Procedural outcomes of percutaneous closure of perimembranous and other ventricular septal defects using Konar-MF occluder and short-term follow-up

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ABSTRACT

Introduction : **The study aims to assess the procedural outcomes and follow-up after transcatheter closure of ventricular septal defects (VSDs) in children utilizing the Konar-MF™ occluder (Lifetech Scientific, Shenzhen, PRC) device.**

Materials and Methods : **Clinical features, demographic characteristics, and follow-up findings of children undergoing percutaneous VSD device closure were retrospectively analyzed from the medical records.**

Results : **Fifty-seven patients underwent VSD closure using the Konar-MF occluder between January 2019 and April 2023. Median age and body weight of patients were 36 (5–216) months and 12.5 (3.8–42) kg, respectively. The mean size of the defect on the left ventricular side was 6.5 ± 2.4 mm on echocardiography; the mean pulmonary artery pressure was 19.1 ± 9.7 mmHg. Three patients with severe pulmonary hypertension had successful device closure. The most used device size was 8 mm × 6 mm. The initially chosen device was upsized in 4 (7.01%) patients and downsized in 1 (1.7%) patient. Forty-five patients (78.9%) had device closure through the retrograde route. The procedure was successful in 53 (93.0%) patients. Immediate shunt occlusion was achieved in 86.8% of patients. Major complications, namely, embolization (1) and moderate aortic regurgitation (1) in two patients were successfully managed by surgery. One patient with severe tricuspid regurgitation has been on close follow-up. There was no mortality. Late complications such as valve regurgitation or rhythm disturbance were not identified on a median follow-up of 6 (1.5–47) months.**

Conclusion : **Transcatheter VSD closure using a Konar-MF occluder device is safe and effective, even in smaller children. The ability to deliver both anterogradely and retrogradely is a unique advantage.**

Keywords : Aortic cusp prolapse, Gerbode defect, retrograde ventricular septal defects closure, transcatheter ventricular septal defects closure, ventricular septal defects device closure in children

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INTRODUCTION

Ventricular septal defects (VSDs) remain the most common congenital heart disease (CHD), excluding bicuspid aortic valve, occurring in 40% of the children with CHDs.[1] The most common type of VSD is perimembranous VSD, which accounts for 60%–80% of defects.[2] Surgical closure has drawbacks such as prolonged hospital stays and complications related to cardiopulmonary bypass. While large or nonrestrictive defects (with a diameter equal to that of aortic annulus or more) are repaired surgically, transcatheter closure is offered for restrictive VSD. Since its first description by Lock *et al.* in 1988, various devices have been used to close VSD percutaneously.[3]

In May 2018, the Konar-MF™ multifunctional occluder (MFO) device (Lifetech Scientific, Shenzhen, PRC) received CE-mark approval for VSD closure.[4,5] This study aims to assess the procedural outcomes and the short-term results of the closure of perimembranous and muscular VSD with this device.

MATERIALS AND METHODS

Patients undergoing transcatheter closure of VSD using MFO from January 2019 to April 2023 were included in the study.

Patient selection

Indications for device closure included perimembranous and muscular VSD with failure to thrive, recurrent respiratory infections, and/or symptoms of heart failure despite adequate medical management; evidence of significant left-to-right shunt in the form of left ventricular (LV) end-diastolic dimension *Z*-score >+2, the cardiothoracic ratio in chest X-ray >0.5, pulmonary flow: systemic flow (Qp:Qs) >1.5 measured on echocardiography; or history of infective endocarditis.

We excluded VSDs other than perimembranous or muscular (inlet and outlet/doubly committed VSDs), large VSDs (with a diameter equal to that of the aortic annulus or more), small VSD with Qp:Qs <1.5, gross aortic cusp prolapse, or aortic cusp prolapse with mild or more aortic regurgitation (AR), severe pulmonary arterial hypertension (PAH) that is not reversible after oxygen (with pulmonary vascular resistance index [PVRi] >8 WU.m^2), active infective endocarditis, iliac vein/artery thrombosis, and concomitant other cardiac defects requiring surgery.

