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Article

Assessment of Immediate, Short- and Long-Term Outcomes After Transcatheter Perimembranous Ventricular Septal Defect (PM VSD) Closure by KONAR-MF Occluder Device

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ABSTRACT

Background: Perimembranous ventricular septal defect (PM VSD) is the most prevalent congenital heart defect, traditionally managed by surgical closure with associated morbidity. Minimally invasive transcatheter approaches have shown promise, yet data on the KONAR-MF occluder's long-term safety and efficacy remain limited in paediatric populations. **Objective**: This study aimed to evaluate the immediate, short-, and one-year clinical outcomes of transcatheter PM VSD closure using the KONAR-MF occluder device in children, focusing on closure rates, valvular function, and rhythm disturbances. **Methods**: A prospective, single-arm cohort study was conducted at the National Institute of Cardiovascular Diseases (NICVD), Karachi, enrolling 42 patients aged <18 years with PM VSD suitable for device closure. Patients with right coronary cusp prolapse, pulmonary hypertension, or multiple congenital defects requiring surgery were excluded. Echocardiography, angiography, and electrocardiography were performed at baseline, post-procedure, and at 1, 3, 6, and 12 months. The study received ethical approval and adhered to the Declaration of Helsinki. Descriptive analysis was conducted using SPSS v26. **Results**: The mean age was 9.6 ± 5 years and weight 23.6 ± 12.4 kg. Immediate closure was achieved in 97.6%, sustained in 95.2% at 12 months. No cases of AV block, haemolysis, or significant arrhythmias were observed. Mild, non-progressive aortic regurgitation occurred in one patient (2.4%); tricuspid regurgitation improved over time. One unrelated death occurred at 12 months. Valvular function and ECG remained stable with no statistically significant deterioration ($p > 0.05$). **Conclusion**: Transcatheter PM VSD closure using the KONAR-MF occluder is a safe and effective alternative to surgery in selected paediatric patients, offering high closure rates and a low complication profile, supporting its clinical applicability in structural heart disease management.

Keywords: Ventricular Septal Defect; KONAR-MF Occluder; Transcatheter Closure; Paediatric Cardiology; Atrioventricular Block; Valvular Regurgitation; Minimally Invasive Procedures.

INTRODUCTION

Ventricular septal defect (VSD) is among the most frequently encountered congenital heart anomalies, accounting for approximately 20% of all congenital heart disease cases, with an estimated incidence of 5.3 per 1000 live births (1,2). While VSDs can occur as isolated defects, they may also present as part of more complex congenital cardiac malformations. The perimembranous type (PM VSD) is the most prevalent, representing nearly 70% of all VSD cases (3).

Traditionally, surgical closure has been the standard approach for PM VSD repair, offering low morbidity and mortality rates. However, surgical intervention requires sternotomy, general anesthesia, and cardiopulmonary bypass, which can prolong hospital stay and recovery (4,5). In contrast, transcatheter closure is a less invasive alternative for selected patients, particularly those with favorable defect anatomy and adequate subaortic rims. It reduces hospital stay, avoids open-heart surgery, and minimizes postoperative discomfort (6,7).

Despite these advantages, percutaneous closure is not without risk. One of the most feared complications is atrioventricular (AV) block, due to the proximity of the conduction system to the perimembranous septum. The incidence of AV block following transcatheter closure ranges from 0.5% to 6.8%, while it is typically <2% in surgical cases (4). Device design plays a crucial role in minimizing such risks. The KONAR-MF (Multi-Functional) occluder, developed by Lifetech (China), was engineered to address concerns regarding mechanical stress on the cardiac conduction system.

This self-expanding nitinol device features a flexible, low-profile frame designed to conform to septal anatomy with reduced radial force. It allows both retrograde and anterograde delivery, providing procedural flexibility while minimizing interference with valvular structures (6–9). The device received CE certification in Europe in May 2018 and has shown promising short- and mid-term results in several international studies (10). This study aimed to evaluate the safety, efficacy, and clinical outcomes of the KONAR-MF occluder for PM VSD closure in the paediatric population, with a specific focus on immediate, short-, and one-year follow-up outcomes. Given the limited data on long-term performance, particularly from South Asia, this study seeks to contribute meaningful insights into the device's clinical utility.

