3.75 ± 1.25). Mean fluoroscopic time was 43 min. VSD types were muscular in 2 patients, and the rest of the defects were all perimembranous type. All of the perimembranous defects were aneursymatic and mostly tunnel shaped. In perimembranous aneursymatic defects, distance of the defect to the aortic valve was approximately zero ranged between 0–3.95 mm.

One of the patients had 2 separate VSDs. The distance between 2 defects were 7 mm. Therefore we have used 2 separate devices to occlude them. One of the defect was 3.2 mm, occluded with ADO II sized 5×4 from arterial side. The other one was 3.4 mm width and closed with 5×6mm ADO II from venous side. Therefore 2 VSDs were closed separately with 2 ADO II devices from different vascular sides at the same session (Fig. 1). We had both arterial and venous

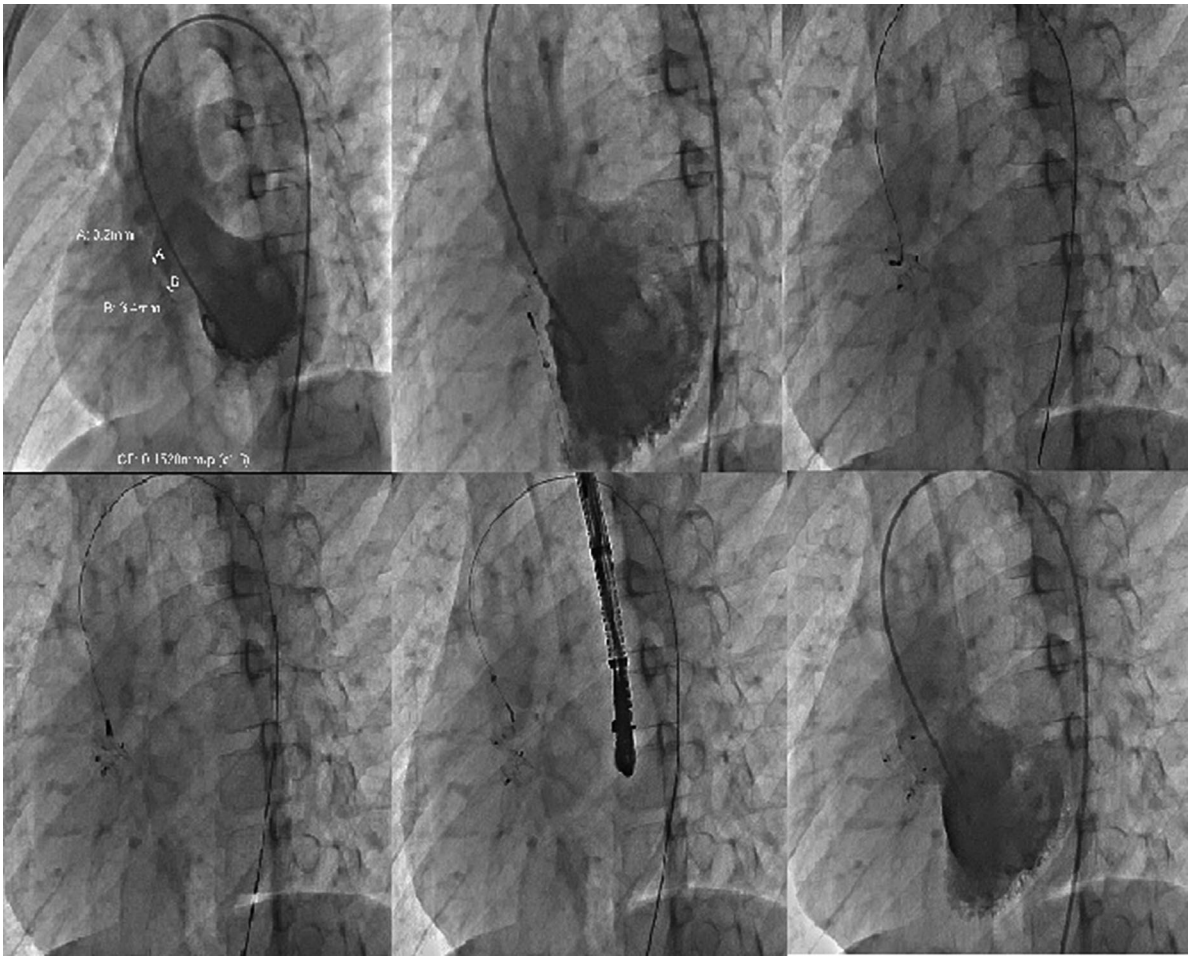

Figure 1. Closure of 2 separate VSD with different routes.

