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Original Article

Initial experience of transcatheter closure of subarterial VSD with the Amplatzer duct occluder

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Abstract

Background: The traditional treatment of subarterial ventricular septal defect (VSD) is open heart surgery. This study aimed to evaluate the feasibility, safety and outcome of transcatheter closure with the Amplatzer duct occluder (ADO).
Methods: Between March 2012 and June 2015, a total of 16 patients (8 male and 8 female) with subarterial VSD who underwent transcatheter closure with the ADO were enrolled retrospectively. Their age ranged from 3.0 to 65.6 years, with the median of 35.6 years; their body weights ranged from 14 to 92 kg with the median of 60 kg. All patients had prolapse of the right coronary cusp without subaortic rim. Mild aortic regurgitation was noted in 11 (69%) patients.
Results: Left ventriculogram showed VSD size ranged from 1.3 to 9.3 mm with the median of 3.5 mm. The device was successfully implanted in 88% (14/16) of the patients. Although one patient had mild skin allergy to contrast medium, no other complication was noted. Complete closure rate was 64%, 86%, 86% and 86% at 1-day, 1-month, 6-month and 12-month follow-up, respectively. Two patients developed new or worsening aortic regurgitation during follow-up.
Conclusion: Transcatheter closure of subarterial VSD with ADO is technically feasible and safe in patients older than 7 years of age. However, development or worsening of aortic regurgitation requires long-term follow-up.

Keywords: Amplatzer duct occluder; Cardiac catheterization; Doubly committed; Subarterial; Transcatheter closure; Ventricular septal defect

1. Introduction

Ventricular septal defect (VSD) is the most common congenital heart disease. Although less prevalent in the Western world, subarterial type VSD is relatively commonplace in the Asian and Far East populations, accounting for about 30% of all VSDs.[1] The synonyms for VSD include but are not limited to type I, supracristal, outlet, conoseptal, conal, subpulmonary, doubly committed. This defect is closely related to the aortic valve which might induce prolapse and thereafter cause regurgitation.[2,3] Because spontaneous closure is uncommon, and subsequent aortic valve complication is relatively frequent and usually progressive, early intervention to avoid aortic valve deformity and replacement is warranted. Device closure of VSD is currently viable for muscular and perimembranous-type defects. However, device closure of subarterial VSD is considered difficult

Conflicts of interest: The authors declare that they have no conflicts of interest related to the subject matter or materials discussed in this article.

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to accomplish due to its proximity to the aortic valve with possible impingement and subsequent development/worsening aortic regurgitation; therefore, surgical closure is recommended in most cases.

There are some recent reports of transcatheter closure of subarterial VSD (intracristal subtype) using eccentric devices,[4,5] but those devices are expensive and not globally available. The Amplatzer duct occluder (ADO, St. Jude Medical) was successfully used to close perimembranous VSD with the advantage of low cost and technical ease. This study retrospectively reviewed our experience of transcatheter closure of subarterial VSD using the ADO.

2. Methods

2.1. Study design

This is a retrospective, cohort study conducted in accordance with the Declaration of Helsinki and the ethics regulations of our hospital.[6] Between March 2012 and June 2015, a total of 16 patients with subarterial VSD who refused surgical closure and underwent transcatheter closure with ADO after informed consent was obtained were enrolled retrospectively. The inclusion criteria of patients included: 1) subarterial VSD as shown by echocardiography, and 2) age ≥3 years old. Exclusion criteria included: 1) moderate to severe prolapse of aortic valve, 2) moderate to severe aortic regurgitation, 3) sepsis, and 4) inability to obtain informed consent. There were 8 males and 8 females, ranging in age from 3.0 to 65.6 years with the median of 35.6 years. Study subject body weight ranged from 14 to 92 kg with the median of 60 kg. Echocardiographic imaging showed all patients had a prolapse of the right coronary cusp without subaortic rim. Mild aortic regurgitation was noted in 11 (69%) patients. Symptoms included chest pain in 13 patients, exercise intolerance in 9, palpitation in 8 and syncope in one. The demographic data was summarized in Table 1.

