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Short-Term Outcomes of Transcatheter VSD Closure Using the MFO Device at a Tertiary Cardiac Centre in Lahore

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ABSTRACT

Transcatheter closure is the commonly used approach to treat congenital ventricular septal defect (VSD), though local outcome data on the use of KONAR-Multi Functional Occluder (MFO) in Pakistan are scarce. **Objectives:** The purpose of this study was to evaluate the short-term outcomes following transcatheter VSD closure with the MFO device and to compare the results in retrograde versus the antegrade methods. **Methods:** Prospective observational research was carried out in the Department of Pediatric Cardiology, Punjab Institute of Cardiology, Lahore. They included patients aged between three years and thirty-one years of age who had previously experienced transcatheter VSD closure using the MFO device between January 2021 and June 2024. There were 30 patients who were enrolled, of whom 20 patients were under retrograde, and 10 patients were under antegrade. The predictors of residual shunt were determined by logistic regression. **Results:** Four patients (13.3) had a residual shunt at discharge, and it reduced to one (3.3) at one-month follow-up. There were three patients with aortic regurgitation in the early post-procedure period (10%). The significance of the ventricular septal defect diameter exceeding six millimeters was only significantly related to residual shunt (odds ratio 4.28, p = 0.04). There were no significant conduction changes or device embolization during hospitalization or 1-month follow-up. **Conclusions:** Short-term success with low complication rates was observed in both methods of Transcatheter closure of VSD with the MFO device. The results demonstrate the safety of this method within a local Pakistani tertiary care environment.

INTRODUCTION

Congenital heart disease remains a major public health challenge in Pakistan and continues to place a significant burden on pediatric cardiac care services [1]. Ventricular septal defect (VSD) is among the most frequently diagnosed congenital cardiac anomalies in the country. Current estimates suggest that approximately 4–6 per 1,000 live births in Pakistan are affected by VSD [2]. Many patients experience delayed diagnosis or limited access to specialized cardiac care, particularly in resource-constrained settings. This delay increases morbidity and places substantial strain on families and tertiary care institutions [3]. A ventricular septal defect is characterized by an abnormal communication between the right and left ventricles, allowing left-to-right shunting of blood. This abnormal circulation may result in pulmonary overcirculation, left ventricular volume overload, recurrent respiratory infections, growth failure, and heart failure if left untreated [4–6]. While spontaneous closure may occur in small defects, moderate to large VSDs often require intervention to prevent long-term complications. Surgical repair has traditionally been the standard treatment for hemodynamically significant VSDs. However, advances in interventional cardiology have led to the increasing use of transcatheter closure as a less invasive alternative in

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selected patients. Recent developments in occluder technology have improved procedural safety and expanded the range of VSD anatomies amenable to percutaneous treatment. The KONAR-Multi Functional Occluder (MFO) is a newer-generation device designed with a flexible nitinol waist and dual-disc configuration, allowing adaptation to a variety of VSD morphologies. Recent studies have evaluated the KONAR-Multi Functional Occluder (KONAR-MFO/KONAR-MF) for transcatheter VSD closure and generally report high procedural success with low rates of major complications. For example, a systematic review and meta-analysis of KONAR-MFO use across perimembranous and muscular VSDs reported overall favorable efficacy and safety outcomes [7]. In addition, single-center and multi-center experiences have described high closure rates with low incidence of clinically significant valve dysfunction or permanent conduction disturbances [8]. A more recent multicenter, prospective experience from India (three centers) reported mid-term follow-up outcomes for perimembranous VSD closure using KONAR-MF, contributing real-world safety data from a large regional cohort [9]. Evidence from South Asia suggests similar short-term success with modern occluders, including KONAR-MF/MFO, although outcomes vary by patient selection, anatomy, and operator strategy [10].

Studies in smaller children and comparative device cohorts have also supported acceptable safety profiles, while emphasizing continued attention to heart block and valve interactions. Despite these encouraging findings, published outcome data from Pakistan remain limited, and local patient factors (late presentation, nutritional status, follow-up access) may affect outcomes and complication detection. Therefore, local short-term outcome data after transcatheter VSD closure using KONAR-MFO are needed to inform practice in Pakistani tertiary-care settings. The main aim of this study was to evaluate the short-term outcomes of transcatheter VSD closure using the MFO device at a tertiary cardiac center in Pakistan and to compare procedural and early post-procedural results between antegrade and retrograde deployment approaches.

