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ORIGINAL ARTICLE / ÖZGÜN MAKALE

Optimized retrograde approach and device selection with Konar-MF™ for pediatric transcatheter ventricular septal defect closure

Konar-MF™ ile pediatrik transkateter ventriküler septal defekt kapatmada optimize retrograd yaklaşım ve cihaz seçimi

Gamze Vuran[1], Murat Muhtar Yılmazer[1], Mehmet Murat[1], Ceren Karahan[1], Mertkan Bilen[1], Mustafa Karaçelik[2], Timur Meşe[1]

Author Affiliations:

[1]Department of Pediatric Cardiology, University of Health Sciences, İzmir Dr. Behçet Uz Pediatric Diseases and Surgery Training and Research Hospital, İzmir, Türkiye

[2]Department of Pediatric Cardiac Surgery, University of Health Sciences, İzmir Dr. Behçet Uz Pediatric Diseases and Surgery Training and Research Hospital, İzmir, Türkiye

ABSTRACT

Background: This study aims to evaluate the mid-term outcomes of transcatheter ventricular septal defect closure with the Konar-MF™ device and to investigate the impact of an optimized device selection strategy using a retrograde approach.

Methods: Between January 2019 and November 2023, a total of 58 patients (32 males, 26 females; median age: 4.5 years; range, 8 months to 16 years) who underwent transcatheter closure of ventricular septal defects using the Konar-MF™ device were retrospectively analyzed. Patient demographics, procedural details, and follow-up data were recorded.

Results: Procedural success was achieved in 95% of cases, with a median procedure time of 60 min and fluoroscopy time of 12.6 min. Retrograde implantation was used in 79% of patients, significantly reducing procedural time and minimizing complications associated with an arteriovenous loop. Our refined strategy of selecting smaller devices when anatomically feasible played a crucial role in reducing interference with surrounding cardiac structures, substantially contributing to the absence of complete atrioventricular block in our cohort. Major complications included device embolization, moderate aortic regurgitation due to device dislocation, and right ventricular perforation (each in 1.8% of patients). The median follow-up was 34.5 months. Residual shunt rates were initially 42% on postoperative Day 1, reducing to 1.8% by the end of the follow-up period.

Conclusion: The Konar-MF™ occluder demonstrated high procedural success and acceptable complication rates for perimembranous ventricular septal defect closure. The use of a retrograde approach and a refined device selection strategy were key factors in achieving favorable outcomes, minimizing complications such as atrioventricular block and valve interference. The device offers significant advantages, making it a suitable alternative to surgical ventricular septal defect closure.

Keywords: Konar-MF, pediatric, transcatheter closure, ventricular septal defect.

ÖZ

Amaç: Bu çalışmada Konar-MF™ cihazı ile yapılan transkateter ventriküler septal defekt kapatılmasının orta dönem sonuçları değerlendirildi ve retrograd yaklaşımla optimize edilmiş cihaz seçimi stratejisinin etkisi araştırıldı.

Çalışma planı: Ocak 2019 - Kasım 2023 tarihleri arasında Konar-MF™ cihazı kullanılarak transkateter ventriküler septal defekt kapatılması uygulanan toplam 58 hasta (32 erkek, 26 kız; medyan yaş: 4.5 yıl; dağılım, 8 ay-16 yıl) retrospektif olarak incelendi. Hastaların demografik özellikleri, işlem detayları ve takip verileri kaydedildi.

Bulgular: İşlem başarısı olguların %95'inde elde edildi ve medyan işlem süresi 60 dk. ve floroskopi süresi 12.6 dk. idi. Hastaların %79'unda retrograd implantasyon yapıldı ve bu yöntem işlem süresini anlamlı düzeyde kısaltıp, arteriovenöz loop ile ilişkili komplikasyonları en aza indirdi. Anatomik olarak uygun durumlarda daha küçük cihazların tercih edilmesi, çevredeki kardiyak yapılarla etkileşimi azaltarak hasta grubumuzda tam atriyoventriküler blok oluşumunun önlenmesine önemli katkı sağladı. Majör komplikasyonlar cihaz embolizasyonu, cihaz yer değişimine bağlı orta derecede aort yetersizliği ve sağ ventrikül perforasyonu (her biri %1.8 hastada) idi. Medyan takip süresi 34.5 ay idi. İşlem sonrası birinci günde rezidüel şant oranı %42 iken, takip dönemi sonunda bu oran %1.8'e geriledi.

Sonuç: Konar-MF™ oklüder cihazı, perimembranöz ventriküler septal defekt kapatılmasında yüksek işlem başarısı ve kabul edilebilir komplikasyon oranları ile öne çıkmıştır. Retrograd yaklaşımın kullanımı ve optimize edilmiş cihaz seçimi stratejisi, atriyoventriküler blok ve kapak yetersizliği gibi komplikasyonların en aza indirilmesinde kilit faktörler olmuştur. Cihaz, cerrahi ventriküler septal defekt kapatılmasına uygun bir alternatif olarak önemli avantajlar sağlamaktadır.