2.2. VSD classification

All patients were evaluated pre-procedure by transthoracic echocardiography, and all defects were located in the infundibular septum roofed by fibrous continuity without a muscular component. VSDs were classified according to their location.[7] Subarterial VSDs were further subclassified as supracristal and intracristal, based on their position on an analog clockface in the short-axis parasternal view on transthoracic echocardiography. In this view, intracristal VSD was seen at 12 o'clock and supracristal VSD was seen between the 1–2 o'clock directions (Fig. 1). In our series, there were supracristal type VSDs in 9 patients and intracristal type in 7 (see Figs. 2 and 3).

2.3. Procedure

For all study subjects, informed consent was obtained from patients or their guardians. The device closure procedure was conducted as briefly described below. Antibiotics (cefazolin

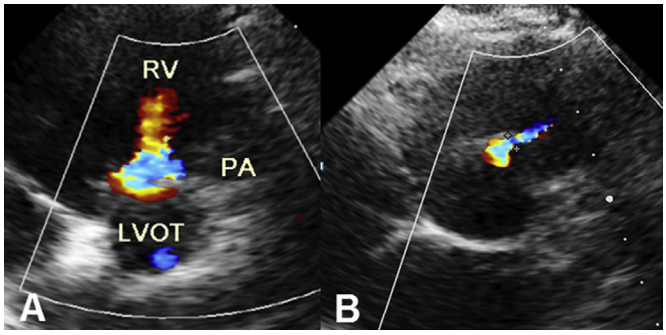

Fig. 1. Subtype of subarterial VSD. Parasternal short-axis view on transthoracic echocardiography shows the intracristal VSD located at 12 o'clock (A) and supracristal VSD at 1–2 o'clock position (B). LVOT: left ventricular outflow tract; PA: pulmonary artery; RV: right ventricle: VSD: ventricular septal defect.

Table 1
Patient demographics before procedure.

No.	Age (yr)	Gender	Body weight (kg)	VSD subtype	AR	Associated diagnosis	NYHAclass	Palpitation	Chest pain	Syncope
1	23.5	F	58	supracristal	−		II	+	+	−
2	63.1	M	65	intracristal	−	DCRV, HT, DM	II	−	+	−
3	30.4	F	60	intracristal	mild		II	+	+	+
4	46.7	M	85	intracristal	mild		I	−	+	−
5	29.9	F	57	intracristal	mild	bicuspid AV, epilepsy	III	+	+	−
6	15.3	M	55	intracristal	−		I	−	+	−
7	7.0	F	27	intracristal	−		I	−	−	−
8	26.8	F	78	supracristal	mild		II	−	−	−
9	35.6	F	60	supracristal	mild		III	+	+	−
10	35.7	M	76	supracristal	−		I	−	−	−
11	42.3	F	53	supracristal	mild		II	+	+	−
12	39.2	M	82	intracristal	mild		I	+	+	−
13	65.6	F	55	supracristal	mild		III	+	+	−
14	55.2	M	72	supracristal	mild		I	−	+	−
15	41.9	M	92	supracristal	mild		II	+	+	−
16	3.0	M	14	supracristal	mild		I	−	+	−

AR: aortic regurgitation; AV: aortic valve; DCRV: double chambered right ventricle; DM: diabetes mellitus; F: female; HT: hypertension; M: male; NYHA: New York Heart Association; VSD: ventricular septal defect.