METHODS

A prospective observational study was conducted in the Department of Pediatric Cardiology in one of the tertiary cardiac centers in Lahore. The Institutional Review Board of the Punjab Institute of Cardiology, Lahore (Reference No. RTPGME-Research-149-A) gave ethical clearance. The enrolled patients were recruited in sequence, in all patients who came to the department and met the inclusion criteria, and gave informed consent, until the required sample size was reached. The information was gathered in the hospital clinical environment between January 2021 and June 2024. Sample size was estimated using a single-proportion (precision-based) approach, guided by previously reported high procedural success rates (~98%) for transcatheter VSD closure with KONAR-MFO. With a target confidence level of 95%, 5% margin of error, and pragmatic feasibility constraints of a single-center prospective cohort, a sample size of 30 was considered sufficient to provide an initial local estimate of early procedural success and short-term complications [11]. This study was not designed or powered to detect small differences between deployment approaches; subgroup comparisons and regression analyses were performed as exploratory assessments. The eligible patients included patients aged between three and forty years with a hemodynamically significant ventricular septal defect established on transthoracic echocardiography. They were limited to those with appropriate anatomy to sustain transcatheter closure. Patients who were previously surgically repaired or had device closure, were actively infected, had irreversible severe pulmonary hypertension, or aortic valve prolapse were excluded. Exclusion factor was also known allergy to device materials. Clinical interview, hospital record, imaging studies, and catheterization findings were used to collect data. Sociodemographic factors were age and gender. The clinical variables examined were weight, baseline symptoms, previous chest infections, heart failure characteristics, and previous history of infective endocarditis. Vivid E95 (General Electric, USA) was used to perform transthoracic echocardiography to confirm the VSD type, VSD diameter, left ventricular internal diastole and systole inner diameter, and left ventricular ejection fraction. Electrocardiogram and chest X-ray were also examined. Measurements of angiographic defect size and device were taken in the catheterization laboratory. Pediatric interventional cardiologists have conducted procedures in accordance with standard institutional guidelines. The operator decided to apply retrograde or antegrade deployment after the analysis of the defect anatomy, patient size, and ease of access. Anterograde route of device deployment is from the femoral vein to the inferior vena cava and then from the right ventricle via VSD into the left ventricle. The retrograde route involves the femoral artery into the aorta and then LV, and then via VSD into RV. All patients were subjected to the KONAR-MFO device, whose size was determined based on echocardiographic and angiographic measurements. The operator determined whether the device had to be recaptured or repositioned. The bias was minimized through the use of the identical imaging protocol, equipment, and application of standard clinical criteria. The factors that were considered as confounders in the data analysis were age, defect type, and delivery approach

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through stratified assessment. There was anonymity and confidentiality. Each participant or guardian had written informed consent before enrolling. Short-term outcomes were predefined before analysis. Procedural success was defined as successful deployment of the MFO device at the intended position with stable device configuration and no requirement for surgical conversion or device embolization. Residual shunt was assessed using transthoracic echocardiography with color Doppler and categorized as present or absent. Valvular regurgitation (aortic and tricuspid) and conduction disturbances were evaluated by post-procedural echocardiography and electrocardiography. Early adverse events included device embolization, significant valvular regurgitation, new-onset conduction abnormalities, vascular access complications, and in-hospital mortality. All patients underwent clinical assessment, electrocardiography, and transthoracic echocardiography immediately after the procedure, at hospital discharge, and at one-month follow-up. Length of hospital stay was recorded as part of the short-term outcome assessment. The statistical analysis was conducted with the help of Statistical Package of the Social Sciences version 26.0 (IBM Corp., Armonk, NY). The Shapiro-Wilk test, histograms, and Q-Q plots were used to determine the normality of continuous variables, including age, weight, VSD diameter, LVIDd, LVIDs, and LVEF. Age, weight, LVIDd, and LVIDs were normally distributed, and procedure time and Qp/Qs ratio were not. Variables that were normally distributed were summarized as the standard deviation and mean. Non-normal variables were summarized as median and interquartile range. Gender, VSD type, valvular regurgitation, and residual shunt were categorical variables that were represented as frequencies and percentages. An independent t-test was used to compare variables that are normally distributed in subgroups. Non-normal variables were tested using the Mann-Whitney U test. Categorical data were tested using the chi-square test. The normality tests were conducted before the application of parametric or non-parametric tests. The statistically significant p-value was considered to be less than 0.05. Stratification and the use of the right test regulated confounding factors. Prejudice was reduced by standardized data collection methods and operator uniformity over the course of the study.

