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Pediatric Cardiology

Clinical Experience of Transcatheter Closure for Ventricular Septal Defects in Children Weighing under 15 kg

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Background: Failure to thrive and poor weight gain are the main problems associated with ventricular septal defects complicated by heart failure in pediatric patients. Recent advances in transcatheter closure have enabled safe and effective interventions in these patients.

Objectives: The purpose of this study was to describe our experience with transcatheter closure of ventricular septal defects in young children with low weight.

Methods: Pediatric patients weighing < 15 kg who underwent transcatheter closure of ventricular septal defects between January 2018 and December 2019 at our hospital were retrospectively enrolled.

Results: Twelve patients were enrolled: one with a muscular defect, two with outlet defects, and nine with perimembranous defects. Their median age was 24 (7-60) months, and their median weight before the procedure was 11.8 kg (4.7-14.9 kg; mean Z-score: -1.3). The median precordial echocardiographic defect diameter was 5.6 (2.0-9.3) mm. Successful transcatheter closure was achieved in 11 cases. The mean weight at 1-month follow-up after defect closure was 13.5 kg (6.2-19.8 kg; mean Z-score: -0.2). The mean length of hospitalization was 2.7 days.

Conclusions: This study highlights the potential safety and therapeutic efficacy of transcatheter ventricular septal defect closure in infants with low weight. Considerable weight gain and heart failure symptom attenuation at 1 month after transcatheter closure were observed.

Key Words: Children • Device closure • Poor body weight gain • Transcatheter • Ventricular septal defect

INTRODUCTION

Ventricular septal defects (VSDs) are the most common congenital heart condition.[1] Failure to thrive and poor weight gain are the main problems associated with VSDs complicated by heart failure during childhood. The relatively low body weight of patients with VSDs is an obstacle to surgical repair because it results in high risks of mortality and morbidity.[1-3] Surgical closure of VSDs remains the gold standard because it is safe and effective; however, postoperative complications, residual surgical scarring, and morbidity associated with sternotomy or thoracotomy and cardiopulmonary bypass cannot be prevented.[2] Nonetheless, a delay to repair can result in the aggravation of congestive heart failure, and medication can control symptoms to only a limited degree. Transcatheter closure of VSDs has become an option, but data are limited regarding its use in young children, especially those with low body weight.[4] Low body weight also makes the intervention more challenging in terms of device selection, vascular access, and the large size of the stiff delivery sheath.[5,6] This paper reports our experience with transcatheter closure of VSDs in patients with low body weight.

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METHODS

Patients

We retrospectively reviewed the medical records of pediatric patients who underwent transcatheter closure of VSDs at our institute from January 2018 to December 2019. Patients with a body weight of < 15 kg were included in this study. The indication for transcatheter VSD closure was the same as that for surgical repair. Patients with echocardiograms indicating considerable left-to-right shunts and presenting with clinical congestive heart failure were included. The inclusion criteria were: 1) poor weight gain and failure to thrive; 2) a cardiothoracic (C/T) ratio of ≥ 0.5 on chest X-ray or pulmonary venous congestion; 3) left atrial or left ventricular enlargement on an echocardiogram; and 4) a pulmonary circulatory blood volume to systemic circulation volume ratio (Q_p/Q_s) of ≥ 1.5 in a catheterization hemodynamic study. The exclusion criteria were: 1) age < 6 months; 2) VSD diameter > 10 mm; and 3) anomalies other than VSD.

The clinical data of each patient including age, weight, sex, imaging study results [chest X-ray, electrocardiography, echocardiography, computed tomography (CT), and angiography], catheterization data, procedure duration, fluoroscopy duration, radiation dose, and follow-up echocardiography results were collected and reviewed. Chest X-ray, echocardiography, and electrocardiography were performed before and after the procedure. Written informed consent for the procedure was obtained from patient's parents before the procedure. Weight was assessed on the basis of the 2019 World Health Organization (WHO) Child Growth Standards[7] and thus calculated using Z-scores. Z-scores, also called standard deviation (SD) scores, are used to describe how far a measurement is from the mean value. Z-score lines on WHO growth charts are numbered positively (1, 2, or 3) or negatively (-1, -2, or -3) to indicate that the score is above or below the mean value, respectively.