Anahtar sözcükler: Konar-MF, pediatrik, transkateter kapatma, ventriküler septal defekt.

Corresponding author: Gamze Vuran.
E-mail: gamzetalay@hotmail.com

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Ventricular septal defects (VSDs) are the most common congenital heart defects in children, accounting for more than 20% of all congenital heart diseases.[1] The ongoing search for effective transcatheter closure techniques has led to the development of various devices specifically designed to address these defects. However, transcatheter approaches have historically faced challenges, particularly in the closure of perimembranous VSDs (PMVSDs), due to the complex anatomical features associated with these defects. The Amplatzer™ (Abbott Cardiovascular, IL, USA) asymmetrical membranous VSD device was initially praised for its specialized design, but its widespread use was limited by the high risk of complete heart block associated with the procedure.[2] Although alternative devices, such as the Nit-Occlud® Lê VSD-Coil (BVM Medical Ltd., UK), have been introduced, the closure of PMVSDs continues to pose challenges due to anatomical variability and the proximity of these defects to critical cardiac structures.

In this context, the LifeTech Multifunctional Occluder (Konar-MF™) has emerged as a promising option. Approved by the CE in 2018, this device offers a flexible, hybrid design that allows both antegrade and retrograde deployment through a small sheath. Its unique construction is aimed at minimizing potential damage to surrounding structures and reducing the risk of complications, such as complete heart block. Nevertheless, comprehensive data on the efficacy, safety, and long-term outcomes of the Konar-MF™ device remain limited.

This study aims to evaluate the mid-term outcomes of transcatheter VSD closure using the Konar-MF™ device, with a focus on its effectiveness and clinical relevance. While the device offers several advantages, such as flexible deployment and a reduced risk of complications, it is important to acknowledge the challenges posed by anatomical variations and the learning curve associated with mastering its technique. In the present study, we aimed to uniquely investigate the combined benefits of retrograde approach and tailored device selection, filling a gap in the current literature on pediatric VSD closure.

PATIENTS AND METHODS

This single-center, retrospective study was conducted at University of Health Sciences, İzmir Dr. Behçet Uz Pediatric Diseases and Surgery Training and Research Hospital, Department of Pediatric Cardiology between January 2019 and November 2023. Patients with hemodynamically significant VSDs, as evidenced by a left ventricular (LV) end-diastolic diameter Z-score ≥2 on echocardiography, were included in the study. Clinical significance was determined based on factors such as a history of recurrent respiratory infections, symptoms of heart failure (including dyspnea, fatigue, and edema), and evidence of growth retardation. These clinical indicators were used to ensure that the selected patients presented with VSDs severe enough to warrant intervention. Patients with PMVSD and significant aortic valve prolapse, moderate-to-severe aortic regurgitation (AR), a subaortic rim <2 mm without aneurysm, severe pulmonary hypertension (>8 Wood units × m^2), or a right-to-left shunt were excluded. A total of 58 patients (32 males, 26 females; median age: 4.5 years; range, 8 months to 16 years) who underwent transcatheter closure of VSDs at our center were included. All hemodynamic outcomes and procedural data were meticulously collected and analyzed retrospectively from our catheterization archives. This included detailed recordings of each patient's pre-procedural cardiac function, defect morphology, procedural duration, fluoroscopy times, and immediate post-procedural outcomes. Written informed consent was obtained from the parents and/or legal guardians of the patients. The study protocol was approved by the University of Health Sciences, İzmir Dr. Behçet Uz Pediatric Diseases and Surgery Training and Research Hospital Ethics Committee (Date: 24.02.2022, No: 673). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Device selection

As supported by previous studies[3,4] and information provided by the manufacturer, for PMVSDs, we initially selected a device where the right ventricular (RV) disk was 1 to 2-mm larger than the measured defect size on the RV side. This approach aimed to ensure complete closure while accommodating potential anatomical variations. Although this sizing strategy was effective in cases with conical defects and sufficient aortic rims, it occasionally led to interference with the aortic valve or tricuspid apparatus. As we gained more procedural experience, we refined our device selection strategy, and in later cases, we typically selected a device size only 0.5 to 1-mm larger than the RV measurement. In some patients with severely deficient aortic rims, we even opted for a device size equal to the RV measurement. This more individualized approach was particularly useful in

defects involving septal aneurysms, which often presented with multiple openings on the RV side. In these cases, the width of the aneurysm was carefully considered during device selection to ensure optimal filling while minimizing contact with the heart valves, thereby facilitating the use of smaller devices, even in complex defects.

For muscular VSDs, we applied a similar strategy, typically selecting a device size with a 0.5 to 1-mm margin on the RV side, which was sufficient to achieve complete closure while preventing unnecessary extension into adjacent structures.

