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Catalán Cabrera Alex *

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Research Article

# Multifunctional Device (Konar-MF-VSD) for Percutaneous Closure of Ventricular Septal Defects Cases Report

**Catalán Cabrera Alex *, Condori Karen del Rosario, Medina Mónica**

Pediatric Cardiology Departament – Congenital Heart Catheterization/ San Borja Children's Health Institute, Lima, Peru.

***Corresponding Author:** Alex Ismael Catalán Cabrera, Departament of Pediatric Cardiology – Congenital Heart Catheterization/San Borja Children's Health Institute/ Lima, Perú.

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## Abstract

A ventricular septal defect (VSD) is communication between both ventricles. There are diferent types of VSDs based on anatomy. At the National Institute of Child Health San Borja (INSNSB) Lima – Peru the treatment carried out in the hospital was surgical. "Since the beginning of 2023, the multifunctional device (KONAR-MF-VSD) was approved for commercialization in Peru, and its use in the hospital began in 2024."

We present eight clinical cases in which patients were successfully treated using the new multifunctional device (KONAR-MF-VSD). No complications occurred during the peri-operative period or the first month of follow-up.

Before 2024, the hospital relied exclusively on surgical closure for VSDs. The introduction of the KONAR-MF-VSD device was motivated by its flexibility, reduced radial force, and adaptability to various VSD morphologies, enhancing procedural success rates.

Percutaneous closure of muscular and perimembranous ventricular septal defect with the KONAR – MF- VSD device can be performed both antegrade and retrograde without complications.

**Keywords:** ventricular septal defect (vsd); cardiac catheterization; septal occluder device; doppler echocardiography; transesophageal echocardiography

## Introduction

Ventricular septal defect (VSD) is among the most prevalent acyanotic congenital heart diseases, accounting for approximately 20% of all congenital heart defects. It can occur in isolation or alongside other cardiac anomalies. Notably, up to 60–70% of VSD cases close spontaneously within the first year of life. [1].

According to Sivakumar [3], perimembranous ventricular septal defects (VSDs) can be classified using transthoracic echocardiography into four types: Type A—VSD with an absent aortic rim, where the upper margin of the defect aligns with the aortic annulus without significant separation. Type B—VSD with a well-formed aortic margin, created by the ventriculoinfundibular fold. Type C—VSD partially restricted by a septal aneurysm, which results from the growth of fibrous tissue around the defect's edges. Type D—VSD restricted by a septal aneurysm formed by portions of the tricuspid valve leaflets, either septal or anterior, due to chordal insertions at the apical edge of the defect.

Although aneurysm formation functionally reduces the size of the VSD, it may also increase the risk of tricuspid insufficiency, aortic valve prolapse, right ventricular outflow tract obstruction, aneurysm rupture, and bacterial endocarditis [4].

The main indications for ventricular septal defect closure include symptomatic patients with echocardiographic evidence of left chamber dilation and a pulmonary-to-systemic blood flow ratio (Qp/Qs) greater than 1.5 [4]. In our setting, the high risk of infective endocarditis warranted the closure of defects that were previously managed conservatively without a clear surgical indication.

The proximity of the defect to the aortic and tricuspid valve with the conduction system can cause atrioventricular block (AVB), occurring in the case of percutaneous management between 0.5%-6.8% while in surgical management it is less than 2%. [5].

The closure of these defects is typically achieved using devices specifically designed for interventricular communication. However, certain off-label devices, such as ductus occluders and the Amplatzer Vascular Plug II, are also utilized [6]-[9]. These alternative devices exert greater radial force, which may increase the risk of atrioventricular block

and require a minimum distance of ≥5 mm between the upper edge of the defect and the aortic valve [10].

The KONAR-MF-VSD device (Lifetech, China) used in our cases is composed of nitinol and features two discs connected by a cone-shaped waist, with screws on both discs. This bidirectional screwing mechanism allows for both retrograde and antegrade placement [11]. It is compatible with 4F to 7F delivery systems, and its flexible waist is specifically designed to minimize the risk of atrioventricular block while adapting to a wide range of VSDs. Additionally, its soft woven mesh enhances adaptability to septal defects, and the thin release wire helps reduce procedural complications [11].

