

## Experiences of Two Centers in Percutaneous Ventricular Septal Defect Closure Using Konar Multifunctional Occluder

### ABSTRACT

**Background:** Transcatheter closure of perimembranous ventricular septal defect still poses a challenge due to the adjacent structures of the tricuspid and aortic valves and the risk of atrioventricular block. We report our experience at 2 centers using the KONAR-MF (multifunctional occluder) ventricular septal defect device, which gained its CE mark in May 2018.

**Methods:** A retrospective study was carried out on all patients who underwent transcatheter ventricular septal defect closure with the KONAR-MF (multifunctional occluder) ventricular septal defect device at 2 centers.

**Results:** A total of 47 patients were identified. The median age and weight of the patients were 25.8 months and 11 kg. The ventricular septal defects that were closed in 5 cases were post-operative hemodynamically significant residual ventricular septal defects. Forty-eight devices were used in the 47 cases. As for the location of the ventricular septal defect, 40/48 (83.33%) ventricular septal defects were perimembranous and 8/48 (16.66%) were muscular. The percutaneous device closure was successful in 46 procedures (95.8%). Device embolization was observed in 2 patients, and a significant residual shunt was observed in 2 cases. In the follow-up, there was no enhancement in the residual shunt in the remaining cases. Temporary atrioventricular block occurred in 2 cases during the procedure and improved after long sheath withdrawal.

**Conclusion:** Soft, flexible, and low-profile KONAR-MF (multifunctional occluder) occluders ensure easy and safe implantation, and small sheath sizes allow for their use in small infants. Although near and mid-term follow-ups did not indicate any permanent atrioventricular block, a larger sample of patients and a longer follow-up period is necessary to understand long-term outcomes.

**Keywords:** Atrioventricular block, percutaneous VSD closure, KONAR-MF (multifunctional occluder)

### INTRODUCTION

Since the first percutaneous closure of ventricular septal defect (VSD) was achieved by Lock et al.<sup>1</sup> transcatheter VSD closure has been considered as a treatment option for selected cases. With the development of many closure devices and deployment techniques, transcatheter VSD closure has been regularly performed at many centers recently.

The proximity of the defect to the aortic and tricuspid valves and the conduction system complicates the transcatheter closure of the perimembranous VSD (pmVSD). Specifically, a complete heart block poses an important problem.<sup>2,3</sup> Previously, several devices, both on-label and off-label, such as the Amplatzer pmVSD device, duct occluder devices (Amplatzer™ patent ductus arteriosus (PDA) devices [ADO I and II; St. Jude Medical, St. Paul, MN, USA]), and even the Amplatzer vascular plug-2, were used for the transcatheter closure of pmVSDs.<sup>4</sup>

Unfortunately, we do not have a device today that is suitable for every structure, which allows the procedure to be performed easily and without any complications. However, studies are continuing on new devices for these purposes. The

### ORIGINAL INVESTIGATION

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KONAR-MF (multifunctional occluder (MFO)) VSD device (Lifetech, Shenzhen, China) was first used in humans in 2013 and received the CE mark in May 2018. Here, we present our early- and mid-term results of percutaneous closure of pmVSD with the KONAR-MF (MFO) VSD device.

## METHODS

### Patient Selection

This study was developed by retrospectively examining patient data from 2 centers.

The records of all patients who had cardiac catheterization for VSD closure using the Lifetech KONAR-MF device at the 2 institutions were reviewed in detail. Patient demographics, features of the defect, procedural data, procedural outcome, complications, and follow-up data were recorded.

Ventricular septal defect was considered to be hemodynamically significant in patients with left heart chamber enlargement, findings of pulmonary hypertension, pulmonary Qp/Qs > 1.5, cardiomegaly on chest x-ray, and other symptoms, including frequent respiratory infections and/or failure to thrive and loss of weight. A left-to-right shunt was considered to be significant left atrial enlargement, defined as a left atrial to aortic ratio >1.5 on parasternal long-axis view, and left ventricular dilatation, defined as a left ventricular end-diastolic diameter  $\geq 2$  standard deviations.

In addition to the fact that the VSDs to be closed are hemodynamically important, patients with ventricular septal aneurysm, an aortic rim > 2 mm, and a VSD that is adequately separated in space from adjacent cardiac structures, including the aortic and tricuspid valves, were considered suitable for closure with a transcatheter MFO occluder. Aortic valve prolapse and aortic valve regurgitation is an accepted indication for VSD closure. Although transcatheter closure is controversial in these cases, we included them in the study unless there was severe aortic valve regurgitation.

## HIGHLIGHTS

- One of the most dreadful complications of transcatheter perimembranous ventricular septal defect (pm-VSD) closure is the complete atrioventricular (AV) block.
- Until now, no method or device has been reported to completely eliminate this complication.
- Light, soft, flexible, and low-profile devices are required to perform VSD closure percutaneously, especially for pm-VSDs, to prevent an AV block.
- KONAR-MF™ VSD occluder, which received CE mark approval in May 2018, was developed to decrease the incidence of an AV block.
- The previous results reported with this device appear gratifying.
- AV block was not encountered yet in the early period and in the short- to medium-term follow-up in this study.