Preprocedural evaluation

On preprocedural transthoracic echocardiography (TTE), we assessed the nature of the defect and its known associations: aortic cusp prolapse, AR, tricuspid regurgitation (TR), direct or indirect Gerbode defect, and associated CHDs. VSD was measured on the LV and right ventricular (RV) sides. The presence of a septal aneurysm, subaortic rim (specifically in cases with the absence of septal aneurysm), and number of exits on the RV side were noted. The subaortic rim was classified as sufficient (≥2 mm) or deficient (<2 mm). Shunt quantification (Qp:Qs), measurement of LV dimension on M-mode, and estimation of PAH were done using echocardiography. LV dimension was given more importance than shunt fraction in patient inclusion, as Qp:Qs quantification was often prone to interobserver variation.

Device selection

The device[4] was selected based on echocardiographic and angiographic diameters; the latter was the deciding factor if there was a discrepancy of >1 mm between these two measurements. Defects with RV exit-to-LV entry ratio (RV side/LV side) ≤0.5 were classified as conical, whereas defects with RV exit-to-LV entry ratio >0.5 were classified as tubular. In perimembranous conical defects with septal aneurysm and posterior and upper muscular VSD, the left waist diameter (D2) of the chosen MFO was 1–2 mm larger than the defect dimension on the LV side. In tubular defects, the device was oversized by choosing D2 as 2–3 mm larger than the LV side dimension. In perimembranous defects without septal aneurysm and outlet muscular defects with sufficient subaortic rim (≥2 mm), the left waist of the MFO was 1–2 mm larger than the defect diameter on the LV side. If the subaortic rim was deficient (<2 mm), the left waist of the chosen MFO was equal to the defect dimension on the LV side. Patients with more than mild PAH received a device larger by an additional 1–2 mm.

Interventional procedure

The procedure was performed through femoral artery and venous access. Intravenous unfractionated heparin was given at a dose of 100 U/kg after vascular access and repeated if required to keep the activated clotting time above 200 s throughout the procedure. Periprocedural antibiotics were administered. Pulmonary artery pressures were recorded.

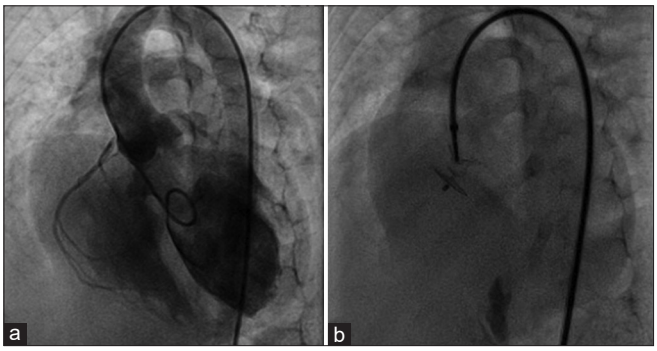

Figure 1: Left ventricular angiogram in left anterior oblique 30°–cranial 30° view showing perimembranous ventricular septal defects (a) and the same being closed by a Konar-MF occluder (b)

LV angiography was performed in left anterior oblique (LAO) 30°, cranial 30° (for posterior muscular VSD), and LAO 60° – cranial 20° (for perimembranous VSD [PMVSD]) views, with optional use of additional angiographic views (right anterior oblique in outlet muscular defects) [Figure 1]. Measurements were taken on the LV side and RV side of the defect.

Catheters to cross the defect from the LV side over a hydrophilic glidewire (Terumo Corporation, Tokyo, Japan) included Judkin's right coronary catheter (Cordis Corporation, Miami, FL) and Picard catheter (Cook Medical, Bloomington, IN), etc.

The device was delivered across the defect either retrograde from the LV side through femoral arterial access or antegrade from the RV side through femoral venous access after forming an arteriovenous loop. Antegrade technique was used in situations when a larger device was needed in a smaller child to avoid a larger arterial delivery system or when there was difficulty in placing an arterial sheath through narrow defects or complex aneurysms.

The delivery sheath manufactured by Lifetech to use with Konar-MF occluder is not widely available in India yet. Hence, we used four different long delivery systems in all our procedures: Amplatzer TorqVue™ 180° delivery system (Abbott, Plymouth, MN) (PDA delivery sheath), Judkin's right coronary guide catheter (Cordis, Miami, FL), Mullin's introducer sheath (Cook Medical, Bloomington, IN), and Amplatzer TorqVue™ LP delivery system (Abbott, Plymouth, MN) (Amplatzer Duct Occluder [ADO] II delivery sheath). We found the ADO II delivery cable to be compatible with the MFO.