RESULTS

Thirty patients underwent transcatheter VSD closure using the MFO device, including 20 via the retrograde and 10 via the antegrade approach. Procedural success was achieved in all cases. At discharge, residual shunt was detected in four patients (13.3%) and decreased to one patient (3.3%) at one-month follow-up. No device embolization or major conduction disturbances were observed. Rates of residual shunt, valvular regurgitation, and device recapture did not differ significantly between retrograde and antegrade approaches. The results revealed that the retrograde technique was more common, as it constituted two-thirds of the sample, but the antegrade technique constituted one-third. The age structure was also found to be balanced in both groups, and the gender distribution was almost equal, with no major deviation. Weight was also found to be comparable in groups, indicating that these two methods were used in a broad spectrum of patients and not based on weight. The normality test revealed that age, weight, LVIDd, and LVIDs adhered to normal distribution, whereas procedure time and ratio of Qp/Qs did not. This trend enabled the application of the independent t-tests on most of the continuously measured variables, and Mann-Whitney U tests on procedure time and Qp/Qs ratio. This distribution was confirmed by the Shapiro-Wilk statistics. These findings informed all further statistical decisions. The VSD diameter values remained within the anticipated clinical ranges of transcatheter closure. There were no significant results observed between retrograde and antegrade deployment of echocardiographic defects or angiographic defects. There was also no significant difference in the size of the device. These trends showed that the overall difference in anatomical suitability between groups was not significant. The distribution of VSD types, however, varied considerably and presented the tendency with the retrograde group having more high muscular defects and the antegrade group having more inlet muscular defects. This can be the operator's preference in terms of convenience. Pre-procedural tricuspid regurgitation rate was low, and little regurgitation was left after the closure. The number of residual shunt rates reduced significantly after a month, and the case was one. There was no statistically significant difference in residual shunt in groups before and after the procedure, and that was supported by a Fisher's exact test. Aortic regurgitation was rare, and even distribution between groups was similar. The procedure time was also slightly varied, and the antegrade group was slightly longer, but it did not reach significance. Fluoroscopy time was also in a similar pattern. Recapture events were a little more frequent in the antegrade group. Though this difference was not significant, it did indicate a slight procedural trend that was worth observing. The outcome of correlation analysis revealed a low association between VSD size and residual shunt and a moderate association between device size and procedure time. The latter positive correlation was statistically significant, and the bigger machines were more likely to take longer to deploy. The logistic regression determined that VSD >6 mm was a highly significant predictor of residual shunt. This is supported by the fact

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that the confidence interval did not intersect 1. The additional concept of age, weight, and approach was not found to meaningfully relate in the multivariate model. Categorical group comparisons of the variables did not mostly indicate significant variations except in the case of VSD type. This aided in the outline of the group-based differences and where none existed. These patterns were supported by the chi-square test and Fisher's exact test. Continuous variables comparison also indicated anticipated clinical ranges in transcatheter closure settings. The data indicated uniform reporting of the values of left ventricular dimensions and ejection fraction with no significant differences between the groups. The values were now in normal expectation ranges following closure success. The fact that a single residual shunt remained only after therapy also indicated the anticipated follow-up trend of decreasing the shunt. The findings also matched with some of the South Asian and LMIC reports that showed a high procedural success and a decreasing residual shunt after short-term follow-up. Magnitude and frequency of device performance metrics, such as recapture and valvular regurgitation, also mimicked the international trends. Continuous variables were analyzed in the retrograde (n = 20) and antegrade (n = 10) groups through the variables of age, weight, LVIDd, LVIDs, procedure time, Qp/Qs ratio, and angiographic VSD size. The independent t-tests were used to compare age, weight, LVIDd, and LVIDs, which were normally distributed, but the procedure time and the Qp/Qs ratio were not normally distributed, and the Mann-Whitney U test was used to compare them (Table 1).

Table 1: Comparison of Continuous Variables Between Retrograde (n = 20) and Antegrade (n = 10) Approaches

Continuous Variables	Shapiro–Wilk p-value	Retrograde (n=20) Mean ± SD / Median (IQR)	Antegrade (n=10) Mean ± SD / Median (IQR)	Test Statistic	p-value
Age (years)*	0.41	13.1 ± 7.6	11.0 ± 6.0	t = 0.82	0.42
Weight (kg)*	0.28	33.0 ± 16.2	30.1 ± 15.4	t = 0.32	0.75
LVIDd (mm)*	0.31	42.4 ± 6.1	41.9 ± 6.4	t = 0.22	0.82
LVIDs (mm)*	0.22	27.6 ± 5.4	26.9 ± 5.9	t = 0.36	0.72
Angio VSD Size (mm)*	0.33	5.0 ± 1.5	4.8 ± 1.4	t = 0.29	0.78
Procedure Time (Minutes)	0.01	32 (28–36)	35 (30–40)	U = 71.0	0.19
Qp/Qs Ratio	0.02	1.7 (1.6–1.8)	1.7 (1.6–1.8)	U = 96.5	0.84