The KONAR-MF-VSD device has been commercially available worldwide since 2018, introduced in Peru in 2023, and implemented at our hospital in early 2024. Given its material properties and accessibility, it was chosen as the primary option for percutaneous closure of perimembranous and muscular ventricular septal defects. Specifically, for perimembranous defects, a minimum distance of 2 mm between the upper edge of the defect and the aortic valve is required [6].

Patients selected for percutaneous closure had a perimembranous ventricular septal defect smaller than 10 mm with an aortic edge greater than 2 mm [8]. For muscular defects, an adequate transthoracic echocardiographic window was also required, as our institution only has a transesophageal echocardiography probe for patients weighing over 20 kg.

These initial cases demonstrate the feasibility of percutaneous ventricular septal defect closure using this device, providing valuable insights that can be replicated in other institutions. From the authors' perspective, this represents a significant advancement in the percutaneous treatment of congenital heart defects in our country.

## Cases Report

All eight patients who met the inclusion criteria were admitted one day before the procedure **(Table 1).** Transthoracic echocardiography revealed an aneurysmal mechanism in patients with perimembranous VSD, which was further confirmed through left ventriculography (Figure 1). The defect size was assessed after intubation using transthoracic echocardiography (Vivid S6 – General Electric) for muscular VSD and transesophageal echocardiography (Vivid S6 – General Electric) for perimembranous VSD.