MATERIALS AND METHODS

This prospective, single-arm observational cohort study was conducted at the Pediatric Cardiology Department of the National Institute of Cardiovascular Diseases (NICVD), Karachi, including its affiliated satellite centers. The study was carried out over a period of one year and involved children under 18 years of age diagnosed with perimembranous ventricular septal defect (PM VSD). Inclusion criteria required evidence of PM VSD with adequate subaortic rim (≥3–4 mm), absence of right coronary cusp prolapse or aortic regurgitation, and a pulmonary-to-systemic flow ratio (Qp/Qs) greater than 1.5:1. Patients with additional congenital heart anomalies requiring surgical correction (e.g., patent ductus arteriosus, atrial septal defect, multiple muscular VSDs), or those with pulmonary hypertension defined by a pulmonary vascular resistance index (PVRI) exceeding 6 Wood units, were excluded. A non-probability consecutive sampling technique was employed for participant recruitment. Written informed consent was obtained from the guardians of all participants after thorough explanation of the procedure and associated risks.

Data were collected using a structured questionnaire that included demographic details, anthropometric measurements, and clinical history. The primary outcome was successful transcatheter closure of PM VSD with the KONAR-MF occluder device, defined as complete or near-complete closure without significant residual shunt and absence of serious procedural complications. Secondary outcomes included the incidence of new-onset aortic or tricuspid regurgitation, arrhythmias including atrioventricular block, device embolization, haemolysis, and mortality during follow-up. All patients underwent baseline assessment with transthoracic echocardiography (TTE), including color and continuous-wave Doppler imaging to determine defect size, location, and proximity to valvular structures. Procedural measurements were confirmed by angiography using a standard 60° left anterior oblique (LAO) and 20° cranial projection, with VSD dimensions calibrated against a pigtail catheter. Device size was chosen to be 1–2 mm larger than the narrowest angiographic VSD diameter. Transoesophageal echocardiography (TEE) was employed selectively during the procedure for enhanced visualization. The retrograde approach was the default technique, with antegrade access used only when required due to anatomical constraints. All procedures were performed under conscious sedation with percutaneous vascular access via the right femoral artery and vein.

After arterial access, heparin (75–100 units/kg) was administered to prevent thrombotic complications. Device deployment involved initial release of the right ventricular disc followed by the left ventricular disc under fluoroscopic and echocardiographic guidance. Devices were released only after confirming optimal positioning, absence of valvular interference, and satisfactory closure. Post-procedural assessment included TTE within 24 hours and prior to discharge. Aspirin (3–5 mg/kg/day) was prescribed for six months, and patients were advised prophylaxis against infective endocarditis until complete closure was confirmed. Follow-up evaluations were conducted at 1, 3, 6, and 12 months, and included physical examination, TTE, and 12-lead electrocardiography. Any adverse events or complications observed during these visits were documented.

The study was conducted in accordance with the Declaration of Helsinki. Ethical approval was obtained from the institutional ethics review board, and confidentiality of participants' data was maintained through anonymization and restricted data access protocols. All data analyses were performed using SPSS Statistics for Windows, Version 26.0 (IBM Corp., Armonk, NY). Continuous variables were expressed as mean with standard deviation or median with interquartile range based on data distribution, while categorical variables were presented as frequencies and percentages. The normality of continuous variables was assessed using the Kolmogorov–Smirnov test. Since this was an observational study with no comparator group, only descriptive statistics were employed to summarize findings (13).

RESULTS

A total of 42 paediatric patients underwent transcatheter closure of perimembranous ventricular septal defect (PM VSD) using the KONAR-MF occluder device. The mean age of the patients was 9.6 ± 5 years, and the mean weight was 23.6 ± 12.4 kg. Among these, 22 (52.4%) were male. Echocardiographic and angiographic measurements indicated mean defect diameters of 4.0 ± 0.9 mm and angiographically assessed right and left ventricular diameters of 3.7 ± 1.0 mm and 5.8 ± 1.8 mm, respectively.

The average distance between the defect and aortic valve was 4.5 ± 0.8 mm. Septal aneurysm was noted in 14.3%, and right coronary cusp prolapse was present in 7.1%. No patients had pulmonary-to-systemic blood flow ratios (Qp/Qs) exceeding 1.5 at baseline. Detailed patient characteristics are summarized in

Table 1. The most frequently selected device sizes were 9/7 mm (23.8%) and 10/8 mm (14.3%). Device selection closely matched defect sizes measured angiographically, reflecting appropriate procedural planning and minimal device adjustments during implantation. Detailed distribution of device sizes utilized is presented in Table 2.

