THE ANATOLIAN JOURNAL OF CARDIOLOGY

Official journal of the TURKISH SOCIETY OF CARDIOLOGY

Efficacy and Safety of Transarterial Retrograde Approach in Ventricular Septal Defect Closure: A Systematic Review and Meta-Analysis

ABSTRACT

Background: Transcatheter closure approaches of ventricular septal defects (VSDs) include anterograde through the right ventricle using an arteriovenous loop and retrograde transarterial approach. This systematic review assesses the outcomes and complications associated with transcatheter closure of VSD through a retrograde approach.

Methods: PubMed was searched for articles in English on retrograde closure of VSD from 2006 to 2024. The pooled estimates of success and complication rates were done by the random effects model.

Results: A total of 11 publications comprising 482 patients with variable types of VSD were included in this analysis. The pooled estimate of success was 89.3% (95% CI: 0.84-0.93). The most common complication is residual shunt pooled estimated is 7.1% (95% CI: 0.02-0.20). Others included valvular lesions pooled estimate is 6.4% (95% CI: 0.02-0.14), arrhythmias pooled estimate is 5.5% (95% CI: 0.02-0.12), conduction abnormalities pooled estimate rate is 5.3% (95% CI: 0.01-0.13), and death pooled estimated rate is 2.8% (95% CI: 0.08-0.07).

Conclusion: This analysis suggests that transcatheter retrograde closure of VSD is safe and effective with promising results. The limitations of this study are difficulties in analyzing the types of devices and VSDs individually. Clear inclusion and exclusion criteria including the patient's age, weight, VSD type, and other features must be considered before proceeding with this approach.

Keywords: Retrograde approach, transarterial approach, ventricular septal defect

META-ANALYSIS

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Received: May 16, 2025
Accepted: September 9, 2025
Available Online Date: October 27, 2025

Cite this article as: Ali HHA, Sayed SBH, Gafoon AAA, et al. Efficacy and safety of transarterial retrograde approach in ventricular septal defect closure: a systematic review and meta-analysis. *Anatol J Cardiol.* 2026;30(1):2-8.

DOI:10.14744/AnatolJCardiol.2025.5475

INTRODUCTION

Ventricular septal defects (VSDs) represent the most prevalent form of congenital heart disease, accounting for 30% of cases.[1] Patients with unresolved VSDs may experience long-term issues such as pulmonary hypertension.[1] Ventricular septal defects are typically classified based on their size, number, and position within the ventricular septum.[2-7] The size of VSDs can be described as large, medium, or small, which aids in determining which patients need treatment. These defects can be singular, paired, or multiple.[3-5] In terms of location, VSDs are categorized as perimembranous, supracristal, atrioventricular septal, muscular, and Gerbode.[5-8] Membranous defects are the most frequently occurring among VSDs, with an 80% prevalence rate.[9]

Consequently, it is advised to close the defect in patients exhibiting a significant left-to-right shunt (Qp:Qs>2:1).[10] Treatment options include surgical intervention or a transcatheter approach. Traditionally, a transcatheter anterograde method is employed to implant the device. The initial report on transcatheter VSD closure detailed 6 patients with various VSD types who underwent closure using the Rashkind double umbrella device.[10] Following this, numerous reports have documented successful defect closures with different devices, such as the Rashkind device, vascular coils, the buttoned device, and the Starflex device.[11-15] Indications for opting for transcatheter VSD closure include cardiomegaly or left heart enlargement as seen on an echocardiogram, a Qp:Qs ratio exceeding 1.5, failure to thrive, worsening symptoms according to the New York Heart Association classification, recurrent respiratory infections, and a history of infective endocarditis.[16]

There are 3 main approaches for the transcatheter closure of VSDs. The antegrade approach is a frequently described method that generally involves forming an arteriovenous wire loop to facilitate the advancement of the delivery system. This technique is applicable for closing membranous, muscular, and postsurgical residual defects, as well as postinfarction VSDs.[16]

The retrograde approach: A wire is threaded from the femoral artery through the defect to the femoral or jugular vein, as previously outlined. The distal end of the long delivery sheath is pre-shaped to ensure it follows the concave path from the femoral artery, around the arch, and through the aortic valve. Additionally, the very tip of the sheath/dilator is bent in the opposite direction to create a long "shepherd's crook" curve at the end, allowing it to enter the VSD. After applying generous local anesthesia around the arterial entry point, the large, long sheath is inserted into the femoral artery and advanced retrogradely over the through-and-through wire, crossing the aortic valve to reach the left ventricular side of the defect, as previously described for the mid-muscular VSD closure using the retrograde approach.[17]