The Z-score of an observed point in a distribution is calculated as follows: Z-score = (observed value) – (mean reference value)/Z-score of the reference population. This study was approved by the Institutional Review Board (AER-109-081) of National Cheng Kung University Hospital.

Procedure

Transcatheter VSD closure was performed as described by Wang and Yang.[8,9] In brief, closure was performed under anesthesia with intravenous propofol without endotracheal tube insertion. Prophylactic antibiotics were administered before the procedure, and heparin (100 IU/kg) was administered during the procedure. Continuous pulse oximetry and electrocardiography were performed throughout. In all cases, both femoral artery access and vein access were used. The procedure was performed under fluoroscopy with the assistance of transthoracic echocardiography. The devices used included a symmetric VSD occluder (HeartR Membranous VSD Occluder, LifeTech Scientific Co., Shenzhen, China), Amplatzer vascular plug (AVP) II (Abbott, IL, USA), and Amplatzer duct occluder (ADO) I and II (Abbott). The devices were selected on the basis of the size, morphology, and position of the VSD, as determined through left ventricle (LV) angiography, which was performed using an Arrow Berman Angiographic Catheter (Arrow International Inc., PA, USA) or pigtail catheter (Cordis, Fremont, CA, USA) and a transthoracic echocardiography device using the largest diastolic diameter. The size of the device was selected to be at least 2 mm larger than the maximal measured defect size.[10] A 0.035-inch hydrophilic guidewire (Terumo, Tokyo, Japan) was delivered via a Judkins right (JR) coronary catheter (Cordis) or a cut pigtail catheter to pass across the defect from the LV to the right ventricle (RV) and then anchor to the pulmonary artery. The guidewire was then snared and withdrawn from the femoral vein, establishing an arteriovenous loop. A long delivery sheath was then carefully advanced via the femoral vein access into the RV through the arteriovenous circuit. To prevent direct contact of the guidewire with the VSD when they were crossed by the sheath, we advanced the JR catheter from the left side and used the "kissing catheter technique."[11] The delivery sheath was then placed in a suitable position in the LV or descending aorta. The LV disc was first deployed in an anterograde manner within the LV chamber or descending aorta in a tulip shape to cross the aortic valve, and was gently pulled back to the intraventricular portion of the VSD under fluoroscopic guidance. We attempted to advance the long sheath by using the kissing technique to the LV through the arteriovenous circuit first. If this was unsuccessful because the LV chamber of the child was too small, we avoided multiple catheter manipulations in the LV. The LV disc was

therefore deployed in an anterograde manner within the descending aorta in a tulip shape to cross the aortic valve, and was gently pulled back to the intraventricular portion of the VSD under fluoroscopic guidance.

It is unclear why perimembranous VSDs undergo an aneurysmal transformation, which makes the flow exit much smaller than the original defect, especially for small babies with large VSDs complicated by heart failure. When using a symmetric VSD device, we placed the left disc at the left side of the inlet and the right disc at the right side of the outlet during deployment. The entire aneurysm was then compressed by pressing together the left and right discs of the occluder.[12,13] When using the ADO I device, we pulled the partially extruded device into the aneurysm and completely opened the retention skirt. With the retention skirt fully open in the aneurysm, further gentle traction was applied to the device to confirm the device's stability.[12,13]

Precordial echocardiography was performed immediately after the procedure, and follow-ups were conducted at 1 day, 1 month, and 3 months after the procedure. All patients were hospitalized for 1 day after the procedure, and they received aspirin (3-5 mg/kg/day) for 6 months.