Interventional procedure

All procedures were performed under general anesthesia or deep sedation, chosen based on patient age, health, and defect complexity, with general anesthesia favored for younger children and longer procedures. Prior to device deployment, a comprehensive assessment of the VSD was conducted to determine the defect's diameter, morphology, location, and its relationship with critical surrounding structures, such as the aortic and tricuspid valves. In the first three patients, transthoracic echocardiogram (TTE) and transesophageal echocardiogram (TEE) were used to map the defect and plan the closure. For later cases, TTE alone proved sufficient. To further guide the procedure, left ventriculography was performed using precise angiographic angles, tailored to the type of defect being addressed.

Although the traditional approach for VSD closure has primarily relied on the antegrade route, the Konar-MF™ device's adaptability for both antegrade and retrograde approaches necessitates a distinct strategy. The retrograde approach, which involves advancing the device from the femoral artery to position it from the LV side of the defect, provides a more direct route and eliminates the need for atrioventricular (AV) loop formation. This approach is preferred for both perimembranous and muscular defects, making the procedure more efficient and straightforward. However, in cases with defects located close to the aortic valve or with mild aortic valve prolapse, the antegrade route can be more advantageous. Additionally, when access from the RV side is favorable, the device can be implanted directly via the antegrade route without the need for AV loop formation. Once the device was positioned, its placement was thoroughly confirmed using TTE before release to ensure that it was appropriately aligned with the defect and that there was no impingement on surrounding structures, such as the aortic or tricuspid valves. After the device was released, additional post-release assessments were conducted using a combination of TTE, left ventriculography, and aortography. Aortography was also employed in some cases to specifically check for any new or worsened aortic regurgitation (Figure 1, Videos 1 and 2).

Follow-up protocol

On the first day after the procedure, each patient underwent a comprehensive evaluation that included a 12-lead electrocardiogram (ECG), echocardiography, and chest radiography.

Follow-up visits were scheduled at one, three, six, and 12 months after the procedure. During these visits, repeat ECG and echocardiography were performed. Following the first year, patients continued to undergo annual evaluations, ensuring sustained surveillance for potential late complications.

In cases where early post-procedural symptoms or ECG findings suggested arrhythmia or conduction disturbances, we employed 24-h Holter monitoring. Even in patients without evident arrhythmias, Holter monitoring was routinely performed at one to two years post-procedure to ensure there were no asymptomatic, but clinically significant rhythm disturbances.

All patients were prescribed low-dose acetylsalicylic acid (3 to 5 mg/kg/day) for six months to prevent thromboembolic events during the critical endothelialization phase of the device.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 26.0 software (IBM Corp., Armonk, NY, USA). Continuous variables were expressed in mean ± standard deviation (SD) or median and interquartile range (IQR), while categorical variables were expressed in number and frequency. Continuous variables were assessed for normality using the Kolmogorov-Smirnov test. For comparisons between antegrade and retrograde approaches, categorical variables were analyzed using the chi-square or Fisher exact test, where applicable. Continuous variables were compared using the Mann-Whitney U test due to non-normal distribution. A cumulative sum (CUSUM) analysis was performed to assess the procedural learning curve. The CUSUM chart was constructed based on the occurrence of procedural failure and major complications which enables the

