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RESEARCH

Konar-MF ™: Versatile Utility Suggests Potential to Simplify Congenital Catheterization Laboratory Inventory

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Abstract

KONAR-MF™ device is a novel, cone-shaped, medium profile, self-expanding, double-disk, nitinol occlusive device designed for the ventricular septal defect (VSD). Due to its unique design and easy deployment from either side and multiple occlusion layers, it has also been used to occlude defects other than VSD. A retrospective review was done from 2019 to 2024 from three institutions. All patients where the KONAR-MF™ device was used other than for VSD closure were included in this study. Standard post-procedure follow-up was at 1, 6, and 12 months for all patients. 79 off-label implantations of the KONAR-MF™ device were done for conditions that included 59 shunt lesions (patent ductus arteriosus -34, coronary arteriovenous fistula -12, pulmonary arteriovenous fistula -2, systemic arteriovenous fistula -3, aortopulmonary window -3, aortopulmonary collateral -5, Fontan fenestration closures -7, Fontan antegrade pulmonary valve closures -2, Abernethy malformations -3, decompressing vein -2, and paravalvular leak -2, others 4. The median fluoroscopy time was 10 min (IQR 6–18). The median duration of hospital stay was 2 days (IQR 1–4 days). There were no significant complications. Complete occlusion at the end of the procedure was documented in 72 (91.13%) patients. At a median follow-up of 18 months (IQR 12–28 months) in all except one patient who had mild residual flow with no device-/(procedure) related complications. The unique structure and compact profile of KONAR-MF™ enable a wide range of uses in catheter-based management of various CHDs with the potential to simplify the inventory of the catheterization laboratory.

Keywords Congenital heart disease · Device closure · Trans catheter closure

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Introduction

Several congenital heart defects can now be closed in the catheterization laboratory using a wide variety of occlusive devices that are often specifically designed for each defect. The variety of lesions coupled with a wide range of defect sizes and body weights poses a significant challenge, because it requires the maintenance of a large inventory of devices in the catheterization laboratory. A large inventory can be wasteful, because a number of devices will remain unused at their expiration dates. This adds substantially to the costs of catheter interventions in children and the complexity of inventory management.

The KONAR-MF™ (Lifetech Scientific (Shenzhen) Co., Ltd, Guangdong Province, PRC) device is a novel, self-expanding device that was primarily designed for catheter closure of membranous ventricular septal defects (VSD) [1–4] Figs. 1 and 2. After its introduction, the device was also found useful for closing muscular VSDs [2]. Because of

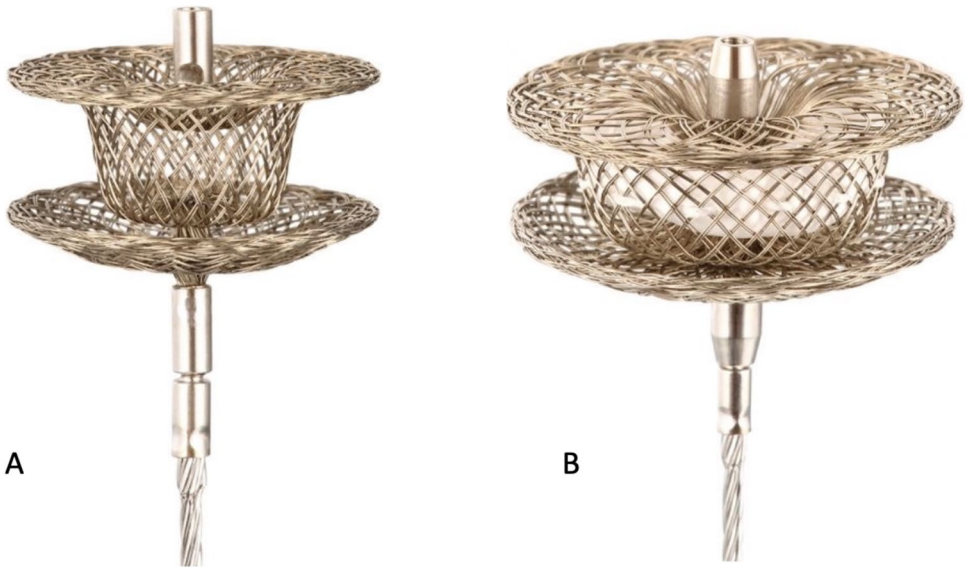

Fig. 1 KONAR-Multifunctional occluder. Device sizes 5–3 to 8–6 are without an inner PTFE membrane (**A**). Sizes from 9–7 to 14–12 have a PTFE membrane within which promotes complete closure in larger defects (**B**)