Follow-ups

The patients underwent echocardiography 1 day and 1 month after the procedure. Their body weight was recorded, and their medications were adjusted at the outpatient clinic 1 month after the procedure.

Statistical analysis

All continuous variables are expressed as the mean ± SD or median with range as appropriate, and categorical variables are presented as frequencies and percentages.

RESULTS

The data of 12 patients (8 boys and 4 girls) who underwent transcatheter closure of VSDs during a 2-year period (January 2018 to December 2019) were retrospectively reviewed. Hemodynamically considerable left-to-right shunts were revealed by echocardiograms in all cases. The median age of the patients was 24 (7-60) months, and the median weight was 11.8 kg (4.7-14.9 kg; mean Z-score: -1.3). Failure to thrive, diagnosed on the basis of anthropometric criteria, was found in nine patients before the procedure (Table 1).[14] The median VSD diameters measured through echocardiography, CT, and angiography were 5.6 (2.0-9.3), 6.1 (3.3-9.0), and 5.1 (2.5-8.5) mm, respectively. The median Q_p/Q_s was 2.2 (1.5-3.7), and the median pulmonary artery pressure (mean) measured through a catherization hemodynamic study was 18 (13-28) mmHg. Regarding VSD morphology, one muscular, two outlet, and nine perimembranous VSDs were identified. The procedure

Table 1. Patient demographics and characteristics

Patient No.	Age (months)	Gender	Weight (kg)	Medication	Failure to thrive	Other cardiac defects	Underlying problems	Cardiothoracic ratio
1	7	F	5.1	C, D, Fu	Yes	-	Down syndrome	0.56
2	7	F	4.9	D, S	Yes	-	-	0.64
3	7	M	4.7	C, D, Fu, S	Yes	Bilateral SVC	-	0.54
4	36	F	12.8	-	Yes	ASD	-	0.58
5	24	F	12.5	D, S	-	-	-	0.57
6	24	M	11.8	D, Fu	Yes	-	-	0.57
7	36	M	9.5	D, Fu	Yes	PDA post device closure	-	0.58
8	24	M	14.6	-	-	RCC prolapse with mild AR	-	0.54
9	36	M	14.2	D, Fu	-	-	-	0.6
10	60	M	14.9	-	Yes	RCC prolapse with mild AR		0.57
11	60	M	12.7	D, Fu	Yes	-	-	0.53
12	15	M	7.9	D, Fu, S	Yes	-	-	0.66

AR, aortic regurgitation; ASD, atrial septal defect; C, captopril; D, digoxin; F, female; Fu, furosemide; M, male; PDA, patent ductus arteriosus; RCC, right coronary cusp; S, spirolactone; SVC, superior vena cava.

was unsuccessful in one case without complications because the VSD was discovered using LV angiography to be morphologically misaligned, rendering it unsuitable for device closure. The devices employed were eight LifeTech VSD occluders, two ADO II devices, two ADO I devices, and one AVP. The median procedure time was 1 h 58 min (53 min to 2 h 53 min), and the median fluoroscopy time was 15 min 22 s (13 min 2 s to 58 min 43 s). The mean radiation exposure was 12.1 ± 11.2 (3.18-39.1) Gy cm^2. The mean hospital stay was 2.7 ± 0.6 days (Table 2). The mean body weight after VSD closure was 13.5 ± 5.2 kg (6.2-19.8 kg; mean Z-score: -0.2), and 1 month after closure, the median body weight had improved by 14.8%. Oral medications including furosemide, digoxin, and spironolactone were successfully discontinued in nine cases (Table 3). The median C/T ratio before catheterization was 0.57; 1 month after closure, it was 0.51 (Figure 1). The patients' cardiac rhythm re-