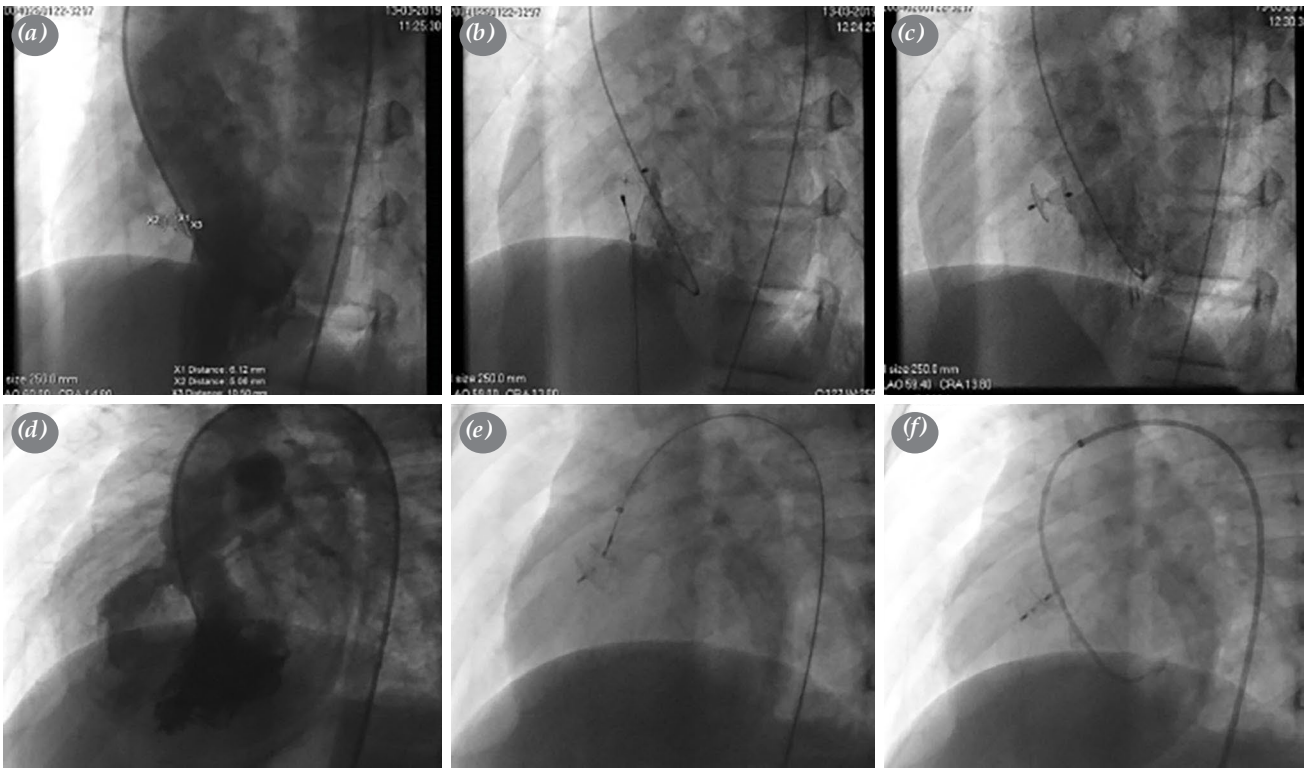
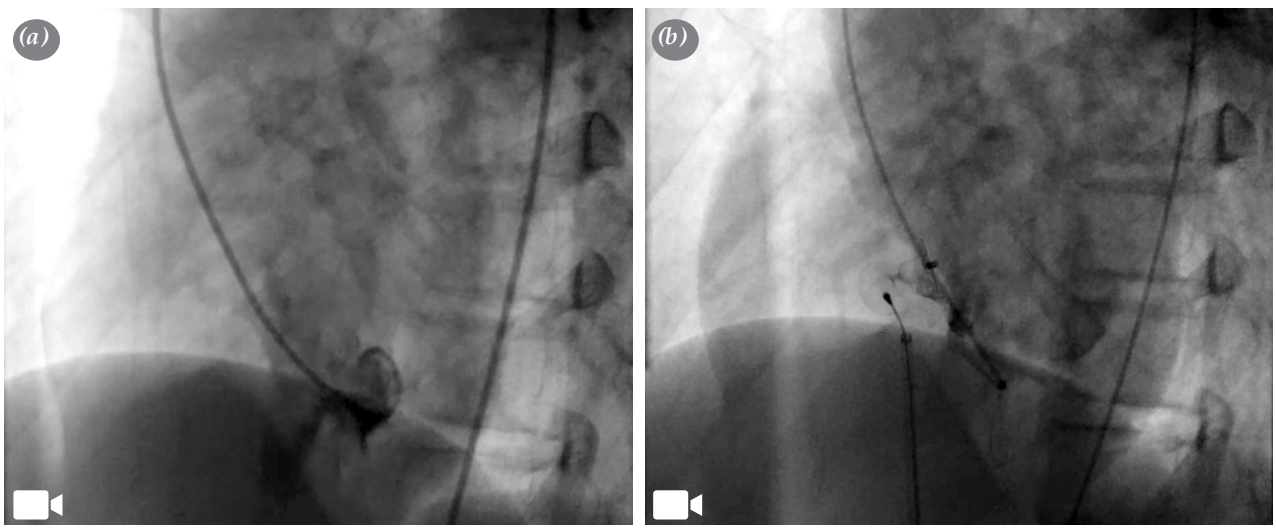


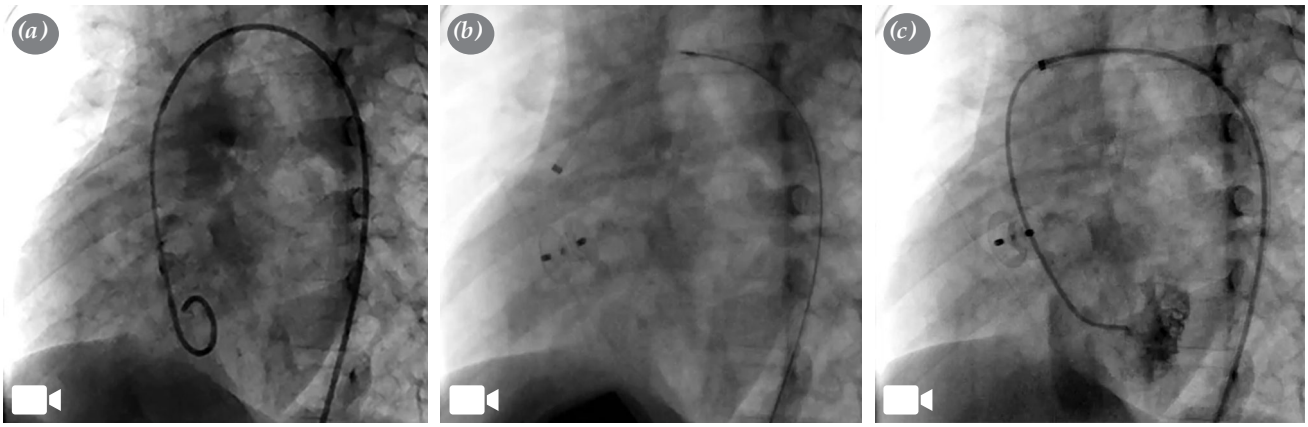
Figure 1. Antegrade VSD closure: **(a)** The left ventricular angiogram illustrates the left-to-right shunt via a PMVSD. **(b)** The left and right ventricular discs of the device are shown in their open position. **(c)** The device's final position and configuration following release are displayed. Retrograde VSD closure: **(d)** The left ventricular angiogram illustrates the left-to-right shunt through a PMVSD. **(e)** The left and right ventricular discs of the device are shown in their open position. **(f)** The device's final position and configuration following release are displayed.