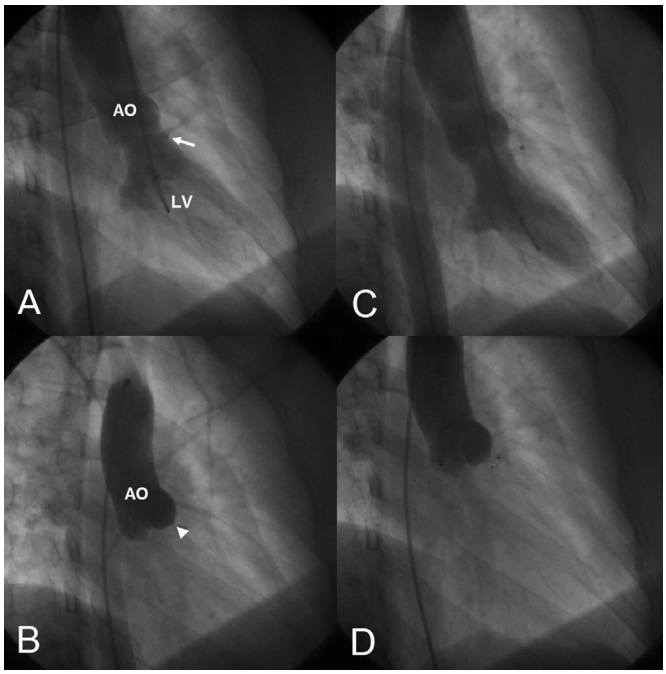

Fig. 2. Angiographic evaluation before and after device closure of VSD in patient 1. (A) Left ventriculography in the right anterior projection with caudal angulation showing a subarterial VSD (arrow) which was just beneath the aortic valve. (B) Aortography in the same projection showing the prolapsed right coronary cusp (arrowhead) without aortic regurgitation. (C) Left ventriculography showing the good device position and no residual shunt. (D) Aortography after device implantation showing no aortic regurgitation. AO: aorta; LV: left ventricle.

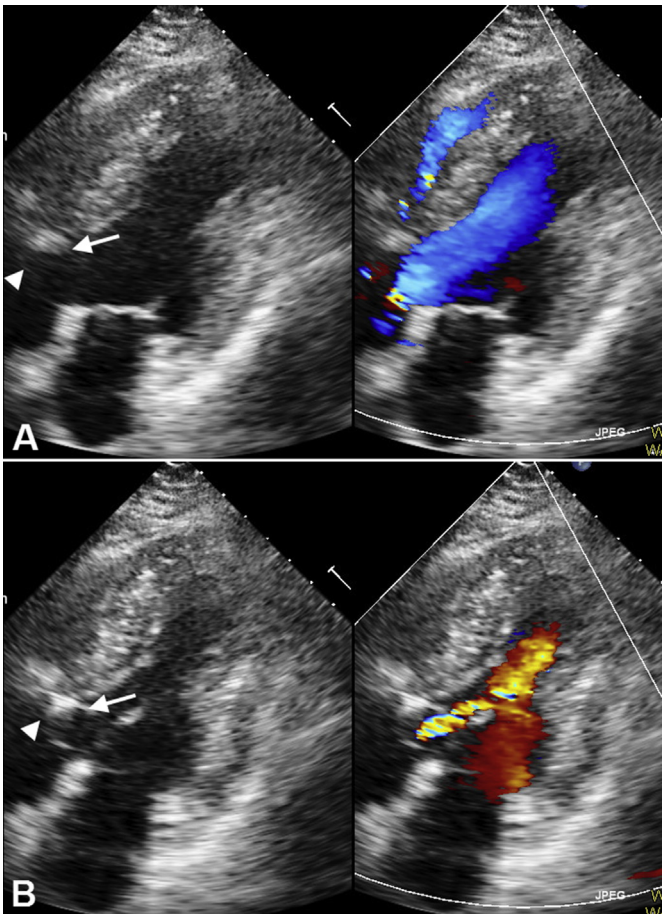

Fig. 3. Transthoracic echocardiogram 12 months after device closure of VSD in patient 12. The aortic end of device (arrow) did not touch the right coronary cusp (arrowhead) during systole (A) but impinged it during diastole (B), resulting moderate aortic regurgitation in 5-chamber view.