Hybrid Approach: In young children, surgically closing muscular VSDs can be challenging due to the difficulty in directly visualizing the defects, which may lead to significant residual defects.[18] Additionally, percutaneous closure of these defects is often restricted by hemodynamic instability caused by the manipulation of large sheaths in a child's body. A direct periventricular puncture of the right ventricular (RV) free wall can significantly enhance access to the defect, facilitating the placement of large devices. Through either a full or limited sternotomy, and under echocardiographic guidance, the device can then be deployed.[16]

Catheter-based interventions are showing promising results compared to surgery since the first reported case in 1988 with acceptable results. In this study, investigating the efficacy and safety of the transcatheter retrograde approach is being investigated. To the authors' knowledge, this is the first systematic review that analyzes studies using the mentioned approach.

METHODS

We conducted this systematic review and meta-analysis following the PRISMA flowchart statement for systematic reviews and meta-analyses. Every phase of this review adhered to the guidelines outlined in the Cochrane Handbook for Systematic Reviews and Meta-Analyses. The research question was formulated using the PICO (Population, Intervention, Comparison, Outcome) framework, which includes population, intervention, comparison, and outcome.

Search Strategy

We searched in PubMed and Google Scholar for English literature from 2006 to 2024 using the following search strategy: (ventricular septal defect AND retrograde closure). A distinctive and thorough search string incorporating Boolean operators (AND, OR) and Medical Subject Headings terms, along with pertinent builder options, were employed to optimize the search outcomes. Duplicates were eliminated using EndNote software, after which all the collected citations were evaluated for eligibility in 2 stages: During the initial screening stage, 2 reviewers independently assessed the titles and abstracts of the articles for potential inclusion. This was succeeded by a full-text screening phase, where specific eligibility criteria were applied. Any disagreements between the reviewers in both phases were resolved through discussions or by a third reviewer. Studies that met the criteria were included in the research.

Selection Criteria

All articles reporting the use of transarterial retrograde approach to close VSD defect (using any type of device) in humans and written in English were included. The search identified 502 articles. Four hundred ninety-one papers were excluded from analysis. Studies were excluded based on the following criteria: studies that report using surgical approach and traditional transcatheter transvenous anterograde, those involving animal subjects, in vitro experiments, studies with duplicate datasets, non-English full texts, before 2006 and after 2024, studies that compare anterograde with retrograde, studies that include patients with postoperative residual VSD, VSD after hypertrophic cardiomyopathy (HCM), studies that investigate a group of patients with certain body weight, studies with postinfarction VSDs, focusing on using Konar-MF only, focusing on patients with congenital garbode type only, patients with dextrocardia, studies focused on patients with occluded femoral veins, studies that focused on the use of CERA devices only, studies with ADO1 only, conference abstracts, review articles, book chapters, theses, and editorial pieces, studies focused on choosing between 2 types of devices regardless of the approach. Therefore, a total of 11 articles were analyzed (Figure 1).

Data Extraction

Data were extracted independently by 2 authors (Hiba and Mohamad) and entered in an electronic database. Data including first author, year, study period, country, VSD type, device type, number of patients, mean age, and the clinical characteristics of patients are summarized in Tables 1 and 2. The successful rate was defined as a correct placement of the device with complete closure or trivial residual defect confirmed by image immediately or at 24 hours. The successful rate at the follow-up period was not included. Complications rate including heart block, death, valvular lesions, arrhythmia, and others were discussed and analyzed.

Risk of Bias Assessment

All eligible studies that were included were assessed for risk of bias using the Joanna Briggs Institute critical appraisal checklist and Critical Appraisal Skills Program checklist for case series and cohort studies, respectively. The risk of bias in individual studies was classified as low, moderate, and high. Studies with a high risk of bias were excluded from this study.

