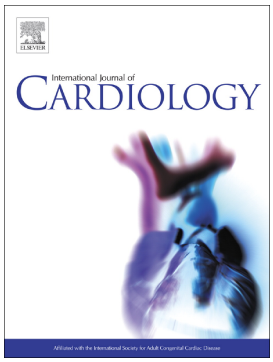

Use of Lifetech™ Konar-MF, a device for both perimembranous and muscular ventricular septal defects: A multicentre study

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1. Abstract

BACKGROUND: The objective of this study was to evaluate the safety and efficacy of transcatheter closure of ventricular septal defects (VSD) using the LifeTech™ multifunctional occluder device (MF-Konar). **METHODS:** Clinical features and demographic characteristics and follow-up findings were evaluated retrospectively from three centers. **RESULTS:** MF-Konar was used in 98 patients. The median age and weight of the patients were 3.8 years (range 5.4 months–50 years) and 15.3kg (range 5.5–80 kg), respectively. The mean fluoroscopy time was 13.7±8.2 min (range 3.4–42.6 min). Procedural success was obtained for 96 out of 98 patients (98%). In 54 out of 98 patients, closure was performed via the antegrade route. Major complications occurred in four patients (embolization in two, complete heart block in one, and device dislocation needing surgical treatment in one). All of the complications were treated successfully, and there was no mortality. Mild residual flow in eight patients (8%), new onset tricuspid valve insufficiency in one (moderate), and new onset aortic valve insufficiency in one (mild) were observed during a mean follow-up duration of 224±149 (10–515) days. Minor rhythm disturbances were observed in eight patients. **CONCLUSIONS:** Transcatheter closure of VSDs in selected patients using the LifeTech MF-Konar device seems effective. Its advantages are softer design, use of both an antegrade and retrograde approach, and an advanced smaller delivery system. Increasing the number of usage and the experience will provide more accurate data and low complication rates.

2. Introduction

Ventricular septal defects (VSDs) are a common form of congenital heart disease and can occur in isolation or in combination with other structural defects. They account for approximately 40% of all coronary heart diseases (CHDs). Perimembranous ventricular septal defects are the most common type of ventricular septal defects, accounting for approximately 60–80% of all ventricular septal defects [1-3]. Surgical treatment is a well-known treatment and can be performed to all VSD patients. On the other hand, since Lock et al. published their account of the first transcatheter VSD closure in 1988, thanks to the development of many devices and deployment techniques, especially in the last ten years, transcatheter VSD closure has produced promising results and is regularly performed in many countries for selected patients. Generally, transcatheter closure could be performed in older and weightier patients, comparing with surgical cases, due to delivery sheaths. [1, 2, 4-7].

Several devices, both on-label and off-label, are used for transcatheter treatment of VSDs. Amplatzer (St. Jude Medical, St. Paul, MN), is the best-known and most frequently used device in this field. The Amplatzer perimembranous VSD (pmVSD) occluder is no longer clinically available, owing to a high incidence of complete heart block (CHB) [1, 4]. However, Amplatzer-like devices developed by other companies (Cera family of VSD occluders; Lifetech, Shenzhen, China), Occlutech membranous and muscular VSD occluders (Helsingborg, Sweden), and the Shanghai pmVSD occluder (Shape Memory Alloy Ltd, Shanghai, China and LEPU Medical Technology Co. Ltd, Beijing, China) are still widely in use outside the USA.[1, 3, 6, 8]. The Amplatzer membranous VSD occluder II was designed to prevent conduction abnormalities by reducing radial force and increasing device stability. Moreover, the Amplatzer muscular VSD (mVSD) occluder is still available commercially and has been FDA approved since 2007 [1, 9, 10].

The Nit-Occlud Le VSD Coils (PFM Medical AG, Cologne, Germany) is designed for membranous and muscular VSD closure, and received a CE certification mark from the European Economic Area (EEA) in 2010 for dedicated VSD closure [1, 4, 6, 11, 12].

In addition, Duct Occluders (DO) (Amplatzer; St. Jude Medical, Inc., St. Paul, Minnesota, USA), Cocoon (Vascular Innovations Co. Ltd, Nonthaburi, Thailand), Cera (Lifetech Scientific Co. Ltd, Shenzhen, China), Occlutech (Occlutech International AB, Helsingborg, Sweden) and Amplatzer Duct Occluder II (ADO 2) and Amplatzer vascular plug-2 (AVP-2) are commonly used off-label devices for VSD occlusion [1, 2, 4, 5, 13-17].

In May 2018, the KONAR-MF (multi-functional) VSD device (Lifetech, Shenzhen, China) received the CE mark for VSD closure [18]. In the present paper, we describe the early– midterm experience with this new VSD device at three medical centers.

