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Closure of transcatheter ventricular septal defect using Lifetech™ Konar-MF Occluder in children weighing less than 10 kilograms: mid-term results, a tertiary single center experience

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Abstract. – OBJECTIVE: Transcatheter closure of medium and large ventricular septal defects (VSDs) in young children is limited due to the use of over-sized devices that can cause hemodynamic instability and arrhythmia. In this study, we aimed to retrospectively evaluate the safety and efficacy of the device in the mid-term in children weighing less than 10 kg whose transcatheter VSD was closed only with the Konar-MFO device.

PATIENTS AND METHODS: Among 70 children whose transcatheter VSD was closed between January 2018 and January 2023, 23 patients weighing less than 10 kg were included in the study. Retrospectively, the medical records of all patients were reviewed.

RESULTS: The mean age of the patients was 7.3 (4.5-26) months. 17 of the patients were females, 6 of them were males, F/M: 2.83. The average weight was 6.1 (3.7-9.9) kg. The mean the pulmonary blood flow/ systemic blood flow (Qp/Qs) was 3.3 (1.7-5.5). The mean defect diameter was 7.8 mm (5.7-11) for the left ventricle (LV) side, and 5.7 mm (3-9.3) for the right ventricle (RV) side. Based on the utilized device dimensions, the measurements on the LV side were recorded as 8.6 mm (range 6-12), while those on the RV side were recorded as 6.6 mm (range 4-10). Antegrade technique was applied to 15 (65.2%) patients and retrograde technique was applied to 8 (34.8%) patients in the closure procedure. The procedure success rate was 100%. The incidence of death, device embolization, hemolysis, or infective endocarditis was zero.

CONCLUSIONS: Perimembranous and muscular VSDs in children under 10 kg can be successfully closed under the management of an experienced operator with the Lifetech Konar-MFO device. This is the first study in the literature to evaluate the efficacy and safety of the device in children under 10 kg in whom only Konar-MFO VSD occluder device is used for transcatheter VSD closure.

Key Words:
Konar-MFO, Ventricular septal defect, Transcatheter closure, Weight <10 kgs.

Introduction

Ventricular septal defect (VSD) is the most common pathology, accounting for approximately 20% of all congenital heart anomalies[1]. It can be seen together with other structural heart defects as well as isolated. Surgical closure is the widely accepted treatment modality for all hemodynamically significant VSDs. Surgical VSD closure is an important procedure that involves risks of sternotomy, cardiopulmonary bypass, blood transfusion, permanent scarring, possible complete heart block, early and late arrhythmias, post-pericardiotomy syndrome and even death[2]. After the closure of the VSD with the transcatheter method for the first time in 1988 by Lock et al[3] the closure of even large VSDs in young children with the transcatheter method is applied as a less invasive alternative treatment method than surgery, thanks to the newly developed devices[4]. Transcatheter closure of medium and large VSDs in young children is limited due to the use of over-sized devices that can cause hemodynamic instability and arrhythmia. For this reason, surgical closure is still the first preferred treatment method in infants and young age groups in centers where appropriate patient and correct device selection cannot be made, and which do not have sufficient experience in transcatheter closure.

Both labeled and non-labeled devices are used for transcatheter VSD closure[5]. LifeTech™ multifunctional Occluder (Konar-MF VSD Occluder)

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has a very soft and flexible structure compared to other devices. It also reduced complications such as complete heart block, thanks to its thin cable and flexible waist minimizing damage to adjacent structures[6]. In this study, we aimed to retrospectively evaluate the safety and efficacy of the device in the mid-term in children less than 10 kg whose transcatheter VSD was closed with the Konar-MFO device. Our study is the first in the literature to include VSDs closure using only Konar-MFO in children under 10 kg.

Patients and Methods

Between January 2018 and January 2023, 23 patients under 10 kg were included in the study, among a total of 70 children whose transcatheter VSD was closed at Izmir Tepecik Training and Research Hospital of different ages. Retrospectively, the medical records of all patients were reviewed. For each patient, informed consent has been obtained from the parents or guardians. Patients with significant additional cardiac anomalies that would require emergency surgery were excluded from the study. The study has been approved by the Ethics Committee of Izmir Tepecik Training and Research Hospital (dated 05/04/2023 and numbered 2023/03_39)

Inclusion criteria: Two-dimensional dilation of the left ventricle or left atrium [+2 standard deviation (SD)] in transthoracic echocardiography (TTE), pulmonary blood flow/ systemic blood flow (Qp/Qs) >1.5, cardiomegaly on chest x-ray, patients with unrelated growth retardation of malnutrition were included in the study. Defects within 3 mm of the aortic or tricuspid valve, prominent aortic valve prolapse, and patients who did not exceed a mild level of aortic insufficiency were considered suitable for transcatheter closure.