Table 2. Procedure details and patient complications

Patient No.	VSD type	Size measurement (mm)			Qp:Qs	PA pressure (mmHg)	Device type and size (mm)	Approach side	Procedure time (hour: min)	Fluoroscopy time (min: sec)	Radiation dose ($gycm^2$)	Residual shunt	AR	TR	EKG
		Echo	CT	Angio											
1	PT	7.3	9.0	8.4	3.6	53/41	sVSD (10)	Antegrade, Ao	1:30	20:29	3.18	-	Mild	Mild	NSR
2	MT	6.5	8.1	5.8	2.8	50/35	AVP (8×7)	Antegrade, LV	2:34	43:17	8.21	Yes	-	Mild	NSR
3	MI	4.6	4.7	4.6	2.7	42/31	ADOI (8×6)	Antegrade, Ao	2:46	31:07	4.13	-	-	Mild	NSR
4	PT	5.4	N	5.3	3.7	43/25	sVSD (8)	Antegrade, Ao	1:32	20:17	22.5	-	-	Mild	NSR
5	PT	3.9	N	4.4	1.7	30/20	sVSD (6×3)	Antegrade, Ao	0:53	13:02	6.8	-	-	Mild	NSR
6	PT	3..0	3.3	3.5	1.5	24/13	sVSD (7×3)	Antegrade, Ao	1:08	20:41	7.0	-	-	Mild	NSR
7	PT	6.9	5.9	7.2	3.6	45/39	sVSD (10)	Antegrade, LV	2:53	58:43	35.5	-	-	Mild	NSR
8	PO	2.2	N	2.5	1.3	16/11	ADOII (5×4)	Antegrade, Ao	2:17	37:27	9.6	-	Mild	Mild	NSR
9	PT	6.2	N	4.4	1.9	29/17	sVSD (10)	Antegrade, Ao	1:07	40:17	39.1	-	-	Mild	NSR
10	PO	1.8	N	2.5	1.5	35/22	ADOII (5×4)	Retrograde,RV	2:11	N	N	Yes	Trivial	Mild	NSR
11	PT	2.6	N	3.8	1.4	20/18	sVSD (7)	Antegrade, Ao	2:35	N	N		-	Mild	NSR
12	PI (Malalignment)	5.8	7.7	8.5	2.5	36/24	sVSD (12)	Antegrade Ao, LV	4:52	N	N	fail		Moderate	NSR

ADOI, Amplatzer duct occluder I; Angio, angiography; Ao, aorta; AR, aortic regurgitation; AVP, Amplazter vascular plug; CT, computed tomography; Echo, echocardiography; EKG, electrocardiography; LV, left ventricle; MI, muscular inlet; MT, muscular trabecular; N, no data available; NSR, normal sinus rhythm; PA, pulmonary artery; PI, perimenbranous inlet; PO, perimembranous outlet; PT, perimembranous trabecular; Qp:Qs, pulmonary-systemic flow ratio; sVSD, symmetric ventricular septal defect occluder; TR, tricuspid regurgitation; VSD, ventricular septal defect.

Table 3. Body weight gain and cardiothoracic ratio change after ventricular septal defect closure

Patient No.	Weight before closure (kg/Growth %th)	Z-score	Weight one month after closure (kg/Growth %th)	Z-score	Weight gain (%th)	Cardiacthoracic ratio (Day 1 before closure)	Cardiacthoracic ratio (one month after closure)
1	5.1 (0.01)	-3.0	6.2 (0.03)	-2.0	0.02	0.56	0.51
2	4.9 (0.01)	-3.0	6.4 (1.72)	-2.0	1.71	0.64	0.55
3	4.7 (0.01)	-3.0	6.3 (0.11)	-2.5	0.1	0.54	0.51
4	12.8 (10.6)	-1.0	17.9 (90.3)	+1.5	7.9	0.58	0.52
5	12.5 (22.1)	+0.5	15.2 (70.9)	+1.5	48.8	0.57	0.52
6	11.8 (8.12)	-0.5	12.0 (17.7)	+1.5	9.6	0.57	0.54
7	9.5 (1.5)	-2.0	10.5 (2.2)	+0	19.5	0.58	0.54
8	14.6 (25.5)	+0	15.5 (37.7)	+2.0	12.2	0.54	0.50
9	14.2 (37.0)	+0.5	19.8 (97.3)	+0.5	60.3	0.60	0.54
10	14.9 (6.0)	-2.5	16.9 (8.1)	+0	2.1	0.57	0.50
11	12.7 (26.6)	-1.0	13.1 (27.5)	-0.5	0.9	0.53	0.51