TTE was done after device delivery to assess the stability of the device, residual flows around and through the device, new onset TR or AR, and any restriction of aortic cusp movement. An angiogram through the side port of the long sheath was further performed to assess the orientation of the device and the distance between the LV disc and the aortic cusp.

Postprocedure, pedal pulse was checked after sheath removal and hemostasis. Transient pulse loss was treated with heparin. Patients were started on oral aspirin 3–5 mg/kg once a day and continued for 6 months. Uncomplicated cases were discharged 24–48 h after the procedure. Follow-up with echocardiography was done at 1 week, 6 weeks, 3 months, 6 months, 1 year, and thereafter annually.

RESULTS

Demographic data

Of 1073 patients with VSD who attended the pediatric cardiology outpatient department between January 2019 and April 2023, 171 underwent transcatheter VSD closure. Fifty-seven patients with VSD who underwent or attempted to have closure using a Konar-MF occluder at our center were included in this study [Table 1]. Eleven (18.9%) infants and 20 patients (35.1%) with body weight <10 kg underwent closure with MFO. Table 1 additionally provides anatomical details of the VSD and the associations.

Procedural data

Following echocardiographic assessment, three patients underwent hemodynamic study for severe PAH. Two patients had reversible PAH (PVRi <6 WU.m^2); one patient with borderline PVRi (>6 WU.m^2) underwent acute vasodilatory testing with 100% oxygen and was found to be operable. All the three underwent device closure [Table 1]. Device size selection was done as described above. Disagreement (defined as a difference in the size of >1 mm) between echocardiographic and angiographic measurement of the defect size was found in 9 cases (15.8%). We observed disagreement when multiple exit openings were on the RV side [Table 2].

Outcome analysis

Procedural success was obtained in 53 (93.0%) patients. Failure to deploy the device occurred in four patients. Patient 1 (32 months, 10.5 kg, PMVSD without septal aneurysm, 6.2 mm on LV side, tubular defect, aortic rim <2 mm) developed moderate AR after 8 mm × 6 mm MFO device placement and was sent for surgical closure. Patient 2 (40 months, 15.4 kg, PMVSD with septal aneurysm with indirect Gerbode defect, 11.5 mm on LV side, tubular defect) developed significant para-device flow even after using the largest 14 mm × 12 mm MFO device, closed with muscular VSD device subsequently. Patient 3 (5 months, 4.2 kg, PMVSD without septal aneurysm, 7.4 mm on LV side, tubular defect, aortic rim >2 mm) failed as a 10 mm × 8 mm MFO device could not be deployed in a stable position despite attempts of both antegrade and retrograde approach. Surgical closure was done as the patient's small body weight did not allow for the use of a larger device through a larger delivery system. Patient 4 (29 months, 9.5 kg, PMVSD with septal aneurysm, 10.5 mm on LV side, tubular defect, aortic rim >2 mm): 14 mm × 12 mm MFO device embolized to RV, whereas the patient was in the recovery room sent to surgery.

Procedural complications

The complications are listed in Table 3. One patient developed second-degree heart block after the device release and reverted to sinus rhythm before discharge after treatment with intravenous dexamethasone. In the patient with moderate AR, the device was not released. One patient who developed severe TR due to accidental trauma to the tricuspid valve chordae while placing