accesses in all patients. VSDs were closed mostly from venous side (17 patients). Arterial side was used only in 3 patients. Qp/Qs value's mean was 22 ± 0.68 (ranging from 1.6 to 4.2). Median pulmonary arterial pressure (PAP) was 24 mmHg (ranged between 16–37 mmHg). Angiographic properties of the patients were described in Table 1. Follow-up was done 1, 3, 6, and 12 months after the procedure and yearly thereafter. Physical examinations, ECG, and TTE were performed at each visit. Longest follow-up interval was 42 months. We checked the rhythm, PR interval by ECG, residual shunts, device position, aortic and tricuspid valves by TTE. We have seen that enlarged LV and LA; decreased to normal size during the follow-up. The complete VSD closure rate immediately after the procedure was 85% documented by angiography. Residual shunt was detected in 3 patients immediately which had been persisted only in 1 patient. Complete closure occurred in all the cases (95%) on follow up.

There were no major complications like death, vascular complications, device embolizations, malposition, hemolysis, thromboembolism and infective endocarditis during the study period. Cardiac monitorisation was done during the procedure, ECG was seen after 1st day and on each control (1st, 3rd, 6th months, yearly thereafter). In fact serious complications like various degrees of heart block in transcatheter device closure is very common, we have not seen any heart block with ADO II implantation. There was no incidence of left bundle branch block, P-R prolongation, or complete heart block. Aortic regurgitation was not seen in any

Table 1. Angiographic Data of Patients

Pt No	VSD Diameter (mm)	Qp/Qs	VSD Type	Device Size	Aortic Rim (mm)	Major Complication	Minor Complication	Closure Side	Floroscopy Time
1	2.1	1.3	Perimembranous	4 × 4	0	None	None	Venous	32.00
2	2.1	1.66	Muscular	3 × 6	6.8	None	Minimal residual shunt	Arterial	10.00
3	5	1.4	Perimembranous	6 × 4	0	None	Minimal residual shunt	Venous	55.00
4	4.5	1.9	Perimembranous	6 × 4	0	None	None	Venous	19.50
5	3.1	1.4	Perimembranous	5 × 6	0	None	None	Venous	67.80
6*i*	3.2	2	Perimembranous	5 × 4	0	None	None	Arterial	67.80
6*ii*	3.4	2	perimembranous	5 × 6	0	None	None	Venous	73.20
7	3	1.7	Perimembranous	4 × 6	0	None	None	Venous	16.60
8	2.6	2	Perimembranous	3 × 4	0	None	None	Arterial	78.00
9	3.8	1.6	Perimembranous	3 × 4	0	None	None	Venous	20.30
10	3	1.4	Perimembranous	4 × 4	2.3	None	None	Arterial	74.00
11	6	1.8	Perimembranous	6 × 6	5.6	None	Minimal residual shunt	Venous	27.00
12	3.2	1.6	Perimembranous	3 × 4	1.9	None	None	Venous	35.00
13	4.8	1.6	Perimembranous	6 × 4	0	None	None	Venous	39.00
14	3.5	1.6	Perimembranous	4 × 4	0	None	None	Venous	28.00
15	4.5	1.75	Perimembranous	3 × 4	0	None	None	Venous	42.00
16	5	1.5	Perimembranous	6 × 4	0	None	None	Venous	53.00
17	3	2	Perimembranous	4 × 4	3	None	None	Venous	22
18	4	2.1	Perimembranous	6 × 4	1	None	None	Venous	32
19	5	4	Perimembranous	6 × 6	2	None	None	Venous	50
20	3.3	3.3	Muscular	5 × 6	5	None	None	Venous	32

patient during transthoracic echocardiography follow-up after defect closure.