PMVSD: Perimembranous ventricle septal defect.



Video 1. (a) The left ventricular angiogram demonstrates a left-to-right shunt through a PMVSD. **(b)** Antegrade VSD closure: The device's left and right ventricular discs are displayed in their deployed configuration.

PMVSD: Perimembranous ventricle septal defect; VSD: Ventricle septal defect.



Video 2. (a) The left ventricular angiogram demonstrates a left-to-right shunt through a perimembranous multi-fenestrated VSD. **(b)** Retrograde VSD closure: The device's left and right ventricular discs are displayed in their deployed configuration. **(c)** Checking for residual shunt with left ventricular injection after device release is shown.
VSD: Ventricle septal defect.

identification of performance trends over time by visualizing deviations from an expected event rate across consecutive cases. A p value of <0.05 was considered statistically significant.

RESULTS

Of the patients, 55 had PMVSD and three had muscular VSD. Five of those with perimembranous defects had postoperative residual VSDs; one following tetralogy of Fallot repair and four with previous VSD surgeries. The median weight of the patients was 18 (range, 5.6 to 57) kg. Demographic and pre-procedural echocardiographic findings of the patients are summarized in Table 1.

The median procedure duration was 60 (range, 30 to 150) min, and the median fluoroscopy time was 12.6 (range, 6.2 to 43) min. In the initial cases, the antegrade approach was predominantly utilized due to its familiarity and procedural control; however, as operator experience increased, there was a clear shift in preference toward the retrograde method. Consequently, a retrograde approach was employed in 79% of cases, with the 6/4 mm device emerging as the most frequently selected size, as detailed in Table 2. Notably, the retrograde method significantly reduced both procedure duration and fluoroscopy time, underscoring its efficiency advantages (Table 3).

Table 1. Demographic characteristic and pre-procedural details of patient

	n	%	Median	Range
Demographics				
Age (year)			4.5	0.8-16
Weight (kg)			18	5.6-57
Sex (ratio)				
Male	32			
Female	26			
Pre-procedure details (transthoracic echocardiography, n=58)				
VSD type				
Perimembranous	55	95		
Residual	5	9		
Muscular	3	5		
VSD RV size (mm)			4	3-10
Tricuspid aneurysmal tissue formation	28	48		

VSD: Ventricular septal defect; RV: Right ventricle.

Table 2. Procedure details

	n	%	Median	Range
Procedural details				
Procedure time (min)			60	30-150
Fluoroscopy time (min)			12.6	6.2-43
Angiography data				
VSD LV end size (mm)			5.7	3-15
VSD RV end size (mm)			3.5	2.5-12
Hemodynamic data				
Pulmonary artery mean pressure (mmHg)			18	11-38
Qp/Qs ratio			1.8	1.2-4.5
Retrograde approach for device deployment	46	79		
Device size used				
5-3	5			
6-4	30			
7-5	10			
8-6	7			
9-7	3			
12-10	1			
14-12	2			
Device LV end size (mm)			6	5-14
Device RV end size (mm)			4	3-12
PTFE membrane devices				
With PTFE membrane	6			
Without PTFE membrane	52			

VSD: Ventricle septal defect; LV: Left ventricle; RV: Right ventricle; Qp/Qs: Pulmonary flow/systemic flow; PTFE: Polytetrafluoroethylene.

Table 3. Comparison of approaches for transcatheter ventricular septal defect closure

	Antegrade (n=12)				Retrograde (n=46)				
	n	%	Median	Range	n	%	Median	Range	*p**
Age (year)			4.5	0.8-15			5	0.7-16	0.27
Weight (kg)			17.4	6.6-57			18.5	5.6-56	0.38
≤10 kg	2	17			10	21			0.95
>10 kg	10	83			38	79			
Procedure time (min)			77.5	60-120			60	30-150	**0.04**
Fluoroscopy time (min)			16.1	11-33.4			11.4	6.2-43	**0.01**

* p-value significant if ≤0.05.