Exclusion criteria: Those with irregular defect limits and insufficient rims, those with more than mild aortic insufficiency, those with abnormalities that may require simultaneous mitral/ tricuspid valve repair, other lesions that require surgical correction, and those whose parents did not give consent for transcatheter closure were excluded and referred to surgery.

All patients underwent a comprehensive TTE evaluation prior to transcatheter device closure. The proximity of the defect to the aortic and tricuspid valves, the relationship of these valve leaflets with the defect, its size, and the presence of any aortic or tricuspid valve regurgitation were detailed with TTE.

Device Description

The Konar-MF VSD Occluder is a low-profile device with a soft woven mesh made of 0.002-inch Nitinol wires. The self-expanding device is a hybrid design consisting of two discs joined by a cone-shaped attachment waist. Since there are screws on both disc sides, it can be used by the LV or RV, that is, retrograde or antegrade. The device comes with a delivery sheath ranging from 4F to 7F (LifeTech, Shenzhen, China). The device is available in eight sizes from 5/3 mm to 14/12 mm, the waist of four large models is securely sewn with a polytetrafluoroethylene membrane using nylon threads to increase occlusion capacity, while four smaller models do not have a membrane inside.

Technique

The patients were admitted to the hospital the day before the procedure. Routine complete blood count, biochemical parameters, serological tests and coagulation values were checked before the procedure. In order to evaluate the rhythm problems that may develop after the closure procedure, all patients underwent 12-channel ECG before the procedure. Cefazolin IV was administered to all patients as antibiotic prophylaxis before the procedure. All procedures were performed under general anesthesia. After the short sheath was placed in the right femoral artery and vein, the patients were heparinized with 50 U/kg heparin. The heparin dose was repeated in cases where the active clotting time was above 200 seconds when checked at the 1st hour of the procedure. Shunt evaluation was performed by calculating Qp/Qs by taking blood gases. For angiographic identification, a pigtail catheter was injected into the LV in the left anterior oblique projection with cranial tilt at 60o-20o and 30o-30o angles for all perimembranous (PM) defects. In cardiac catheterization, defect transition procedures were applied from antegrade or retrograde approach according to the guidelines7,8. Device size for PM defects was chosen by adding 1-2 mm to the largest diameter of the defect on the RV side. In the presence of aneurysmal tissue on the right ventricular side, the device was placed inside the aneurysm sac to minimize friction between the device and the aortic valve. Similarly, 1-2 mm larger devices were preferred for muscular defects.

While the device placement was checked by TTE and fluoroscopy, the device, which was gradually removed from the delivery sheath was carefully placed on the defect. In echocardiography, the placement of the device in the ventricular septum, the presence of significant residual shunt, whether the device caused a disturbance in the coaptation mechanism due to compression of the aortic valve cusps by the LV disc, the presence of aortic insufficiency and tricuspid valve insufficiency were evaluated. The device was released in case of no problems.

During the first 24 hours after the procedure, continuous ECG monitoring was performed to detect arrhythmias. Clinical examination, ECG and TTE were performed before discharge (first day after intervention), 4 weeks later, 3 months, 6 months, and 1 year after device closure. Aspirin (3-5 mg/kg/po daily) was prescribed for 6 months to uncomplicated patients after the procedure.

Statistical Analysis

Statistical analyses were performed with the statistical package program SPSS Statistics V 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics are expressed as the number of units (n), percent (%), median (M), minimum (min) and maximum (max) for categorical variables and mean±standard deviation/median (range) for continuous variables.