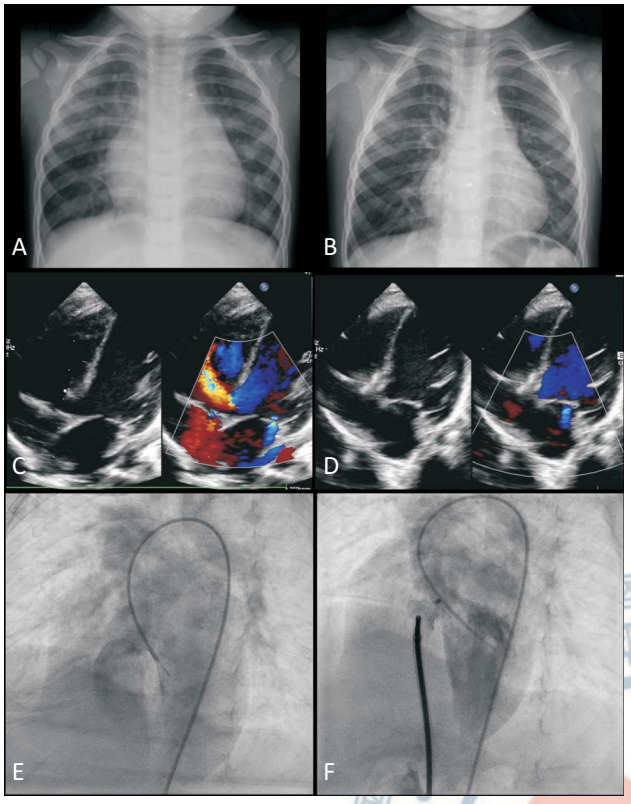

Figure 1. *(A) Chest X-ray shows cardiomegaly and pulmonary congestion in Case 7. (B) Chest X-ray shows resolution of pulmonary congestion after ventricular septal defect (VSD) closure in Case 7. (C) Color Doppler echocardiography in Case 1 shows a large left-to-right-shunt. (D) Echocardiography in Case 1 shows no residual shunt after VSD closure with the device in situ. (E) Left ventricle (LV) angiography in Case 1 before closure shows contrast flow, demonstrating the VSD shunt to the right ventricle. (F) Postclosure LV angiography in Case 1 shows no residual shunt contrast flow.*

mained in sinus rhythm after the procedure and during the follow-up period. Two patients had a small residual shunt, and one patient had new-onset mild aortic regurgitation (AR; Case 1) discovered through echocardiography; mild AR was found in two other patients (Cases 8 and 10) before and during follow-up. Unsuccessful closure occurred in one patient (Case 12) due to a large VSD with mild misalignment. In brief, transthoracic echocardiography showed that the VSD was 7.5 mm in size. We used Terumo wire and snare wire to create an arteriovenous loop, and a 7-Fr LifeTech delivery sheath was used to deploy the 10-mm LifeTech VSD occluder from the aortic side; however, the device failed to anchor at the proper position. We then changed the delivery sheath to an 11-Fr sheath and upgraded the device to a 12-mm LifeTech VSD occluder deployed from the aortic side, however the device could not be deployed at the proper position because of the misalignment of the VSD. Therefore, we decided to abort the procedure. The overall success rate in this series was 91.7% (11/12).