Discussion

Although many of the ventricular septal defects are small in size and they close spontaneously, the larger defects often persist to cause significant shunt and pulmonary hypertension.[1] In the past surgical closure was the only treatment modality but by the time, as the new devices produced and new techniques developed; percutaneous closure was started to be done more commonly.[2]

In this study we aimed to share the experience of our center and to show that percutaneous closure of small VSDs with ADO II device is a safe and effective method with low complication rates. Percutaneous VSD closure has certain risks like complete heart block, aortic, tricuspid insufficiency. In order to minimize such risks; appropriate device should be selected according to the type, location, and the size of the defect. Various devices have been used in percutaneous VSD closure in the literature: Rashkind double umbrella,[3,4] Bard Clamshell, Buttoned device,[5,6] Amplatzer septal, duct, muscular VSD occluder[7,8] or Gianturco coils.[9]

Amplatzer Ductal Occluder is actually designed for ductal closure. The first report that described that ADO could be used for VSD closure was by Tan et al.[10] Later on Dilawar et al.[11] also reported three cases that had muscular and aneursymatic perimembranous VSD which were all closed with ADO 1. It is mushroom shaped. They told that the shape of aneursymatic VSD resembled PDA. Therefore it makes closure of VSD with septal aneurysm possible with the Amplatzer duct occluder. The left ventricular margin of the VSD is larger than the right one. The left ventricular margin

resembles the aortic side and ampulla of a PDA while the right ventricular margin and septal aneurysm resembles the narrowing of a PDA at the pulmonary artery margin.[10]

Most common type of VSD are perimembranous and percutaneous closure of it is much more critical than the other types. Because it is close to the aortic valve, atrioventricular valves, and conduction tissue. Therefore decision for appropriate device for perimembranous defects is much more important. Previously it was shown that his bundle courses at the postero-inferior margin of perimembranous VSD and it is vulnerable to heart blocks during transcatheter closure.[12,13] But it was also known that anatomically; aneursymatic perimembranous defects mostly, but not always, free of conduction tissue so they are less prone to AV block formation.[14] We did not face with any conduction disorder in our study. This could be due to all of our perimembranous defects were aneursymatic. Also this could be due to the design of the ADO II device which is soft in nature with no polyester material that does not apply a direct force on conduction system. This property of the device was previously emphasized by Vijayalakshmi et al. In that study, only three cases developed transient junctional bradycardia in that study and only one patient with Gerbode defect developed transient complete heart block (1.3%), none of the patients had complete heart block.[15]

Another clue for succesful transcatheter closure of VSD is the location of the defect. It has to be remote from the tricuspid and aortic valves, with an adequate rim. proximity of the defects to the aortic and atrioventricular valves restricted the utilization of the muscular VSD occluder devices. A minimum of 5 mm distance between the upper margin of the defect and the aortic valve is required to utilize the device. After the asymmetric Amplatzer membranous VSD occluder devices came into use, defects which are 1–2 mm distant from the aortic valve are able to be closed percutaneously.[16,17] In our study, distance of the defect to the aortic valve was approximately zero ranged between 0–3.95 mm. In contrast that defects were very closely located to aortic valve we did not face with any complication related to aortic valve. ADO II has low-profile retention discs that can adapt to the different shapes of PDA without obstructing pulmonary artery and aorta.[18] This property gives the advantage that it can better fits in the aneursym without disturbing the aortic as well as tricuspid valve. During forty months follow-up we did not face with any aortic insufficiency because the devices were all positioned in the aneursym pouch which kept direct contact of the device to the aortic valve.

So far, there are only case reports concerning the use ADO II for transcatheter VSD closure. Simultaneously to our study a retrospective follow-up study of patients including adults with interventional closure of ventricular septal defects by ADO II was just published from Berlin, Germany by Kanaan et al.[19] They reported the largest series in VSD closure of pediatric population with ADO II. They have done transcatheter closure of 31 VSD in 8 years interval. We have done 21 VSD closures in 3 years interval therefore we also have a considerable amount of patients. The success rate in that study was 93.5%, in our study was 100%. They did not face with any conduction abnormalities, aortic or tricuspid regurgitation neither did we. So the results of our study were compatible with the literature. Summarizing both studies the low incidence of complications and missing AV block or other conductance abnormalities during implantation or follow-up could be confirmed.

Conclusion

Perimembraneous ventricular septal defects are difficult and risky for percutaneous closure because of its proximity to aortic, atrioventricular valves and conduction tissue. We suggest that ADO II device can be safely and effectively used for such defects in particular if an aneurysm formation is present which is also compatible with the literature.

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