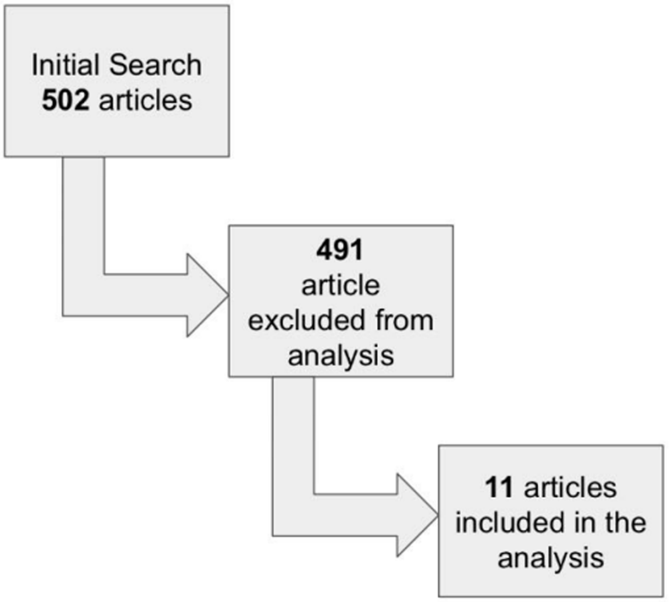

Figure 1. Flowchart depicting the selection process of the articles.

Statistical Analysis

Aiming to represent a larger random sample from various populations, a pooled estimate of success and complications rates were obtained using a random effects model, while each individual study has its unique effect size.

RESULTS

Study Selection and Characteristics

A total of 11 studies comprising 482 patients who underwent transarterial retrograde transcatheter closure of VSDs were included in this meta-analysis. The included studies involved a range of VSD types and utilized various occlusion devices. All studies were observational, and most involved pediatric populations. Patient characteristics, procedural approaches, and devices used varied across studies.

Publication Bias Assessment

Egger's regression test was used to assess the risk of publication bias for each outcome in the meta-analysis. A *P*-value less than .05 was considered indicative of potential bias.

OUTCOMES

Success Rate

The pooled success rate of retrograde VSD closure was 89.3% (95% CI: 84.7%-93.1%), based on a random effects model. Moderate heterogeneity was observed (I^2 = 41.8%).

Three studies reported 100% success rates, while the lowest was 73%. No significant publication bias was detected (Egger's test *P* = .11) Figure 2.

COMPLICATIONS RATE

Device Embolization

Device embolization occurred in 7 patients across all studies. The pooled estimate was 1.1% (95% CI: 0.4%-2.7%) with no heterogeneity (I^2 = 0%). The event was rare, and in all cases, devices were retrieved successfully without long-term sequelae. Seven studies reported no embolization.[19-21,24,26-28] No publication bias was found (*P* = .68) Figure 3).

Residual Shunt

The pooled rate of immediate residual shunt was 7.1% (95% CI: 2.1%-20.5%), with substantial heterogeneity (I^2 = 74.5%). At follow-up, the pooled rate of persistent residual shunt decreased to 3.4% (95% CI: 1.2%-8.9%), indicating spontaneous closure in many cases. Egger's test suggested potential publication bias for immediate shunt data (*P* = .03) (Figure 4 and 5).

Arrhythmias

The pooled incidence of transient arrhythmias [including ventricular tachycardia, supraventricular tachycardia (SVT), and premature ventricular contractions (PVCs)] was 5.5% (95% CI: 2.2%-12.4%; I^2 = 40.2%). Most arrhythmias were self-limiting and managed conservatively. No significant

Table 1. Clinical Characteristics of the Patients

Study	Female	Male	Age, Years (Median)	Weight (Median)	Height (cm)	Perimembranous VSDs	Muscular VSDs	Defect Size (mm)
1	7	5	26.9 (18-58)		168.8 (155-185) cm	7	4	6.24 (5-10 mm)
2	1	0	14	NA	NA	1	0	5 mm
3	5	3	17.1 (5-32)	NA	NA	8	0	6.6 (4.5-8.6 mm)
4	32	31	(0.7-14.5)	12.5 (7-31)	NA	63	0	5 (3.4-6.5 mm)
5	7	6	11 m (2 m-3 yrs)	7.2 (4.3-11.5)	NA	13	0	4.8 (3.2- 6.2 mm)
6	3	2	5 (3-9)	NA	NA	3	2	5 (3-6 mm)
7	9	6	4.5 (1.4-10)	NA	NA	15	0	5.3 (4-8 mm)
8	4	5	5.5 (2.5-9)	19.6 (11.2-27.5)	19.6 (87-125)	9	0	4.5-6 mm
9	73	74	5.9	NA	NA	103	6	5.5 (3-7.5 mm)
10	79	74	7 m-20 yrs	3.7-62	NA	139	7	3-22 mm
11	3	4	2.2-15 yrs	12-31	NA	0	6 (outlet), 1 (apical)	5.4 (3-12.5 mm)

NA, Not Available, VSD, ventricular septal defect.