3. Materials and Methods

3.1. Study population

This was a retrospective multicenter study. The records of all patients undergoing cardiac catheterization for attempted ventricular closure using the Lifetech KONAR-MF device at three institutions (Gaziantep University Hospital (Center A) (n=41), University of Health Sciences, Istanbul Mehmet Akif Ersoy Hospital (Center B) (n=37), and Acıbadem University Hospital (Center C) (n=20)) between November 2017 and May 2019 were reviewed. Patient demographics, cardiac diagnosis, procedural data, complications, size and type of the device, re-interventions needed, procedural outcome, ECG recordings, and follow-up data were recorded. Institutional review board approval was obtained for each of the participating institutions from the University of Health Sciences, Istanbul Mehmet Akif Ersoy Hospital ethical committee.

If the size of the VSD requires larger device than 14/12 device, these patients were excluded. Also, if patient had no ventricular septal aneurysm (VSA) and aortic rim, patients with malalignment VSDs and patients with aortic valve prolapse were all excluded. But if patients had VSA, we deployed the device into the aneurism as adequacy of aortic rim was not so important in patients with VSA.

3.2. Definitions

Inclusion criteria were moderate left to right shunt, Qp/Qs > 1.5, age > 5 months, weight > 5 kg, and at least one of the following: dilation (+2 SD) of the left ventricle or left atrium on two-dimensional echocardiography, symptoms of heart failure, failure to thrive, or cardiomegaly seen on chest radiography. Patients with concomitant lesions requiring cardiac surgery, pulmonary vascular resistance > 8 Wood units, significant aortic regurgitation, and right-to-left shunt were excluded from closure using the device [1, 4, 13].

Residual shunt: Based on the width of the Color Doppler jet around the device, residual shunts are typically defined as small (1–2 mm), moderate (2–4 mm), and large (> 4 mm) [1].

Complications were categorized as major or minor. The following complications were considered to be major: procedure-related death, life-threatening adverse events, or events requiring surgery, such as device embolism, myocardial perforation, vessel rupture, severe residual shunt, severe hemolysis, valvular injury, or persistent complete heart block that required the insertion of a permanent pacemaker. The following

complications were considered to be minor: nonfatal complications that regressed spontaneously or with medication, such as access site hematoma, hemolysis that required only medication, the need for a blood transfusion because of blood loss, transient complete heart block, bundle branch block, fascicular block, first degree or Mobitz I type Atrioventricular (AV) block, rash, and fever. Total complication was the sum of minor and major complications.

Procedure success was defined by the absence of major complications and appropriate position of the implanted device on echocardiography 24 hours after the procedure.

3.3. Data collection

Pre-procedural and procedural details included procedure time, fluoroscopy time, mean pulmonary artery pressure, pulmonary to systemic blood flow (Qp/Qs) ratio, angiographic and echocardiographic defect size, the size of the devices used during the procedure, complications, aborted procedures, or failed implantations.

Post-procedural follow-up data about rhythm disturbances, echocardiographic device position, residual leaks, and AV valve insufficiency (aortic and tricuspid valves) were collected.

3.4. The Lifetech Konar-MF device

The MFO occluder device is a self-expandable, double-disc device made from double nitinol wire mesh layers with 144 threads of nitinol wires. It is designed as a hybrid of single-disc and double-disc PDA devices. Two discs are linked together by a cone-shaped waist and there are two screws on the left and right disc. It can be screwed together at both sides and therefore its placement can be from the left ventricle (LV) or right ventricle (RV), in other words retrograde or antegrade (Figure 1).

Device sizes are given as LV waist diameter and then RV waist diameter. The sizes start from 5/3 mm and up to 14-12 mm, the length in total being 4 mm without stretching. In total, eight sizes are available. The waist of the four largest models is sewn with PTFE membranes, whereas the four smaller models have no membrane (Table 1).

The device is used through a 4-7 F sheath. The flexible waist is designed to reduce the risk of CHB and can be adjusted to a variety of VSDs. Its soft woven mesh provides high conformability with septal defects. There is also a slim cable to minimize unwanted damage (Table 1).

3.5. Intervention procedure

Cardiac catheterization was performed under either general anesthesia or deep sedation, as per the institutional protocols of the participating centers. Procedures were performed according to the guidelines either from antegrade approach (Figure 2 a, b, c) or from retrograde approach (Figure 2 d, e, f).[19, 20]

Repeated left ventriculography and transthoracic/transesophageal echocardiography were performed to confirm the result after detachment (Figure 2 g, h).

Patients in whom the procedure was uncomplicated were discharged from hospital 24 h later. Oral aspirin (5 mg/kg daily) was prescribed for 6 months.

3.6. Device selection

- Muscular defects: defect size +2 (right ventricle disk size)
- Perimembranous defect:
    - Without ventricular aneurism: right ventricular side of the defect +2mm, but if the devices left ventricular disk (including rims) will exceed left ventricular side of the device and will touch aorta, device selection will be decreased to same size or +1 mm of right ventricular disc.
    - With ventricular aneurism: right ventricular side of the defect +2mm, but if the devices left ventricular disk (including rims) will exceed aneurism size device selection will be decreased to same size or +1 mm of right ventricular disc.