Results

Of the 70 patients included in the study for percutaneous closure of the ventricular septal defect, 23 (32.8%) patients weighing less than 10 kg were found to meet the criteria. The mean age of the patients was 7.3 (4.5-26) months. 17 of the patients were females and 6 of them were males, F/M: 2.83. The average weight was 6.1 (3.7-9.9) kg. Right heart catheterization was performed before the device was turned off. The mean Qp/Qs was 3.3 (1.7-5.5). The mean defect diameter was LV side: 7.8 mm (5.7-11), RV side: 5.7 mm (3-9.3). In terms of defect type, there were 12 perimembranous (PM), PM-inlet: 2, PM-outlet: 4, Muscular: 5 VSD, 3 of which were aneurysmatic. Demographic data of the patients are shown in Table I. In accordance with the utilized device dimensions, LV side measured 8.6 mm (range: 6-12 mm) while RV side measured 6.6 mm (range: 4-10 mm). The smallest device used was 4/6 and the largest 10/12. Antegrade technique was applied to 15 (65.2%) patients and retrograde technique was applied to 7 (34.8%) patients in the closure procedure. Mean fluoroscopy time and mean procedure time were 21.3±6.2 min and 44±8.3 min, respectively (Table II). The mean radiation dose was 1,493±511 cGy/min. The procedure success rate was 100%. No significant complications were observed during or after the procedure. Aortic regurgitation was not observed in any of our patients before and after the procedure. Negligible minimal residual shunt was observed in 3 (13%) patients before discharge. Left branch bundle block (LBBB) developed during the procedure in one patient and was resolved before the device was placed. No severe tricuspid/mitral valve damage or complete AV block was observed in the whole series. The incidence of death, device embolization, hemolysis, or infective endocarditis was zero (Table III). In our study, the mean follow-up period was 38.2 (6-59) months. In the follow-up of the cases with insufficient weight gain, rapid weight gain was observed in all of them. The increased LV end diastolic diameter regressed to age-appropriate normal Z scores from the 3rd month. No arrhythmic pathology was observed in any patient during follow-up. A fistula occurred between the femoral artery and the femoral vein in one patient. In the follow-up, spontaneous closure of the fistula was confirmed by Doppler ultrasound performed by the radiology unit.

Isolated VSD was present in 77.2% of the patients. Small secundum atrial septal defect was the most common accompanying cardiac anomaly in three patients, mild mitral regurgitation in two patients and patent ductus arteriosus (PDA) in one patient. Two of the cases were diagnosed with Trisomy 21.

Discussion

VSD is the most common congenital heart disease. If not diagnosed at the right time, it can lead to pulmonary hypertension, heart failure, and many other complications[9]. Closure of hemodynamically significant VSDs with transcatheter device was the most preferred treatment method compared to surgery in the last two decades in eligible patients. Transcatheter closure has come to the fore with the development of existing devices and the increase in operator skills. As indicated by the parents, the preference for this treatment approach is attributed to its minimal

Table I. Demographic and clinical data.

Patient No.	Age (months)	Weight (kg)	Gender	VSD type	VSD size LV side (mm)	VSD size RV side (mm)	Concomitant pathology
1	5.5	3.7	F	MM	6.0	4	ASD
2	14.0	8.5	M	PM	10	5	-
3	11.0	7.0	F	PM	6.0	4	-
4	11.0	8.3	F	PMI	9.0	5	ASD, Down S.
5	26.0	9.8	F	PMI	7.0	4	MR (mild)
6	15.0	8.3	F	PM	6.0	4	-
7	12.0	9.2	M	PM	7.0	4.5	ASD
8	4.5	6.0	F	UM	11	7	-
9	8.0	5.2	M	PM Multiple	7.0	6	-
10	3.0	4.4	F	MM Multiple	7.0	4	-
11	7.0	6.5	F	PMO	5.7	5.6	-
12	8.0	7.3	F	PMO	7.1	7.1	-
13	18.0	7.5	M	MO	6.8	6.6	-
14	5.0	5.2	F	MO	9.2	9.3	-
15	11.0	7.2	M	PM	10	7	-
16	9.0	4.6	F	PM	8.0	6.8	-
17	17.0	8.6	F	PM	6.0	4	-
18	11.0	7.0	F	PM	6.5	4	MR (mild)
19	18.0	8.6	F	PM	7.0	5	Down S.
20	17.0	9.4	F	PM	5.8	4.3	-
21	14.0	8.6	F	PM	5.0	3	-
22	14.0	9.9	M	PM	7.7	5	-
23	11.0	5.7	F	PM	7.4	5.2	PDA

PM = perimembranous; PMI = perimembranous inlet; MM = mid muscular; PMO = perimembranous outlet; UM = upper muscular; MO = muscular outlet; ASD = atrial septal defect; MR = mitral regurgitation; PDA = patent ductus arteriosus.