Our exclusion criteria were an aortic rhythm < 2 mm, severe pulmonary artery hypertension and a right-to-left shunt, presence of any other associated congenital heart defects requiring cardiac surgery, more than mild aortic valve regurgitation, large defect requiring a device larger than 14/12, active bacterial infections or endocarditis or sepsis (local/generalized), patients with malalignment VSD.<sup>1,5-11</sup> Both of the institutions considered these criteria for VSD closure.

### Device

The KONAR-MF™ VSD occluder is made from double Nitinol wire (Figure 1). It is a self-expanding and low-profile device designed with 2 discs. Device sizes are categorized according to waist diameters: D2 from the left ventricle (LV) side and D1 from the right ventricle (RV) side of the device (Figure 2). There are 8 available sizes (5/3, 6/4, 7/5, 8/6, 9/7, 10/8, 12/10, and 14/12 mm) (Table 1). All devices have a 4-mm long waist. The device is delivered with a SteerEase™ introducer (Lifetech, Shenzhen, China), with sheath sizes ranging from 5F (for devices up to 8/6) to 6F or 7F for larger devices.



Figure 1. Lifetech KONAR-MF occluder.

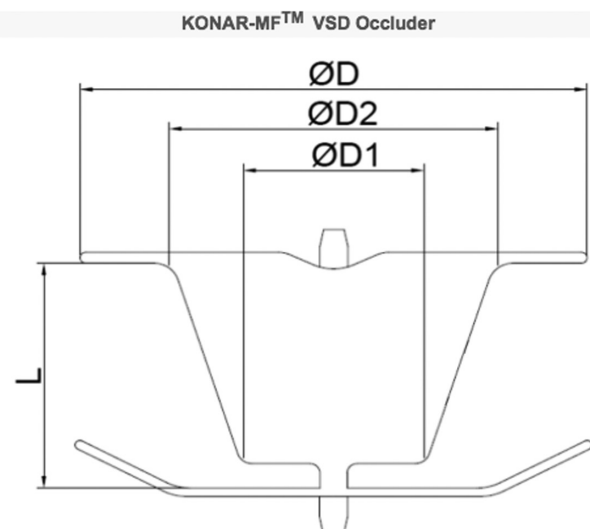


Figure 2. Lifetech KONAR-MF occluder.

**Table 1. Device Specifications**

Specification	D Disc	D1 Waist	D2 Waist	L Waist	Recommended Delivery Sheath (Fr.)	PTFE Membrane
	Diameter (mm)	Diameter RV Side (mm)	Diameter LV Side (mm)	Length (mm)		
MFO-5-3	10	3	5	4	4-5	No
MFO-6-4	10	4	6	4	4-5	No
MFO-7-5	12	5	7	4	4-5	No
MFO-8-6	12	6	8	4	4-5	No
MFO-9-7	14	7	9	4	6	Yes
MFO-10-8	14	8	10	4	6	Yes
MFO-12-10	16	10	12	4	7	Yes
MFO-14-12	18	12	14	4	7	Yes

MFO, multifunctional occlude; PTFE, polytetrafluoroethylene; LV, left ventricle; RV, right ventricle.

The waist of the 4 large models is securely stitched with a polytetrafluoroethylene (PTFE) membrane using nylon threads (9/7-14/12), while the 4 smaller models have no membranes (5/3-8/6). It can be screwed on both sides; therefore, its placement can be from the LV or RV, which means retrograde or antegrade.

It is known that it will also be effective in closing PDA, coronary or pulmonary artery fistula, or major aorto pulmonary collateral arteries (MAPCA).

### Procedure

Informed written consent was obtained from the guardians of all patients before intervention. Cardiac catheterization was performed under general anesthesia at both centers, with transthoracic (TTE) or transesophageal echocardiography (TEE) and fluoroscopic control. Procedures were performed according to the guidelines using either an antegrade approach or a retrograde approach.<sup>8,9</sup>

At both centers, interventionalist operators chose a retrograde approach, especially if the main goal is to close by covering the LV entry of the defect, the rims are sufficient, and if the tricuspid valve and leaflets give the impression (e.g., if the VSD aneurysm is very large and extends toward the tricuspid valve) that closing from the right side is not suitable. Another important point about retrograde approach is that this method can be applied in older children who can use 7-8 French arterial introducer. In some cases, the procedure was performed with an antegrade approach without forming an arteriovenous loop since the direct passage of the guidewire from the RV to the LV was possible with gentle manipulation.

Usually, when short introducer sheaths are used, venous access is on the right side and the arterial line is on the left side. Intravenous heparin and prophylactic antibiotic therapy using intravenous cefazolin were administered at the beginning of the procedure. Standard right and left cardiac catheterization, standard left ventriculography, and angiographies of the ascending aorta were performed in all cases, and VSD was visualized by left ventriculography (50-60 left anterior oblique and 20 cranial degrees) using a 5Fr pigtail catheter. Ventricular septal defect location, shape, size, and its relationship with adjacent aortic and tricuspid valves

were confirmed by utilizing intraoperative TTE or TEE. The LV entry diameter of the defect was measured on angiography, and the RV exit diameter or aneurysmal anatomy was evaluated on echocardiography.

