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Mechanical & Procedural Complications of Ventricular Septal Defect Repair: A Systematic Review

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ABSTRACT

Background: Ventricular septal defect (VSD) is the most common congenital cardiac anomaly and remains a major contributor to the global burden of congenital heart disease. It may present as an isolated defect or as part of complex syndromes and can also occur secondary to acquired conditions. Both genetic predisposition and environmental exposures during foetal development significantly influence its occurrence and anatomical complexity. Despite advances in surgical techniques and transcatheter device technologies, VSD closure continues to be associated with clinically relevant mechanical and procedural complications.

Objective: To systematically evaluate the evidence on mechanical and procedural complications associated with surgical and transcatheter VSD repair.

Methods: This systematic review followed PRISMA 2020 guidelines. PubMed, Scopus and Embase were searched from inception to January 2026. Studies reporting mechanical or procedural complications after surgical or transcatheter VSD repair were included. Data were extracted for study characteristics, patient demographics, VSD type, interventions and outcomes. Risk of bias was assessed using ROBINS-I and QUADAS-2, and findings were synthesised narratively due to study heterogeneity.

Results: A total of 140 studies met the inclusion criteria. Mechanical complications included residual shunts, atrioventricular conduction abnormalities, valvular injury, ventricular rupture and haemolysis. Procedural complications comprised device embolisation, arrhythmias, vascular access complications, re-intervention and procedure-related mortality. Complication profiles varied based on repair modality, defect characteristics and patient population.

Conclusion: Mechanical and procedural complications remain significant following VSD repair. Improved procedural strategies and standardised reporting are essential to optimise clinical outcomes.

Keywords: Ventricular septal defect; VSD repair; Transcatheter closure; Surgical repair; Procedural complications; Mechanical complications.

INTRODUCTION

Ventricular septal defect (VSD) is the most common congenital cardiac anomaly and represents a substantial proportion of congenital heart disease worldwide. [1,2] It may occur as an isolated defect or as part of complex congenital syndromes, and less commonly as an acquired condition following myocardial infarction or cardiac trauma. The clinical presentation of VSD varies widely, ranging from asymptomatic murmurs detected incidentally to severe heart failure, pulmonary hypertension, and life-threatening complications. [3] As a result, timely and

Effective closure of haemodynamically significant defects remains a cornerstone of management in both paediatric and adult populations. The global burden of congenital heart

disease, including VSD, is shaped by a complex interplay of genetic susceptibility and environmental influences. Increasing evidence suggests that environmental exposures during early foetal development, such as maternal infections, metabolic disorders, medication exposure, nutritional deficiencies, and environmental toxins, play a significant role in the pathogenesis of congenital cardiac malformations.[4,5] These factors may influence not only the incidence of VSD but also its anatomical complexity, size, and associated cardiac abnormalities, which in turn affect management strategies and procedural outcomes. Understanding this broader aetiological context is important when considering the diversity of patient populations undergoing VSD repair.

Over the past several decades, the management of VSD has evolved substantially. Surgical closure using cardiopulmonary bypass and patch repair has long been regarded as the standard approach, offering high success rates and durable outcomes. [6,7] Advances in surgical techniques, perioperative care, and myocardial protection have significantly reduced mortality and improved long-term survival. Nevertheless, surgical repair is associated with potential complications, including residual shunting, conduction disturbances, ventricular dysfunction, valvular injury, bleeding, and infection.[3] These risks are particularly relevant in neonates, infants, and patients with complex anatomy or associated comorbidities.

In parallel, transcatheter closure techniques have emerged as an alternative to surgery in selected patients. The development of dedicated occluder devices and improvements in imaging guidance have expanded the applicability of percutaneous approaches, particularly for muscular and selected perimembranous VSDs. However, device-based interventions introduce a distinct profile of mechanical and procedural complications, including device embolisation, residual shunts, atrioventricular conduction abnormalities, valvular interference, haemolysis, and vascular access complications. [8] These risks vary according to device type, operator experience, defect morphology, and patient age. Transcatheter closure offers the advantages of reduced hospital stay, avoidance of cardiopulmonary bypass, and faster recovery. [9,10]