Table 2. Demographic Data

No.	First Author	Published Year	Study Period	Country	VSD Type	Device Type	Number of Patients	Mean Age
1	Ertugrul Ercan[19]	2017	2013-2015	Türkiye	PM, M, post op. residual	Amplatzer, Cera occluder	12	26.9
2	Brina Suligoj[20]	2016	2016	USA	PM	Amplatzer	1	14
3	Pankaj Jariwala[21]	2019	2015-2018	India	PM	ADO I ADOII	8	17.1
4	Nageswara Rao Koneti[22]	2012	Not written	India	PM	ADOII	57	Median (3.7)
5	Raymond N. Haddad[23]	2023	2015-2020	–	PM	ADOII, MFO	59	Median (4.3)
6	Nageswara Rao Koneti[24]	2010	2009-2010	India	PM, M	ADOII	11	Median (48 months)
7	Alejandro Rasines[25]	2022	–	Spain	PM, TOF, DCRV	ADOII,ADOI, Piccolo, Konar, ASO	12	Median (4 y)
8	Nurun Nahar Fatema[26]	2020	2014-2019	Bangladesh	PM, M	ADOII	147	5.94 y ± 4.67
9	Kalyanasunderam Muthusamy[27]	2014	2009-2014	India	PM, M, subpulmonic	ADOII	153	7-20 y
10	Al-Ata Jameel[28]	2006	2003-2005	Saudi Arabia		AmVSDo	7	6.9 ± 4.5
11	Rania Diaa Abou Shokka[29]	2019	2016-2018	Egypt	PM	AVPII	15	4.9 y

PM, Perimembranous ventricular septal defect; M, muscular; VSD; defect in the muscular part of ventricular septum; TOF, tetralogy of fallot; DCRV, double-chambered right ventricle.

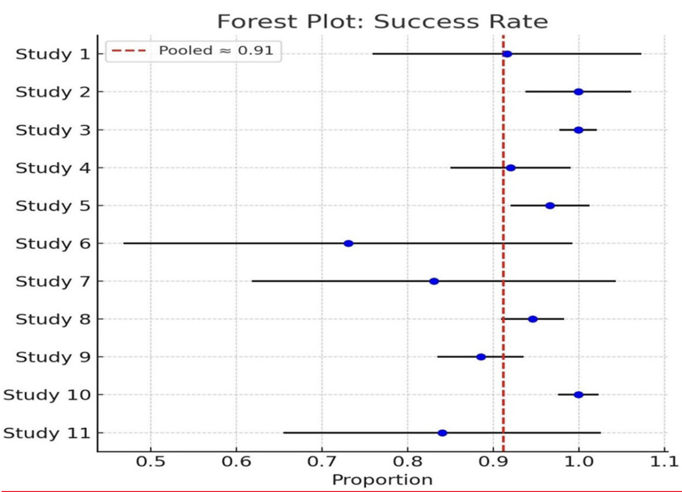

Figure 2. Forest plot of success rate.

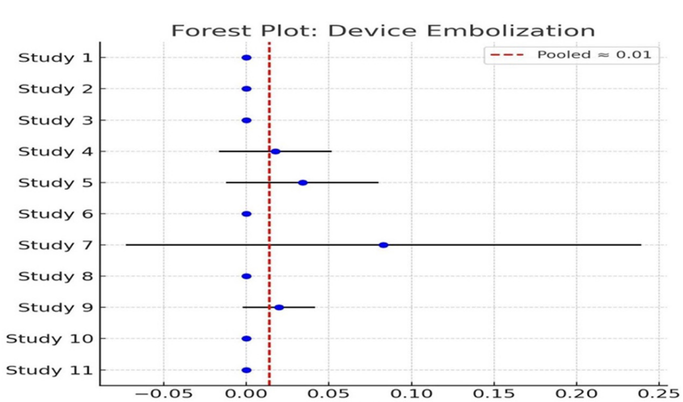

Figure 3. Forest plot of embolization.

publication bias was detected ($P = .14$). One study reported 8 cases of transient arrhythmia[26] and 2 studies showed 2 cases of PVC[23,28] Figure 6.