3.7. Follow-up

During the first 24 h after the procedure, continuous ECG monitoring was used to detect arrhythmias. Echocardiography was performed to check for acute complications and residual shunt immediately and 24 h after the procedure. Urine was tested to detect hemolysis.

Routine follow-up examinations included physical examination, ECG, and echocardiography and arranged for 4–6 weeks, 3 months, 6 months, and thereafter annually.

3.8. Statistical analysis

Statistical analyses were performed with SPSS Statistics 23.0 (IBM Corp., Armonk, NY, USA). Continuous variables are expressed as mean ± standard deviations or median and quartiles. Categoric data are presented as frequencies and percentages.

4. Results

4.1. Study population

From November 2017 to May 2019, 98 patients underwent percutaneous closure of muscular or perimembranous VSD using the Lifetech KONAR-MF device in three centers. The baseline characteristics of participants are presented in Table 2.

4.2. Interventional procedure

Eighty-four (86%) of the patients had perimembranous and 14 (14%) had muscular VSDs. The general procedure and device data are presented in Table 3.

The success of the procedure was 96/98 (98%). Two device embolizations occurred during the procedure (Center A). Both were due to underestimation of the VSD size and happened after the release of the device. One patient's device was snared and referred to surgery (unsuccessful procedure). The other patient's device embolized into the left pulmonary artery (LPA). The first 6/4 device was retrieved from the LPA, and the 8/6 device was successfully deployed. The subject of the other unsuccessful procedure was a five-year-old, 18-kg girl who had a midmuscular VSD (Center B). The size of the VSD was 8 mm on the left side and 8 mm on the right, so a 12/10 device was chosen. The device was dislodged five minutes after the procedure. The patient was followed up in the ward, but the residual leak was too great, and the patient was referred to surgery two days after the procedure. These complications occurred in different centers and within interventionists' initial cases.

Among successful interventions, in 57 out of 96 (59%) patients were on the antegrade route, in 37 (39%) patients were on the retrograde route, one patient had both devices deployed at the same time (one from antegrade, the other from retrograde) and in one other (1%) patient, the hybrid procedure was used. Hybrid procedure was a 7 month-old-boy who had tetralogy of Fallot and an additional large apical muscular VSD. After initiation of cardiopulmonary bypass, surgical team decided to close VSD via hybrid procedure because of the difficulty of surgical exposure and closure of the VSD. Before surgical correction of RVOT and VSD closure, apical muscular VSD was closed with a 10/8 device. Right ventricular disc of the device was stabilized with two sutures. After the completion of the operation, an epicardial echocardiography revealed no residual shunt trough the device.

4.3. Procedure-related complications and follow-up

The adverse events during the procedure and follow-up are presented in Tables 3 and 4. The mean follow-up time was 224±149 (10–515 days). Complications occurred in 13 patients (13%). Most of the adverse events were categorized as minor complications (nine patients, 9%). Major complications occurred in four

patients (4%). Major complications were device embolization detected in two patients (2.2%) patients and device dislocation in one patient (1.1%; detailed information is given above) (Table 3).

Residual shunt after the procedure was observed in 13 patients (six trivial and seven mild). During follow-up, residual shunt had disappeared in five of these patients and the remaining eight patients experienced only mild residual shunt. The follow-up time of the patients with residual shunt was 8.6±5.6 months (1.5–17 months). Six of these patients had pmVSD, of whom four had aneurysm tissue. Among the five patients who had still residual shunt, follow up period was less than one year. New onset tricuspid valve insufficiency was observed in one patient (moderate) and new onset aortic valve insufficiency in one patient (mild). In two patients, two devices were used to close the VSD (Figure 3, Table 3).

Persistent CHB that required the insertion of a permanent pacemaker occurred in one (1%) patient (Center B). This was a five-year-old girl weighing 17 kg with perimembranous VSD whom antegrade closure was performed. After an AV loop had been created, CHB developed, but without any treatment this disappeared within seconds. After a five-minute wait to observe the rhythm, it was found that no block developed. Therefore, the procedure was continued and a 5.5 mm defect was closed with a 9/7 device. The patient was monitored for more than 24 hours and no rhythm disturbance occurred. She was discharged, but on the next day she was admitted to the emergency department with fatigue, and an ECG revealed complete heart block. She was hospitalized but despite medical treatment (steroids and inotropic and chronotropic agents), CHB persisted, so surgical removal of the device and closure of the VSD was performed. After the operation, CHB disappeared and normal AV conduction was restored. No AV block recurred in the following 10 months.

Complete right bundle branch block (n=2), left anterior fascicular block (n=4), and left bundle branch block (n=1) was observed during follow-up in 96 (successful procedures) patients.