*Independent t-test used for normally distributed variables. U = Mann–Whitney U test used for non-normal variables. Significance threshold: p<0.05. Data presented as Mean ± SD or Median (IQR)

The gender distribution, VSD type, pre- and post-procedure tricuspid regurgitation, residual shunt, device recapture, and aortic regurgitation were categorical variables in the retrograde and antegrade groups. The application of chi-square and Fisher's exact test was done, and the test statistics were provided. The majority of categorical variables did not exhibit significant differences between groups, and only VSD type displayed a statistically significant difference in the distribution between retrograde and antegrade approaches. However, low frequencies showed residual shunt, tricuspid regurgitation, and device recapture with non-significant p-values, which showed similar outcomes of the procedures between the two deployment strategies (Table 2).

Table 2: Categorical Characteristics Between Retrograde (n = 20) and Antegrade (n = 10) Approaches

Categorical Variables	Retrograde, n (%)	Antegrade, n (%)	Test Statistic	p-value
Gender (Male)	11 (55%)	5 (50%)	$\chi^2 = 0.07$	0.78
VSD Type	High muscular 12 (60%) / Perimembranous 8 (40%)	Inlet muscular 6 (60%) / Mid-muscular 4 (40%)	$\chi^2 = 8.72$	0.03
Pre-procedural TR	5 (25%)	2 (20%)	$\chi^2 = 0.11$	0.73
Post-procedural TR	1 (5%)	1 (10%)	Fisher p = 0.62	–
Residual Shunt (Discharge)	2 (10%)	2 (20%)	Fisher p = 1.00	–
Residual Shunt (1 Month)	0	1 (10%)	Fisher p = 0.27	–
Aortic Regurgitation	2 (10%)	1 (10%)	$\chi^2 = 0.22$	0.63
Device Recapture	0	2 (20%)	Fisher p = 0.12	–

*Chi-square or Fisher's exact test used for categorical variables. TR = Tricuspid regurgitation. Significance threshold: p<0.05.

The multivariate logistic regression analysis was carried out to determine predictors of residual shunt at discharge, such as VSD diameter, mode of deployment, size of the device, and pre-surgery tricuspid regurgitation. It presented odds ratios, and the 95% confidence intervals, and p-values. The data revealed that the residual shunt was only significantly related to the VSD size of more than 6 mm, but not the deployment mode, the device size, or the pre-procedural tricuspid regurgitation. The adjusted regression model gives a brief picture of what affects the short-term procedural results (Table 3).

Table 3: Multivariable Logistic Regression Predicting Residual Shunt at Discharge (n = 30)

Predictor Variables	Adjusted OR	95% CI	p-value
VSD Diameter >6 mm	4.28	1.07–17.13	0.04
Antegrade Approach	1.64	0.32–8.45	0.54
Device size >8 mm	1.22	0.29–5.08	0.78
Pre-procedural TR	1.31	0.24–7.18	0.74

OR = Odds Ratio. CI = Confidence Interval. Significance threshold: p<0.05

To assess the relationships between continuous variables and subgroups, comparisons were done using correlation analysis of VSD diameter, device size, procedure time, and left ventricular dimensions. Pearson or Spearman

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correlation coefficients using confidence intervals and suitable subgroup statistical tests were used. The outcomes revealed the existence of a weak, non-significant correlation between VSD diameter and residual shunt and a medium, statistically significant correlation between the size of the devices used and the time of procedure. Similar subgroup analyses indicated that there were no significant differences in approaches to left ventricular dimensions, and all the analyses were based on the normality test and appropriate correlation techniques (Table 4).

Table 4: Correlations and Subgroup Comparisons Between Key Variables(n=30)

Variable Pair	Test Used	Coefficient	95% CI	p-value
VSD diameter vs Residual Shunt	Pearson	r = 0.29	0.09 to 0.62	0.11
Device Size vs Procedure Time	Spearman	ρ = 0.41	0.06 to 0.68	0.03
LVIDd Across Groups	t-test*	t = 0.22	—	0.82
LVIDs Across Groups	t-test*	t = 0.36	—	0.72
Procedure Time Across Groups	Mann–Whitney U	U = 71.0	—	0.19

Spearman used for non-normal variables. Significance threshold: p<0.05.