Table 1. Baseline Characteristics and Defect Profile

Parameter	Value
Mean Age (years)	9.6 ± 5
Mean Weight (kg)	23.6 ± 12.4
Male (%)	22 (52.4%)
Mean Defect Size on Echo (mm)	4.0 ± 0.9
Mean RV Diameter on Angiography (mm)	3.7 ± 1.0
Mean LV Diameter on Angiography (mm)	5.8 ± 1.8
Mean Distance from Aortic Valve (mm)	4.5 ± 0.8
Septal Aneurysm (%)	6 (14.3%)
Qp/Qs Ratio >1.5 (%)	0 (0%)
RCC Prolapse (%)	3 (7.1%)
History of Coarctation Repair (%)	1 (2.4%)
Coarctation Repair + PDA Ligation (%)	1 (2.4%)
VSD with Dual Jet (%)	1 (2.4%)

Table 2. KONAR-MF Device Size Distribution

Device Size	Frequency (n)	Percentage (%)
6/4 mm	1	2.4%
7/5 mm	5	11.9%
8/6 mm	3	7.1%
9/7 mm	3	7.1%
10/8 mm	6	14.3%
12/10 mm	3	7.1%
7/5 mm (variant)	4	9.5%
7/50 mm	1	2.4%
8/6 mm (variant)	3	7.1%
8/60 mm	3	7.1%
9/7 mm (variant)	10	23.8%

Table 3. Clinical Outcomes at Baseline and Follow-up

Outcome Measure	Baseline (n=42)	Immediate	1 Month	3 Months	6 Months	12 Months	p-value
Aortic Regurgitation (None)	42 (100%)	42 (100%)	41 (97.6%)	41 (97.6%)	41 (97.6%)	41 (97.6%)	0.845
Aortic Regurgitation (Mild)	0 (0%)	0 (0%)	1 (2.4%)	1 (2.4%)	1 (2.4%)	1 (2.4%)	
Tricuspid Regurgitation (None)	35 (83.3%)	35 (83.3%)	37 (88.1%)	38 (90.5%)	38 (90.5%)	39 (92.9%)	0.673
Tricuspid Regurgitation (Mild)	6 (14.3%)	7 (16.7%)	5 (11.9%)	4 (9.5%)	4 (9.5%)	3 (7.1%)	
Tricuspid Regurgitation (Moderate)	1 (2.4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Normal ECG	42 (100%)	41 (97.6%)	40 (95.2%)	42 (100%)	42 (100%)	42 (100%)	0.214
Complete Closure	-	41 (97.6%)	40 (95.2%)	40 (95.2%)	40 (95.2%)	40 (95.2%)	NA
Residual Shunt	-	1 (2.4%)	1 (2.4%)	1 (2.4%)	1 (2.4%)	1 (2.4%)	NA
Death	-	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (2.4%)	NA

Immediate procedural success, defined as complete or near-complete defect closure without significant residual shunting, was achieved in 41 patients (97.6%). Closure rates remained consistently high (95.2%) at 1, 3, 6, and 12 months of follow-up, with only one patient exhibiting a trivial, clinically insignificant residual shunt. Valvular function assessments indicated stable outcomes. Aortic regurgitation (AR) was absent initially and immediately post-procedure but was observed as mild in only one patient (2.4%) at the 1-month follow-up, remaining stable thereafter. Tricuspid regurgitation (TR), initially mild or moderate in 7 patients (16.7%), improved progressively, with 92.9% free from TR at 12 months. ECG evaluations revealed no significant conduction disturbances or persistent abnormalities at any follow-up interval, apart from a transient finding in one patient immediately post-procedure. Chi-square analysis indicated no statistically significant variations over time for AR ($p = 0.845$), TR ($p = 0.673$), or ECG findings ($p = 0.214$). There were no occurrences of haemolysis, device embolization, or significant vascular complications. One patient (2.4%) died by the 12-month follow-up from causes unrelated to procedural complications.

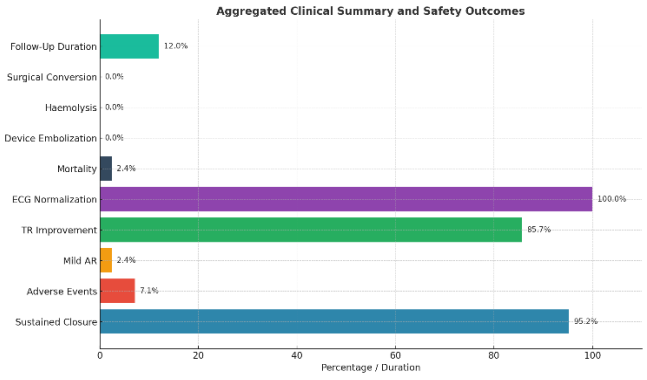

Figure 1 Summary of Clinical and Safety Outcomes

DISCUSSION

The present study demonstrated that transcatheter closure of perimembranous ventricular septal defect (PM VSD) using the KONAR-MF occluder device is a safe and effective therapeutic option in appropriately selected paediatric patients. With a procedural success rate of 97.6% and sustained complete closure in 95.2% of cases at one year, the findings align closely with previously published reports that highlight the growing clinical acceptability of this device. For instance, Koneti et al. observed closure rates improving from 90% at discharge to 97% at one month using the same device (11), while Laha et al. reported 86.8% immediate occlusion with 93% overall procedural success (12). The consistently high closure rates in the present study likely reflect meticulous patient selection, standardized procedural techniques, and close echocardiographic guidance, emphasizing the procedural learning curve and device-specific familiarity that enhances outcomes over time.