At both centers, the device size was chosen as the defect size +2 mm (RV disc size) for muscular defects; for pm defects, the preferred device size should be the right ventricular side of the defect +2 mm. But if the devices' left ventricular disc (including rims) exceeds the left ventricular side of the defect or in cases with subaortic rim limited, the device size will be decreased to the same size or +1 mm of the right ventricular disc for pm defects. In cases with deep ventricular aneurysm or RV exit-to-LV entry diameters ratio > 0.5, the device was slightly oversized (RV side of the defect +2 mm) as long as the aortic rim is sufficient like in the study of Haddad et al.<sup>11</sup>

Two different approaches were used for device implantation, antegrade and retrograde. While using antegrade pathway, defect was crossed from the LV to the RV side using a 4- or 5-F Judkins right coronary catheter (Cordis Corporation, FL, USA), together with a hydrophilic guidewire, and advanced to the pulmonary artery or one of both caval veins. The wire was then snared to establish an arteriovenous circuit. An appropriate 5, 6, or 7Fr SteerEase™ delivery sheath, according to the size of the chosen device, was advanced from the right femoral vein, the right atrium, and the RV through the VSD into the LV or the ascending aorta. Under echocardiography and fluoroscopic monitoring, the device was advanced in the long sheath and then the distal disc was opened in the LV and withdrawn to the septum. After that, the proximal disc was opened, taking care to avoid any entrapment of the aortic valve with the disc of the device.

When using the retrograde route, the defect was crossed from the LV to the RV side using a 4 or 5F Judkins right coronary catheter (Cordis Corporation) together with a hydrophilic guidewire. Hydrophilic guidewire is placed on pulmonary artery. According to the size of the chosen device, an appropriate 5, 6, or 7F SteerEase™ delivery sheath was advanced to the RV over the wire. Under TEE and fluoroscopic monitoring, the delivery sheath pulled back and right disk was embedded in the RV. Then the entire system

(delivery cable and sheath) rests on the septum. After checking up with echocardiographic examination, left disk of the device was placed in the LV opening.

In another antegrade method, which we use while closing VSD, VSD was crossed from the RV using a 4 or 5F Judkins right coronary catheter (Cordis Corporation) together with a hydrophilic guidewire. Hydrophilic guidewire is placed on LV or descending aorta without an arteriovenous circuit. Then long sheath was advanced over hydrophilic guidewire from the right femoral vein, the right atrium, and the RV through the VSD into the left ventricular apex. The device was advanced in the long sheath and then the distal disc was opened in the LV and withdrawn to the septum. The proximal disc was then opened, taking care to avoid any entrapment of the aortic valve. Finally, the correct position was confirmed and the device was released. When this method is used, arterial access was used only for angiography to document defect size, during deployment, and following release of the device.

After the full deployment, shape, and position of the device, the residual shunt (RS) and valvular regurgitation were reassessed using different echocardiographic views, and a hand injection into the ascending aorta was performed to ensure that there was no problem intended for the aortic valve.

Patients in whom the procedure was uncomplicated were discharged the next day. Before discharge, all patients were subjected to clinical examination, 12 lead electrocardiogram (ECG), and echocardiography. All patients were placed on oral acetylsalicylic acid once daily for 6 months.

Follow-up echocardiography, ECG, and clinical examination were scheduled at 1 month, 3 months, 6 months, and every 12 months after the procedure. A residual shunt was defined as trivial (<1 mm color jet width), small (1-2 mm color jet width), moderate (2-4 mm color jet width), or large (>4 mm color jet width).

## RESULTS

### Patient Characteristics and Defect Features

Percutaneous closure of muscular or pmVSD using the Lifetech KONAR-MF device was attempted on 47 patients, 23 patients from the first center and 24 patients from the second center. Twenty-five (53.2%) of the cases were male, and 22 (46.8%) were female.

At the time of the intervention, the youngest case was 1.8 months old and weighed 4 kg; the patients' median age was 25.8 months (min 1.8 and max 200 months), and the median body weight was 11 kg (min 4 max 93 kg). Demographic characteristics and procedural data of the study population are summarized in Tables 2 and 3.

While VSD was isolated in 42 (89.3%) of the cases, PDA was observed in 1 patient, and pulmonary stenosis accompanied VSD in 4 cases. The VSDs that were closed in 5 cases were postoperative hemodynamically significant residual VSDs (double outlet RV in 1 patient, transposition of the great arteries in 2 patients, truncus arteriosus in 1 patient, and postsurgical VSD closure in 1 patient). One of the patients had 2 separate VSDs, and these VSDs were closed with 2 separate devices in the same session.

As for the location of VSDs, 40/48 (83.33%) of VSDs were perimembranous, 8/48 (16.66%) of VSDs were muscular.

When we examine the indications for VSD closure, 30 (63.8%) of the cases were with abundant shunt and Qp/Qs above 1.5, LV dilatation in 26 (55.3%) of them, and 12 (25.5%) cases complaining of failure to thrive. Some patients had 2 indications concurrently. The left ventricle end-diastolic dimension (LVEDD) z score of the study patients was  $+1.9 \pm 1.2$ , but when evaluated among those with large LVEDD, the z-score was  $+2.6 \pm 1.4$ . When we examine the cases with low weight or failure to thrive, the weight of 8 patients was at 3 percentile and the weight of 4 patients was at <3 percentile.