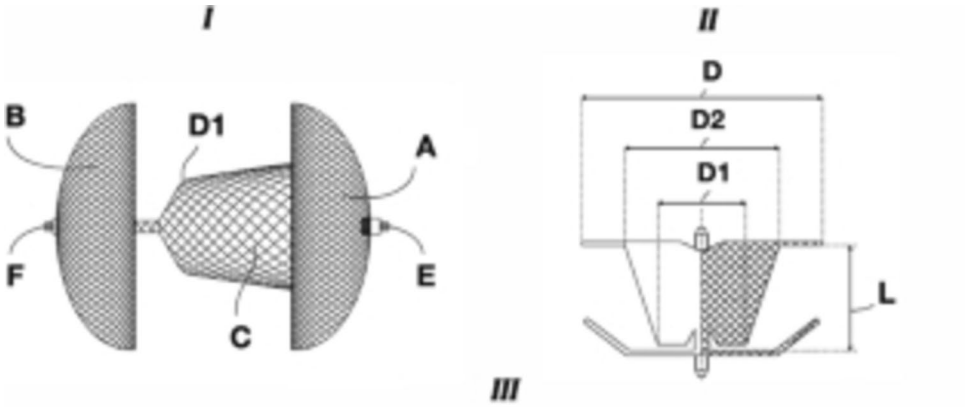

Fig. 2 KONAR-Multifunctional occluder. I. A High-pressure disk, B low-pressure disk, C central cone with incremental diameter, D1 lower disk diameter, E retention screw on the high-pressure side, and F retention screw on the low-pressure side. II. D Disk diameter, D1 minimum diameter, D2 maximum diameter, and L: length. III. Dimensions of the device, compatible guide catheters, and delivery sheaths (JR: Judkin's Right)

Device Size (D2/D1)	Disc diameter (D)	PTFE membrane	Compatible JR guide catheter (Fr)	Recommended delivery sheath (Fr)
5/3	10	Absent	5	4-5
6/4	10	Absent	5	4-5
7/5	12	Absent	5	4-5
8/6	12	Absent	6	4-5
9/7	14	Present	7	6
10/8	14	Present	7	6
12/10	16	Present	-	7
14/12	18	Present	-	7

the unique shape and design, ease of deployment from either side, and multiple occlusion layers, it is suitable for off-label use in a number of conditions other than VSD closure. The 'off-label' uses described in various reports include patent ductus arteriosus (PDA), aortopulmonary window (APW), and coronary arterial fistula [5–7]. Using a single device for a wide range of lesions offers the prospect of greatly simplifying the inventory of pediatric cardiac catheterization laboratories

thereby minimizing the chances of wastage from unused devices. We describe the pooled experience from three centers on the off-label use of the KONAR-MF™ device in a wide variety of lesions in children and adults with congenital and structural heart defects.

Methods

A retrospective review of all patients who underwent interventional cardiac catheterization using the KONAR- MF™ device from the three participating centers from 2019 to 2024 was done. Data collected included demographic details, complete diagnosis, indications for interventional catheterization, procedural details (approach, size of the device, delivery system used, fluoroscopy and procedure times, complications), as well as follow-up data.

All patients were thoroughly evaluated using echocardiography and additional imaging modalities as required. The size, shape, length, diameter of the lesion, adjacent structures, and relevant physiology were ascertained before the catheterization procedure and through appropriate angiographic assessment during the procedure. The size of KONAR- MF™ device was decided based on the narrowest diameter of the lesion. The device size was generally 1–4 mm larger than the narrowest diameter, depending on the age, weight, defect anatomy, and defect size. In AV fistulas with adequate landing zone, device was selected such that the larger dimension of the device would be twice the narrowest portion. In APW, size was chosen such that the smaller dimension of the device is 2–4 mm more than the APW size. Similar strategy was used for Fontan fenestration closures as well. The sizing in PDA was following the usual practice. The device is loaded such that the larger disk would be facing the chamber with higher pressure once deployed. A long introducer sheath or appropriately sized coronary guide catheter was used for device delivery (Fig. 1).