Table 1: Baseline characteristics of patients

Parameters (*n*=57)	Mean±SD or (*n*)	Median or percentage	Range
Age (months)	46.01±29.5	36.0	5–216
Body weight (kg)	14.01±7.9	12.5	3.8–42
Sex			
Male	28	49.1	
Female	29	50.9	
Defect location			
Perimembranous	50	87.7	
With septal aneurysm	46	80.7	
No septal aneurysm	4	7	
Aortic rim ≥2 mm	2	3.5	
Aortic rim <2 mm	2	3.5	
Muscular	7	12.3	
Upper muscular	5	8.8	
Posterior muscular	1	1.7	
Outlet muscular	1	1.7	
Size of VSD (mm)			
LV side, on TTE	6.5±2.4	6.2	2.2–11.5
LV side, on angiography	6.7±2.8	6.3	2–12.1
RV side, on TTE	4.4±1.7	4.2	1.5–9.1
RV side, on angiography	4.4±2.4	4.4	1.4–11
Shape of VSD			
Conical (RV side/LV side ≤0.5)	19	33.3	
Tubular (RV side/LV side >0.5)	38	66.7	
Size distribution of VSD, LV side (mm)			
≤4	9	15.8	
4.1–8	34	59.6	
>8	14	24.6	
Gerbode defect			
Direct Gerbode	2	3.5	
Indirect Gerbode	11	19.3	
RCC prolapse			
With no AR	9	15.8	
With trivial AR	2	3.5	
Septal aneurysm with multiple (≥2) exits on the RV side	2	3.5	
Mitral regurgitation			
Mild (due to annular dilatation)	6	10.5	
Moderate (due to annular dilatation)	6	10.5	
Severe (AML prolapse and annular dilatation)	1	1.7	
Tricuspid regurgitation			
Trivial	7	12.3	
Mild	48	84.2	
Moderate	2 (Ebstein's anomaly Carpentier type A - 1, indirect Gerbode - 1)	3.5	
Acquired mild infundibular stenosis/gasul phenomenon	3	5.3	
Associated CHD			
Ebstein's anomaly	1 (Carpentier type A)	1.7	
Atrial septal defect	1 (on follow-up)	1.7	
Patent ductus arteriosus	2 (both closed in the same sitting)	3.5	
Bicuspid aortic valve	1 (no AS/AR)	1.7	

SD: Standard deviation, VSD: Ventricular septal defect, LV: Left ventricle, RV: Right ventricle, TTE: Transthoracic echocardiography, RCC: Right coronary cusp, AML: Anterior mitral leaflet, CHD: Congenital heart disease, AS: Aortic stenosis, AR: Aortic regurgitation

the RV disc continued to remain on follow-up without any surgical intervention. A 29-month-old patient with embolization of device to RV in the recovery room was sent to surgery without any attempt for transcatheter retrieval due to small patient size. One patient had hemoglobinuria for 36 h after device closure, accompanied by a drop in hemoglobin level of 1 g/dl, without the appearance of anemia or renal failure. We managed the patient conservatively by intravenous hydration. Transient pulse loss after retrograde device delivery through a large braided duct occluder delivery system was seen in three patients and recovered after heparin.

Follow up

The follow-up was complete with a median follow-up duration of 6 months (range: 1.5–47 months). We did not notice any new onset complications such as valve regurgitation or rhythm disturbance during follow-up.

Table 2: Procedural details of patients

Parameters (*n*=57)	Mean±SD or (*n*)	Median or percentage	Range
Pulmonary arterial hypertension			
No	44	77.2	
Mild	8	14.0	
Moderate	2	3.5	
Severe	3	5.3	
Mean pulmonary arterial pressure (mmHg)	19.1±9.7	15	10–48
Approach used for device closure (all femoral access)			
Antegrade (from RV side, after arteriovenous loop via femoral vein)	12	21.1	
Retrograde (from LV side, via femoral artery)	45	78.9	
Delivery system used for device closure			
PDA delivery sheath	34	59.6	
The right coronary guide catheter	20	35.1	
Mullin's sheath	2	3.5	
ADO II delivery sheath	1	1.7	
Implanted device size (mm) (including all 57 cases)			
5×3	3	5.3	
6×4	4	7.0	
7×5	7	12.3	
8×6	16 (failure of device closure in 1 case)	28.1	
9×7	5	8.8	
10×8	8 (failure of device closure in 1 case)	14.0	
12×10	6	10.5	
14×12	8 (failure of device closure in 2 cases)	14.0	
Device characteristic			
Without PTFE membrane	30	52.6	
With PTFE membrane	27	47.4	
Device size changed from first selection			
Upsized	4/57	6.8	
Downsized	1/57	1.7	
Duration of procedure (min)	53.4±20.8	45	24–110
Fluoroscopy time (min)	11.1±6.5	10.1	2.4–26.3
Fluoroscopy dose (Gy)	116.2±67.5	107	20–302
Dose-area product (mGy.cm^2)	16,925.3±11,907.9	13,441	1102–42,309