5. Discussion

There are several choices of device, both on-label and off-label, for the closure of VSDs. The Konar MF device is relatively new in Europe, being first used in human implantation in 2013, although it has been used for several years in some Asian countries. It received the CE mark certification for VSD closure in May 2018 in Europe. [18]

5.1. Procedural success and residual shunt / complete closure rates

Having recently conducted a systematic meta-analysis, Santhanam et al. reported that the pooled estimate of successful device implantation is 97.8% (95% CI: 96.8–98.6) and of residual shunt 15.9% (95% CI:

10.9–21.5) for transcatheter VSD closure. Although the incidence of residual shunt seems high, most cases do not need any further intervention, as the shunt is often small and hemodynamically insignificant. Rates of residual shunts on follow-up were also far lower than those noted immediately after device closure, suggesting that time was essential for small shunts to seal. Residual shunts were noted to be permanent with a pooled rate of 1.7% (95% CI: 0.8–2.7). [3]

Procedural success with the Amplatzer Duct Occluder I or the Lifetech Duct Occluder was 90–98%, and residual shunts were less than 5% at one-year follow-up and less than 1% in two years [1, 4, 5, 13]. For the ADO-2 device, recent published series has described procedural success rates greater than 90–98%, with complete closure rates approaching more than 95% during follow-up. Most of the remaining residuals were observed at a short follow-up time and were trivial [1, 2, 15, 21, 22]. PFM device implantation procedure was successful in 92–99% of cases, and complete closure was observed in up to 97% of the cases during follow-up. [1, 4, 6, 11] Surgical removal of a device for severe residual shunt has been reported only rarely. However, most of the second interventions related to residual shunting occur with PFM devices [1, 6].

In our series, procedural success was 98% and residual shunt was encountered in eight patients (8%). Unsuccessful procedures were recorded among the centers' initial cases and happened owing to underestimation of the defect and inexperience with the devices. All the residual shunts were mild during 8.6±5.6 months (1.5–17 months) follow-up. In five of the patients, the follow up time was less than 1 year, which suggests us that the problem can be resolved over time.

5.2. AV block

The literature shows that a significant limitation on the widespread use of percutaneous VSD closure with devices is the unacceptably high rate of CHB, owing to the proximity of PM devices to the conduction system. This complication may happen very early or very late after the procedure, may be reversible with medication, or may become persistent and require permanent pacemaker insertion. For this reason, percutaneous VSD closure has been largely abandoned in many countries, and surgical closure has been accepted as the contemporary standard therapy for PmVSD [1, 5].

Early CHB may be the consequence of significant direct mechanical trauma caused by the delivery system or device deployment during the procedure, while late CHB may be due to fibrosis, compression, or inflammation of the conduction system. The conventional PmVSD occluders have a high tendency to cause damage to the ventricular septum and other adjacent structures because of the size of the delivery system needed for large-profile devices, along with the high clamping force caused by double-disc design and high radial stress

due to high device stiffness. Thus, another device with a lower profile and ease of implantation may reduce the trauma, clamp force, and radial stress to the ventricular septum and, therefore, decrease the incidence of CHB [4, 5].

In the meta-analysis by Santhanam et al., the pooled estimate of arrhythmias was 10.3% (95% CI: 8.3–12.4) and about a fifth of arrhythmias were permanent, with a pooled rate of 2.1% (95% CI: 1.1–3.4). The incidence of CHB was 1.1% (95% CI: 0.5–1.9) [3]. Although CHB was mostly observed within 1 week after transcatheter closure, cases have been reported up to 3 years after the procedure. Moreover, several procedures were aborted because CHB occurred during the procedure [1, 3].

Recent studies of the published CHB rates according to device types were 0.7% for ADO I, very rare with ADO-2 and 1.4% for Nit-Occlud [1, 2, 4-6, 13, 15, 21-23]. However, in some of the cases, CHB did not persist and recovered with medical treatment, whereas in others, permanent pacemaker implantation was required. In the present series, one patient developed CHB (1%) and did not recover with medical treatment but did recover after surgical treatment and did not require a permanent pacemaker.

The incidence of CHB in our series is similar to that described in the literature (1%). Owing to the funnel shape and flexibility of the device, the defect may be filled rather than treated with a stent or clamped; thus, radial force is not exerted inside the septum or pressure on the surrounding structures. However, CHB occurred in some cases, in spite of these features. In our patient, CHB occurred after an AV loop was established. It may be concluded that if CHB occurs after a wire or long sheath has been advanced through a VSD, devices should not be used to close this type of VSD due to high risk of CHB during follow up. Thus, this complication is not directly correlated with use of the device. The incidence of other minor arrhythmia complications was 8%, which is similar to that experienced with other devices, according to reports.