The overall procedural success rate was 95% (55/58). Three cases were considered unsuccessful. In one patient with a history of tetralogy of Fallot surgery, the device embolized into the left pulmonary artery immediately after release due to an insufficient aortic rim, leading to termination of the procedure. Another case involved the development of AV block during the creation of an AV loop using the antegrade approach. The third failed case involved a multi-fenestrated PMVSD, where the antegrade method was unsuccessful due to entrapment of the tricuspid valve cords, and the retrograde approach revealed a tendency for the device to shift toward the aorta before release.

Complications and follow-up

Major complications were observed in three patients (5.4%), including device embolization, AR due to device dislocation, and RV perforation. In one patient with a PMVSD and trivial pre-existing AR, the device had to be surgically removed due to worsening AR within the first postoperative week. Notably, valve repair was not required, and the AR resolved after device removal. Another case involved RV perforation during retrograde defect closure, which resulted in cardiac tamponade. This complication occurred due to excessive contact of the long sheath with the RV apex. In this patient, pericardial fluid was drained surgically, and a small perforation in the RV apex was repaired. In the third case, the device embolized into the left pulmonary artery immediately after release. It was successfully retrieved using a snare, and the VSD was closed with a larger device, resulting in a favorable outcome.

The median follow-up was 34.5 (range, 1 to 56) months. On postoperative Day 1, 23 out of 54 (42%) patients were found to have residual shunts on echocardiography. Among these, 21 patients had minimal shunts (<2 mm), while two patients had moderate shunts (2 to 4 mm). During long-term follow-up, minimal residual shunt persisted in only one patient, indicating that the majority of the residual defects spontaneously resolved over time. Among the 58 patients included in our study, 10 weighed less than 10 kg, and the procedure was successful in all of them, with four exhibiting residual shunts immediately post-procedure. However, during follow-up, all residual shunts resolved completely.

During follow-up, new-onset mild tricuspid regurgitation (TR) was observed in one patient, while another patient developed trivial AR in the early postoperative period. By the three-month follow-up, the AR had completely resolved. A patient with a prior history of VSD surgery and minimal AR before the procedure progressed to mild-to-moderate regurgitation. Additionally, one patient developed stenosis in the RV outflow tract with a peak gradient of 29 mmHg post-procedure. By the first-year follow-up, the stenosis completely resolved, with a gradient reduced to 10 mmHg.

Table 4. Complications and follow-up data

Major complication	n	%
Embolization	1	1.8
Aortic regurgitation due to device dislocation	1	1.8
Right ventricle perforation	1	1.8
Residual shunt*		
Postoperative	23	42
6 months	9	16.6
1 year	4	7.4
2 years	1	1.8
Minor complication	13	24
Femoral artery thrombosis	3	5.4
Pseudoaneurysm	1	1.8
New onset tricuspid regurgitation	1	1.8
New onset aortic regurgitation	1	1.8
Right ventricular outflow tract stenosis (transient)	1	1.8
Arrhythmia	6	11
Second-degree AV block (transient)	1	1.8
Incomplete right bundle branch block	2	3.6
Nodal rhythm (transient)	1	1.8
Supraventricular tachycardia	2	3.6

AV: Atrioventricular; * Residual shunts decreased significantly over time, with only 1.8% persisting at the end of follow-up.

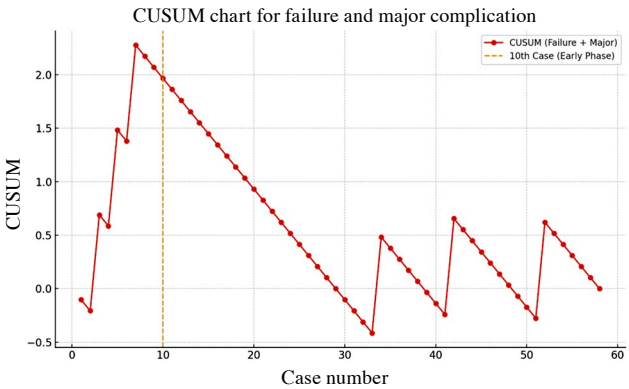


Figure 2. CUSUM chart demonstrating cumulative deviations for procedural failure and major complications. A learning curve is evident, with a turning point around the 10th case, after which the complication rate progressively declined.

CUSUM: Cumulative sum.

Femoral artery thrombosis occurred in three patients, but Doppler ultrasound at the one-month follow-up revealed normal blood flow in all cases. In one patient, a femoral artery pseudoaneurysm developed, which was successfully treated by thrombin injection, leading to complete resolution.