Standard cardiac catheterization protocols were followed. Procedures were done under sedation/general anesthesia as appropriate. All patients received 100 IU per kilogram of unfractionated heparin at the start of the procedure. Post-procedure anticoagulation/antiplatelet strategy was tailored to the individual patient and lesion. As per institutional protocols, patients were observed in the hospital for at least 24 h after the procedure and longer if required. Standard follow-up timings after the interventional procedure was followed, including at 1, 6-, and 12-month post-procedure.

Results

From 2019 to 2024, 79 off-label implantations of MF™ devices were performed. Demographic details and indications for using the KONAR-MF™ device are summarized in Table 1. Pre-procedure assessment was primarily based on an echocardiogram. Additional imaging (Computed Tomography −16, transesophageal echocardiography −1) was performed for 17/79 (21.5%).

Fifty of the 79 (63.3%) procedures were done antegradely from venous access and the rest, 29/79, (36.7%) retrogradely from arterial access. The median fluoroscopy time was 10 min (IQR6-18). Five patients needed ICU care, two each for pre-existing heart failure and sepsis and one for observation. The median duration of hospital stay was 2 days (IQR 1–4 days).

The sizes of KONAR-MF™ used are shown in Table 2. A long sheath of appropriate size as per information for users was used in 50 (63.29%) patients. In 29 patients (36.7%), device delivery was done using Judkin's right coronary guide catheter. Complete occlusion at the end of the procedure was documented in 72 (91.13%) patients. The residual flow was mild in 6 and trivial in one. There were no major complications (device embolization/need for emergency open heart or other surgery, cardiac arrest, or death).

77 patients were followed up for a median of 18 (IQR 12–28) months. Complete occlusion at follow-up was documented in all except one patient with the paravalvular leak of the prosthetic pulmonary valve, who had mild residual flow.

Table 1 Demographic details and indications for using KONAR-MF™

Variable	Number of patients (%)
Age (Months, median IQR)	60 (24–132)
Sex (male) percentage	48/79 (61)
Weight (kilograms, median IQR)	16 (10–25)
Diagnoses/Indications for using KONAR- MF™ (percentage)	
Patent ductus arteriosus	34 (43)
Aortopulmonary window	3 (3.8)
Aortopulmonary Collateral	5 (6.3)
Systemic Arteriovenous Fistula	3 (3.8)
Coronary Arteriovenous Fistula	12 (15.2)
Pulmonary Arteriovenous Fistula	2 (2.5)
Abernethy malformation	3 (3.8)
Antegrade flow occlusion	2 (2.5)
Fontan Fenestration Closure	7 (8.9)
Decompressing vein	2 (2.5)
Paravalvular leak	2 (2.5)
Pseudoaneurysm closure	1 (1.3)
Levoatrial cardinal vein	1 (1.3)
Left ventricle to left atrial shunt	1 (1.3)
Pulmonary artery end of isolated left subclavian artery	1(1.3)

Table 2 KONAR-MF™ device sizes with frequencies used in the study

Device sizes used	Frequency
5–3	5
6–4	13
7–5	13
8–6	6
9–7	14
10–8	9
12–10	10
14–12	9

Discussion

The extraordinary variety of lesions with numerous anatomic variations as well as the wide range of body weights pose a unique challenge for pediatric cardiac catheterization. Using bespoke devices tailored to each patient is largely unrealistic. KONAR- MF™ is a Nitinol double-disk device joined at the cone-shaped waist, which is stretchable. We have analyzed our retrospective data on the 'off-label' use of the occluder and found the usefulness of various unique features for closing various congenital and structural cardiac and extracardiac defects.

The advantages of KONAR-MF are (i) medium profile, (ii) narrow stretchable connector, (iii) cone-shaped high-pressure disk, (iv) retention screws on either side, and (v) multiple layers of wire braid.