**Table 2. Patient Characteristics and Defect Features**

	Number	Mean $\pm$ SD (Minimum-Maximum) or n (%)	Median [IQR]
Total patient	47		
Male	25 (53.2%)		
Female	22 (46.8%)		
Age (month)		37.2 $\pm$ 38.11 (1.8-200)	25.8 [30.6]
Weight		13.7 $\pm$ 13.03 (4-93)	11 [5.7]
VSD types	48 VSD		
Perimembranous	40 (83.33%)		
Muscular	8 (16.66%)		
VSD size	LV side	6.63 $\pm$ 1.98 (3-11)	6.5 [2.6]
	RV side	5.42 $\pm$ 1.8 (2.3-10.5)	5 [1.6]
VSA		16 (40%)	
Aortic overriding		9 (23.6%)	
Aortic valve prolapse		4 (10.5%)	
Aortic insufficiency	Trace	4 (10.5%)	
	Mild	4 (10.5%)	

SD, standard deviation; IQR, interquartile range; VSD, ventricular septal defect; LV, left ventricle; RV, right ventricle; VSA, ventricular septal aneurysm.

**Table 3. Procedural Features**

	Number	Mean $\pm$ SD (Minimum-Maximum) or n (%)	Median [IQR]
Total procedure	48		
Mean PAB		21.8 $\pm$ 6.76 (10-36)	21 [7.5]
Q <sub>p</sub> /Q <sub>s</sub>		1.8 $\pm$ 0.6 (1.5-3.2)	1.8 [2]
Device size		8.8 $\pm$ 1.45 (6-12)	9 [2]
Procedure time (min)		48.6 $\pm$ 32.6 (20-135)	36 [41]
Route used during the procedure			
Antegrade35 (73)			
Antegrade without AV looping14 (40)			
Retrograde13 (27)			
Fluoroscopy time (min)		21.1 $\pm$ 14.2 (5-65)	20 [13]
Success rate	46 (95.8)		

SD, standard deviation; IQR, interquartile range; VSD, ventricular septal defect; LV, left ventricle; RV, right ventricle; RA, right atrium; PAB, pulmonary artery pressure.

### Procedural Features and Outcomes

On echocardiographic examination, the defect of LV entry had a median diameter of 6.5 mm (min 3 max 11 mm), and on the right ventricular side, the median diameter was 5 mm (min 2.3 max 10.5). Median size of the devices used was 9  $\times$  7 mm (min 6  $\times$  4 mm max 12  $\times$  10 mm).

Forty-eight devices were used in 47 cases. Since 2 separate defects were closed in 1 case, 2 separate devices were implanted.

Forty of these patients had pmVSD, 16 of whom had aneurysm tissue. There was aortic overriding in 9 cases, aortic valve prolapses in 4 patients, and related aortic regurgitation in 8 patients before the procedure (Figure 3).

While the mean pulmonary artery pressure was 21.8  $\pm$  6.76 mmHg (min 10 mmHg and max 36 mmHg), the pulmonary artery pressure of a patient who had residual and additional apical VSD was close to the systemic level. Q<sub>p</sub>/Q<sub>s</sub> ratios detected in the study was 1.8  $\pm$  0.6 (min 1.5 max 3.2).

The antegrade route was used in 35 (73%) out of 48 procedures, and the retrograde route was utilized in the remaining 13 (27%) procedures. It was possible to pass directly from the RV to the LV without making an arteriovenous loop in 14 (40%) procedures using an antegrade approach.

Percutaneous device closure was successful in 46 procedures (46/48; 95.8%). There was no difference in terms of complication rates between those under the age of 1 year and those who were 1-year-old and above ( $P > .05$ ).

Device embolization was observed in 2 cases. The procedure failed in 2 cases after the device fell into the RV and the defect was surgically closed. Age and weight of the children on whom VSD closure was performed surgically were 48 and 16 months and 15 and 11 kg, respectively. Ventricular septal defect type in both cases was pm, and the LV side of the VSD was 6 mm and the other was 10 mm. There were no ventricular septal aneurysms in either of the VSDs, but aortic overriding occurred in these patients. Device sizes used in these children were 8  $\times$  6 mm and 12  $\times$  10 mm.

Temporary atrioventricular (AV) block occurred in 2 cases during the procedure and improved after long sheath withdrawal. Age and weight of these children were 6.5 and 10.3 months, and 4 and 8.7 kg, respectively. One of these children was operated on for the transposition of great arteries. Ventricular septal defect types of these defects were pm. Defect sizes were 7 and 5 mm. One patient had a ventricular septal aneurysm. There was no aortic overriding or aortic valve prolapses. Device sizes used in these children were 10  $\times$  8 mm and 8  $\times$  6 mm.

Residual shunts were evaluated in 45 patients, as 2 cases required surgical intervention in the same session due to failure of the procedure. While no RS was observed in 21 (46.6%) cases after the device was released, there was a RS inside the device in 22 patients (trivial in 12 cases, mild in 9 cases, and medium in 1 patient), and significant RS was observed in 2 patients. Surgical VSD closure was performed for these 2 patients 2 days and 7 days after the procedure due to RS and device malposition, and 1 of these 2 patients had concurrently significant tricuspid valve insufficiency.