SD: Standard deviation, LV: Left ventricle, RV: Right ventricle, PDA: Patent ductus arteriosus, ADO II: Amplatzer duct occluder II, PTFE: Polytetrafluoroethylene

DISCUSSION

Percutaneous closure of restrictive VSDs with suitable anatomy is an effective surgical alternative, unlike large defects that need surgical closure. ADO I and II are widely used for transcatheter VSD closure.[6] While ADO II has the advantages of low profile, low incidence of complications, and residual shunt, the sizes are limited, and the largest device diameter is 6 mm. ADO I has a wide variability of sizes but can be delivered only through the antegrade technique often after arteriovenous loop formation, which has inherent disadvantages in the method.[7] In this context, MFO offers multiple advantages.

Versatility of Konar-MF occluder

The device is available in various sizes, from 5 mm × 3 mm to 14 mm × 12 mm.[4]This allows the safe closure of relatively larger defects that otherwise require surgery. Device closure strikingly decreases hospital stay and surgical complications. Among 14 patients in our group with a considerably large defect (LV side >8 mm), 12 (85.7%) underwent successful device closure.

Ease of delivery

The unique design enables antegrade and retrograde delivery of MFO.[5] The retrograde technique significantly shortens the procedure time and radiation exposure, as arteriovenous loop formation can be avoided.[8,9] Incidence of procedural bradycardia, seen with antegrade technique during the passage of the long sheath across the defect into the ascending aorta, is also avoided. One limitation of the retrograde approach is the need for a relatively large arterial delivery sheath in small children. In such small patients, the procedure can be successfully completed with antegrade delivery of the same device. We used the retrograde technique in 78.9% of patients, resulting in an appreciably low rate of complications and a complete absence of atrioventricular nodal block or bradycardia.

Unique advantages of device profile

Medium profile and softer woven mesh allow the device to be easily adjusted to the shape of the defect. Low radial and clamping forces reduce the incidence of heart block due to reduced trauma, compression, or inflammation of the septum and the conduction system.[8] Another

commendable advantage is using a slender delivery system and thinner delivery cable. A 6 Fr guiding catheter that allows delivery of devices up to 10 mm × 8 mm in size is easy to maneuver from the arterial side compared to the much stiffer braided delivery system.[10] Our bench tests found compatibility with delivery sheath/guiding catheters smaller than the manufacturer's recommended sizes [Supplementary Table 1].

Ventricular septal defects closure in smaller children

With the distinct features of MFO (medium profile, wide range of sizes, screw attachment on both discs, and use of slender delivery sheath), the success rate and safety in smaller children are impressive. The feasibility of retrograde delivery avoids the inherent complications related to the splinting of small cardiac structures by arteriovenous loop formation. Other authors have reported successful VSD closure using MFO in infants [Table 4].[4,8,9,11,12] All infants except 1 (of 11) in our study had a successful closure; the unsuccessful attempt was in a patient with 4.2 kg body weight and 7.4 mm defect, despite adequate rims (patient 3). This highlights the importance of careful case selection in small children.

Procedural success

The procedural success rate was 93.0% in our series, which is comparable to other studies [Table 4]. The success rate was similar to that of ADO I (98.2%) and ADO II (98.0%).[4] The rate of complete shunt occlusion in our series immediately after the procedure, at 3 months and at 6 months of follow-up, was 86.8%, 98.1%, and 100%, respectively. None of our patients had a para-device residual flow on follow-up, owing to the selection of the device based on the size and shape of the defect, along with the presence of a septal aneurysm and subaortic rim.

Complications

According to the literature, the incidence of complete heart block (CHB) is very low with duct occluders: 0.7% for ADO I, which is very rare with ADO II.[9,13] In our experience, low radial and clamping force and increased flexibility of the soft MFO device contributed to avoiding postprocedural heart block. Even though there was no CHB in our series, it was reported earlier with MFO, with an incidence of 1%.[9] Hemolysis was rare with MFO compared to 1%–5% incidence with other occluders.[9] We had one patient (1.7%) with immediate postprocedure hemolysis. Slender delivery sheath/guide catheters contributed to the low incidence of vascular complications. We observed no major permanent vascular complication other than a transient pulse loss in three patients. Other researchers reported a 1% incidence of vascular complication (femoral hematoma).[9] Even though we referred the patient with the embolized device