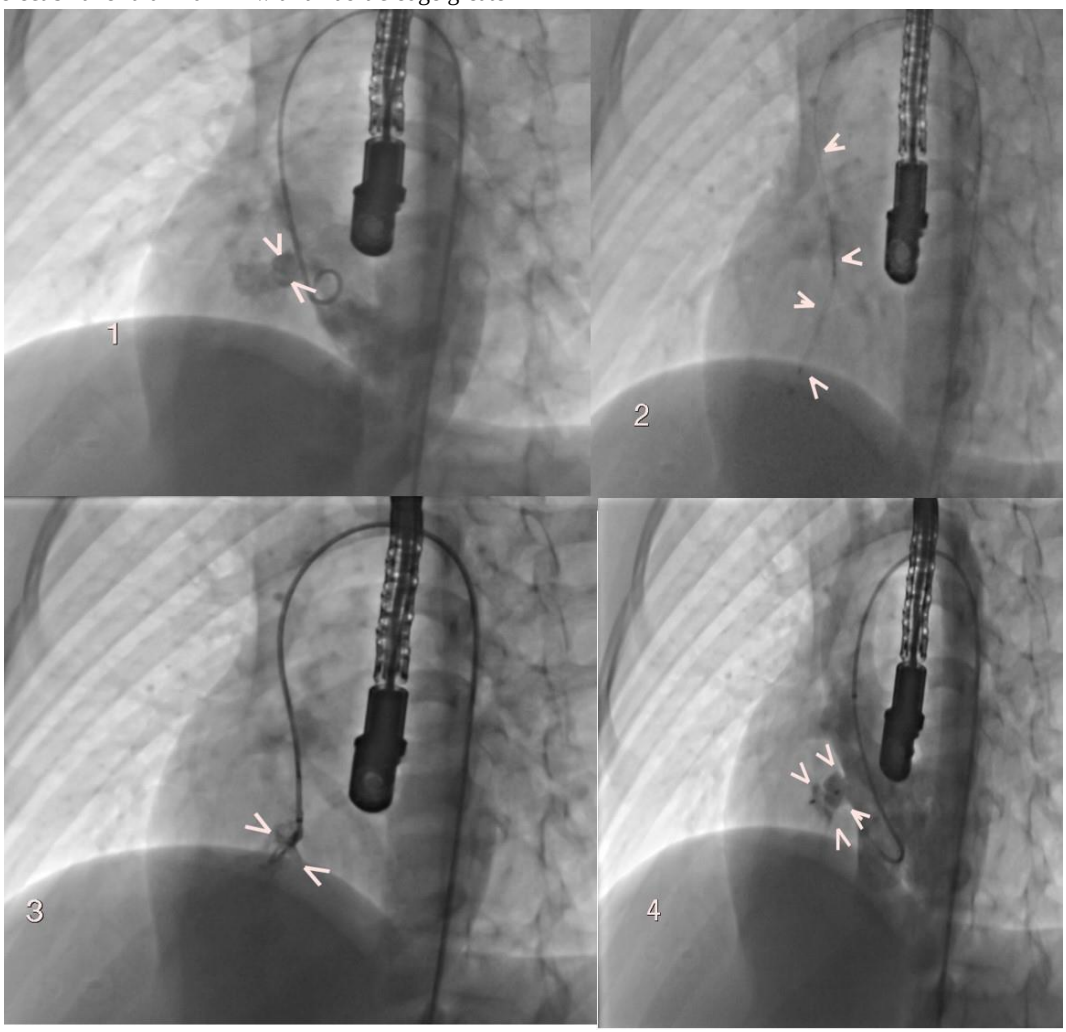


**Figure 1-**Left ventriculography to visualize interventricular communication with aneurism(white arrow). 2.- Device still inside the long introducer positioned in the right ventricle. 3.- Device being approximated at the level of the interventricular communication. 4.- Device released without residual short circuit on left ventriculography performed.

The size of the device to be used was at least 1 mm larger than the size of the defect and in the case of having an aneurysm (perimembranous VSD type C and D) its proximal part was also considered [12].

In the first two cases, the antegrade approach was initially selected, but after evaluating procedural efficiency and patient anatomy, the retrograde route was preferred for the remaining six cases due to its shorter procedural time and improved maneuverability. 100 IU/kg of unfractionated heparin was administered [17].

Left ventriculography was performed with a 4/5 Fr Pig tail catheter in the left anterior oblique 30-40° and cranial 40°-50° to visualize the size and shape of the ventricular septal defect.

In the case of muscular VSD (Case 1) and the first perimembranous VSD (Case 2), the anterograde route was used **(Figure 2),** however, in the other 6 cases the retrograde route was used. In all cases, to pass through the interventricular defect from the left ventricle to the right ventricle, a 4-5 Fr Pigtail catheter was used with the proximal tip cut, with a 0.035" x 260 cm curved tip hydrophilic guidewire **(Figure 3).**