25 mg/kg, up to 1 g) were administered intravenously before the procedure. Vascular access was obtained from the right femoral vein and right femoral artery. Heparin (70 IU/kg, up to 5000 IU) was given intravenously to keep activated clotting time above 200 s. The procedure was performed under conscious sedation and transthoracic echocardiographic guidance. Routine right and left heart catheterizations were done for evaluation of the pulmonary to systemic flow ratio (Qp/Qs). Left ventriculography and aortography (30° right anterior oblique/15° caudal and lateral projection) were performed for location/measurement of VSD and determination of the presence of aortic valve prolapse or regurgitation. A 4 or 5 French partly cutoff pigtail or Judkins right catheter was advanced retrogradely to the left ventricular outflow tract. A 0.032-inch 260 cm glide wire was advanced through the catheter to cross the VSD and then into the pulmonary artery or superior vena cava. The wire was captured with a snare catheter through the femoral vein to establish an arteriovenous loop. An appropriate sized ADO was chosen to be its pulmonary end, usually 2–4 mm larger than the VSD size measured by ventriculography. An appropriate 180° Amplatzer long sheath was advanced to the aorta through the arteriovenous circuit and positioned above the aortic valve. The tip of the long sheath was then adjusted to the left ventricular apex using the kissing technique. If it failed, the long sheath was just left in the aorta. Through the long sheath, the ADO was deployed under fluoroscopic guidance. Prior to release, adequate device position, residual shunt and valve influence were corroborated by left ventriculography and transthoracic echocardiography. After the procedure, oral aspirin 3–5 mg/kg, up to 100 mg daily was prescribed for 6 months in patients without residual shunt.

2.4. Follow-up and outcome assessment

Follow-up of VSD and valvular condition was evaluated by left ventriculography and angiography 5 min after device implantation and by transthoracic echocardiography 1 day, 1 month, 3 months, 6 months, and 12 months after intervention. Thereafter, electrocardiography was performed with the same follow-up interval. Procedural success was defined by device release in the appropriate position without embolization or worsening aortic regurgitation. Outcomes included echocardiographic assessment of residual flow,[8] device position, aortic valve morphology/function and adverse events.

3. Results

The results were summarized in Table 2. The Qp/QS ranged from 1.0 to 2.5 with the median of 1.39. Only one patient had mild pulmonary hypertension, with the mean pressure of

Table 2
Results of transcatheter closure of subarterial VSD.

No.	Qp/Qs	Mean PA pressure	VSD Size (mm)	ADO size (mm)	Successful implantation	Fluoroscopy time (min)	Procedure time (min)	Complications
1	1.52	20	1.8	6/4	Y	26.8	66	N
2	1.81	23	5.2	10/8	Y	24.6	95	N
3	2.50	22	6.7	12/10	Y	17.9	85	N
4	1.25	30	5.0	12/10	Y	39.2	97	N
5	1.14	17	3.6	8/6	Y	50.2	105	N
6	1.00	19	1.5	6/4	Y	31.2	80	N
7	1.29	15	1.3	6/4	Y	22.2	55	N
8	1.44	13	1.5	6/4	Y	28.2	90	N
9	2.11	11	3.4	10/8	Y	22.8	55	N
10	1.16	12	3.0	8/6	Y	14.9	45	N
11	1.80	11	2.6	6/4	Y	45.4	125	N
12	1.00	24	3.6	10/8	Y	22.8	77	Contrast allergy
13	1.50	19	5.0	10/8	Y	22.5	83	N
14	1.17	14	3.1	10/8	Y	19.7	52	N
15	1.42	11	9.3	12/10	N	51.6	172	N
16	1.35	15	3.6	8/6	N	26.1	120	N

ADO: Amplatzer duct occluder; N: no; Qp/Qs, pulmonary to systemic flow ratio; PA: pulmonary artery; VSD: ventricular septal defect; Y: yes.

30 mmHg.VSD size ranged from 1.3 to 9.3 mm with a median of 3.5 mm. Overall, the device was successfully implanted in 88% (14/16) of the patients. Among the reasons for failure were excessively large defect in one patient (case 15), and device-induced significant aortic regurgitation in another case (case 16); both were supracristal-type VSD. Fluoroscopy time ranged from 14.9 to 51.6 min, with the median of 25.4 min. Procedure time ranged from 45 to 172 min with the median of 84 min. One patient had mild skin allergy to contrast medium. No device migration/embolization, stroke, shock or other complication was noted.

