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Outcome And Short Term Follow Up of Transcatheter Perimembranous VSD Closure with Konar- Multifunctional Occluder Device in Children: A Tertiary Single Center Experience

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ABSTRACT

Background: Transcatheter device closure of VSD has gradually become promising, especially for perimembranous defects with reported success rate of closure especially in pediatric population.

Objective: The study aimed to investigate the efficacy and the short-term outcome of using the innovative Konar-Multifunctional Occluder (MFO) to close Perimembranous Ventricular Septal Defects (PM-VSDs) in children.

Patients and methods: This retrospective study was applied on 28 pediatric patients who underwent transcatheter closure of hemodynamically significant PM-VSDs done in the Pediatric Cardiac Catheterization Unit in Cairo University Specialized Pediatric Hospital during the period from December 2020 to October 2022 using MFO device. Pre-procedural, procedural, post-procedural data were collected from patient files. Regular post procedural follow up was done for 12 months. **Results:** Twenty-eight patients underwent VSD closure using Konar-MFO. Median age and body weight of patients were 4.96 (2.6-14) years and 16 (12-60) kg respectively. The mean size of the left ventricular side of the VSD was 7.34 ± 1.61 mm on transthoracic echocardiography. The most used device size was 9/7 mm. The procedure was successful in 100% of cases. No major complications (device embolization, valve injury, complete heart block and thromboembolism) were reported. Four (14.3%) cases had immediate small residual flow with 2 of them spontaneously closed at 6 months follow up. No neo-tricuspid or aortic valve insufficiency or cardiac dysrhythmia was detected during follow up.

Conclusion: Transcatheter closure of perimembranous VSD using Konar- MFO device is safe and effective in children with satisfactory short-term outcome.

Keywords: Perimembranous VSD, Konar -MFO device, Children.

INTRODUCTION

Ventricular septal defects (VSDs) constitute the most frequently diagnosed form of congenital heart diseases (CHDs) representing a substantial proportion, approximately 40%, of all CHD cases identified [(1)]. Within the diverse classification of VSDs, the perimembranous ventricular septal defects (PM-VSDs) are anatomically the most commonly encountered subtype, accounting for a significant majority, specifically about 60% to 80% of all reported ventricular septal defects [(1)]. This anatomical location often involves the membranous portion of the interventricular septum, making them particularly prevalent.

The clinical indications for the closure of PM-VSDs are comprehensively well-established and are crucial for optimizing patient outcomes. These include a persistently elevated estimated pulmonary-to-systemic blood flow ratio (Qp/Qs) exceeding 1.5, which signifies a substantial left-to-right shunt burden. Furthermore, compelling evidence of left atrial and/or left ventricular (LV) enlargement indicates the heart's compensatory but ultimately unsustainable response to volume overload. A documented history of infective endocarditis directly related to the VSD represents a critical indication due to the high morbidity and mortality associated with recurrent infections. Lastly, the presence of clinical symptoms such as frequent recurrent respiratory infections and/or persistent failure to thrive in pediatric patients strongly warrants intervention, as these are direct consequences of chronic hemodynamic compromise [(2)]. While surgical closure of PM-VSDs has long been the gold standard, it remains particularly preferred in specific pediatric populations, notably in children with low birth weight who also present with large ventricular septal defects. However, it is essential to acknowledge that conventional surgical intervention is frequently associated with several notable drawbacks. These include the inevitable formation of a large thoracic scar, which can have significant long-term cosmetic and psychological implications for the patient. The procedure also carries the potential for psychological trauma for both the child and their family, and typically necessitates a prolonged hospital stay for recovery and postoperative monitoring [(3)]. In recent years, significant advancements have been made in the application of transcatheter closure for PM-VSDs, which has emerged as a highly promising and increasingly viable alternative to traditional surgical repair. This less invasive interventional approach has consistently demonstrated comparable clinical outcomes to surgical closure while offering distinct and substantial advantages. These benefits encompass a rapid recovery time for patients, significantly reduced physical trauma due to the absence of a large thoracotomy, and a remarkably shorter overall hospital stay [(4)], contributing to earlier discharge and improved patient experience. A pivotal development in this evolving field occurred in May 2018, when the innovative Konar-MFO VSD device (manufactured by Lifetech, Shenzhen, China) successfully attained its CE certification for the purpose of VSD closure, marking a significant milestone in its clinical adoption [(5)]. Despite the clear benefits of device-based closure, it is crucial to

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recognize the spectrum of reported complications associated with VSD devices. These can include the presence of residual defects (persistent shunts), the development of potentially life-threatening atrioventricular block (affecting cardiac conduction), tricuspid or aortic insufficiency (valvular regurgitation), device embolization (migration of the device from its intended position), hemolysis (destruction of red blood cells), and a risk of infective endocarditis [6]. These potential complications necessitate careful patient selection and vigilant post-procedural monitoring.