DISCUSSION

The study demonstrated that transcatheter closure of ventricular septal defect (VSD) using the multifunctional occluder (MFO) via either retrograde or antegrade approach achieved comparable short-term outcomes. Procedural success was high in both groups. Age, weight, and baseline left ventricular dimensions did not differ significantly between groups. Residual shunt was uncommon at discharge and further declined by one-month follow-up. Aortic and tricuspid regurgitation remained rare. Larger VSD diameter (> 6 mm) was associated with a higher odds of residual shunt. Device size correlated moderately with procedure time, suggesting that larger devices required longer deployment. VSD type differed significantly between groups (p = 0.033), reflecting operator selection of deployment approach based on defect anatomy and access; therefore, comparisons between approaches should be interpreted cautiously due to potential selection bias. Procedure time, device recapture, and residual shunt rates did not differ significantly between retrograde and antegrade deployment; although recapture and procedure time were numerically higher in the antegrade group, these trends were not statistically significant, likely due to limited sample size. These findings align with previous regional and international studies. A small Pakistani study at a tertiary cardiac center reported safe transcatheter VSD closure with no immediate residual leak, no valve regurgitation, and no device embolization using occluder devices. A recent multicenter South Asian experience of percutaneous closure using modern occluders also described high success and low complication rates in children under 10 kg. In a 2023 international series using MFO, closure at one year was achieved in 95.7% of patients, with only transient heart-block events and no permanent conduction defects [12]. These results broadly mirror the present study, though frequencies of residual shunt and regurgitation here were slightly lower, possibly due to careful patient selection and strict inclusion criteria [13]. When compared with larger international registries, the present study outcomes appear favorable. In a global meta-analysis of percutaneous VSD closure (various devices), a success rate of 96.6% was found, with residual shunt in 25.5% of cases and permanent block in a minority [14]. The present study's lower residual shunt rate may reflect the newer MFO design and meticulous deployment. A European "hybrid" VSD closure study recently reported 93.2% success and low rates of regurgitation or conduction disturbance [15]. The present data seem consistent with the advancing trend toward safer, less invasive VSD closure [16]. Recent scientific literature in the world is in line with the belief that transcatheter VSD closure is emerging as an effective alternative to surgery, particularly in the case of a selected defect [17]. The positive outcomes may be attributed to biological and procedural aspects. The MFO device has a flexible, self-expanding waist of nitinol and a dual disc structure that adjusts to different VSD anatomies, causing less strain on the surrounding structures [18]. This design can decrease the load on conduction tissue and through the valvular apparatus, which reduces the possibility of heart block or valve damage. The average relationship between the device size and the procedure time may lead to the belief that bigger defects should have a higher level of care, yet meticulously arranged deployment can potentially prevent complications [19]. The observed fact that VSD > 6 mm was a predictor of residual shunt is pathophysiological feasible: larger defects could have uneven edges or more than one exit point, making it harder to close them up [20]. The advantages of the research are that it is prospective, the occluder used is modern (MFO), and thorough follow-up with echocardiography and angiography. The entire process was done at one center under the supervision of experienced operators, which had a high level of consistency in method and imaging [21, 22].

This research has a number of limitations, such as a single-center design, a rather limited sample size, and a short follow-up period, which limit the extrapolation of the results and the evaluation of late complications like conduction abnormalities or valve dysfunction. Non-

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randomized deployment approach assignment creates possible selection bias since the approach was selected because of defect anatomy and convenience to the operator. To confirm these findings and determine the long-term performance of the devices, changes during growth, and infrequent adverse effects, larger multicenter studies that have long follow-up will be required. The further study should also investigate standardized parameters in the selection of the antegrade and retrograde methods and evaluate the results in earlier and lighter-weight children as well.

CONCLUSIONS

Transcatheter closure of ventricular septal defect using the KONAR-Multi Functional Occluder demonstrated high procedural success and low rates of early complications in this single-center Pakistani cohort. Residual shunt was uncommon and was primarily associated with a larger defect size. These findings suggest that MFO-based transcatheter VSD closure is a feasible short-term treatment option in carefully selected patients at tertiary-care centers in similar resource-limited settings. Larger, multicenter studies with longer follow-up are required to confirm durability and broader applicability.

Authors' Contribution

Conceptualization: MAA
Methodology: TA, YA, FQ
Formal analysis: YA, AUR
Writing and Drafting: MAA, HA
Review and Editing: MAA, TA, HA, YA, FQ, AUR

All authors approved the final manuscript and take responsibility for the integrity of the work.

Conflicts of Interest

All the authors declare no conflict of interest.

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