Table II. Catheterization data.

Patient No.	VSD type	QP/QS	PAP	Device	Sheath	Approach	Fluoroscopy time (mm)
1	MM	2.28	24	6/8	FV 5F, FA 4F	Antegrad	19.2
2	PM	2.30	19	6/8	FV 6F, FA 5F	Antegrad	53.9
3	PM	1.70	10	4/6	FV 6F, FA 5F	Antegrad	21.3
4	PM	2.42	17	8/10	FV 5F, FA 5F	Antegrad	18.7
5	PM	1.93	21	5/7	FV 5F, FA 5F	Retrograd	17.9
6	PM	2.14	22	6/8	FV 6F, FA 5F	Antegrad	26.1
7	PM	2.61	27	6/8	FV 5F, FA 4F	Retrograd	8.5
8	UM	4.90	28	10/12	FV 5F, FA 5F	Antegrad	24.3
9	PM Multiple	2.37	36	7/9	FV 5F, FA 5F	Retrograd	25.7
10	MM Multiple	2.00	27	6/8	FV 5F, FA 5F	Antegrad	22.4
11	PMO	3.20	45	6/8	FV 5F, FA 4F	Antegrad	16.0
12	PMO	3.10	37	7/9	FV 6F, FA 5F	Antegrad	11.0
13	MO	2.40	38	8/10	FA 5F	Antegrad	24.0
14	MO	5.50	42	7/9	FV 5F, FA 5F	Antegrad	13.0
15	PM	2.54	23	6/8	FV 5F, FA 5F	Retrograd	15.4
16	PM	2.67	25	6/8	FV 5F, FA 4F	Antegrad	16.0
17	PM	2.73	26	6/8	FV 5F, FA 5F	Antegrad	27.1
18	PM	2.48	24	5/7	FV 5F, FA 5F	Retrograd	9.2
19	PM	2.62	21	7/9	FV 5F, FA 5F	Antegrad	16.5
20	PM	1.97	20	5/7	FV 5F, FA 4F	Retrograd	15.1
21	PM	1.89	19	4/6	FV 6F, FA 5F	Antegrad	14.4
22	PM	2.27	23	6/8	FA 5F	Retrograd	36.5
23	PM	3.1	26	5/7	FV 5F, FA 4F	Retrograd	21.3

PM = perimembranous; PMI = perimembranous inlet; MM = mid muscular; PMO = perimembranous outlet; UM = upper muscular; MO = muscular outlet; FA = femoral artery; FV = femoral vein.

pain, absence of chest wall scarring, reduced hospitalization duration, and lack of requirement for intensive care[10-12]. Due to operator experience and case selection, closure is mostly considered in older children. In children with a large VSD weighing less than 10 kg with symptoms of heart failure, transcatheter closure can be performed under the management of an experienced operator because of the technical difficulty and high risk of complications. There are few studies[6] in the literature on this subject. In several studies[13,14] published previously, in percutaneous VSD closure in children under 10 kg, many labeled and off-label devices such as Cera PDA occluder (Lifetech Scientific Co. Ltd., Shenzhen, Guangzhou, China), Cera VSD occluder (Lifetech Scientific Co. Ltd., Shenzhen, Guangzhou, China) Amplatzer duct occluder Type II (St. Jude Medical Inc., St. Paul, MN, USA) , Cocoon duct occluder (Vascular Innovations Co. Ltd., Bangtanai, Pakkret, Nonthaburi, Thailand), Amplatzer membranous VSD occluder (St. Jude Medical Inc., St. Paul, MN, USA), Amplatzer vascular plug II (St. Jude Medical Inc., St. Paul, MN, USA) were used.

This is the first study in the literature to evaluate the efficacy and safety of the device in children under 10 kg in whom sole Konar-MFO VSD occluder device was used for transcatheter VSD closure. Konar-MFO device obtained CE certification for VSD closure in Europe in May 2018, although it has been used in some Asian countries before[15]. The most important feature of the device is that it facilitates the whole procedure thanks to its flexibility. Especially in medium-wide muscular VSDs and PM-VSDs with aneurysmal tissue, the use of the double-disc Konar-MFO device without anatomical narrowing on the right side provides convenience compared to other devices. The fact that the device can be screwed by both discs creates a great advantage in antegrade and retrograde placement[6,16,17]. The extensive carry sheaths of the STARFlex® and CardioSEAL® (NMT Medical, Inc., Boston, MA, USA) devices used in transcatheter closure made handling difficult and caused residual shunt during recapture and positioning movements18. The ability to advance the Konar-MFO device through a smaller diameter (4-5F) carrying sheath causes less trauma to the patient and increases the success of the procedure.

