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Retrograde transcatheter closure of perimembranous and muscular ventricular septal defects in pediatric and adult patients: 12-month outcomes in a case series of 60 patients from Iran

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Abstract

BACKGROUND: Conventional antegrade transcatheter closure of ventricular septal defects (VSDs) requires prolonged fluoroscopy and risks right-heart complications. This study evaluated the safety, efficacy, and 12-month outcomes of the retrograde approach using direct left ventricular access in pediatric and adult patients.

METHODS: Between January 2022 and June 2024, 60 consecutive Iranian patients (median age 10 years, range 1–40 years) with perimembranous (n = 48) or muscular (n = 12) VSDs underwent retrograde transcatheter closure using LifeTech occluders via bilateral femoral arterial access and left-sided transthoracic echocardiography at two centers in Kerman, Iran.

RESULTS: Technical success was 100%, with 95% achieved on the first attempt. Median defect size was 6.2 mm (range 2.8–11 mm). The Qp/Qs ratio decreased from 2.2 ± 0.5 to 1.1 ± 0.2 ($P < 0.001$), and ejection fraction increased from 58.5 ± 7.2% to 62.2 ± 6.5% ($P < 0.05$). Mean fluoroscopy time was 13.3 ± 4.1 minutes, radiation dose was 2.8 ± 1.1 mGy, and hospital stay was 1.2 ± 0.5 days. Minor complications occurred in five patients (8.3%; all Clavien-Dindo Grade I) and resolved without sequelae. At 12-month follow-up with cardiac CT or MRI in all patients, no device migration, embolization, aortic erosion, or significant residual shunt was observed.

CONCLUSION: Retrograde transcatheter VSD closure appears to be safe and effective, and it may be reducing radiation exposure safe and highly effective, significantly reducing radiation exposure, making it a potential attractive alternative to conventional techniques in children and pediatric and adult patients.

Keywords: Heart Septal Defects; Ventricular; Cardiac Catheterization; Septal Occluder Device; Congenital Heart Defects; Treatment Outcome

Introduction

Ventricular septal defect (VSD) is the most common congenital heart defect, accounting for 20%–40% of all congenital heart disease. Although many small defects close spontaneously, moderate-to-large VSDs frequently cause volume overload, left ventricular dilatation, heart failure, and pulmonary hypertension if left untreated[1,2]. Surgical repair has long been the gold standard, achieving excellent long-term outcomes but at the cost of sternotomy, cardiopulmonary bypass, prolonged hospitalization, and visible scarring; disadvantages that are particularly relevant in pediatric patients and resource-limited countries[3–5].

Over the past two decades, transcatheter VSD closure has emerged as a less invasive alternative. The conventional antegrade approach from the right ventricle is well established, with technical success rates of 85%–96% using devices such as the Amplatzer and LifeTech occluders[5–7]. However, this route often requires complex arteriovenous loop formation, prolonged fluoroscopy (typically 20–40 minutes), and carries risks of tricuspid valve injury and conduction disturbances[8,9]. Radiation exposure is a particular concern in children and young adults, in whom the lifetime attributable risk of malignancy is significantly higher[10,11]. Consequently, there is growing interest in techniques that minimize radiation while preserving high success rates, aligning with broader strategies for the prevention of atherosclerotic cardiovascular disease[12].

Retrograde transcatheter closure via left ventricular access has been proposed as a radiation-sparing alternative that avoids loop formation and right-heart manipulation[12–14]. Initial reports, primarily from Asia and the Middle East, have described shorter fluoroscopy times and comparable efficacy with the retrograde approach[15,16]. However, the published series remain small (≤ 35 patients), rarely include both pediatrics and adults, and provide limited or no imaging follow-up beyond 6–12 months[15–18]. Moreover, most studies have used first-generation devices, whereas newer nitinol occluders (LifeTech multifunctional and symmetrical devices) may offer improved deliverability and lower complication profiles[19].

To address these evidence gaps, we prospectively evaluated the safety, radiation exposure, and 12-month outcomes of retrograde transcatheter VSD closure using LifeTech occluders in a consecutive case series cohort of pediatric and adult Iranian patients.

Materials and Methods

Study design and setting

This case series study included 60 consecutive patients with ventricular septal defect (VSD) who were treated at Shafa and Mehrgan Hospitals, Kerman University of Medical Sciences, Iran, between January 2022 and June 2024. The ages of the patients ranged from 1 to 40 years (mean: 12.5 ± 8.2 years), and their weights ranged from 9.20 to 80.35 kg (mean: 35.3 ± 10.1 kg), with an average pulmonary artery pressure of 24 ± 5.8 mmHg.

Inclusion criteria required VSD confirmation by transthoracic echocardiography (TTE) with a defect size greater than 2 mm and a pulmonary-to-systemic flow ratio (Qp/Qs) exceeding 1.5, along with a body weight greater than 9 kg to ensure safe femoral access.