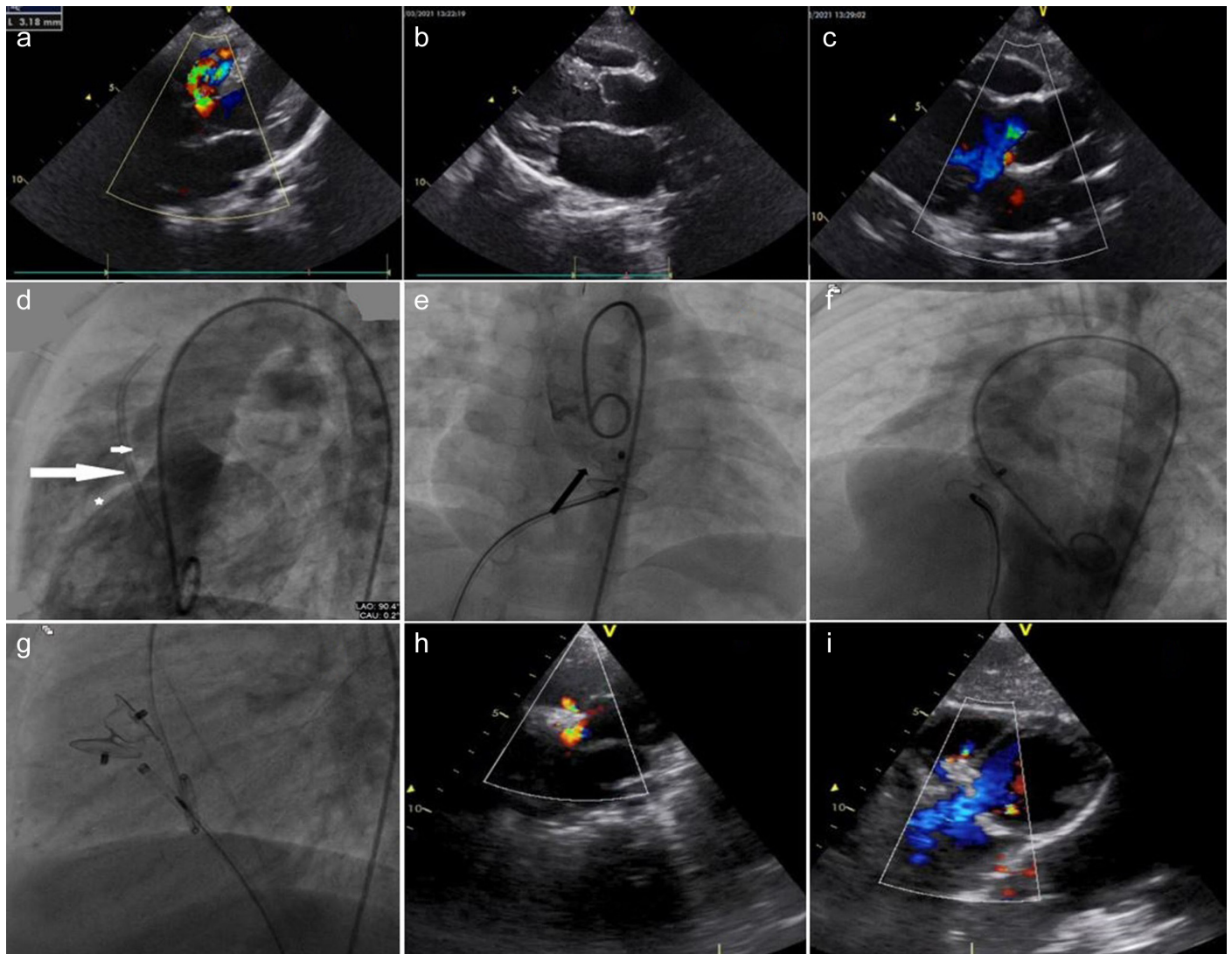
Significant tricuspid valve regurgitation occurred after the device was released in 1 patient. This patient underwent surgical intervention, as previously mentioned.

As an additional procedure, PDA closure was necessary in 1 case, and pulmonary stenosis balloon valvuloplasty was required in 3 cases.

The median procedure time was 36 minutes (min 20 minutes and max 135 minutes); the median fluoroscopy time was 20 minutes (min 5 minutes and max 65 minutes). The patient, who prolonged the duration of the procedure and fluoroscopy time, was the patient in whom 2 separate VSDs were closed in the same session. Complications and follow-up results are summarized in Table 4.

### Follow-up

Median follow-up time of the patients was 16 months (min 1 max 36 months). There were no major vascular access-related complications or procedure-related mortality.



**Figure 3. (A) Color flow image of the defect shunt in a patient with perimembranous outlet and aortic overriding, respectively, on echocardiographic imagination. (B) Marked overriding of the aortic valve. (c) Color flow image of mild regurgitation of aortic valve. (D) Interventricular septum (star) in left ventricular injection, view of the right cusp of the aortic valve overriding the septum (short arrow), and left-to-right shunt due to defect (long arrow). (E) Right aortic cusp is jailed by the device (black arrow). (F) Recovering the right aortic cusp by redeployment. (G) Post-release images of the device in catheter angio. (H) A passage from the center of the device and trace-mild valve insufficiency in modified 5-chamber imaging. (I) Left ventricular outflow tract image without obstruction.**

Device-related infective endocarditis, late device erosion, and thromboembolism were not observed during the follow-up period.

In the follow-up, there was no enhancement in the RS; RS disappeared in 5 cases (even medium grade) and was reduced in 1 case from mild to trivial. Final RS was appraised on 43 patients since 4 patients were excluded due to surgical closure. Consequently, there was no RS in 26 (60.4%) cases, and a trivial residual shunt was observed in 17 (17/43; 39.6%) cases. To summarize that complete occlusion rates early after in cath lab by angiography on the next day, 1 month, and 3 months was 46.6%, 48.8%, 51.1%, and 60.4% on final echo control.