Valvular Lesions

Valvular complications, primarily tricuspid and aortic regurgitation, were observed in 6.4% of patients (95% CI: 2.3%-14.0%). Heterogeneity was moderate to high ($I^2 = 65.9\%$). No significant publication bias was detected ($P = .05$) Figure 7).

Conduction Abnormalities

Three studies only reported transient heat blocks.[23,26,27] The pooled rate of conduction abnormalities, including transient heart block, was 5.3% (95% CI: 1.5%-13.6%) with no heterogeneity ($I^2 = 0\%$). All conduction disturbances resolved spontaneously or with steroid therapy. No publication bias was observed ($P = .67$) Figure 8).

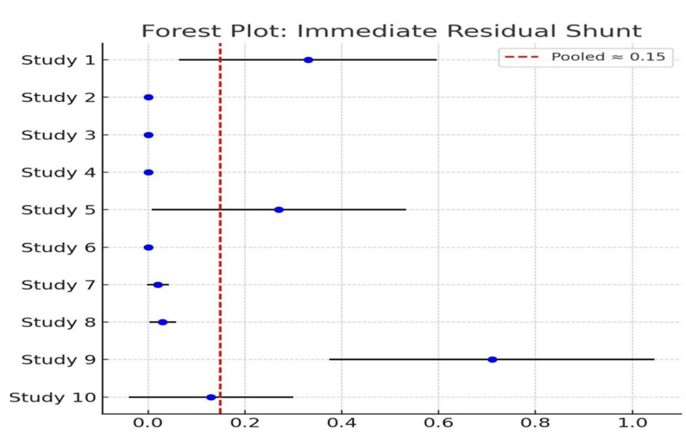

Figure 4. Forest plot for immediate residual shunt.

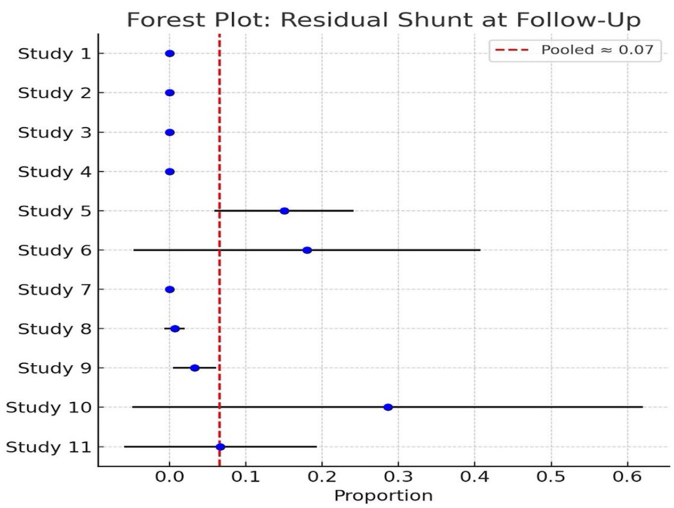

Figure 5. Forest plot for persistent residual shunt at follow-up.

Mortality

Death was among the lowest complications. Only 1 study documented death in 3 patients.[25] The pooled mortality rate was 2.8% (95% CI: 0.8%-7.1%), with low heterogeneity (I^2=30.2%). These cases involved patients with complex congenital syndromes or postoperative complications. No evidence of publication bias was found (P=.15) Figure 9).

Fluoroscopy Time

All of the studies reported a shorter fluoroscopy time in comparison to the traditional technique. Table 3 summarizes the fluoroscopy times in all studies.