Exclusion criteria included complex congenital heart defects (tetralogy of Fallot), active infections, hemodynamic instability, or inappropriate VSD anatomy (proximity to the aortic valve). Overall, seven patients were excluded: four due to complex anatomy and three due to active infections. To minimize selection bias, all eligible patients presenting during the study period were enrolled consecutively, and exclusion criteria were applied consistently with documented rationale. The enrollment process is illustrated in Figure 1.

Outcomes

The primary endpoints were technical success rate, procedure-related major adverse events (defined as death, device embolization, complete atrioventricular block, stroke,

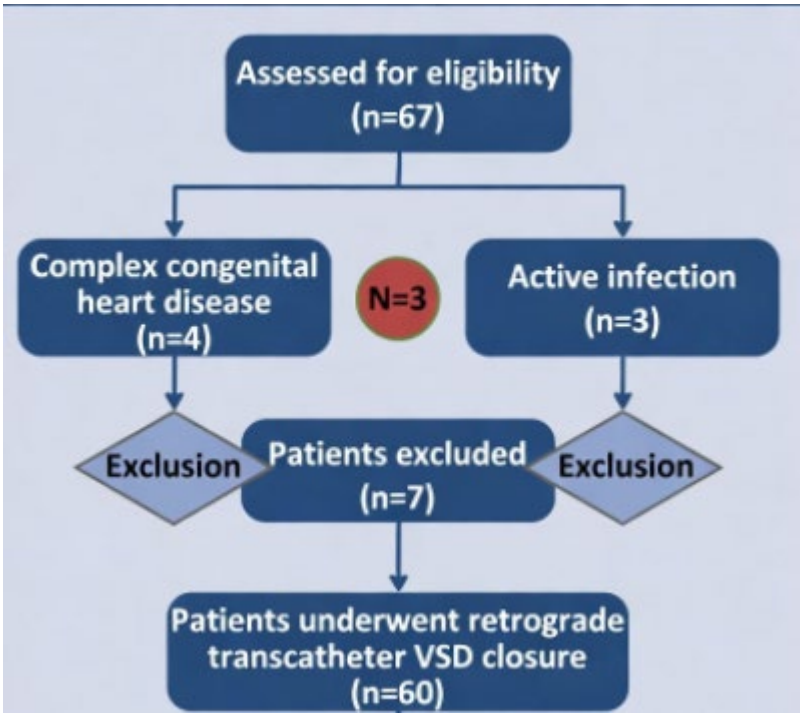

Figure 1. Patient enrollment flow diagram

significant new valve regurgitation, or need for surgical intervention), fluoroscopy time, and radiation dose. Secondary endpoints included first-attempt deployment success, minor complications (Clavien-Dindo Grade I), hemodynamic and echocardiographic improvement, left ventricular remodeling, and device stability at 12-month imaging follow-up (cardiac CT or MRI).

Pre-Procedure Evaluation

Pre-procedural evaluation included transthoracic echocardiography (TTE), which measured defect size (median 6.2 mm, range 2.8–11 mm), Qp/Qs ratio (mean 2.2 ± 0.5), left ventricular dimensions (end-diastolic diameter 55.5 ± 6.8 mm; end-systolic 25.6 ± 4.7 mm), ejection fraction (58.5 ± 7.2%), cardiac output (4.2 ± 0.9 L/min), and pulmonary artery pressure (24 ± 5.8 mmHg). Findings were confirmed by angiography and independently validated by two experienced cardiologists.

Procedure

The retrograde transcatheter closure of ventricular septal defects (VSDs) was performed using a left-sided transthoracic approach with bilateral femoral artery punctures, utilizing 6 French (1.9-mm) sheaths. This method accessed the VSD via the left ventricle, thereby minimizing fluoroscopy time and radiation exposure compared with right-sided antegrade methods[20].

LifeTech devices[19] were selected based on TTE and angiographic findings, with membranous devices (3 mm waist) used for membranous VSDs and muscular devices (7 mm waist) used for muscular VSDs, ranging in size from 6/4 to 14/12. A Judkins Right catheter and a Terumo guidewire were utilized to cross the VSD from the left ventricle, with a super-stiff guidewire positioned in the right ventricle (n = 52, 86.7%) or pulmonary artery (n = 8, 13.3%) to facilitate device deployment. The right ventricular disc was deployed first, followed by the left ventricular disc, under continuous fluoroscopy and TTE guidance, achieving a mean fluoroscopy time of 13.3 ± 4.1 minutes (range: 3.6–47.8 min) and a radiation dose of 2.8 ± 1.1 mGy. Device deployment success was recorded per attempt,

and intra-procedural device displacement was assessed via TTE.