There were aortic valve prolapse and trivial aortic regurgitation in 8 cases before the procedure and trivial aortic regurgitation in 2 cases after the procedure, but in these cases, no increase was observed in valve insufficiency and aortic regurgitation reduced and turned from mild to trivial in 2 cases.

No significant increase in tricuspid valve insufficiency was observed during the follow-up, except in 1 patient who was subjected to surgical intervention.

The patients who underwent surgery due to device embolization (2 cases), significant tricuspid valve insufficiency and device malposition (1 case), and the other significant RS

**Table 4. Complications and Follow-Up Results**

		Mean $\pm$ SD (Minimum-Maximum) or n (%)	Median [IQR]
Complications	Total	5 (10.4)	
	Device embolization	2 (4.1)	
	Temporarily CAVB	2 (4.1)	
	Non-sustained VT	1 (2)	
Follow-up (month)		15.3 $\pm$ 8.22 (1-36)	16 [9]
Aortic insufficiency	New onset	2 (2.7)	
Tricuspid insufficiency	After procedure	1	
Surgical intervention		2 (4.16)	
Residual shunt	Total	24 (53.3)	
	Trivial	12 (50)	
	Mild	9 (37.5)	
	Moderate	1 (4.2)	
	Severe	2 (8.3)	
Final Residual shunt	Total	17	
	Trivial	17	

CAVB, complete atrioventricular block; VT, ventricular tachycardia.

(1 case) were discharged from the hospital after a short time from the operation and no complications were encountered in the follow-up.

One of the cases, whose temporary block improved after long sheath withdrawal, had non-sustained ventricular tachycardia and it was recovered with medical treatment.

In the follow-up, the rate of freedom from surgical and/or transcatheter reintervention and going without an event (in the new event after procedure, only 2 new onset trivial aortic regurgitations were seen) was  $97 \pm 3.83\%$  at the end of 1.5 months,  $88 \pm 6.71\%$  at the end of the sixth month, and  $73 \pm 10.08\%$  at the end of the follow-up (Figure 4). No significant difference between those with and without aortic overriding was found in the follow-up in terms of not requiring reintervention and a lack of complications (Figure 5).

## DISCUSSION

Light, soft, flexible, and low-profile devices are required to perform VSD closure percutaneously, especially for PmVSDs, to prevent an AV block. The new KONAR-MF™ VSD occluder, which received CE mark approval in May 2018, was produced for this purpose. Due to regulations, only devices with CE certificates can be used in our country.

KONAR-MF™ VSD occluder can be used in residual VSDs, as well as in muscular and pmVSD. It is known that it will also be effective in closing PDA, coronary or pulmonary artery fistula, or MAPCA. In this study, the procedure success rate was 95.8%. By using the KONAR-MF™ VSD occluder, procedural success was 98% in Tanidir et al<sup>10</sup> and 100% in Haddad et al.<sup>11</sup> These results are comparable to those of other studies using conventional double-disc devices (such as Amplatzer Membranous VSD Occluder),<sup>12</sup> off-label devices (such as Amplatzer Duct Occluder and Amplatzer Duct Occluder II),<sup>13-15</sup> and new specific VSD closure devices (such as Nit-Occlud LÊ VSD Coil)<sup>16</sup> for PmVSD closure.

The average age and weight of our study subjects are smaller than in other studies; therefore, we have shown that this device can be used even in children as young as 1.8 months and as small as 4 kg. SteerEase™ introducer (Lifetech), with sheath sizes ranging from 5F (for devices up to 8 $\beta$ ) to 6F or 7F for larger devices, allows for use in small infants.

Tanidir et al<sup>10</sup> reported device embolization in 2% of cases with the KONAR-MF™ VSD occluder, and Haddad et al<sup>11</sup> reported that 1 device embolized after 24 hours. In this study, the device fell into the RV in 2 patients (4.1%) during the procedure. These cases had high risks for transcatheter VSD closure due to defect localization or an aortic rim < 2 mm. On the other hand, the other reasons may be underestimation of the defect and inappropriate device size or problems in the device deployment technique.

As for RS rates in the literature, the incidence of RS was 8% in study conducted by Tanidir et al,<sup>10</sup> and in the study conducted by Haddad et al<sup>11</sup> the complete occlusion rate was 40.0% (8/20) at the end of the procedure, rising up to 57.9% (11/19) before discharge and to 84.2% (16/19) at the sixth month of the follow-up. In this study, while no RS was observed in 21 (46.6%) cases before discharge, there was RS inside the device in 22 patients and significant RS in 2 patients. Hence, surgery was performed for a significant residual VSD shunt in 2 patients. No further intervention was required in most cases due to insignificant RS. Complete occlusion rate rose to 60.4% on the last echocardiographic control. The 4 large models were securely sewn with a PTFE membrane using nylon threads to increase their occlusion capacity, while the 4 smaller models had no membrane inside. This means that the risk of RS is more likely in smaller models. However, it has been shown in the literature and in our study that these RS decrease over time.<sup>10,11</sup> It would be appropriate to perform infective endocarditis prophylaxis for 6 months after the procedure and in residual defects as long as the RS remains. Prophylaxis requirement in patient with RS is a handicap of the device.