A major advantage of the KONAR-MF occluder is its favorable interaction with cardiac conduction tissue. In this cohort, no episodes of atrioventricular (AV) block, bundle branch blocks, or significant arrhythmias were noted, consistent with the low radial force and flexible nitinol design of the device. These results corroborate multicentre experiences by Sadiq et al. and Godart et al., where similar freedom from conduction abnormalities was observed (9,14). Compared to other occluders historically associated with higher rates of AV block (up to 6.8%), the KONAR-MF's atraumatic architecture appears to significantly mitigate this risk (13). This is of paramount importance in the paediatric population where the sequelae of permanent pacing can be particularly burdensome over the long term.

Valvular function also remained largely unaffected by the intervention. Only one patient developed mild aortic regurgitation (AR), which did not progress during follow-up. Similarly, tricuspid regurgitation (TR), initially observed in 16.7% of patients, improved over time with 92.9% showing complete resolution at one year. These outcomes are reassuring, especially in light of concerns over device-induced valvular interference. Prior studies have reported similar findings; for instance, Haddad et al. and Kuswiyanto et al. observed minimal to no clinically significant valvular complications during medium-term follow-up (8,10). The soft discs and controlled deployment mechanism of the KONAR-MF likely contribute to this favorable valvular profile, supporting its suitability for use in anatomically sensitive locations.

The procedural approach in this study predominantly utilized the retrograde technique, offering improved control during deployment and reduced procedure time, as supported by previous investigations (17,18). Although anterograde delivery was reserved for select anatomical situations, the ability to switch approaches reinforces the device's flexibility and adaptability in complex anatomies. Furthermore, the tailored selection of device sizes based on angiographic and echocardiographic measurements, with minimal need for intraoperative adjustments, underlines the predictability and precision of the procedure when guided by comprehensive pre-procedural planning.

Notably, the absence of complications such as haemolysis, device embolization, and access site complications further attests to the procedure's safety. The single reported mortality, which occurred at the 12-month follow-up, was not procedurally linked and emphasizes the importance of continued monitoring beyond the initial months post-implantation. Nonetheless, while these findings are promising, they must be interpreted in the context of certain limitations. The study was conducted at a single tertiary center with a relatively small sample size, which may limit external generalizability. Additionally, the absence of a comparator group (e.g., surgical repair or alternative occluder device) restricts definitive conclusions about superiority or comparative effectiveness. Moreover, the lack of inferential analysis in some areas—due to low event frequency—limits the ability to detect subtle clinical differences over time.

Despite these limitations, the strengths of the study include its prospective design, rigorous follow-up protocol, and the use of both echocardiographic and angiographic guidance for procedural accuracy. These elements collectively enhance the internal validity of the results and provide clinically meaningful insights for interventional paediatric cardiology.

Future research should focus on expanding the study population across multiple centers and incorporating longer follow-up periods to assess late-onset complications such as delayed conduction abnormalities or structural valve degeneration. Comparative studies evaluating different device types and techniques in randomized settings would further enrich the evidence base. Additionally, exploring quality-of-life outcomes and economic analyses could offer a broader understanding of the device's impact on patient care and healthcare systems.

In conclusion, the KONAR-MF occluder appears to be a highly effective and safe tool for transcatheter closure of PM VSD in children, offering sustained closure, preservation of valvular integrity, and avoidance of conduction-related complications. These findings support its use as a viable alternative to surgical repair in selected patients, though larger, multicentre trials are warranted to confirm long-term durability and to facilitate wider adoption of this approach in clinical practice.

CONCLUSION

This study demonstrates that transcatheter closure of perimembranous ventricular septal defects (PM VSD) using the KONAR-MF occluder device is a safe, effective, and minimally invasive alternative to surgical repair in appropriately selected paediatric patients. With high rates of immediate and sustained defect closure, minimal valvular interference, and an absence of significant conduction disturbances over one year, the procedure shows considerable promise for routine clinical application. These findings reinforce the device's utility in enhancing patient outcomes while reducing procedural morbidity, hospital stays, and recovery time. Clinically, this supports its integration into interventional strategies for congenital heart disease, particularly in cases where anatomical criteria are met. From a research perspective, the results advocate for larger, multicentre trials and longer-term follow-up

to establish broader generalizability, validate durability, and explore comparative effectiveness against other closure modalities.

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