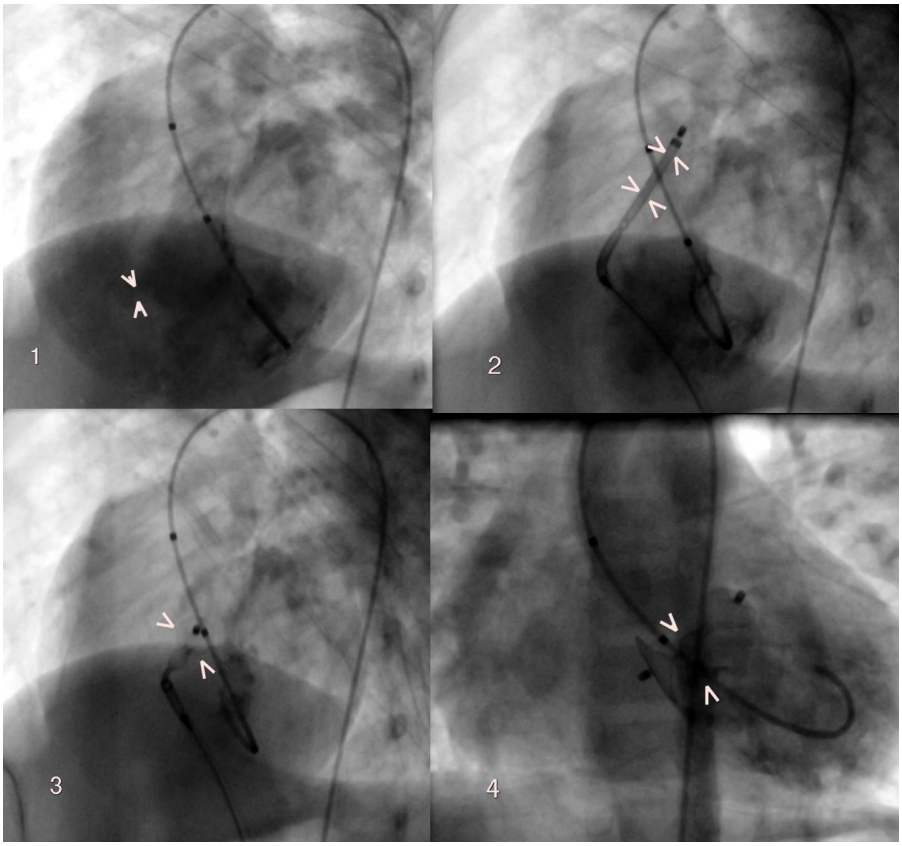


**Figure 2:** Anterograde route. 1.- Left ventriculography with a 4 Fr pigtail catheter to visualize VSD. 2.- VSD device release located in the left ventricle after removing a 0.035" x 260 cm hydrophilic guidewire from the descending aorta. 3.- release of a disc from the device and approach to the interventricular septum.4.- Release of the device from the right ventricle at the level of the VSD.

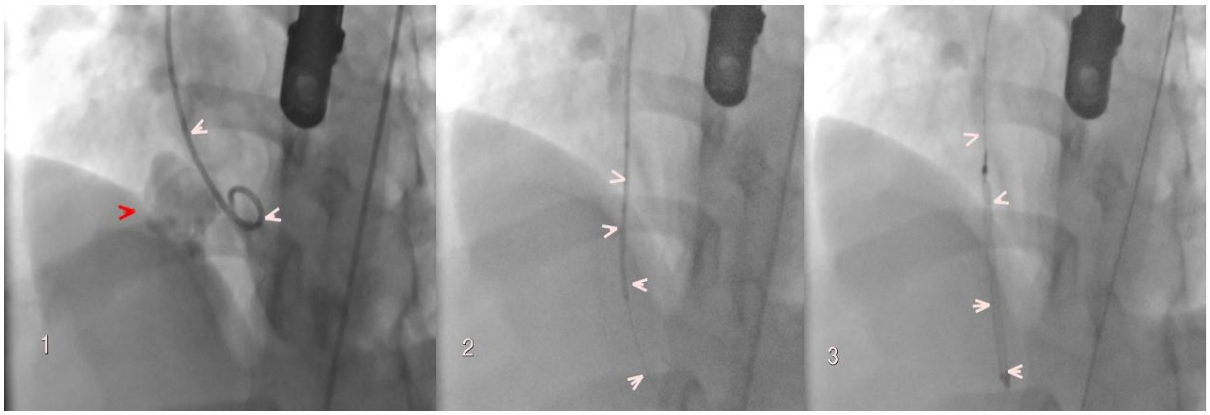


**Figure 3:** Retrograde route. 1.- Left ventriculography with a 5 Fr pigtail catheter to visualize VSD. 2.- 5 Fr pig tail catheter with the tip cut off, used to pass into the right ventricle with a 0.035" x 260 cm hydrophilic guidewire. 3.- VSD occluder device still within its delivery system still in the right ventricle.

Once the 0.035" x 260 cm curved-tip hydrophilic guidewire was advanced from the left ventricle to the right ventricle, it was positioned in the pulmonary artery (TAP). In cases where the antegrade approach was used, the guidewire was retrieved via the venous route with the assistance of a

10 mm loop catheter, establishing an arteriovenous circuit. Subsequently, the short femoral vein introducer was replaced with the appropriate device delivery system, allowing for deployment from the right ventricle (Video 1: https://vimeo.com/manage/videos/1065472472).

For the retrograde approach, once the guidewire was positioned in the right ventricle, the short 5 Fr femoral artery introducer was exchanged for a KONAR device delivery system, selected according to the required size, enabling release from the left ventricle (Video 2: https://vimeo.com/1065264991?share=copy).

Device position, residual shunts, and potential tricuspid or aortic regurgitation were assessed using transthoracic or transesophageal echocardiography (Video 3: https://vimeo.com/manage/videos/1065473196) and confirmed by left ventriculography.