(1) Medium profile: This was useful in closing the various tortuous vascular structures, especially coronary arteriovenous fistula (Fig. 3), and collaterals.
(2) Narrow stretchable connector: This makes the device elongate more in case of long tunnels or tracts such as decompressing vein, levoatrial cardinal vein, and other systemic arteriovenous fistulas.
(3) Cone-shaped structure: Fontan antegrade flow closure and paravalvular leak (Fig. 4).
(4) Retention screws on both sides: Useful to deploy on either side. Some of the PDAs in our retrospective cohort underwent arterial deployment due to interrupted inferior vena cava.
(5) Multi-layered wire braid enhances the occlusion in various conditions like pulmonary arteriovenous fistula and coronary arteriovenous fistula.

KONAR-MF has screws on either side which enable both antegrade and retrograde deployment. The device has a total length of 4 mm but is stretchable due to its unique narrow connector, and sizes range from 5/3 to 14/12 mm. Another useful feature of the device is its medium profile that enables delivery through small caliber introducer sheaths or coronary guide catheters. The presence of multiple occlusive layers makes it an attractive alternative to vascular plugs for most vascular lesions that require occlusion.

Retention skirts of KONAR- MF™ are larger than the waist. This could translate practically into lengthening of the device and possible protrusion into adjacent normal vessels/structures. This should not generally be a matter of concern when occluding long structures like decompressing veins, and aortopulmonary collaterals, and when the landing zone is long enough in systemic, pulmonary or coronary arteriovenous fistulas. On the other hand, if the landing zone is short in any situation, this could unintentionally occlude adjacent vessels or structures.

Retention skirts on the other hand is desirable in APW (Fig. 5), selected PDAs with high PA pressure, Fontan Fenestration, closure of antegrade flow when undesirable in single-ventricle physiology, and paravalvular leak (Fig. 4). In all these circumstances, there are periods of time during the cardiac cycle when pressures may become higher on either side of the defect. The data presented in this paper

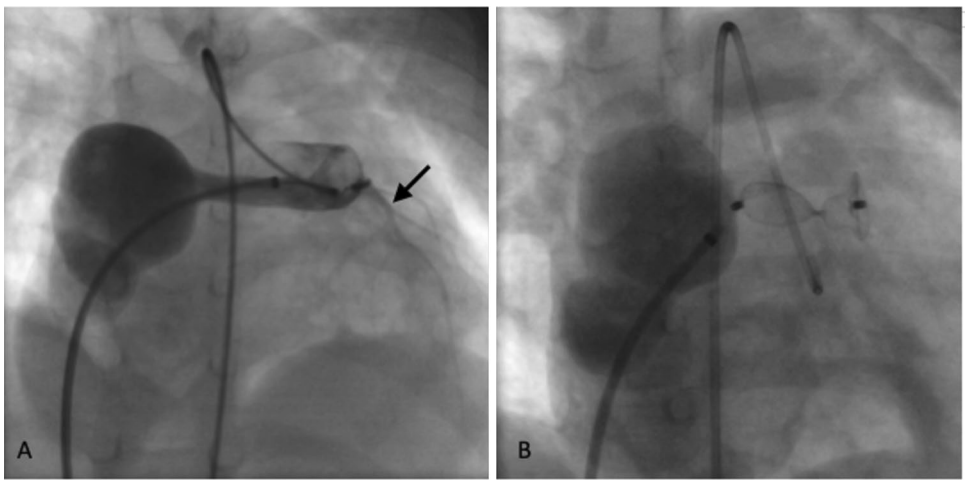

Fig. 3 Transcatheter closure of coronary AV Fistula. **A** Contrast injection through the delivery sheath positioned in the fistula from the venous access in AP cranial view shows large coronary AV fistula arising from left main coronary artery and draining into right atrium. Left anterior descending and left circumflex arteries can be seen filling normally (black arrow) (**B**). The fistula was closed with a 9*7 Konar-MF device antegradely. The residual shunt reduced upon release and further by discharge