Notably, no cases of complete AV block were reported during follow-up in any patients. However, in the early postoperative period, two patients developed supraventricular tachycardia (SVT), one patient exhibited a nodal rhythm, and two patients experienced incomplete right bundle branch block (IRBBB). While SVT and nodal rhythm returned to normal sinus rhythm, IRBBB persisted in two patients. The Holter ECG was performed on a total of 30 (51.7%) patients. During the third year of follow-up, one patient experienced three episodes of second-degree type 2 AV block, specifically during nighttime sleep, as detected on routine Holter ECG monitoring. Subsequent Holter monitoring revealed no recurrence of AV block, indicating transient conduction disturbances. Detailed complications and follow-up outcomes are summarized in Table 4.

A CUSUM chart was constructed to evaluate the procedural learning curve based on the occurrence of procedural failure and major complications. The chart showed a peak during the initial cases, followed by a consistent downward trend after approximately the 10th case, indicating a reduction in serious adverse events as operator experience increased (Figure 2). This pattern supports the presence of a learning curve in the use of the Konar-MF™ occluder device for transcatheter VSD closure.

DISCUSSION

The Konar-MF™ occluder has emerged as an effective and safe device for the transcatheter closure of PMVSDs, achieving a high procedural success rate. In our study, the success rate was 95%, which is consistent with other studies utilizing both conventional double-disc devices and the Konar-MF™ device, reporting success rates ranging from 89 to 98%.[5-18]

The design of the Konar-MF™ device addresses several limitations associated with earlier devices. Its flexible structure and hybrid deployment capability allow for both antegrade and retrograde approaches through a smaller sheath, potentially reducing the risk of injury to adjacent cardiac structures and the conduction system. The waist portion of the Konar-MF™ device tapers in a cone shape, resulting in a diameter 2 mm larger on the LV disc side than on the RV side. This design requires careful consideration during device selection, especially given the complex anatomy often presented by PMVSDs.

Selecting the appropriate device size is critical and should be based on the diameter of the VSD on the RV side, the size of any ventricular septal aneurysm (VSA), the diameter on the LV side, and the size of the aortic rim. Initially, we added a +2 mm margin to the device size on the RV side to ensure complete closure. However, as we gained experience, we adjusted this margin to 0 to 1 mm, optimizing the balance between effective closure and minimizing interference with surrounding cardiac structures. This refined approach led to a reduction in failure rates without a significant increase in residual shunting.

In cases with VSA tissue, multiple shunts from different sites of the aneurysm can be observed. Our strategy involved navigating through the largest shunt and positioning the device's waist and LV disc to cover other shunts, allowing us to use a smaller device effectively. This approach aligns with findings from other studies that emphasize the importance of individualized device selection based on anatomical variations.[8,10]

In our initial use of the Konar-MF™ device, we predominantly utilized the antegrade approach. However, with increasing experience, our preference shifted toward the retrograde method. There were two primary reasons for this transition. First, the retrograde approach resulted in shorter fluoroscopy times and required less manipulation, as it eliminates

the need for creating an arteriovenous loop. This reduction in procedural complexity is particularly beneficial in reducing radiation exposure and procedural risks.

Second, the flexible structure of the Konar-MF™ device allows for adjustments during deployment. Even if the left disc does not fully seat within the defect initially, the screw mechanism permits the device to be pushed and positioned precisely into the defect. This capability enables the operator to move the device away from the aortic valve, minimizing the risk of aortic valve interference or regurgitation. The retrograde approach facilitates this maneuverability, providing better control over device placement relative to the aortic valve.

This shift in approach aligns with findings from other studies that have highlighted the advantages of the retrograde method when using the Konar-MF™ device;[19-22] The retrograde implantation method shortens the procedure and fluoroscopy times and offers a safe alternative in cases where creating an AV loop is challenging or poses additional risks, especially in smaller hearts.[23]

Complete AV block is a major concern in transcatheter VSD closure procedures. Early-onset AV block can result from direct trauma caused by the device or delivery system, while late-onset AV block may arise from inflammation, compression, or fibrosis affecting the conduction system. The incidence of AV block following transcatheter VSD closure ranges from 0 to 1% in various studies.[24,25] In our study, one procedure was terminated without device placement due to complete AV block following AV loop creation. In our practice, severe arrhythmias such as complete AV block or left bundle branch block during transcatheter VSD closure lead us to halt the procedure and deem such cases unsuitable for this approach, a strategy also supported by Tanidir et al.[5] No cases of complete AV block were observed during follow-up, possibly due to the Konar-MF™ device's design, which reduces pressure on the septum and conduction system. However, transient arrhythmias and conduction disturbances occurred in six of 58 patients (10%), primarily during catheter angiography or early postoperatively, resolving spontaneously. Holter ECG was available for 30 patients (51.7%), and second-degree type 2 AV block was observed in one patient during nighttime sleep in the third follow-up year. Control Holter readings for this patient showed no recurrence of AV block.