5.3. Tricuspid insufficiency / aortic insufficiency

The local anatomy of perimembranous ventricular septal defect is sophisticated and adjacent to the tricuspid and aortic valve. The device implantation may affect the surrounding valve, causing valve insufficiency [2]. Aortic regurgitation following implantation of the device is typically mild and rarely severe enough to require removal of the device. Care should be taken to evaluate the distance between the defect and the aortic valve. In most studies, a distance greater than 2 mm is considered acceptable, although this distance may need to be greater with symmetric devices such as the ADO II or the pmVSD occluder. Device placement within aneurysmal tissue on the RV side can potentially reduce the risk to the aortic valve by increasing the distance from the device to the valve [1]. In Santhanam et al.'s meta-analysis, the pooled estimate of valvular defects was

4.1% (95% CI: 2.4–6.1), and the pooled rate of permanent valvular defect was lower at 1.3% (95% CI: 0.6–2.3). The pooled estimate of tricuspid regurgitation (TR) was 3.8% (95% CI: 2.0–6.0) and of aortic regurgitation (AR) 2.0% (95% CI: 0.9–3.4) [3]. In their meta-analysis, Yang et al. reported a slightly higher rate of these complications [24]. Also, it is reported that several procedures were aborted owing to valvular insufficiency [3]. In our series, none of the procedures was canceled because of valvular problems.

The reported incidence of tricuspid regurgitation and aortic regurgitation according to devices was as follows: for ADO-1 TI 0.9% and AI 2.3%, for ADO-2 TI 0-5% and AI 0-2.3%, and for PFM TI 0-6% and no AI [2, 6, 11, 13, 15, 21, 22]. In our series, there was only one patient with moderate TI (1%) and one with mild AI (1%). Although the Konar-MF device is soft, its right ventricular shape is like that of ADO-2, which may cause TI. However, the joint point is flexible, such that the LV and the RV disk is can be placed at different angles, which may decrease TI incidence. Moreover, before deploying the disk with either TEE or TTE, the TI should be assessed. If there is TI, the device may be retrieved and redeployed. Further, the delivery cable is very smooth. The cable can be pushed toward the RV apex and the RV disk shape and position may be changed, which can prevent severe insufficiency. For aortic insufficiency, the practitioner should pay particular attention, as the LV disk is 4 mm larger than the waist, and sufficient distance between the defect and the aortic valve is essential to avoid aortic regurgitation. However, if the patient has an aortic aneurysm without an aortic rim, the device can be easily deployed into the aneurysm. In our series, the patient with AI had a 3 mm aortic rim and no aneurysm. If the VSD aneurysm is very large and extends toward the tricuspid valve, a retrograde approach is preferred to antegrade. Thus, the distance of the device to the tricuspid valve is increased.

5.4. Embolization:

Device embolization has also been reported in 1–3% of cases with DO-1 and ADO-2 or PFM device types [1, 4-6, 22]. In our series, two (2%) devices were embolized, and one of them snared, requiring the defect to be closed with a bigger device, while the other device snared, and the patient had to be referred for surgical closure. Both device embolizations were due to underestimation of the defect and inexperience in the use of such devices in one of the centers.

5.5. Hemolysis

Hemolysis has been reported in 1–5% of cases in most large studies and for different device types. Cases are typically mild and resolve spontaneously within 2 to 3 days of implant. Hemolysis is more common with the PFM device, owing to its design, and is reported in 4–15% of cases. The need for blood transfusion or surgical removal of the device is rare. In addition, it has been reported that a second device was used to close a

residual defect, which caused hemolysis [1, 2, 4, 6, 12, 18, 25]. In the present series, none of the patients experienced hemolysis. The main reason for hemolysis is residual leaking of the blood flow into the device. Although 36 of the 99 devices did not contain mesh, no hemolysis was encountered.

5.6. Endocarditis

Endocarditis is reported 0–0.3% of cases [4]. In the present series, none of the patients had endocarditis within 8±4.8 months. However, no conclusions can be drawn about endocarditis associated with the Lifetech Konar MF device because the device is relatively new, and follow-up of these patients was short.

5.7. Retrograde approach

One of the major advantages of this device is its double screwing hub which gives an advantage of retrograde approach, even it is not a symmetric device. Generally, symmetric VSD closure devices has an advantage of retrograde approach whereas asymmetric one's do not. Nowadays most of the interventionalist prefers retrograde approach which enables the procedure faster and easier. Solely retrograde approach was used in 39% of patients in these series.

5.8. Study limitations

This was a retrospective study with a limited number of participants and a wide age range. Patients were treated at one of three centers by different cardiologists with varying levels of experience in performing the VSD closure procedure. Also, the follow-up duration was limited which is very important for the presentation of long term complications like complete heart block.

6. Conclusion

This new device has the advantages of a DO-1-like wide variety of sizes, not requiring clamping force, reduction of radial stress to the ventricular septum, as well as the advantages of an ADO-2-like softer profile, a small delivery sheath, deployed via a retrograde approach (arterial side) or an antegrade approach (venous side), and a double disc.

The present study shows that transcatheter membranous and muscular VSD closure using a Lifetech Konar-MF device seems feasible, safe, and efficacious in selected patients. There is evidence that, with increasing experience with the device among practitioners, the complication rate will fall. Long-term follow-up and larger, prospective, multicenter studies may confirm the safety and efficacy of this device.

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Three of the authors are (OB, AG and EO) are proctors of the Lifetech company.