DISCUSSION

This meta-analysis provides a comprehensive evaluation of the effectiveness and safety of transarterial retrograde transcatheter closure of VSDs, which to the authors' knowledge is the first meta-analysis investigating the aforementioned approach. This meta-analysis was conducted to further evaluate the minimally invasive transcatheter

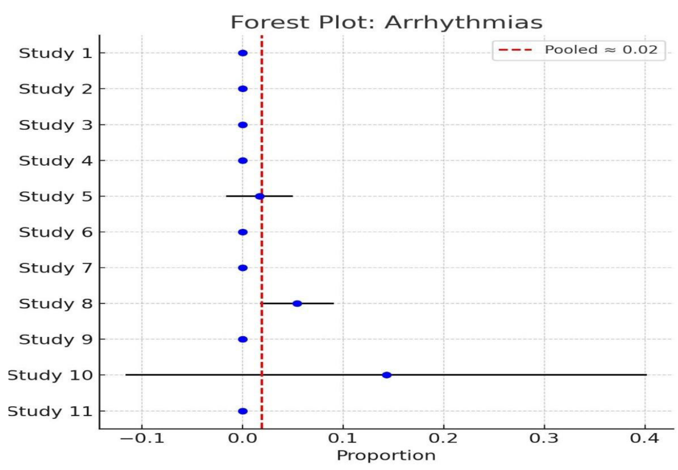

Figure 6. Forest plot for Arrythmia.

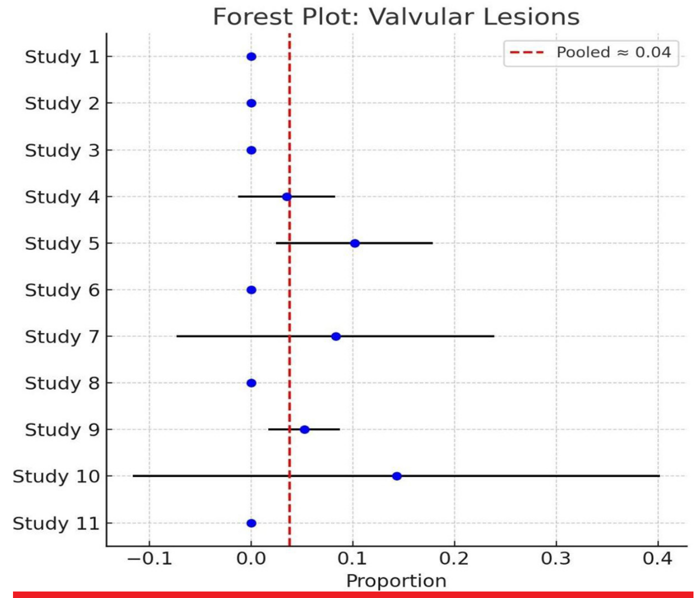

Figure 7. Forest plot for valvular lesions.

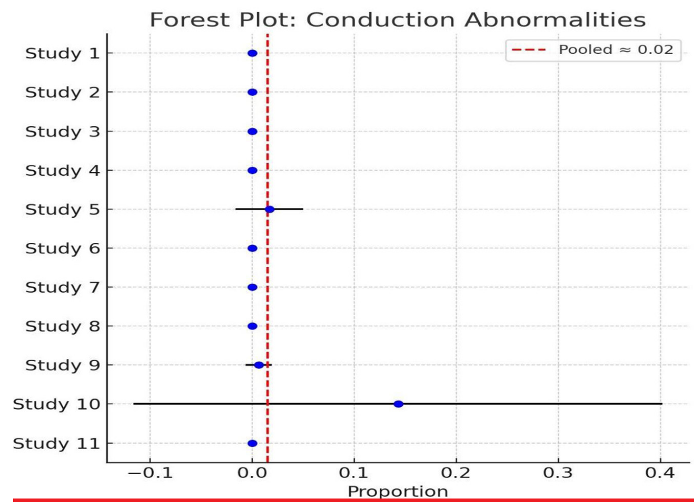

Figure 8. Forest plot for conduction abnormality.

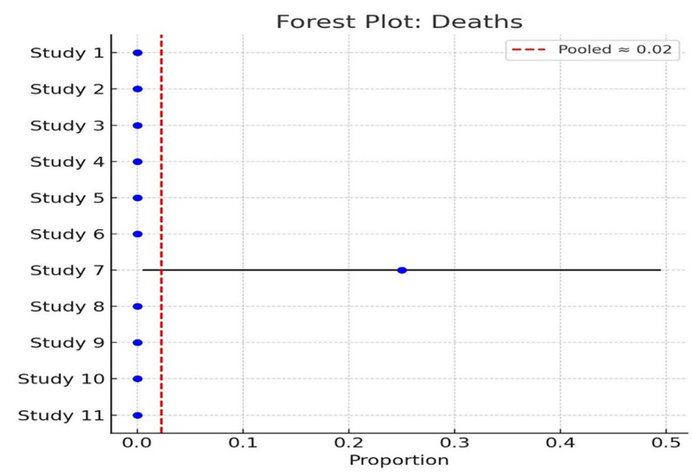

Figure 9. Forest plot for death.