Our study aimed to investigate the results and the short-term outcome of PM-VSD closure using Konar-MFO device in pediatric age group at Cairo University Specialized Pediatric Hospital (CUSPH).

METHODS

Patient selection: This retrospective cohort study was conducted on 28 children patients at the Pediatric Cardiac Catheterization Unit, CUSPH during the period from December 2020 to October 2022.

Inclusion criteria: Pediatric patients with hemodynamically significant PM-VSDs amenable for device closure. Patient age ≥ 2.5 years and weight ≥ 12 kg were included.

Exclusion criteria: Patients with bidirectional or right to left VSD shunt flow, associated other structural heart defects that need surgery and PM-VSDs associated with aortic cusp prolapse with aortic regurgitation.

Preprocedural evaluation: All medical data were collected from patient files including medical history, physical examination, preprocedural Chest X-Ray and ECG. Preprocedural transthoracic and transesophgeal echocardiographic examination was done for all patients.

Procedural data and follow up: Procedural data including vascular access, selected device size, delivery system size, fluoroscopic time and radiation dose were reported. All patients had transthoracic echocardiographic examination and ECG 24 hours after the procedure. Oral aspirin (5 mg/kg/day) was prescribed for 6 months to uncomplicated patients after the procedure. Regular transthoracic echocardiography and ECG follow-ups were done at 4-6 weeks, 3 months, 6 months and 12 months after the procedure.

Ethical approval: The Research Ethical Committee of Faculty of Medicine, Cairo University, had approved the study (approval code: MS-341-2021). The study complied with the requirements of Revised Helsinki Declaration of Bioethics. Prior to their participation in this study, each participant had an informed written consent. Upon reasonable request, the corresponding author provides the data supporting the conclusions of our study. The final version of the manuscript was approved by all authors.

Statistical analysis

The statistical analysis of the collected data was performed using the IBM SPSS software package, version 20.0 (Armonk, NY: IBM Corp), into which all raw data were carefully entered. For the comprehensive description of qualitative data, measures such as absolute numbers and corresponding percentages were systematically utilized to present the categorical variables. Prior to inferential testing, the normality of the distribution for all quantitative variables was rigorously assessed and confirmed through the application of the Shapiro-Wilk test. To effectively characterize the quantitative data, a suite of descriptive statistics was employed, including the range (minimum and maximum values), the mean ± standard deviation (SD) for normally distributed data, and the median with its accompanying interquartile range (IQR) for skewed distributions. For making comparisons involving quantitative variables that were normally distributed across more than two distinct periods, the ANOVA test with repeated measures was specifically utilized to assess within-subject changes over time. Conversely, when comparing binary qualitative variables across more than two time periods, Cochran's Q test was appropriately employed. Throughout all analyses, statistical significance was stringently defined by a P-value ≤ 0.05.

RESULTS

Demographic data: Our study included 28 children patients who had percutaneous device closure of hemodynamically significant PM-VSD using Konar-MFO device during the period from December 2020 to October 2022. The median age at time of intervention was 4.96 years ranging from 2.6 -14 years. Males predominated in the study population accounting for 53.6% (n =15), while females accounted for 46.4% (n =13). Median weight for our cases was 16 kg with minimum weight in our study was 12 kg (Table 1).

Table (1): Demographic data of the studied cases(N=28)

Age (years)	Median (IQR) Mean ± SD Range	4.96 (3.38 – 5.54) 5.75 ± 4.15 2.6-14
Gender	Male Female	53.6% (n =15) 46.4% (n =13)
Weight (kg)	Median (IQR) Mean ± SD Range	16(15-20.5) 20.38 ± 11.72 12.0–60
Weight Z score	Median (IQR) Mean ± SD Range	-0.62 (-1.35 – 0.06) -0.57 ± 1.38 -3.81 – +2.06

Clinical examination: Twenty-five cases (89.3%) had New York Heart Association (NYHA) class II heart failure and was on antifailure medications while three cases (10.7%) had NYHA class I. Twelve cases had failure to thrive (42%), 15 cases (53%) gave history of preprocedural repeated chest infections**.** Cardiomegaly and pulmonary plethora were evident in the chest X –ray of 22 cases (78.6%). All cases had preoperative normal sinus rhythm. **VSD size:** We measured the LV side and the RV side of the defect using transthoracic echocardiography, transesophgeal echocardiography (TEE) and angiography. Table (2) illustrated the correlation between the different techniques and showed that VSD angiographic measurements were best correlated with TEE measurements (P < 0.001).