Post-Procedure Care

Following the procedure, all patients were monitored in the intensive care unit for 4 hours to ensure hemodynamic stability and device integrity. Post-procedural assessments included chest X-ray and transthoracic echocardiography (TTE) to evaluate device position, residual shunts, valve integrity, ejection fraction (EF), left ventricular end-systolic diameter (LVESD), and cardiac output[3].

Device stability was confirmed via TTE to rule out displacement[20].

Post-procedural anticoagulation consisted of intra-procedural heparin (100 U/kg) and aspirin (3–5 mg/kg/day) for 6 months[15]. Complications were graded according to the Clavien-Dindo classification, which is increasingly used in interventional cardiology for standardized reporting of adverse events[21,22]. Minor complications (Clavien-Dindo Grade I) were managed by institutional protocol:

- Transient intraprocedural hypotension (systolic blood pressure <90 mmHg in adults or <70 mmHg in pediatrics; n=2, 3.3%) was treated with a 10 mL/kg normal saline bolus over 10 minutes, repeated once if needed, with resolution within 30 minutes.
- Mild groin hematoma (<5 cm at puncture site; n=3, 5.0%) was managed with manual compression for 10–15 minutes, pressure dressing, and 6 hours of bed rest; ultrasound confirmed no pseudoaneurysm and complete resolution within 48 hours. All minor complications resolved without sequelae. No Grade ≥II complications occurred, and no patient required pharmacological treatment beyond standard care, surgical intervention, or prolonged hospitalization.

Follow-Up

Patients underwent follow-up evaluations at 1, 6, and 12 months post-procedure to monitor clinical outcomes. Follow-up assessments included transthoracic echocardiography (TTE) to evaluate residual shunts (Qp/Qs), device stability, valve function, left ventricular end-diastolic diameter (LVEDD), left ventricular end-systolic diameter (LVESD), cardiac output, ejection fraction (EF), and pulmonary artery pressure.

Ethical Considerations

This study was conducted fully in accordance with the Declaration of Helsinki (as revised in 2013)[24]. Patient anonymity was strictly maintained at all stages; no names, national identification numbers, hospital record numbers, or any other identifying information were recorded or disclosed. Informed written consent was obtained from all adult patients and from the parents or legal guardians of pediatric patients before enrollment. All participants (or their guardians) were fully informed about the nature of the procedure, its potential risks and benefits, alternative treatment options, and the aims of the study. Participation was completely voluntary, and consent for the use of clinical and imaging data for research and publication purposes was explicitly obtained. No financial incentives were provided.

Statistical Analysis

Data normality was assessed using the Shapiro-Wilk test. Continuous variables are presented as mean ± standard deviation or median (range), as appropriate. Categorical variables are expressed as frequencies and percentages. Comparisons were performed using Student's t-test or Mann-Whitney U test for continuous variables, and χ^2 or Fisher's exact test for categorical variables. Paired t-test or Wilcoxon signed-rank test was used for pre- and post-procedure comparisons. Multivariate logistic regression was employed to identify factors associated with fluoroscopy time <12 minutes. A p-value <0.05 was considered statistically significant. Analyses were conducted using SPSS version 26 (IBM Corp., Armonk, NY, USA).

Results

All 60 consecutively enrolled patients completed the procedure and 12-month follow-up (100%

Table 1. Baseline Characteristics, Procedural Data, Subgroup and Learning-Curve Analysis in 60 Consecutive Iranian Patients Undergoing Retrograde Transcatheter VSD Closure

Characteristic	Overall (n=60)	Pediatric (<18 y, n=25)	Adult (≥18 y, n=35)	p-value
Age (years)	10 [6-18]	8 [4-11]	25 [21-30]	<0.001*
Weight (kg)	35.3 ± 10.1	22.4 ± 8.3	52.1 ± 12.5	<0.001*
Male sex, n (%)	32 (53.3)	14 (56.0)	18 (51.4)	0.78**
Perimembranous VSD, n (%)	48 (80.0)	21 (84.0)	27 (77.1)	0.49**
Defect size (mm, median, range)	6.2 (2.8–11)	5.8 (2.8–9.5)	6.5 (3.2–11)	0.12*
Pre-procedure Qp/Qs	2.2 ± 0.5	2.3 ± 0.6	2.1 ± 0.4	0.18*
Fluoroscopy time (min)	13.3 ± 4.1	11.8 ± 3.2	14.3 ± 4.1	0.03*
Radiation dose (mGy)	2.8 ± 1.1	2.4 ± 0.9	3.1 ± 1.2	0.02*
Procedure time (min)	45.2 ± 12.3	42.1 ± 10.8	47.8 ± 13.5	0.09*
Minor complications (Clavien-Dindo Grade I), n (%)	5 (8.3)	2 (8.0)	3 (8.6)	0.92**
Learning curve and subgroup analysis				
Fluoroscopy time – first 20 cases (min)	15.1 ± 4.0	—	—	—
Fluoroscopy time – last 40 cases (min)	12.6 ± 3.5	—	—	0.02***
Patients with fluoroscopy time <12 min, n (%)	28 (46.7)	16 (64.0)	12 (34.3)	0.02**

Data are presented as mean ± SD, median (range), or n (%). *Student's t-test or Mann-Whitney U test for continuous variables; **χ^2 test or Fisher's exact test for categorical variables; ***independent samples t-test (first 20 vs last 40 cases). $p < 0.05$ was considered statistically significant.