Table 3: Outcome analysis, follow-up, and complications related to the procedure

Parameters	Number of patients	
	n or median	Percentage or range
Procedural success		
Successful closure	53/57	93.0
Failure of transcatheter closure with MFO	4/57	7.0
Complete occlusion of shunt		
Immediate	46/53	86.8
3-month follow up	52/53	98.1
6-month follow up	53/53	100
Duration of hospital stay in successful device closure (h)	36	24–51
Surgical VSD closure in the same admission	4/57	7.0
Complications		
Hemolysis (hemoglobinuria)	1/57	1.7
Transient pulse loss, immediate postprocedure	3/57	5.3
Pulse loss at 24 h	0/57	0
New onset or worsening aortic regurgitation		
Trivial to mild	3/57	5.3
Moderate warranting surgery	1/57	1.7
Significant tricuspid regurgitation, but not needing surgery	1/57	1.7
Heart block/AV block		
First-degree	0/57	0
Second-degree, transient, treated with steroids	1/57	1.7
Complete	0/57	0
Device embolization to RV	1/57	1.7
Heparin infusion for loss of pedal pulse (h)	5.5	3–13
Follow-up duration (months)	6	1.5–47
Follow-up duration for patients with RCC prolapse (months) (*n*=10)	10.5	6–38
Follow-up duration for patients with associated direct/indirect Gerbode defect (months) (*n*=12)	7	1.5–39
Patients with at least 3-month follow-up	49/53	92.4
Patients with at least 12-month follow-up	20/53	37.7
Lost to follow-up	0/53	0

MFO: Multifunctional occluder, VSD: Ventricular septal defect, AV block: Atrioventricular block, RCC: Right coronary cusp, RV: Right ventricle

Table 4: Comparison between demographic and procedural data of studies on ventricular septal defect closure with multifunctional occluder

Study	Total number of patients	Age, median (range)	Weight, median (range) kg	Size of VSD (on LV side) mm	MFO device used (mm)	Procedural success	Complications
Haddad *et al.*, 2020[11]	20	6.4 years (8 months – 43.4 years)	17.3 (9–74)	Mean 11.7±2.8	6×4–14×12, all sizes	95% (excluding 1 device embolization)	2 (10%) (embolization, AR)
Tanidir *et al.*, 2020[9]	98	3.8 years (5.4 months – 50 years)	15.3 (5.5–80)	Mean 10.1±3.4	5×3–14×12, all sizes	98%	Major - 4% (embolization, device dislocation, CHB) Minor – 10% (femoral hematoma, arrhythmia)
Fuente *et al.*, 2022[4]	7	14 (8–26) years	54 (23–64)	Mean 8.2±2.6	6×4, 7×5, 8×6, 12×10	86% (6/7)	2 (28.6%) (embolization, progression of preexisting AV block)
Kuswiyanto *et al.*, 2022[8]	132	4.5 (0.3–17.4) years	14.8 (3.5–57)	Median 4 (1–11)	5×3–14×12 all sizes	95.4%	Moderate TR - 4 (3%) Mild AR - 2 (1.6%) VF - 1 (0.7%) RBBB – 1 (0.7%) First-degree AV block - 2 (1.6%)
Sadiq *et al.*, 2022[12]	44	8 (1.7–36) years	20 (11–79)	Median 8 (4–13.4)	6×4–14×12, all sizes	100%	Major - 4.6% (device embolization, worsening of AR)

VSD: Ventricular septal defect, MFO: Multifunctional occluder, LV: Left ventricle, AR: Aortic regurgitation, TR: Tricuspid regurgitation, CHB: Complete heart block, AV block: Atrioventricular block, RBBB: Right bundle branch block, VF: Ventricular fibrillation

for surgical retrieval, the presence of a screw on both discs would facilitate a transcatheter retrieval.[8,9]