Table (2): The correlation between VSD size using different techniques (n = 28)

VSD size (mm)	Transthoracic Echocardiography	Angiogram	Trans esophageal Echocardiography (TEE)	F	P
LV side					
Range	4.0-11.0	4.0-12.0	4.0-11.50	15.735*	<0.001*
Mean ± SD.	7.34 ±1.61	7.41 ± 1.82	6.83 ±1.81		
Median (IQR)	7.50 (6.0-3.0)	7.25(6.25-8.50)	6.65 (5.60-3.0)		
Sig. bet. technique	P_1=1.000, P_2 = 0.001*, P_3<0.001*				
RV side					
Range	2,10-10.0	2.0-8.0	2,0-7.20		
Mean ± SD.	5.59 ± 1.62	5.20 ±1.47	4.59 ±1.33		
Median (IQR)	5.0 (4.50-6.75)	5.0(4.0-6.0)	4.45 (3.65-5.45)	8.515	0.006
Sig. bet. technique	P_1=0.640, P_2>=0.006*, P_3<0.001*				

IQR: Inter quartile range **SD:** Standard deviation**, F:** F test (ANOVA) with repeated measures**, Sig. bet. Periods:** was done using Post Hoc Test (adjusted Bonferroni**), P:** p value for comparing the three studied technique, **P_1:** p value for comparing Transthoracic Echocardiography and Angiogram, **P_2:** p value for comparing Transthoracic Echocardiography and Trans-esophageal Echocardiography, **P_3:** p value for comparing between Angiogram and trans-esophageal Echocardiography, ***:** Statistically significant at $p \leq 0.05$.

Procedural data: Konar- MFO device size was selected based on TEE & Angiography usually by adding 2 mm to the measurements of LV and RV side of the defect. All devices were inserted via retrograde approach from the arterial side. The most commonly used device size was 9/7 (n=10, 35.7%). The mean fluoroscopy time was 19.29 ± 14.19 minutes. The mean used radiation dose was 166.1 ± 93.5 Gy-cm^2. There was one patient had associated large atrial septal defect and it was closed at the same procedure. Details of the devices, short and long sheathes used were illustrated in table (3).

Table (3): Device size, short and long sheath sizes used in the studied cases (n=28)

MFO Device size (mm)	Devices number	Percentage %	Short femoral sheath size (n)	Long femoral sheath size (n)
6/4	1	3.6	5 Fr (1)	5 Fr (1)
7/5	3	10.7	5 Fr (3)	7 Fr (1) 5 Fr (2)
8/6	6	21.4	5 Fr (6)	6 Fr (4) 5 Fr (2)
9/7	10	35.7	6 Fr (10)	6 Fr (10)
10/8	5	17.9	5 Fr (5)	6 Fr (5)
12/10	3	10.7	5 Fr (3)	7 Fr (3)

Fr: French, **n:** number

The procedure was successful in 100% of cases. No major complications were recorded in the form of device embolization, valve injury, complete heart block (CHB), hemolysis and thromboembolism. Only 4 (14.3%) patients had weak arterial pulsations at the limb of femoral arterial sheath. They regained intact pulsations within 36 hours by the use of heparin infusion and warming the affected limb with normal Doppler findings. Minimal residual shunt was found in 4 (14.3%) patients before discharge. All cases had normal sinus rhythm after the procedure. **Follow up:** All cases had regular follow-up visits including clinical examination, transthoracic echocardiography and ECG at 4–6 weeks, 3 months, 6 months and 12 months after the procedure. All patients had NYHA class II heart failure turned asymptomatic by the 4-6 weeks visit and the antifailure medications were stopped. No rhythm disturbances were detected during the follow up. Four cases (14.3%) had small residual VSD flow. Two (50%) residual VSDs spontaneously closed by 6 months. One (25%) spontaneously closed by 12 months and only one (25%) persisted after 12 months. The preprocedural LV dilatation showed gradual regression along the follow up visits. Starting from 3 months after the procedure there was a significant improvement in LV dilatation compared to pre-catheter dimensions (p= 0.031). All cases returned to normal LV diameter at the 12 months visits (Table 4 & figure 1).