Table 3. Fluoroscopy Time in All Studies

Study No.	Mean Fluoroscopy Time (min)
1	26.6
2	5.26
3	13.27
4	Median 8.8
5	Median 8.7
6	18.75
7	Median 15.3
8	9.29 ± 3.73
9	Not Available
10	33.8
11	27.6

retrograde approach for VSD closure to provide an evidence-based option for the treating cardiologist and cardiothoracic surgeon to consider when planning to choose which type of closure is better for a given VSD patient.

The findings suggest that this approach is associated with a high procedural success rate (89.3%) and a low incidence of serious complications. Importantly, the retrograde technique offers advantages such as shorter procedural time, avoidance of arteriovenous loops, and reduced radiation exposure, making it particularly appealing in selected patients. Device embolization was rare (1.1%), and all embolized devices were successfully retrieved. Residual shunts, a common early concern, were found in approximately 7.1% of patients immediately post-procedure but decreased to 3.4% during follow-up, reflecting the natural endothelialization and closure of small defects. Arrhythmias (5.5%) and conduction disturbances (5.3%) were generally transient and manageable, supporting the cardiac safety of the retrograde approach.

Valvular complications, primarily involving the aortic or tricuspid valves, occurred in 6.4% of patients. While most were mild, this reinforces the importance of careful device selection and procedural imaging. The overall mortality rate was low (2.8%), with deaths primarily related to underlying complex conditions rather than the procedure itself. Moderate to high heterogeneity was observed in some outcomes, notably residual shunts and valvular complications, likely reflecting differences in patient populations, operator experience, and device types. The Egger's test identified potential publication bias in a few outcomes, warranting cautious interpretation.

Furthermore, several factors are considered to select the most suitable device, including the left ventricular inlet, RV outlet, the depth of the defect, and other anatomical considerations. The most commonly used devices are ADO II and Cera occluder. Other devices such as ADO I, Konar-MF, and Piccolo can be used for selected patients. ADO II and Cera are small occluders; they can be delivered through smaller delivery systems. This advantage decreases the risk of conduction system injury. Further studies are needed to determine clear selection criteria for different patients.

Despite these promising results, this meta-analysis has limitations. Each study has its own unique inclusion and exclusion criteria for the patient. Therefore, the correct selection of cases is critical in this approach to success. The reasons behind failure were mostly related either to technical difficulties or the wrong selection of candidates. A significant constraint is the limited number of high-quality studies specifically focused on the transarterial retrograde technique, many of which are observational and retrospective in design. This inherently introduces a risk of selection bias and restricts the ability to establish causality. Additionally, there was considerable heterogeneity across studies with regard to patient demographics, VSD morphology, device selection, and procedural protocols, which may have influenced the pooled estimates and limited the comparability of results. The absence of standardized definitions for clinical endpoints, such as residual shunt and arrhythmia, further complicates data interpretation. Moreover, long-term follow-up data were inconsistently reported, limiting the assessment of late complications and durability of closure. These limitations underscore the need for prospective, multicenter trials with standardized methodologies to more definitively evaluate the safety and efficacy of the retrograde approach in diverse patient populations.

Transarterial retrograde closure of VSDs appears to be a safe and effective technique with a high procedural success rate and a low incidence of serious complications. While careful patient selection and procedural planning remain essential, this approach offers a valuable alternative to traditional techniques, particularly in experienced centers. Further large-scale, prospective studies are warranted to validate these findings and refine patient selection criteria.

Peer-review: Internally peer-reviewed.

Author Contributions: Concept – H.A., S.S.; Design – A.G., H.A.; Supervision – S.S., N.A.; Resources – M.A.; Materials – K.S.; Data Collection and/or Processing – E.E., R.S.; Analysis and/or Interpretation – A.A.; Literature Search – M.A.; Writing – H.A., S.S., K.S.; Critical Review – S.S., N.A.

Declaration of Interests: The authors have no conflicts of interest to declare.

Funding: The authors declare that this study received no financial support.

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