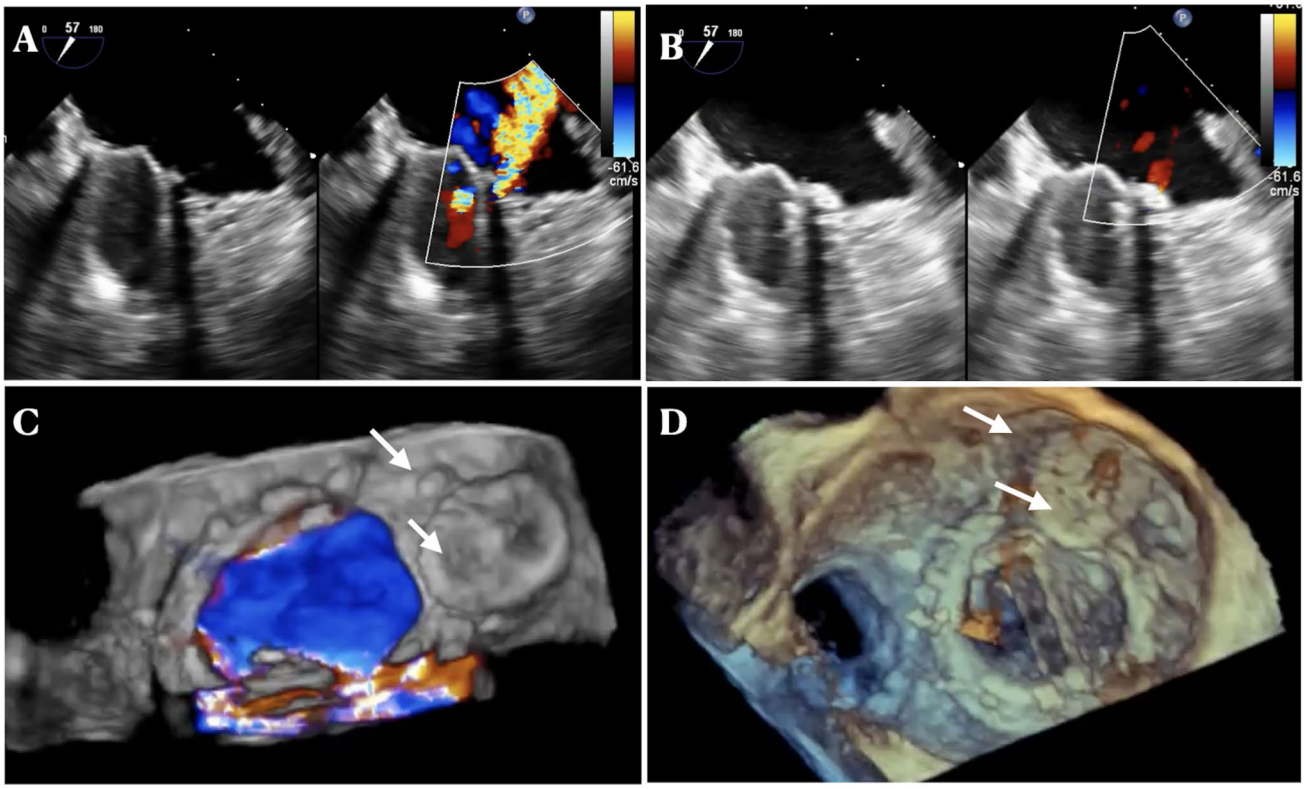

Fig. 4 Transcatheter closure of mitral paravalvular leak. **A** Transesophageal echocardiogram showing moderate mitral paravalvular leak from the posterior-lateral aspect. **B** Post-deployment of two KONAR-MF devices showing good occlusion. **C** and **D** 3-D Transesophageal echocardiogram showing well-positioned two devices. (white arrows)