Valve insufficiency is another significant complication associated with transcatheter VSD closure. Aortic regurgitation may develop if the occluder impinges on the aortic valve leaflets, while TR can occur if the device compresses the chordae tendineae of the tricuspid valve. Studies report the incidence of newly developed TR after transcatheter VSD closure to be between 1 and 9.5%, and newly developed AR between 1 and 5.3%.[24,25] In our study, newly developing mild AR was observed in one patient (1.8%), which resolved by the third month of follow-up. Another patient required surgical removal of the device due to a gradual increase in AR within the first postoperative week.

In cases where the retrograde method was employed, after opening the left disc of the device, we slightly retracted it from the aortic valve using the delivery system before positioning it into the defect. This maneuver helps avoid direct contact with the aortic valve, though it requires careful execution to prevent potential dislocation of the device toward the RV side. Despite our predominant use of the retrograde method, we did not observe a high incidence of aortic valve complications. This may be due to our strategy of selecting smaller-sized devices and adjusting deployment techniques to minimize contact with the valves.

In a meta-analysis, early postoperative residual shunt rates were 15.9%, with permanent residual shunt rates at 1.7%.[25] Haddad et al.[6] reported residual shunt rates of 60% in the early postoperative period, 43% before discharge, and 16% at six months using the Konar-MF™ occluder device. In our study, residual shunt rates were initially 42% on postoperative Day 1, decreasing to 16.6% at six months, 7.4% at one year, and 1.8% at the end of follow-up. This decline over time aligns with findings in the literature, suggesting that many small residual shunts may seal spontaneously during follow-up.[25] Although we adjusted our device selection strategy over time to favor smaller devices when anatomically feasible, this did not lead to an increase in residual shunt rates. Our early postoperative and follow-up residual shunt rates are comparable to those reported in Konar™ studies that employed larger devices based on our strategy.[6,9] Indeed, our experience demonstrated that selecting smaller devices, particularly in cases with complex anatomy or inadequate aortic rims, allowed us to achieve successful closure without compromising outcomes.

Device embolization is a rare but serious complication, with rates reported between

0 and 5% in studies involving the Konar-MF™ device.[5-10] In our cohort, embolization occurred in two (3.6%) patients. One procedure was terminated due to inadequate defect rims, while the other VSD was successfully closed with a larger device after retrieval. Factors contributing to embolization include defect localization, insufficient aortic rims, and improper device selection or technique. The Konar-MF™ device's design allows for either end to be snared, and its softness facilitates easy retraction into the same sheath size used for delivery, which is advantageous in managing such complications.

Carminati et al.[2] reported a case of RV perforation during VSD closure with double-disc devices, requiring urgent surgery. While such perforations are not commonly associated with the Konar-MF™ occluder device,[5-10] we observed this complication in one patient undergoing retrograde VSD closure. It was linked to long sheath manipulation, causing pericardial effusion due to contact with the RV apex. This highlights the importance of careful technique and sheath positioning during the procedure.

Analyses performed in the present study demonstrated that failure rates and major complication rates decreased over time with increasing procedural experience. This trend highlights the presence of a learning curve, with improved safety and success as operator proficiency increases. The observed reduction in complications suggests that the procedure can be safely performed, particularly in centers with greater experience.

Nonetheless, there are some limitations to this study. First, this is a single-center, retrospective study. Second, due to the limited number of patients, regression analyses to identify predictors of procedural failure or major complications could not be performed. Following a major complication in the third case, a strategy of selecting smaller devices was adopted; however, the sample size was insufficient to compare this approach with earlier cases where larger devices were used. Additionally, the number of failures and major complications was too small to allow for a meaningful comparison between the antegrade and retrograde approaches. Also, the follow-up period was not sufficient to assess long-term complications. Early cases demonstrated longer procedure times and higher minor complication rates, reflecting the learning curve associated with retrograde deployment. Further multi-center, large-scale, prospective studies with longer follow-up periods are needed to confirm these results.

In conclusion, the Konar-MF™ device offers a viable and safe alternative to surgical ventricular septal defect closure, particularly in younger patients with challenging anatomies. Despite initially higher residual shunt rates postoperatively, these diminish over time, achieving acceptable defect closure proficiency. The design features of the device offer advantages over traditional devices, particularly in reducing the risk of complete atrioventricular block and accommodating anatomical variations. The shift from an antegrade to a retrograde approach, facilitated by increased experience and the device's flexible design, has further optimized procedural outcomes by reducing fluoroscopy times and improving maneuverability during deployment. However, careful assessment is crucial for procedural decision-making, especially in cases of severe arrhythmias during defect closure or insufficient aortic rims that may predispose to embolization. With increasing experience and careful patient and device selection, the success rate is expected to improve, making the Konar-MF™ occluder a viable alternative to surgical ventricular septal defect closure. Ongoing follow-up is essential to monitor for late complications, particularly arrhythmias and changes in valvular function, to ensure long-term patient safety and optimal outcomes. Future studies are warranted to further validate the long-term safety and efficacy of this approach, particularly in high-risk pediatric populations.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

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