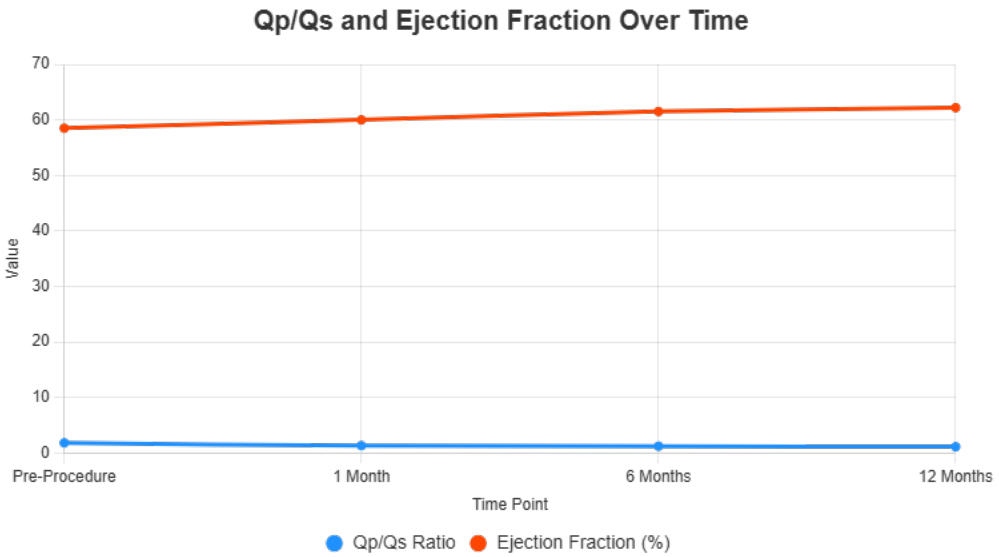

Figure 2. Serial changes in pulmonary-to-systemic flow ratio (Qp/Qs) and left ventricular ejection fraction (LVEF) from baseline to 12-month follow-up

follow-up rate). Between January 2022 and June 2024, 60 consecutive patients (32 male, 53.3%, and 28 female, 46.7%) underwent retrograde transcatheter VSD closure. Mean age was 12.5 ± 8.2, and median age was 10 years (range, 1-40 years), and mean weight was 35.3 ± 10.1 kg (range, 9.2-80.4 kg). Twenty-five patients (41.7%) were younger than 18 years. Forty-eight defects (80%) were perimembranous, and 12 (20%) were muscular. Median defect size was 6.2 mm (range, 2.8-11 mm). Detailed baseline characteristics and procedural data are presented in Table 1.

Procedural outcomes

Technical success was achieved in all 60 patients (100%), with successful device deployment on the first attempt in 57 patients (95%). Mean

fluoroscopy time was 13.3 ± 4.1 minutes (range, 3.6-47.8 minutes), and mean radiation dose was 2.8 ± 1.1 mGy. Fluoroscopy time and total radiation dose (mGy) were automatically recorded and displayed by the angiography system (Artis Zee, Siemens Healthineers, Germany). Procedures were performed using a low-dose pulsatile fluoroscopy protocol (7.5-15 frames/second) with maximal collimation and avoidance of cine-angiography whenever