8. Figure legends

FIGURE 1: Lifetech MF device.

FIGURE 2: Antegrade VSD closure: a: Left ventricular angiogram demonstrating the left to right shunt through a pmVSD. b: The left ventricular and the right ventricular disk of the device shown in the open position. c: Device position and shape after release. Another Konar device was used to close the VSD in the same patient. Retrograde VSD closure in a 4.5-year-old-boy with a 6/4 device: d: Left ventricular angiogram demonstrating the left to right shunt through a pmVSD. e: The right and the right ventricular disk of the device shown in the open position. f: Device position and shape after release. g: 2D modified apical four-chamber echocardiographic view of the device. h: Color-modified apical four-chamber echocardiographic view of the device showing minimal residual flow through the device.

FIGURE 3: Both antegrade and retrograde VSD closure in a 2.7-year-old-boy, with two exits on the right ventricular side: a: Left ventricular angiogram demonstrating the left to right shunt through a pmVSD. b: A 7/5 device was advanced and placed via the antegrade route. c: A 9/7 device was advanced and placed via the retrograde route. d: Device positions and shapes after release.

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TABLE-1: Device Specifications

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

TABLE-2 Baseline characteristics

Age (years, median, range)	3.8	(range 5.4 months – 50 years)
Weight (kg, median, range)	15.3	(range 5.5 – 80)
Female /Male n (%)	52 / 46	(53 /47)
Age groups, n (%)		
<6 years	64	65 %
6–16 years	26	27 %
>16 years	8	8 %
Echocardiography		
VSD LV size (mm, mean ± SD)	10.1 ± 3.4	(range 5-19 mm)
VSD RV size, mm, mean ± SD)	6.5 ± 2.0	(range 2.7-12 mm)
Defect position, n (%)		
Perimembranous	84 / 98	86 %
Muscular	14 / 98	14 %
Aneurysm, n (%)	75 / 84	89 %
Concomitant closure n (%)		
ASD closure	1 / 98	1 %
PDA closure	3 / 98	3 %

VSD: Ventricular septal defect, RV: Right ventricular, LV: left ventricular

TABLE-3 Procedure-related data

Procedure time (min, mean±std, range)	49 ± 22.7	20-120
Fluoroscopy time (min, mean±std, range)	13.7 ± 8.2	3.4-42.6
Anesthesia		
General anesthesia	54 / 98	55 %
Deep sedation	44 / 98	45 %
Catheterization		
PA mean pressure (mm Hg mean±std, range)	21 ± 8.9	10-60
Qp/Qs ratio	1.9 ± 0.6	1.1-4.1
Left ventriculography		
VSD LV size (mm, mean ± SD)	9.4 ± 2.6	5-16
VSD RV size (mm, mean ± SD) *	5.9 ± 1.7	2.3 - 10
Sub aortic rim (mm, mean ± SD)	1.8 ± 1.8	0-7
Echocardiography n (%)		
Transthoracic	74 / 98	75 %
Transesophageal	23 / 98	24 %
Epicardial	1 / 98	1%
Procedure** (successful procedures)		
Antegrade	57 / 96	59%
Retrograde	37 / 96	39%
Antegrade and Retrograde	1 / 96	1%
Hybrid	1 / 96	1%
Success***	96 / 98	98%
Konar MF sizes ** n (%)		
5-3	4 / 99	4%
6-4	10 / 99	10%
7-5	8 / 99	8%
8-6	14 / 99	14%
9-7	16 / 99	16%
10-8	22 / 99	23%
12-10	15 / 99	15%
14-12	10 / 99	10%
Complication	13 / 98	13 %
Major	4 / 98	4 %
Embolization	2****	2 %
Complete heart block	1	1 %
Device dislocation	1	1 %
Minor	9 / 98	10 %
Femoral hematoma	1	1 %
Arrhythmias	8	9 %

* In patients with multiple RV exit the largest one.
** In two patient 2 device is used and in one of them both antegrade and retrograde approach was used.one of the unsuccessful procedure (embolized device) excluded
*** One patients' device was dislocated and referred to surgery and the others device embolized and referred to surgery.
**** One patients' device was snared and closed with a bigger device, the other patients' device was snared, and patient referred to surgery

TABLE 4: Follow-up data

Follow-up (days, mean±std, range)	224±149	10-515 days
Residual shunt after procedure		
Mild	8	8 %
Moderate	0	0 %
Severe	0	0 %
Total	8	8 %
New onset tricuspid valve insufficiency		
Mild	0	0 %
Moderate	1	1 %
Severe	0	0 %
Total	1	1 %
New onset aortic valve insufficiency		0 %
Mild	1	1 %
Moderate	0	0 %
Severe	0	0 %
Total	1	1 %
Arrhythmia		0 %
Left bundle branch block,	1	1 %
Right bundle branch block,	2	2.1 %
Left fascicular block,	4	4.2 %
Transient complete heart block	0	0 %
Permanent complete heart block	1	1 %
First degree AV I block	0	0 %
Total	8	8.3 %