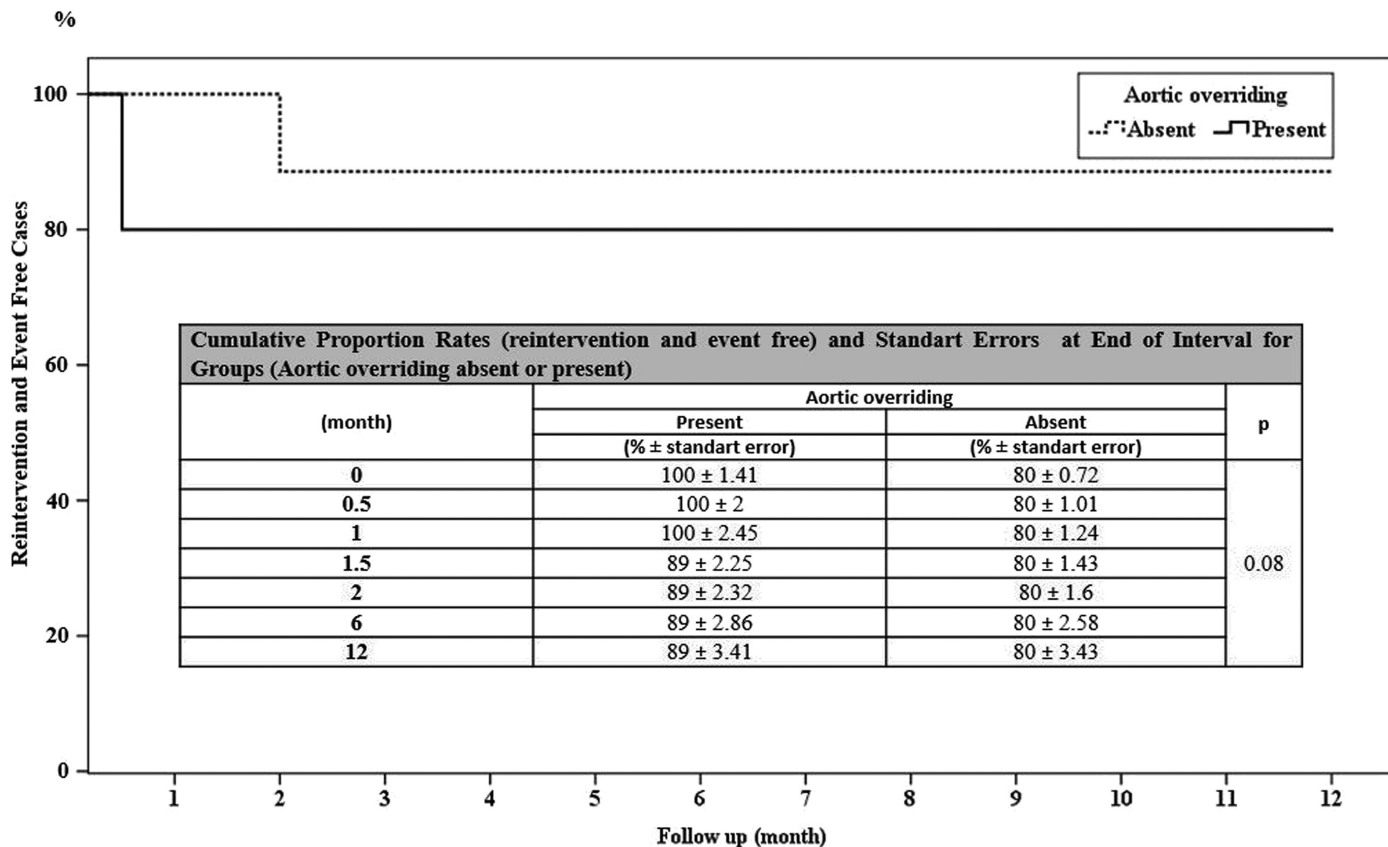


Figure 4. Time and intervention relationship.

It is known that in oversized devices, significant direct mechanical trauma caused by the delivery system or device deployment during the procedure has an effect on the development of early-onset AV block whereas late AV block may be due to fibrosis, compression, or inflammation of the conduction system.<sup>17</sup> Furthermore, it has been suggested

that smaller infants might be at a higher risk for AV block after percutaneous closure of VSD.<sup>18</sup> It may be reversible with medication or may become persistent and require permanent pacemaker insertion. The conventional PmVSD occluders have a big delivery system for large profile devices, whereas the KONAR-MF VSD device can be used through a