Closure of ventricular septal defects with aortic cusp prolapse

A soft, thin, low-profile nitinol mesh occluder such as MFO or ADO II would adapt itself to the moving leaflets of the aortic valve with minimal interference of the leaflet mobility, at least in the short term.[14] In addition, MFO devices smaller than 8 mm × 6 mm are very soft without any fabric, making them feasible to close PMVSDs associated with aortic cusp prolapse. We successfully closed VSD in 10 (out of 11) patients with right coronary cusp prolapse in this series, with no or trivial AR. Only one patient developed moderate AR after device positioning, and the procedure was abandoned. An aortogram through the side arm of the delivery sheath or guiding catheter before and after device release confirmed relatively unhindered movement of aortic valve cusps despite close proximity to the LV disc. There was no increasing or new onset AR on a median follow-up of 10.5 (6–38) months. Successful closure of VSD with aortic cusp prolapse and less than mild AR had been reported earlier using different devices.[8,14] Our short-term follow-up would indicate the safety of using MFO to close VSD in patients with mild aortic valve prolapse and less than mild AR. However, a long-term follow-up would be needed in such patients to ascertain the absolute safety of device closure, as delayed AR might occur with alterations in the stiffness of the device with progressive endothelialization and fibrosis of the leaflets.

Closure of ventricular septal defects with Gerbode defect

In direct or indirect Gerbode defects, device closure is often not considered a standard of care due to the close proximity to the conduction tissues. In our series, 10/11 (90.9%) indirect Gerbode and 2/2 (100%) direct Gerbode defects were successfully closed [Figure 2]. In one patient with an indirect Gerbode shunt, VSD was closed with a muscular VSD occluder device after failure with the largest MFO device. No complications were noted on a median follow-up of 7 (1.5–39) months. Longer duration follow-up would be required to assess the efficacy of transcatheter treatment. Closure of VSD with indirect Gerbode defect using ADO II and MFO device had been reported.[15,16]

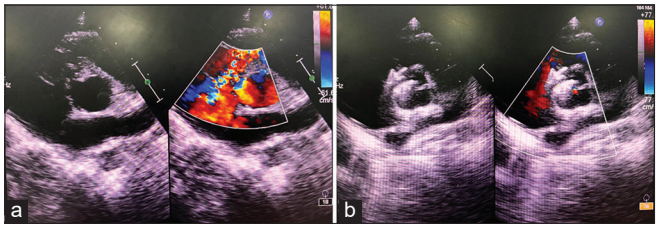

Figure 2: Transthoracic echo (parasternal short axis view) showing perimembranous ventricular septal defects with indirect Gerbode defect (a) closed with a 10 mm × 8 mm multifunctional occluder device through retrograde technique (b)

Disadvantages of Konar-MF occluder

Certain drawbacks of the device were recognized in our experience. When the RV disc was not aligned well with the ventricular septum, it interfered with the closure mechanism of the tricuspid valve, leading to severe TR in one of our patients. The device was less maneuverable as its LV disc was bulkier than ADO II. In cases where the subaortic rim was deficient, deployment of the left retention disc away from the aortic valve cusp was difficult, and this might result in significant AR if not deployed carefully.

Despite being a medium profile device, the large devices (12 mm × 10 mm and 14 mm × 12 mm) required big delivery systems that might lead to serious vascular complications in small children during a retrograde arterial approach.

CONCLUSIONS

Transcatheter closure of VSD with MFO is safe and effective. A wide spectrum of available device sizes facilitates the successful closure of perimembranous and membrane-muscular defects of various sizes in patients, including young children. Careful selection of device size and delivery system aids in successful closure with minimal vascular complications. Global availability of device-specific delivery sheaths (not available in India) by the manufacturer is expected to encourage the use of this occluder.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Supplementary Table 1: Smallest delivery sheath compatible with multifunctional occluder devices of different size according to our experience

Manufacturer recommended delivery sheath (Fr)	Konar-MFO size (mm)	Bench testing compatibility	
		Guide catheter (Fr)	Sheath (Fr)
4–5	5×3	5	4 (ADO II)
4–5	6×4	5	4 (PDA delivery)
4–5	7×5	5	4 (PDA delivery)
4–5	8×6	5	5 (PDA delivery)
6	9×7	6	5 (PDA delivery)
6	10×8	6	6 (PDA delivery, Mullin's sheath)
7	12×10	Not used	6 (PDA delivery)
7	14×12	Not used	6 (PDA delivery), 7 (Mullin's sheath)

MFO: Multifunctional occlude, ADO II: Amplatzer duct occluder II, PDA: Patent ductus arteriosus