Closure of PM-VSDs carries certain risks due to its critical location close to the conduction system and aortic valve. In previous studies[19,20], it was reported that the risk of complete atrioventricular (AV) block after surgical closure ranged from 1-8%. Although the rates of complete AV block and LBBB after percutaneous PM-VSD closure vary according to device types, it has been reported[21,22] to be between 1% and 6%. Although complete AV block is mostly seen within 1 week after transcatheter closure, cases have been reported[23] to occur up to 3 years after the procedure. Narin et al[24] reported that complete AV block developed 6 months after the procedure in a patient younger than one-year old. In addition to various factors such as the location of the defect causing atrioventricular block, device type, device size, Butera et al[4] suggested that age is an important risk factor and reported that being <6 years old increases the risk. When the Konar-MFO device is selected in the appropriate size, its soft structure and flexible design minimizes the trauma and inflammation that may occur against the conduction tissue. AV block or LBBB was not observed in any of our patients in our series.

The distance of the defect to the aortic edge, the short distance between the septal leaflet of the tricuspid valve and the lower edge of the VSD stand out as other risk factors in percutaneous closure. Another important point to be considered in the follow-up is aortic insufficiency[25]. New onset aortic regurgitation (AR) has been reported[26] in up to 17% of PM-VSDs closed using the Amplatzer membranous occluder. Konar-MFO adapts to the plane of the defect in different ways and does not cause deterioration in the aortic or tricuspid valve. The development of aortic regurgitation is related not only to the type of device and the nature of the defect, but also to operator experience. It is important to find an ideal device to minimize such complications in young children. In our study, no pathology was observed in the aortic and

Table III. Complications.

Major complications	Total 1/22 (4.5%)
Valve injury	0
Complete AV block/LBBB	1 (Transient LBBB)
Ventricular perforation	0
Device embolization	0
Thromboembolism	0
Minor complications	Total 1/22 (4.5%)
Transient loss of pulse	0
New on set AR	0
New on set RBBB	0
Arteriovenous fistula	1

AR = aortic regurgitation; RBBB = right branch bundle block; LBBB = left branch bundle block.

tricuspid valves before and after the procedure. In our series, mean fluoroscopy time and procedure time were 21.3±6.2 minutes and 44±8.3 minutes, respectively. Another study[14] from India of 35 children weighing less than 10 kg reported a very low fluoroscopy time of 9.2±2.9 minutes.

Conclusions

Transcatheter closure of large VSDs can be successfully performed by experienced operators in properly selected children weighing less than 10 kg. It is a safe and acceptable alternative treatment compared to surgery with a high success rate. Choosing the right device for VSD closure in young children is very important in terms of complications that may develop during and after the procedure. The Konar-MFO device provides significant advantages compared to other devices in percutaneous closure with its flexibility, ease of application and small carrier system. Our series includes the first mid-term results in the literature using only Konar-MFO device under 10 kg. Multicenter studies with large case series are required to evaluate device safety and efficacy in this patient category. The small number of patients and retrospective data collection are limitations of this study.

Conflict of Interest

N.N. is a proctor and consultant for Lifetech. The other authors have no conflicts of interest to declare.

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Ethics Approval

The study was approved by the Ethics Committee of of Izmir Tepecik Training and Research Hospital (dated 05/04/2023 and numbered 2023/03-39) in accordance with the Declaration of Helsinki.

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Authors' Contributions

K.Y. contributed to conception and design; acquisition, analysis, and interpretation of the data, drafted manuscript; critically revised manuscript, and gave final approval and agrees to be accountable for all aspects of work ensuring integrity and accuracy. N.N. contributed to conception and design, acquisition, critically revised manuscript, and gave final approval and agrees to be accountable for all aspects of work ensuring integrity and accuracy. R.O., S.O., S.B., T.D., R.A., R.N.K. contributed to design, collected the clinical data, analysis C.K. edited and provided supervision.

Informed Consent

For each patient, informed consent has been obtained from the parents or guardians.

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