DISCUSSION

VSDs are the most common congenital heart condition in children. Progressive heart failure caused by a left-to-right shunt results in pulmonary arterial hypertension and ventricular dysfunction if left untreated. Transcatheter closure of VSDs, when performed in a selected subgroup of patients, has a similar procedural success rate to surgical closure but without the increased risk of considerable valvar regurgitation or heart block-age.[15-17] However, performing this procedure in underweight infants remains challenging because of the infants' low body weight, vascular access, underlying physiological conditions, difficult device selection, and other potential problems. Thus, surgical repair of VSDs remains the gold standard, but it is also associated with high mortality and frequent complications related to cardiopulmonary bypass.[2,18] Palliative pulmonary artery banding is suggested in infants weighing < 5 kg to prevent progressive pulmonary congestion and congestive heart failure.[19] Percutaneous transcatheter closure of VSDs under fluoroscopic and echocardiographic guidance has become the optimal option in the treatment of VSDs in children.[20-23] However, low body weight, younger age, the use of an overlarge device, and unfavorable surrounding structures are risk factors for complications during transcatheter closure of VSDs.[6,8] Percutaneous transcatheter VSD closure was successful in 11 of the 12 low-weight infants with congestive heart failure enrolled in the present study.

Vascular access and device choice have been reported to be the two greatest challenges in transcatheter VSD closure in young children and those with a low body weight.[24,25] Considering the small vessel diameters of children with a low body weight, the device and delivery catheter should be selected precisely by using complete echocardiographic and angiographic data. Balloon sizing is also an option for obtaining additional information on how to conduct the procedure. In

our experience with children weighing < 10 kg, a 10-mm LifeTech VSD occluder (inserted via a 7-Fr LifeTech delivery sheath) was successfully deployed in a patient weighing 5.1 kg (Case 1), a 6-mm LifeTech VSD occluder (delivery via a 6-Fr LifeTech delivery sheath) was successfully used in a patient weighing 9.5 kg (Case 7), an 8-mm AVP (inserted via a 5-Fr Cook Ansel sheath) was successfully used in a patient weighing 4.9 kg (Case 2), and an 8-mm ADO I (inserted via a 6-Fr Amplatzer delivery sheath) was successfully used in a patient weighing 4.7 kg (Case 3). In addition, the off-label use of a ductal occluder based on VSD morphology, especially aneurysmal changes, has previously been reported.[22]

Body weight gain was the most impressive result in this study, and contributed to the more rapid recovery from transcatheter VSD closure than from surgical repair; the children enrolled in this study were discharged quickly and returned to normal oral feeding soon after the procedure. Additionally, because the left-to-right shunts had been corrected, the symptoms of congestive heart failure became less severe. These results were reflected by the children's catch-up growth at the 1-month outpatient clinic follow-up.

The major concerns related to percutaneous VSD closure are the possibility of complete atrioventricular block requiring permanent pacemaker implantation and AR.[9] In the present study, only three patients were found to have trivial or mild AR after the procedure; however, this AR did limit the patients' progression during the follow-up period. In addition, valve regurgitation caused by wire stretching and requiring surgical repair has been reported, but aggravation of valve regurgitation after the procedure was not found in our cases. Furthermore, no heart block occurred in our patients.

This study has some major limitations. First, it was a retrospective study. Second, the case number was small. Third, the follow-up period was limited, and thus, long-term outcomes could not be determined. However, this study demonstrates a VSD management strategy for infants with congestive heart failure. The procedure used in this study avoids sternotomy and has the advantages of shorter hospitalization and recovery time. An experienced physician can perform transcatheter VSD closure safely and successfully with low risks of morbidity and mortality. The transcatheter approach is a minimally invasive alternative and can be considered the first choice in select infants with VSDs and low body weight.

CONCLUSIONS

This retrospective study highlights the safety and therapeutic efficacy of the transcatheter approach for closing VSDs in infants with low body weight. Considerable body weight gain and attenuation of heart failure symptoms were observed within 1 month after transcatheter closure.

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CONFLICT OF INTERESTS

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