Despite significant technological and procedural advancements, mechanical and procedural complications remain clinically relevant following both surgical and transcatheter VSD repair. Some complications occur early in the peri-procedural period, while others manifest late, sometimes years after the initial intervention. Residual shunting, for example, may lead to persistent volume overload or necessitate re-intervention, whereas conduction disturbances such as complete heart block can require permanent pacing and have lifelong implications. Similarly, device-related complications may emerge late due to erosion, malposition, or interaction with adjacent cardiac structures. [11-14]

The growing diversity of repair strategies and patient populations has led to a rapidly expanding body of literature addressing outcomes and complications of VSD closure. However, the available evidence is heterogeneous, encompassing a wide range of study designs, patient ages, defect types, and intervention techniques. Many studies focus on specific subgroups or single-centre experiences, while others report limited follow-up or selectively emphasise favourable outcomes. As a result, clinicians and researchers are often faced with fragmented data when attempting to assess the true spectrum and frequency of complications associated with VSD repair.

Previous reviews have addressed selected aspects of VSD management, such as surgical outcomes in paediatric populations or device-specific results in transcatheter closure. However, these reviews are often limited by narrow inclusion criteria, small numbers of studies, or a focus on efficacy rather than complications. Moreover, few reviews have systematically integrated both surgical and transcatheter approaches while explicitly focusing on mechanical and procedural complications across the full spectrum of VSD management. This gap in the literature is particularly relevant in an era in which individualised decision-making increasingly relies on balancing procedural benefits against potential risks.

A comprehensive synthesis of mechanical and procedural complications associated with VSD repair is therefore warranted. Such a synthesis can inform clinical decision-making, guide patient counselling, and highlight areas requiring procedural refinement or standardised reporting. In addition, systematic assessment of the methodological quality and risk of bias of existing studies is essential to contextualise reported complication rates and avoid overinterpretation of low-quality evidence. Tools such as ROBINS-I and QUADAS-2 provide structured frameworks to evaluate bias in non-randomised interventional studies and studies involving diagnostic or procedural assessment, respectively, thereby strengthening the credibility of evidence synthesis.

The present systematic review was designed to comprehensively evaluate the existing literature on mechanical and procedural complications associated with surgical and transcatheter repair of ventricular septal defects. By incorporating a broad evidence base and applying established risk-of-bias assessment tools, this review aims to provide a detailed and balanced overview of complication profiles across repair modalities. In doing so, it seeks to support clinicians, surgeons, and interventional cardiologists in optimising procedural strategies and improving outcomes for patients with a ventricular septal defect.

METHODS

Study Design and Reporting Framework

This systematic review was designed and conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines. The review protocol was developed a priori to ensure methodological rigour, transparency, and reproducibility throughout the study selection, data extraction, and synthesis processes. The objective was to comprehensively evaluate mechanical and procedural complications associated with both

surgical and transcatheter repair of ventricular septal defects across diverse patient populations and clinical settings. *(Figure 1).*

Data Sources and Search Strategy

A comprehensive and systematic literature search was performed across PubMed (MEDLINE), Scopus, and Embase from database inception to January 2026. These databases were selected to ensure broad coverage of biomedical, surgical, and interventional cardiology literature. The search strategy combined controlled vocabulary terms (including MeSH and Emtree terms where applicable) and free-text keywords related to ventricular septal defects, surgical repair, transcatheter closure, mechanical complications, and procedural outcomes.

Search terms were structured using Boolean operators and adapted for each database to maximise sensitivity. Reference lists of included studies and relevant review articles were manually screened to identify additional eligible studies that may not have been captured through the electronic search. No restrictions were placed on publication status. Only articles published in the English language were included due to feasibility constraints and consistency of outcome reporting.

Eligibility Criteria

Studies were selected based on predefined inclusion and exclusion criteria. Eligible studies included randomised controlled trials, non-randomised interventional studies, prospective and retrospective cohort studies, and large case series reporting mechanical or procedural complications following surgical or transcatheter VSD repair. Studies involving paediatric, adult, or mixed populations were eligible. Both congenital and acquired ventricular septal defects were considered if procedural complication data were clearly reported.