Table (4): Comparison between the different studied periods according to LVEDD by transthoracic Echocardiography

	Pre- catheter	4-6 weeks	3 months	6 months	12 months	F	P
LVEDD (mm)							
▪ **Range**	39.0 – 43.0	38.80 – 42.50	38.0 – 42.0	37.50 – 41.0	37.0 – 40.50	20.529*	**<0.001***
▪ **Mean ± SD.**	42.0±2.0	41.38±1.93	40.25±1.71	39.38 ± 1.49	39.0±1.58		
LVEDD Z score							
▪ **Range.**	2.08 – 3.20	2.01 – 3.05	1.82 – 2.46	1.57 – 2.12	1.44 – 1.80	20.430*	**<0.001***
▪ **Mean ± SD.**	2.67 ± 0.55	2.45 ± 0.47	2.11 ± 0.28	1.89 ± 0.24	1.62 ± 0.15		
P_0		**0.085**	**0.031***	**0.018***	**0.017***		

LVEDD: Left ventricular end-diastolic diameter, **SD:** Standard deviation**, F: F** test (ANOVA) with repeated measures**, P_0 :** p value for comparing between pre-catheter and each other periods ***:** Statistically significant at P ≤ 0. 05.

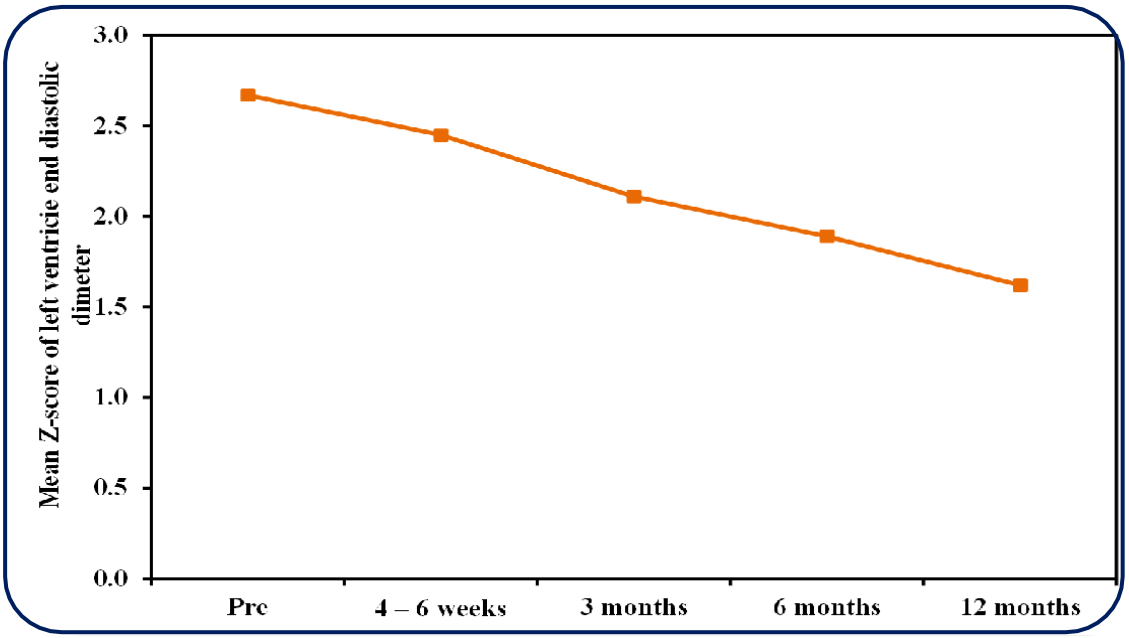

Figure (1): Regression of LVEDD Z-score during follow up.

DISCUSSION

Ventricular septal defects (VSDs) stand as the most prevalent form of congenital heart disease (CHD) in children, representing a significant challenge in pediatric cardiology due to their high incidence and potential for severe complications. When a VSD is hemodynamically significant and left untreated, the persistent left-to-right shunting of blood can lead to a considerable pulmonary hypertension from overflow [(7)]. This pathological increase in pulmonary artery pressure, if allowed to progress unchecked, can ultimately result in the irreversible and life-threatening condition known as Eisenmenger syndrome, characterized by severe pulmonary vascular disease and a reversal of the shunt. In a pivotal shift over the past two decades, the therapeutic landscape for perimembranous VSDs (PM-VSDs) has increasingly favored transcatheter closure as the preferred intervention, moving away from traditional open-heart surgery [(8)]. This paradigm shift is driven by the considerable benefits offered by this minimally invasive approach. Patients undergoing transcatheter closure experience significantly reduced postoperative pain compared to surgical counterparts, owing to the smaller incisions involved. Furthermore, it completely avoids the cosmetic and psychological impact of a sternotomy scar, which is a key advantage, particularly for pediatric patients. The procedure also leads to a shorter hospitalization period, allowing for a more rapid return to normal activities, and substantially diminishes the need for extensive intensive care unit requirements, thereby optimizing resource utilization and improving the overall patient experience [(8)].