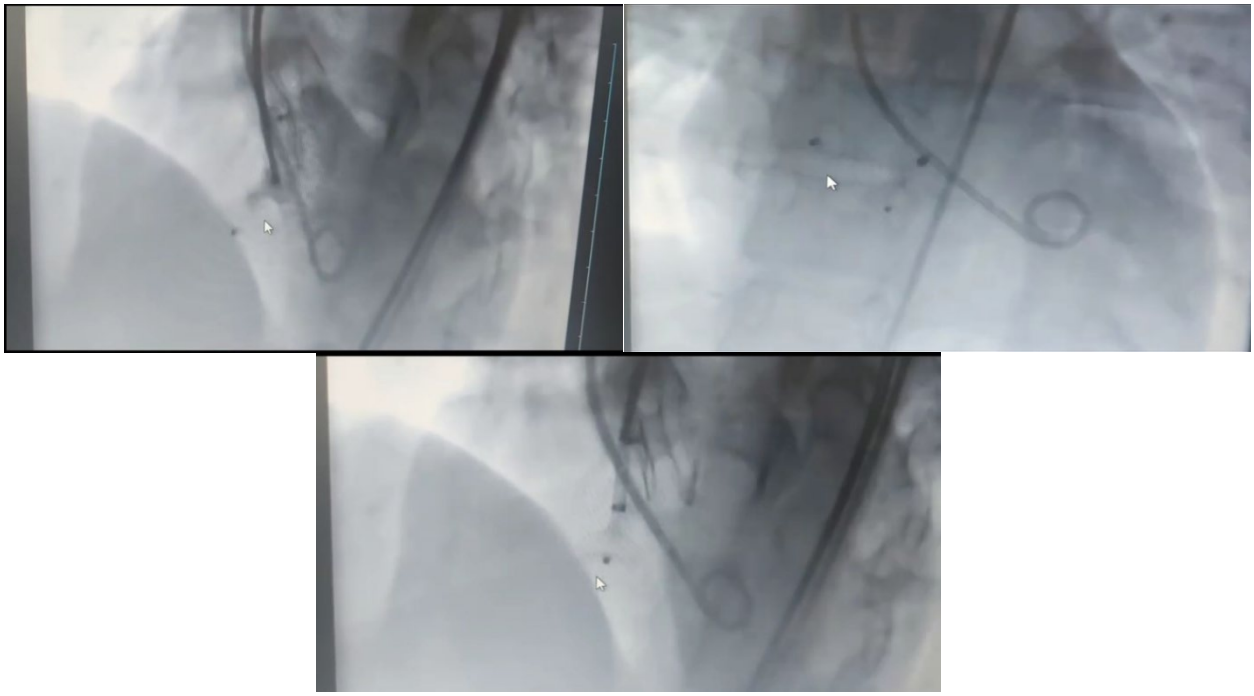

Figure 3. Closure of the ventricular septal defect in a patient with an atrial septal defect, occlusion one year ago