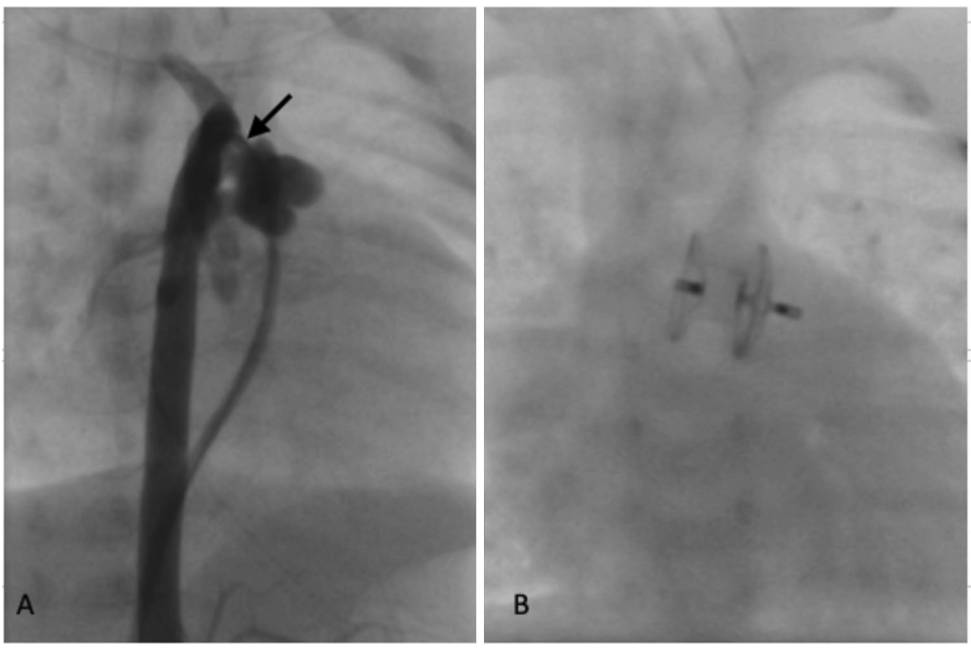

Fig. 5 Transcatheter closure of Aortopulmonary Window in a 1.4-kg pre-term baby with intractable heart failure. **A** Descending aortogram done in RAO view through the delivery sheath from the venous access showing a 3-mm Aortopulmonary window (black arrow). This was closed antegradely using a 6*4 Konar-MF device. **B** Post-release appearance of the device in AP view

demonstrates that KONAR-MF™ can be safely and effectively used in a wide variety of lesions.

The presence of retention screws on either side of the device allows for delivery from either the venous or arterial approach. The potential to deliver from venous access is distinctly advantageous in small babies where there are limits to the size of the arterial access. On the other hand, in certain situations, such as coronary arterial fistula or rupture sinus of Valsalva aneurysm, the retrograde arterial approach may greatly simplify the procedure.

When closing PDAs, there are two primary settings where the KONAR- MF™ device can potentially be useful: (i) when for any reason (such as interrupted inferior caval vein), the PDA cannot be crossed from the pulmonary artery, it can be crossed retrogradely from the aortic side and closed and (ii) second is the hypertensive PDA which qualifies for closure, where a double-disk device is desirable to prevent dislodgment from the high pulmonary artery pressures. The device can be handy for PDA closure in other settings as well (Fig. 6).

Selecting the suitable defect as well as a device for transcatheter closure of APW can be tricky, KONAR_ MF™ is a handy addition to the list of devices that can be considered for the same. In high-flow situations like coronary arteriovenous fistula, KONAR- MF™ with multiple layers of occlusion offers similar advantages to that of vascular plugs [8]. Antegrade flow, which was previously left alone in single-ventricle situations may need to be closed on follow-up. This is generally accessed from the internal jugular vein, through the Glenn anastomosis. The unique structure of the KONAR- MF™ device suits this anatomy where the cone-shaped waist would fit the stenotic lesion, held on the ventricular and pulmonary artery sides by either of the retention skirts. The same applies to Fontan fenestrations, although the thinner wall of the Fontan conduit makes a double-disk atrial sepal occluder well suited. Table 3 lists commonly encountered lesions, the inventory required for all of them, and the scope of KONAR-MF™.

It is notable that in slightly over a third of patients, the device was delivered using a guide catheter as opposed to a long sheath. This is particularly useful when the device is delivered retrogradely from the arterial route and tortuous vascular structures like fistulas. The current design does not allow deployment through the diagnostic catheter, unlike the Amplatzer vascular plug 4 (Abbot Laboratories, Chicago, Illinois, United States). Notably, the seal provided by the KONAR_ MF™ was quite effective immediate post-procedure as well as on follow-up, irrespective of the lesion.

Limitations

This is a retrospective chart review with inherent limitations of same. Head-to-head comparisons with other devices used for the same lesions would have been beneficial but may be challenging to do. The paper integrates data from three Indian centers, reflecting the practices followed in these locations. These are relatively low resource settings with a bias toward improvisations because of limited access to a wide range of occlusive devices. Further data would be needed to substantiate its impact on inventory management.