Many devices have been used off-label for PM-VSD device closure including Duct Occluders (DO) (Amplatzer; St. Jude Medical, Inc., St. Paul, Minnesota, USA), Cocoon (Vascular Innovations Co. Ltd., Nonthaburi, Thailand), Cera (Lifetech Scientific Co. Ltd., Shenzhen, China), Occlutech (Occlutech International AB, Helsingborg, Sweden) and Amplatzer Duct Occluder II (ADO 2) and

Amplatzer vascular plug-2 (AVP-2) [9] . The Konar – MFO device has been widely used for PM-VSD since 2018.

The MFO occluder is an innovative, self-expanding device meticulously constructed from 144 individual wires of 0.002-inch nitinol cables, which are intricately woven into a resilient, layered nitinol wire mesh. Structurally, it is uniquely characterized by a central waist that effectively connects and stabilizes its two distinct discs, forming a double-disc configuration. A key design feature is that each disc is equipped with a precisely engineered 2.4 mm long hub incorporating a screw mechanism. This specialized design confers the significant advantage of allowing the device to be deployed flexibly using either a retrograde or antegrade technique, providing crucial adaptability during interventional procedures. A further notable advantage of the MFO device lies in its remarkable ability to be advanced through smaller diameter (4-5 French) delivery sheathes [10]. This reduced sheath size is particularly beneficial as it significantly minimizes patient vascular trauma, leading to potentially fewer complications and quicker recovery times.

In our serious the Konar–MFO device was applied through the retrograde approach saving the need for establishment of arterio-venous loop. The retrograde approach is preferable than the antegrade approach due to its shorter exposure time and cost effectiveness. Nevertheless, the retrograde approach is difficult to be applied in smaller weight or when aortic valve injury is expected [11]. Procedural success was defined by release of the device in the correct position without embolization and this was achieved in 100% of our cases. Regarding vascular access complications, only 4 patients had weak pulsations that recovered within 36 hours after the procedure and the vascular Doppler findings were normal for the 4 cases.

We followed up our cases for 12 months after the procedure. Small residual VSD flow (measured 1-2 mm within color Doppler echocardiography) was found in four (14.3%) cases. 50% of cases showed spontaneous closure by 6 months, 25% by 12 months and 25% persisted after 12 months. This result goes with agreement of many studies in literature that recorded spontaneous closure of the majority of residual shunts over time [12].

Owing to the critical location of PM-VSD close to the conduction system and aortic valve, early and late CHB was recorded in many studies as a complication to device closure [13]. **Kamali *et al.* [12]** and **Tanidir *et al.* [6]** reported temporary CHB in some cases caused by compression of the delivery system but no late CHB was detected. This finding comes concordant with our finding as no one of our cases had CHB either early or during the 12 months post procedural follow up enhancing the safety of Konar – MFO device on the conductive system.

Another risk factor for PM-VSD device closure is the short distance between the upper edge of the defect and the aortic valve and the short distance between the lower edge of the defect and septal leaflet of the tricuspid valve. This may lead to aortic or tricuspid valve insufficiency after the procedure [14]. Neo aortic regurgitation has been reported in 17% of PM-VSDs closed using the Amplatzer membranous occluder [15]. Neo Aortic or tricuspid insufficiency was not reported in our cases during the serial follow up. Other studies done on Konar-MFO supported the same finding that risk of aortic insufficiency is much lower in Konar –MFO than Amplatzer device due to the way it adapts to the defect that does not cause deterioration in the aortic or tricuspid valve [16]. During our follow up, the LVEDD dilatation showed significant decline starting 3 months after the procedure ($p = 0.031$) and turned to normal Z scores within 6 to 12 months post catheterization.

This study is considered the first experience in our center to use of Konar–MFO novel device for closure of PM-VSD so we used it at first in caution until we trusted its safety margin. We recommends to apply a greater number of cases and smaller weight in our further studies because minimum weight in our study was 12 Kg and we found some literature that recommend use of Konar–MFO below 10 Kg with satisfactory results [17].

CONCLUSION

Transcatheter closure of perimembranous VSD using KONAR MFO device is safe and effective in children. All our studied cases had 100% success rate with no major or minor complications and favorable short-term outcome. This study represented the first experience of our center for the use of KONAR MFO device. Larger prospective studies should be applied on children with the consideration of enrolling smaller weight and age group to study the success and efficacy of the novel device.

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