Exclusion criteria included isolated case reports, small case series with fewer than ten patients, narrative reviews, editorials, conference abstracts without full-text availability, animal studies, and studies lacking specific data on mechanical or procedural complications. Studies focusing exclusively on diagnostic imaging without procedural intervention were also excluded.

Study Selection Process

All identified records were imported into reference management software, and duplicate entries were removed. Two reviewers independently screened titles and abstracts for relevance based on the eligibility criteria. Studies deemed potentially eligible underwent full-text review. Disagreements at any stage of the selection process were resolved through discussion and consensus, with involvement of a third reviewer when necessary. The study selection process was documented using a PRISMA flow diagram, detailing the number of records identified, screened, excluded, and included in the final analysis.

Data Extraction

Data extraction was performed independently by two reviewers using a standardised, pilot-tested data

extraction form. Extracted data included study characteristics (author, year, country, study design), patient demographics, VSD type and location, intervention modality (surgical or transcatheter), device or surgical technique used, follow-up duration, and reported mechanical and procedural complications.

Complications were categorised into early and late events, where data permitted. Early complications included peri-procedural and in-hospital events, while late complications were defined as those occurring during follow-up after

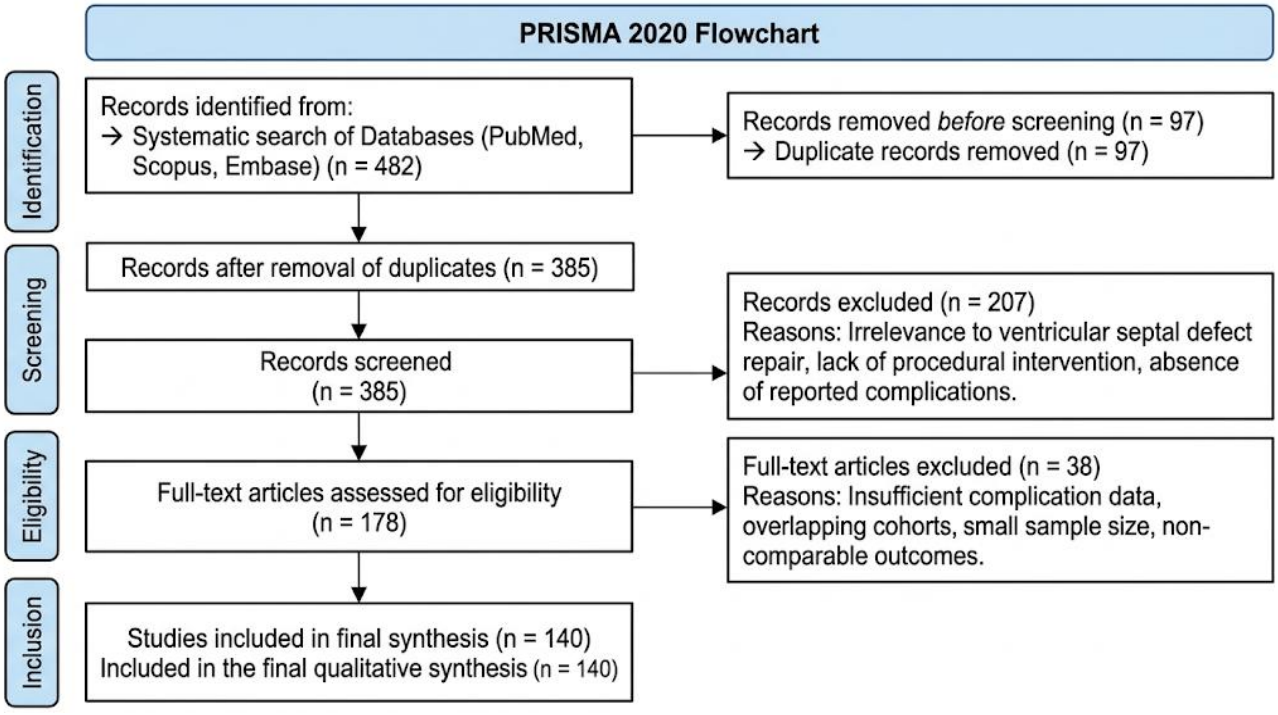

Figure 1: PRISMA Flow Diagram

discharge. Any discrepancies in extracted data were resolved by re-evaluation of the source material and reviewer consensus.