Author statement

Ibrahim Cansaran Tanidir; Writing - Original Draft, Project administration, Visualization, data curation, Conceptualization. Osman Baspinar: Review & Editing, Supervision, Visualization, Data curation. Murat Saygi: Writing - Original Draft, Data curation. Mehmet Kervancioglu: Review & Editing, Data curation. Alper Guzeltas: Review & Editing, Visualization, Supervision. Ender Odemis: Review & Editing, Visualization

Highlights

MF-Konar is feasible, safe and efficacious For VSD closure for selected patients.
Success was 98% and major complications were 4% for VSD closure with MF-Konar.
MF-Konar can be used both antegrade and retrograde approach, smaller delivery system.
Do not close VSD if complete AV block occurred during the procedure.

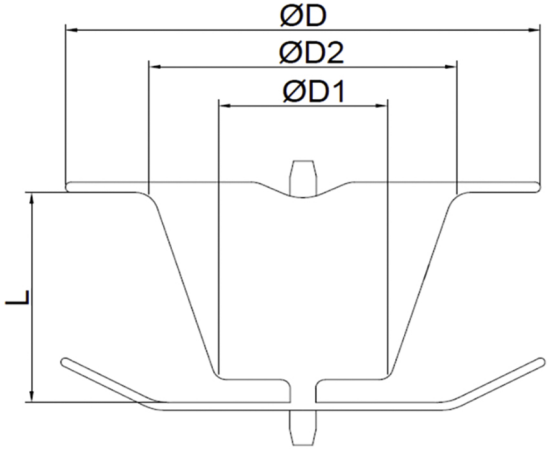
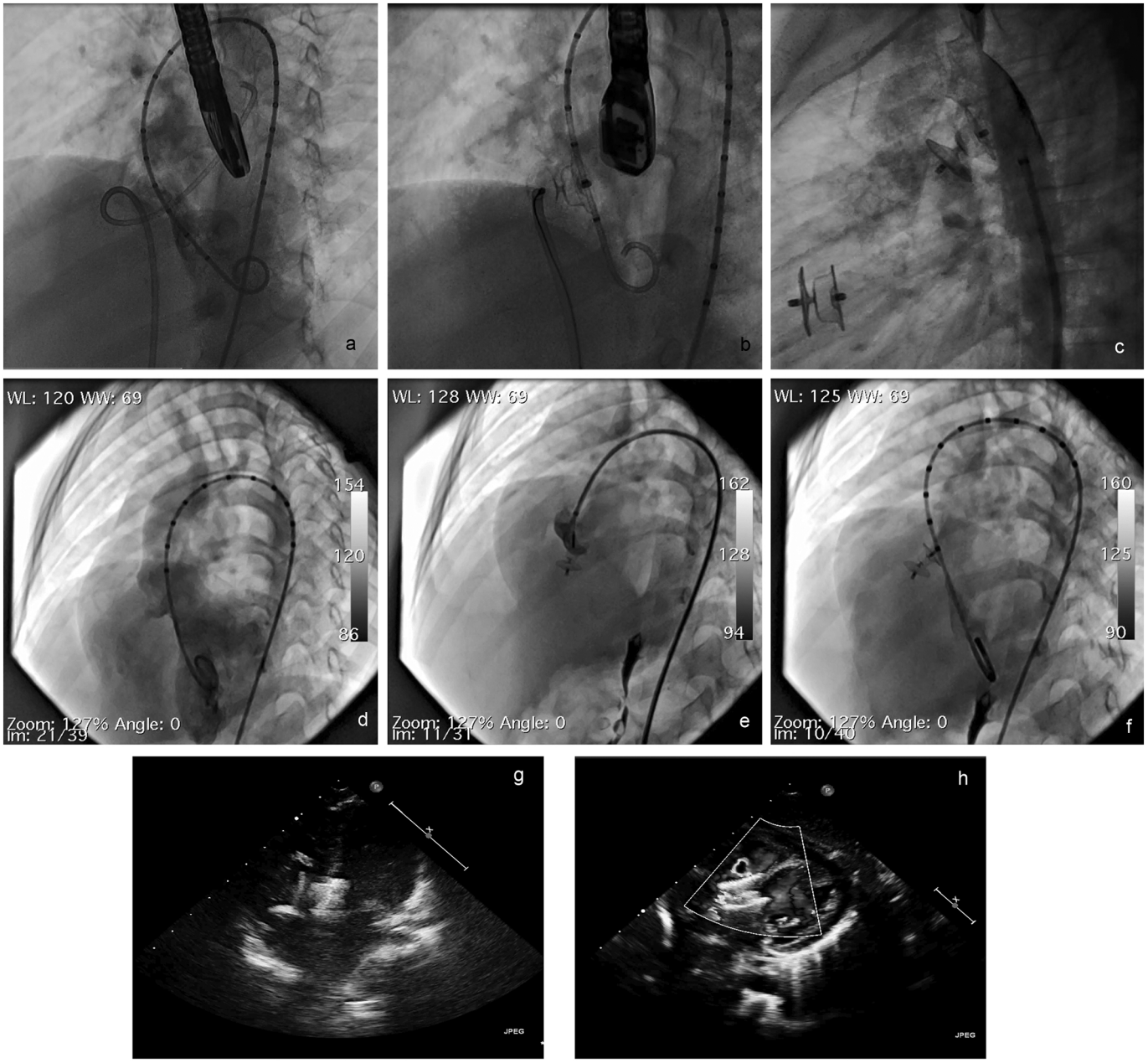