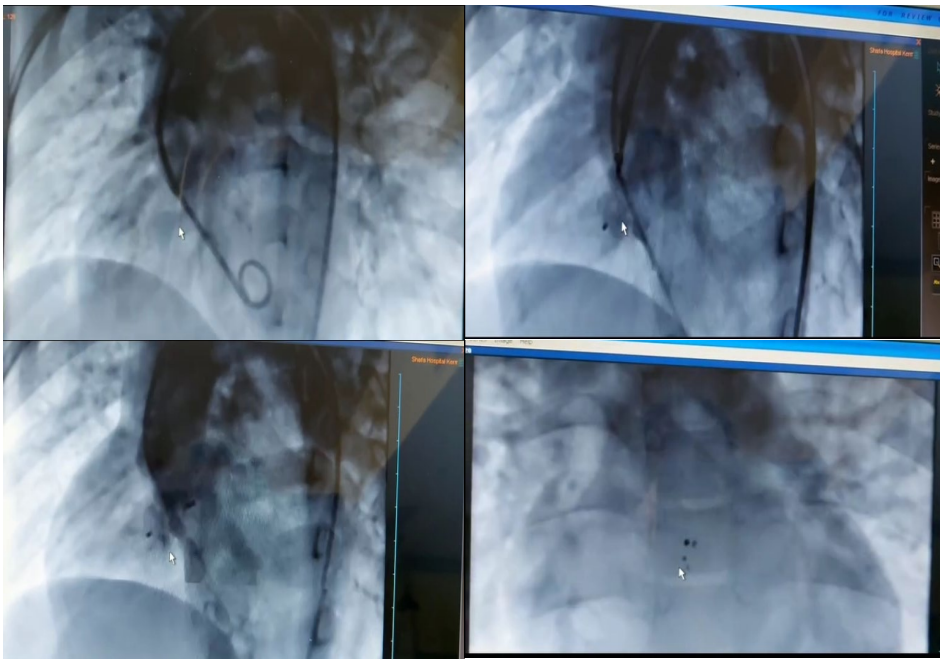

Figure 4. VSD closure in a 5-year-old patient

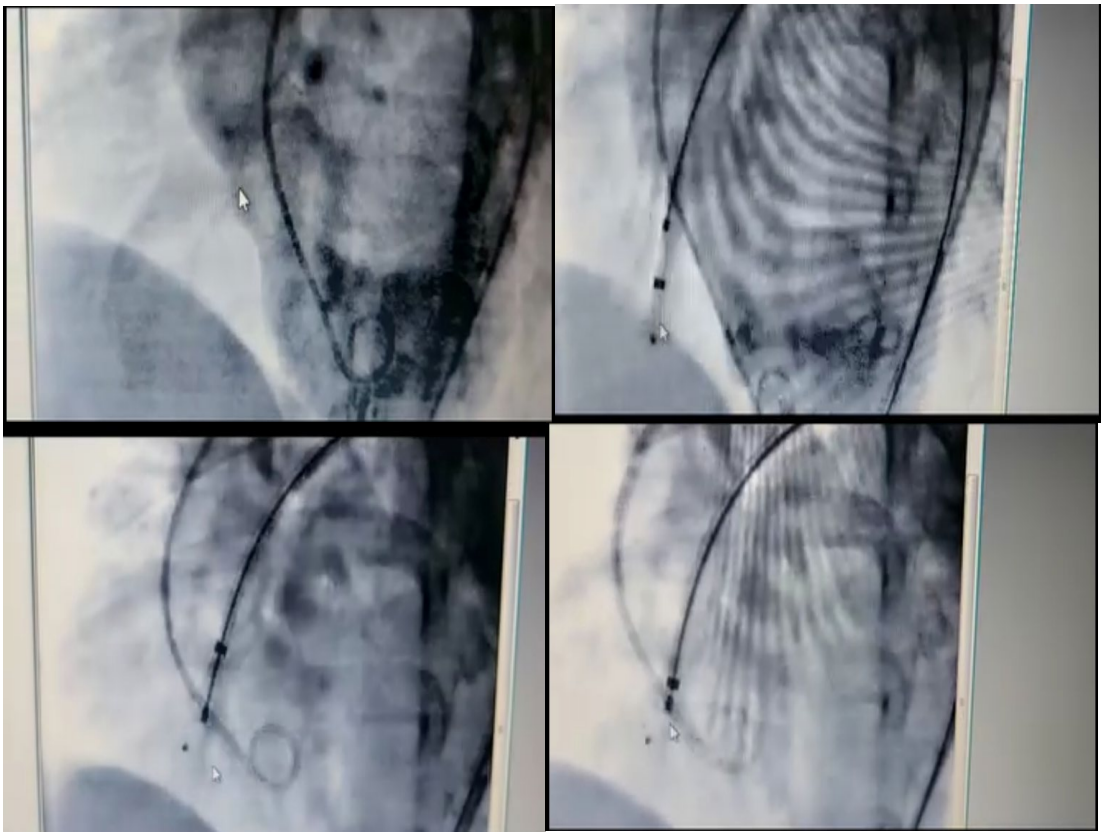

Figure 5. The patient with a premembranous ventricular septal defect below the aortic valve was closed on the left side with an Amplatzer

possible. Mean total procedure time was 45.2 ± 12.3 minutes. Hospital stay was 1.2 ± 0.5 days (Table 1).

Representative procedural images are presented in Figures 3-6. Figure 3 demonstrates retrograde closure in a 5-year-old child with a perimembranous VSD. Figure 4 shows successful device placement in a defect located immediately beneath the aortic valve using the left-sided approach without arteriovenous loop formation. Figure 5 depicts a complex case of VSD closure in a patient with a previously implanted atrial septal defect occluder one year earlier, with no device-device interference. A step-by-step schematic of the retrograde technique is provided in Figure 6.

Haemodynamic and Echocardiographic improvement

At 24 hours, the Qp/Qs ratio decreased from 2.2 ± 0.5 to 1.1 ± 0.2 (P < 0.001), with no residual shunt >2 mm in any patient. Serial changes in the Qp/Qs ratio and left ventricular ejection fraction over 12 months are illustrated in Figure 2. Left ventricular ejection fraction improved from 58.5 ± 7.2% to 62.2 ± 6.5% (P < 0.05), and LV end-diastolic diameter decreased from 55.5 ± 6.8 mm to 44.3 ± 5.9 mm (P < 0.001). At 12-month follow-up, further improvement was observed in ejection fraction (64.1 ± 5.8%), LV dimensions, and pulmonary artery pressure (from 24 ± 5.8 to 20 ± 4.5 mmHg, P = 0.01). Haemodynamic and echocardiographic outcomes are summarised in Table 2.

Subgroup and learning-curve analysis

Paediatric patients had significantly shorter fluoroscopy times (11·8 ± 3·2 vs 14·3 ± 4·1 minutes, P = 0·03) and lower radiation doses (2·4 ± 0·9 vs 3·1 ± 1·2 mGy, P = 0·02) than adults (Table 1). No significant differences were observed in minor complication rates (8·0% vs 8·6%, P = 0·92) or technical success between subgroups (all P > 0·05).