Conclusion

The unique structure and compact profile of the KONAR-MF™ enables application in a wide range of conditions as demonstrated. The device has considerable potential to reduce the need of multiple occluders in f the catheterization laboratory by virtue of its versatility. Additional modifications in the design with smaller retention skirts and further reductions in profile making it small enough for delivery

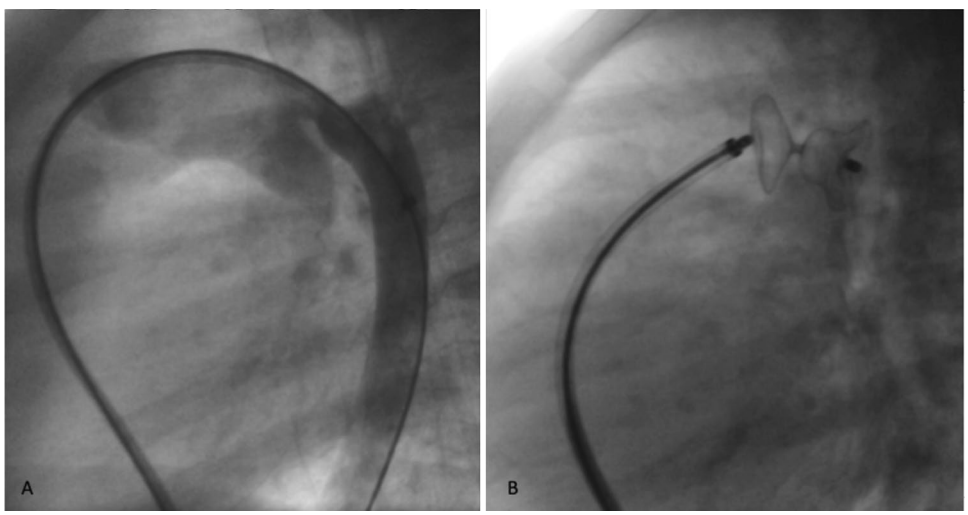

Fig. 6 Transcatheter closure of PDA using Konar-MF device. Angiogram done through the delivery sheath across the PDA from the venous access shows an elongated duct (**A**). The duct was attempted to be closed with a 10*8 Lifetech PDA occluder. The length was inadequate, intra ductal deployment was done and the device migrated to the pulmonary artery prior to release. In order to account for the length of the duct and to provide additional stability by means of the disk at the pulmonary end, the PDA was closed with a 12*10 Konar-MF device (**B**)

Table 3 Overcoming the challenge of a complex inventory with the KONAR- MF™

Lesion	Devices generally used	Scope of KONAR-MF™
PDA, unable to cross antegradely	Amplatzer duct occluder 2 (for smaller ducts)	KONAR-MF offers more size ranges, up to 10*8 size can be deployed through guide catheter (5*3;6*4;7*5—5Fr, 8*6-6Fr, 9*7; 10*8—7Fr) retrogradely
Hypertensive PDA	Oversized ADO 1 or similar device, muscular VSD occluder	MFO offers distinct advantage of conical waist with two retention skirts, thus offering protection from displacement due to higher pulmonary artery pressures
Coronary arteriovenous fistula	Amplatzer Vascular Plug 2, Amplatzer duct occluder 1,	Multiple layers of occlusion of MFO helps, similar to Vascular plug. Large retention skirts of MFO are not necessary, potential to protrude into nearby branches unless landing zone is long enough; delivery feasible via coronary guiding catheter; configures to the vascular structure due to its medium profile
Aortopulmonary Window	Amplatzer duct occluder 1, ADO II	Retention disks on either side of MFO is an advantage. Ideal device does not exist
Antegrade flow closure in single-ventricle physiology	Amplatzer Septal Occluder, Amplatzer duct occluder 1; ASD device; fenestrated ASD device	Waist would ideally occupy the valvar/subvalvar narrowing with LV side of the device to the ventricle and discs on either side
Paravalvular leak	Amplatzer vascular plug 3, Occlutech Paravalvular Leak device, Amplatzer duct occluder 1, Amplatzer vascular plug 2	Medium profile device can get accommodated in the paravalvular defect

through diagnostic catheters especially for the small diameter devices may further expand the scope of the device.

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Data Availability Data will be maintained for 5 years after publication.

Declarations

Conflict of interest The authors declare no competing interests.

Ethical Approval None.

Informed Consent Not applicable.

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