Figure 1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b
c
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154
120
86
Zoom: 127% Angle: 0
Im: 21/39
d
WL: 128 WW: 69
162
128
94
Zoom: 127% Angle: 0
Im: 11/31
e
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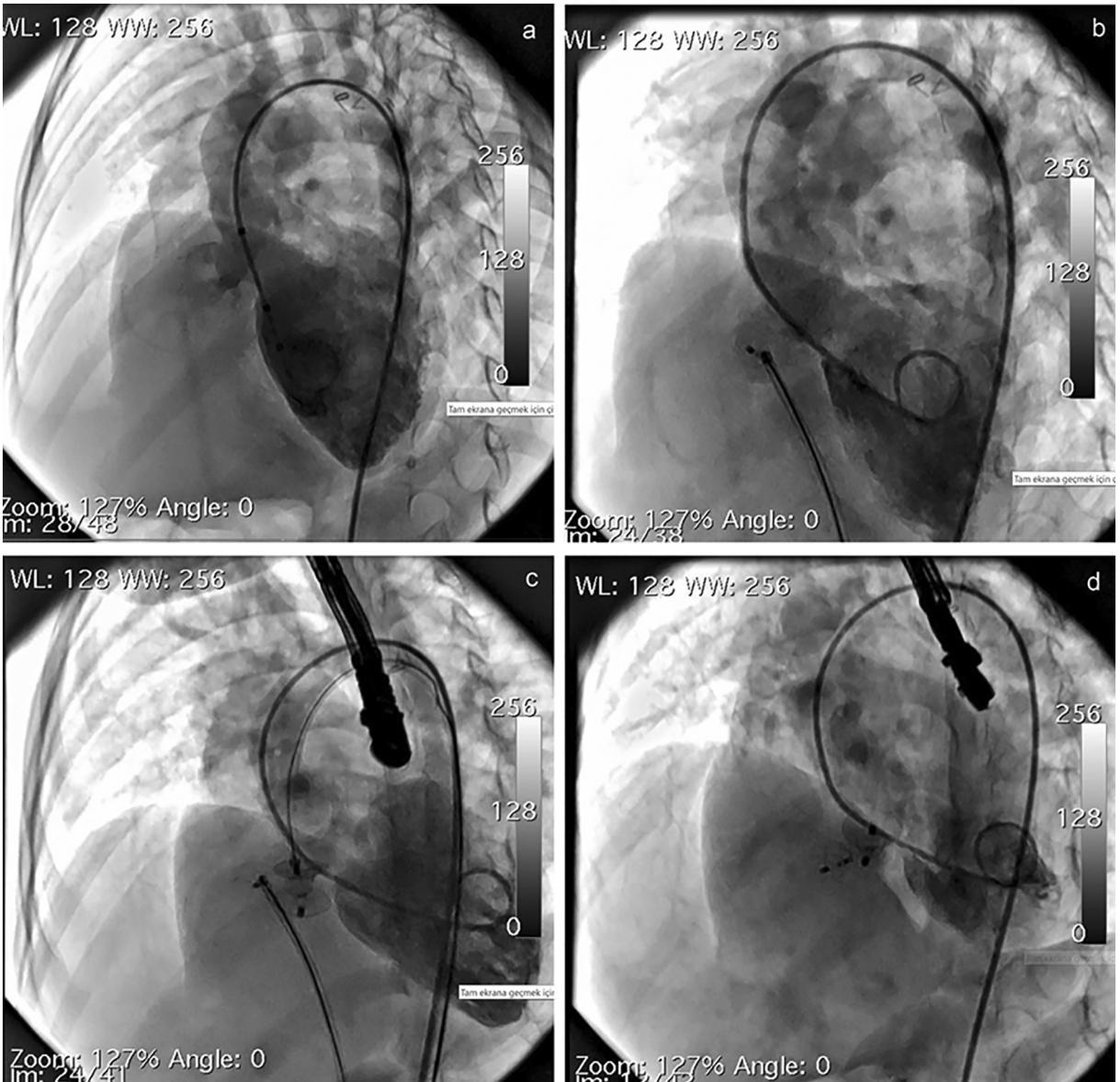
Figure 2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b
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128
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Zoom: 127% Angle: 0
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c
256
128
0
Zoom: 127% Angle: 0
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d
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128
0
Zoom: 127% Angle: 0

Figure 3