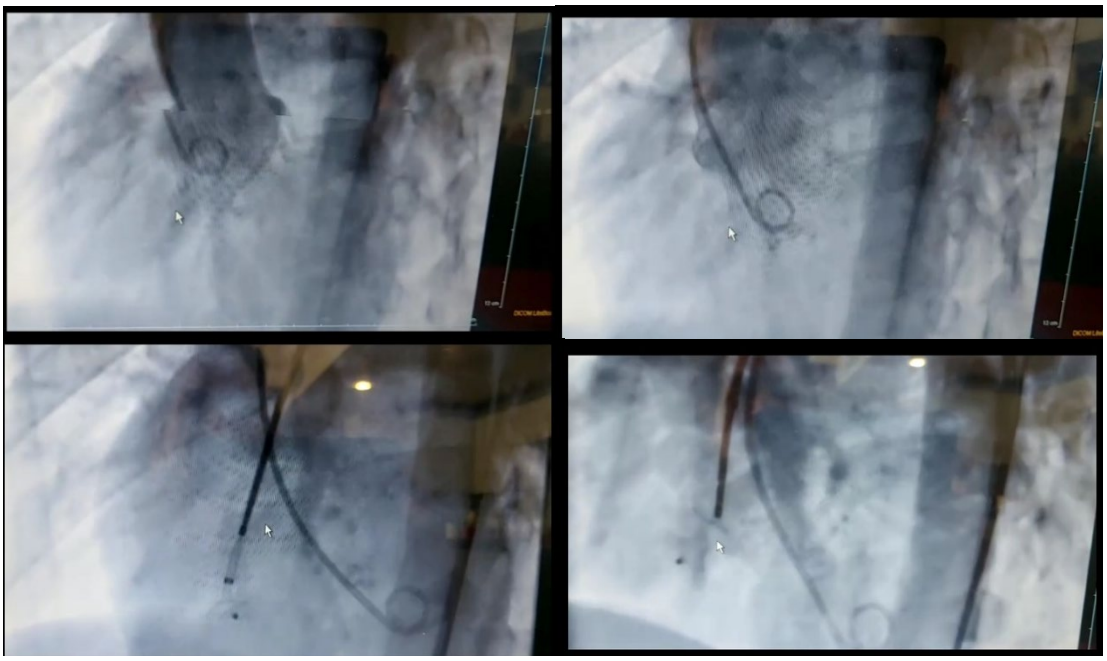

Figure 6. Closure of a ventricular septal defect (VSD) near the aortic valve with a ventricular septal ligament

Table 2. Hemodynamic and Echocardiographic Outcomes Before and After Retrograde VSD Closure in 60 Iranian Patients

Parameter	Pre-procedure	24 hours post-procedure	12-month follow-up	p-value*
Qp/Qs ratio	2.2 ± 0.5	1.1 ± 0.2	1.0 ± 0.1	<0.001*
Left ventricular ejection fraction (%)	58.5 ± 7.2	62.2 ± 6.5	64.1 ± 5.8	<0.001**
Left ventricular end-diastolic diameter (mm)	55.5 ± 6.8	44.3 ± 5.9	38.2 ± 5.1	<0.001*
Mean pulmonary artery pressure (mmHg)	24 ± 5.8	–	20 ± 4.5	0.01**

Data are presented as mean ± SD, p-value refers to comparison between pre-procedure and 12-month values using paired t-test* or Wilcoxon signed-rank test**, as appropriate.

Fluoroscopy time decreased from 15·1 ± 4·0 minutes in the first 20 cases to 12·6 ± 3·5 minutes in the last 40 cases (P = 0·02), demonstrating a clear learning-curve effect (Table 1).

In univariate analysis, younger age and smaller defect size were associated with fluoroscopy time <12 minutes. Multivariate logistic regression (including age, weight, defect size, and VSD type) confirmed younger age (OR 0·94, 95% CI 0·89-0·99, P = 0·03) and smaller defect size (OR 0·81, 95% CI 0·68-0·97, P = 0·02) as factors associated with fluoroscopy time <12 minutes (46·7% of cases).

Safety and long-term follow-up

Patients underwent follow-up evaluations at 1, 6, and 12 months. Clinical examinations recorded heart rate (mean: 85 ± 10 bpm), blood pressure (mean: 70.110 ± 8.12 mmHg), symptom status, and, for pediatric patients, growth metrics (mean weight gain: 2.1 ± 0.8 kg). Device displacement was checked at each visit via TTE. Over the past 12 months, long-term imaging was performed using computed tomography (CT; n = 40, 66.7%) or magnetic resonance imaging (MRI; n = 20, 33.3%, for patients with contraindications to radiation) to confirm device position stability and evaluate aortic wall integrity, ensuring no erosion or aneurysm formation.