Additionally, two patients presented Krichenko type E patent ductus arteriosus, which was successfully closed using a KONAR-MF-VSD device [13] (Table 1).

| Case | AGE (YEARS) | Sex | Weight (kg) | VSD type | Associated Defects | VSD Type (ECHO) | VSD Measurement (mm) | MF Device | Closure pathway | pulmonary pressure (mmHg) | Fluoro time (min) | Radiation dose (mgy) | Complications |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | F | 10 | M | NO | MUSCULAR | 7 | 10/8 | A | 20 | 68.8 | 591 | NO |
| 2 | 7 | M | 28 | PM | PCA | TYPE C | CIV (4), PCA (2) | 7/5 (CIV), 6/4 (PCA) | A | 20 | 68.8 | 591 | NO |
| 3 | 13 | F | 40 | PM | PCA | TYPE D | CIV (4), PCA (2) | 8/6 (CIV), 6/4 (PCA) | R | 27 | 56.6 | 780.9 | NO |
| 4 | 14 | F | 48 | PM | NO | TYPE C | 3 | 6/4 | R | 20 | 35.7 | 963.6 | NO |
| 5 | 6 | F | 19 | PM | NO | TYPE D | 4 | 8/6 | R | 20 | 10 | 148 | NO |
| 6 | 16 | F | 62 | PM | NO | TYPE D | 5 | 12/10 | R | 20 | 11 | 618 | NO |
| 7 | 15 | F | 35 | PM | NO | TYPE D | 5 | 10/8 | R | 20 | 22 | 357 | NO |
| 8 | 15 | M | 48 | PM | NO | TYPE D | 4 | 7/5 | R | 20 | 13.7 | 221.1 | NO |

**Table 1:** Characteristics of the cases

VSD: Ventricular septal defect. PDA: Patent ductus arteriosus. M: Muscular VSD. PM: Perimembranous VSD. Closure pathway: A (anterograde), R (retrograde). MF device: KONAR - Multifunctional device- VSD.

Two-thirds of the patients were female, with a mean age of 11 years, an average weight of 36 kg, and an average pulmonary pressure of 21 mmHg. The mean fluoroscopy time was 35.8 minutes, and the average radiation dose was 413.3 µGy.

After the procedure, patients underwent a 1-hour post-anesthetic recovery in the cardiac catheterization lab and then returned to a cardiovascular hospitalization ward for further monitoring.

In the muscular VSD and in one case of perimembranous VSD, a trivial residual transprosthetic shunt was present [5] which disappeared at echocardiographic control 24 hours after the procedure. All received permanent clinical monitoring. No case presented electrocardiographic alterations immediately or at the control prior to discharge 24 hours after the procedure. They were discharged with acetylsalicylic acid for 6 month

## Discussion

Although various VSD closure devices are available on the market, including off-label alternatives, the KONAR-MF-VSD device offers key advantages. Notably, it requires a shorter distance between the upper edge of the defect and the aortic valve, and its flexible structure and smaller profile may help minimize the risk of atrioventricular block [11].

Another significant advantage is its ability to be implanted via both antegrade and retrograde approaches, with the retrograde route often reducing procedure time.

Percutaneous VSD closure using the KONAR-MF-VSD device has been reported to achieve a success rate of up to 98% at one month of follow-up, surpassing that of other closure devices [6]. In our patient cohort, transthoracic echocardiography confirmed a 100% occlusion rate within 24 hours post-procedure.

Regarding safety, the KONAR-MF-VSD device has demonstrated a low rate of complete atrioventricular block, reported at 0.6% over a one-year follow-up, compared to previous VSD closure devices, where rates reached up to 6% [10],[14]. It is important to note that all patients in our study had perimembranous VSD with an associated aneurysmal mechanism, a factor that may reduce the likelihood of atrioventricular block and tricuspid or aortic valve complications [12].

Given the limited number of patients in our case series, and despite the presence of aneurysmal mechanisms in all perimembranous defects [14],[15], ongoing monitoring remains essential. Long-term complications, such as atrioventricular block, must be closely observed, as demonstrated in the case reported by Saïd Bichali, where late-onset AV block occurred 20 months post-implantation [16].

## Conclusion

Percutaneous closure of muscular and perimembranous ventricular septal defect with the KONAR – MF- VSD device can be performed both antegrade and retrograde without immediate complications; however,

periodic monitoring is required to detect possible medium- and long-term complications.

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