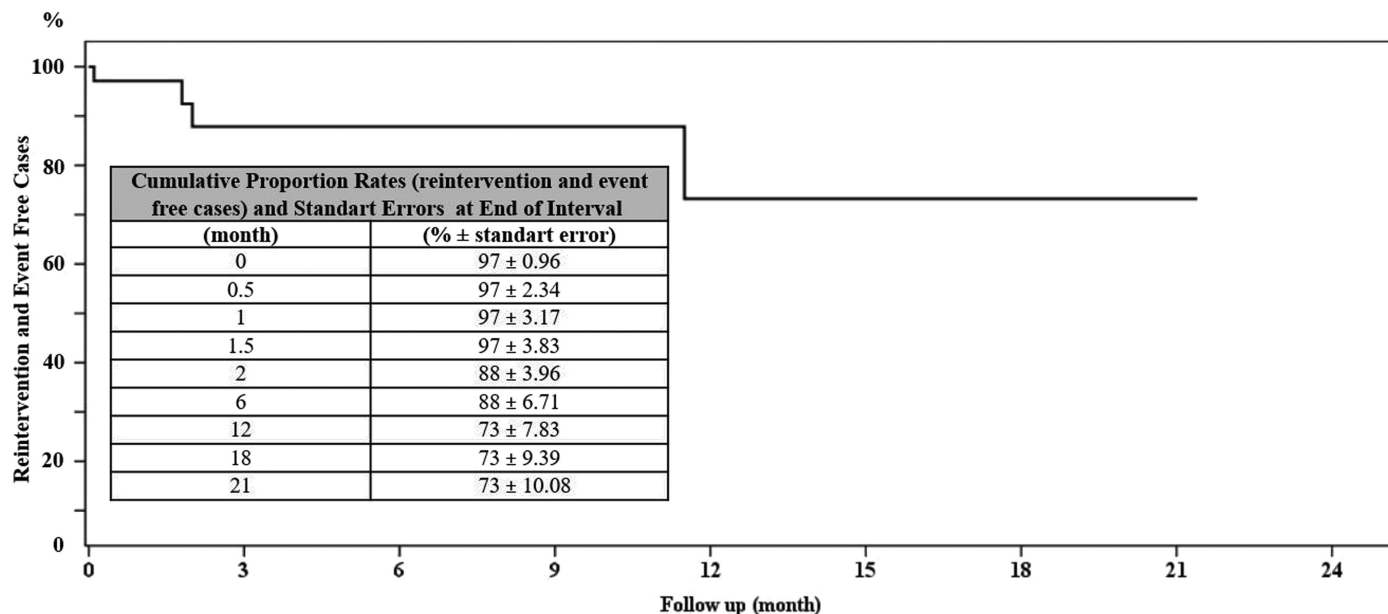


Figure 5. Aortic overriding and reintervention relationship.



4-7 Fr sheath or guiding catheter with a 1.15-1.8-inch inner lumen.<sup>19</sup> Haddad et al<sup>11</sup> reported no cases of complete heart block or rhythm disturbance. Tanıdır et al<sup>10</sup> reported temporary AV block in 2 cases during the procedure, which improved after the long sheath withdrawal, and no patients required a permanent pacemaker. Although the patient population in our study had a lower age and weight compared to other studies, temporary short-term AV block was observed in 2 patients; one of these cases with temporary block and ventricular tachycardia recovered with medical treatment, and none of the patients in our study required a permanent pacemaker. However, families have been informed about the middle- and late-period risks of AV block, and patients are followed up with close ECG and Holter examinations.

Aortic regurgitation and tricuspid regurgitation are other feared complications of this procedure. Haddad et al<sup>11</sup> reported that right disk positioning was continuously evaluated on echocardiography, and in the case of any sign of tricuspid valve interference, the right disk was recaptured into the sheath and then pulled back as close as possible to the septum before full deployment. They reported that they did not experience any tricuspid regurgitation at the end of the procedure or during the follow-up period. Tanıdır et al<sup>10</sup> reported in their study that they encountered only one patient with moderate tricuspid insufficiency (1%). In this study, the device was implanted by checking whether the right disk had contact with the tricuspid valve using a transesophageal echo examination during the procedure. Significant tricuspid insufficiency with device malposition was observed in 1 case, and surgery was performed 7 days after the procedure. It was understood that the tricuspid valve septal leaflet was entrapped in the device rim in this case.

As for aortic valve insufficiency, it was observed in only 1 patient in Haddad et al<sup>11</sup> and mild aortic insufficiency was observed in 1 patient in a study conducted by Tanıdır et al.<sup>10</sup> In cases where the subaortic rim is thought to be insufficient, the risk of aortic regurgitation is of concern. Devices were chosen considering the left retention disk diameter, and in defects with aneurysms, the device was slightly oversized, or else the device could be easily deployed into the aneurysm. In these cases, the antegrade transvenous approach was preferred to control the aortic valve and left retention disk contact. In this study, trivial aortic regurgitation was observed in 2 cases after the procedure, but there was no enhancement insufficiency in the follow-up.

According to our mid-term results, transcatheter VSD closure using the KONAR-MF™ VSD occluder is feasible, safe, and reproducible. With careful defect sizing, proper device selection, and experienced operators, the procedural success rate will increase.

#### Limitations of Study

This is a retrospective study with the limited number of patients. Furthermore, the follow-up duration of study is not long enough to evaluate long-term consequences. Although

we have experience with previously used devices in VSD closure, our experience on this new device, its features, and implementation on closing VSD is novel.

#### CONCLUSION

This low-profile, multipurpose sleek device with 8 available sizes provides an acceptable closure rate, and small sheath sizes allow for their use in small infants. The MFO occluders with a small delivery system provide easy and safe implantation. As patient safety is a priority, surgical VSD closure should be kept in mind for difficult cases.

**Ethics Committee Approval:** The study is evaluated by the Local Ethics Committee. Ethical Statement number is 605 (Istanbul Medipol University, Decision date: 03/06/2021).

**Informed Consent:** The study is retrospectively designed. For this type of study, formal consent is not required.

**Peer-review:** Externally peer-reviewed.

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