The collected data included procedural success rates, complications (graded according to the Clavien-Dindo classification), fluoroscopy time, duration of hospital stay, contrast volume, device deployment success rates per attempt,

Table 3. Procedural Success, Complications, and 12-Month Follow-up in 60 Consecutive Iranian Patients

Outcome	Value
Technical success	60/60 (100%; 95% CI 94.1–100%)
First-attempt successful deployment	57/60 (95%)
Minor complications (Clavien-Dindo Grade I)	5 (8.3%)
Transient intraprocedural hypotension	2 (3.3%)
Mild groin hematoma (<5 cm)	3 (5.0%)
Major adverse events*	0 (0%; 95% CI 0–5.9%)
Complete atrioventricular block	0
Device embolization or migration	0
Significant residual shunt (>2 mm)	0
New significant aortic or tricuspid regurgitation	0
Procedure-related mortality	0
Hospital stays (days)	1.2 ± 0.5
12-month imaging follow-up (CT n=40, MRI n=20)	
Device stability (no migration, erosion, or aneurysm formation)	60/60 (100%)

*Major adverse events were defined as death, device embolization, complete heart block, stroke, significant valve regurgitation, or need for surgical intervention.

and rates of device displacement. Graphical representations, including line plots depicting Qp/Qs reduction and EF improvement over time (pre-procedure, 1, 6, and 12 months), have been prepared, pending user confirmation for visualization (Figure 2).

Five minor complications (8.3% of patients; all Clavien-Dindo Grade I) were observed: transient intraprocedural hypotension in two cases and mild groin hematoma in three cases. All complications resolved spontaneously without sequelae. No major adverse events (complete AV block, device embolization, stroke, significant valve regurgitation, or death) [20,21] were recorded. At 12 months, cardiac CT (n = 40) or MRI (n = 20) confirmed stable device position with no evidence of migration, erosion, or aortic aneurysm formation in any patient. The overall major adverse event rate was 0% (95% CI, 0-5.9%). Complications and long-term imaging follow-up results are shown in Table 3.

Discussion

The present study suggests that retrograde transcatheter closure of perimembranous and muscular ventricular septal defects using LifeTech occluders is a feasible and safe alternative across a wide age range (1-40 years) in a consecutive Iranian case series cohort. The procedure was associated with high technical success, absence of major adverse events, and only transient minor complications in 8.3% of patients. Radiation exposure appeared substantially lower than commonly reported in contemporary antegrade series, while hemodynamic improvement was rapid and sustained over 12 months, with favorable device stability on cross-sectional imaging at 1-year follow-up.

Compared with antegrade transcatheter series, the retrograde approach in our case series cohort showed similar high technical success rates but consistently shorter fluoroscopy times and lower radiation doses [16,25,26]. For example, Haddad et al. (2020) reported 97% procedural success in 45 pediatric patients using the KONAR-MF occluder via antegrade access, but with a mean fluoroscopy time of 18.5 minutes and transient conduction disturbances in 4% [25].

The absence of conduction-related events and reduced radiation exposure in our series are likely attributable to avoidance of right ventricular manipulation and arteriovenous loop formation - inherent advantages of the retrograde technique that have been noted in other recent retrograde reports [27–30]. Minor vascular and hemodynamic events occurred at rates comparable to antegrade cohorts,

suggesting that left-sided arterial access does not confer additional access-site risk when standard hemostasis protocols are applied.

The observed learning-curve effect, with a significant reduction in fluoroscopy time after the initial 20 cases, is consistent with experiences from other centers adopting novel delivery systems or modified techniques in congenital interventions [27,31]. Despite the operator's extensive prior experience in structural heart disease, the rapid optimization observed supports the relative intuitiveness of the retrograde method once basic wire skills are established. Subgroup analysis indicated lower radiation exposure in pediatric patients without differences in safety or efficacy profiles, in line with findings from recent pediatric-focused retrograde series [21,25]. Variables independently associated with very low fluoroscopy time (younger age and smaller defect size) may help guide patient selection to further minimize radiation in this sensitive population.

Strengths and limitations

Strengths include the consecutive enrollment minimizing bias, inclusion of both pediatric and adult patients (rare in retrograde series), 100% follow-up with advanced imaging (CT/MRI in all), and integrated learning-curve/multivariate analyses - elements underrepresented in prior reports[32,33]. These features enhance the study's generalizability to mixed-age cases in resource-limited settings.

Limitations encompass the single-center, observational design without a randomized antegrade comparator, limiting causal attribution of radiation benefits, and a 12-month follow-up, which may miss rare late events like erosion (1-2% at 5 years in registries) [28,29]. Multicenter, longer-term trials are needed.

Conclusion

The retrograde transcatheter approach for VSD closure appears associated with high success, reduced radiation, and favorable midterm outcomes in diverse patients. These observations, from a consecutive series with complete imaging surveillance, support its potential as an alternative to antegrade methods, particularly for radiation-sensitive populations, and call for broader validation in multicenter studies.

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Conflict of interests

The authors declare no conflict of interest.

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Author's Contributions

Study Conception or Design: FDM
Data Acquisition: FDM; RD; AA
Data Analysis or Interpretation: FDM; AA
Manuscript Drafting: FDM; RD
Critical Manuscript Revision: FDM; RD; AA

All authors have approved the final manuscript and are responsible for all aspects of the work.

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