VSD after device implantation was summarized in Table 3. Complete closure rate was 64% (7/14), 86% (9/14), 86% (12/14) and 86% (12/14) at 1-day, 1-month, 6-month and 12-month follow-up, respectively. The condition of aortic regurgitation was summarized in Table 4. One patient (case 2) developed new aortic regurgitation at the 6-month follow-up, and one patient (case 12) developed worsening of aortic regurgitation at the 12-month follow-up. However, no atrioventricular block or other significant arrhythmia was noted.

4. Discussion

To the best of our knowledge, this is the first global report using ADO for transcatheter closure of subarterial VSD. This study demonstrated that transcatheter closure with ADO is technically feasible and safe regardless of the VSD's subtype. Procedure successful rate was 100% (7/7) for intracristal VSD, 78% (7/9) for supracristal VSD and 88% (14/16) for both VSDs. However, development or worsening of aortic regurgitation was observed in 14% (2/14) of patients. In addition, it developed at the 6–12 month follow-up. Yet this phenomenon may be accounted for by the sharp and relatively stiff edge of the left disc of ADO. Because impingement of the aortic valve seems to be inevitable for subarterial VSD closure, softer device such as ADO II or ADO II Additional Sizes could be more suitable.

Our results also showed that ADO implantation can be safely undertaken in patients greater than 7 years of age, and there was no significant complication. One failed case involved a 3-year-old 14-kg child due to device-induced

Table 3
Follow-up VSD after device implantation.

No	5 min	1 day	1 months	3 months	6 months	12 months
1	C	C	C	C	C	C
2	C	C	C	C	C	C
3	SR	SR	C	C	C	C
4	SR	SR	C	C	C	C
5	SR	SR	SR	SR	SR	SR
6	C	C	C	C	C	C
7	C	C	C	C	C	C
8	C	C	C	C	C	C
9	SR	SR	C	C	C	C
10	SR	C	C	C	C	C
11	SR	C	C	C	C	C
12	C	C	C	C	C	C
13	SR	SR	SR	SR	SR	SR
14	C	C	C	C	C	C

C: closure; SR: small residual shunt; VSD: ventricular septal defect.

Table 4
Aortic regurgitation before and after device implantation.

No	Before	5 min	1 day	1 months	3 months	6 months	12 months	AR change
1	N	N	N	N	N	N	N	N
2	N	N	N	N	N	mild	mild	Y
3	mild	mild	mild	mild	mild	mild	mild	N
4	mild	mild	mild	mild	mild	mild	mild	N
5	mild	mild	mild	mild	mild	mild	mild	N
6	N	N	N	N	N	N	N	N
7	N	N	N	N	N	N	N	N
8	mild	mild	mild	mild	mild	mild	mild	N
9	mild	mild	mild	mild	mild	mild	mild	N
10	N	N	N	N	N	N	N	N
11	mild	mild	mild	mild	mild	mild	mild	N
12	mild	mild	mild	mild	mild	mild	moderate	Y
13	mild	mild	mild	mild	mild	mild	mild	N
14	mild	mild	mild	mild	mild	mild	mild	N

AR: aortic regurgitation; N: no; Y: yes.

significant aortic regurgitation during the procedure. Younger patients, possibly having weaker aortic valve structure, must be carefully evaluated before transcatheter closure.

Our follow-up data showed no atrioventricular block or other significant arrhythmia. In contrast to perimembranous VSD, where device closure could cause atrioventricular block, the location of subarterial VSD is far away from the conduction system and concern about atrioventricular block could be omitted.

The limitation of this study was the retrospective nature and the small case number, as well as the limited age population. Further studies are needed to determine the appropriate cut-off point for patient age.

In conclusion, according to our experience, transcatheter closure of subarterial VSD with ADO is technically feasible and safe in patients older than 7 years of age. However, development or worsening of aortic regurgitation necessitates long-term follow-up.

Acknowledgments

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