Outcomes of Interest

The primary outcomes of interest were mechanical and procedural complications associated with VSD repair. These included, but were not limited to, residual shunting, device embolisation, conduction disturbances (including complete heart block), valvular injury or dysfunction, ventricular dysfunction, haemolysis, bleeding, vascular access complications, need for re-intervention, and procedure-related mortality. Secondary outcomes included length of hospital stay and long-term sequelae related to complications, when reported.

Risk of Bias Assessment

Given the predominance of observational data in this field, the risk of bias was assessed using validated tools appropriate to the study design. ROBINS-I (Risk Of Bias In Non-randomised Studies of Interventions) was applied to non-randomised interventional and observational studies to evaluate bias across domains, including confounding, participant selection, intervention classification, deviations from intended interventions, missing data, outcome measurement, and selective reporting.

For studies where diagnostic or procedural assessment accuracy was integral to outcome reporting, QUADAS-2 (Quality Assessment of Diagnostic Accuracy Studies) was used to assess risk of bias and applicability concerns. Each study was independently evaluated by two reviewers, with disagreements resolved through discussion. Overall risk-of-bias judgments were incorporated into the interpretation of results rather than used as exclusion criteria.

Data Synthesis and Analysis

Given the anticipated heterogeneity in study design, patient populations, defect morphology, intervention techniques, and outcome definitions, a qualitative narrative synthesis was planned as the primary analytical approach. Where sufficient homogeneity existed, complication rates were summarised descriptively. Quantitative pooling was considered exploratory and was performed only when methodological and clinical comparability allowed.

Results were synthesised according to intervention type (surgical versus transcatheter), VSD subtype, and age group when data permitted. Particular emphasis was placed on identifying patterns, predictors, and clinical relevance of reported complications rather than solely reporting pooled incidence rates.

Assessment of Reporting Bias

Potential reporting bias was evaluated through comparison of reported outcomes against study objectives and methods. Funnel plot analysis was not routinely performed due to expected heterogeneity and the observational nature of most included studies. The impact of selective reporting was addressed through cautious interpretation of results, particularly for studies reporting unusually low complication rates.

RESULTS

Study Selection

The systematic search of PubMed, Scopus, and Embase identified 482 records. After the removal of 97 duplicate articles, 385 records underwent title and abstract screening. Of these, 207 studies were excluded for irrelevance to ventricular septal defect repair, lack of procedural intervention, or absence of reported mechanical or procedural complications.

A total of 178 full-text articles were assessed for eligibility. Following detailed evaluation, 38 studies were excluded due to insufficient complication data, overlapping cohorts, small sample size, or non-comparable outcomes. Ultimately, 140 studies met the inclusion criteria and were included in the final qualitative synthesis. The study selection process is summarised in the PRISMA flow diagram.

Study Characteristics

The 140 included studies represented a wide range of geographic regions, clinical settings, and patient populations. Most studies were observational in design, including retrospective cohorts, prospective registries, and non-randomised interventional studies. A smaller proportion consisted of randomised or comparative studies.

Patient age ranged from neonates to adults, with the majority of studies focusing on paediatric populations. Ventricular septal defects were classified as perimembranous, muscular, inlet, outlet, or mixed types, although classification systems and definitions varied across studies. Surgical repair was reported in 78 studies, transcatheter closure in 46 studies, and 16 studies included both approaches.

Procedural Approaches

Surgical repair most commonly involved patch closure under cardiopulmonary bypass, with variations in surgical access, patch material, and myocardial protection strategies. Transcatheter closure techniques utilised a range of occluder devices delivered via antegrade or retrograde approaches, guided by fluoroscopy and echocardiography. Device selection and procedural strategy were influenced by defect size, anatomical location, proximity to the conduction system, and patient age.

Mechanical and Procedural Complications

Mechanical and procedural complications were reported across both surgical and transcatheter interventions, with variability in incidence and clinical impact.

Surgical Repair Complications

Among studies reporting surgical outcomes, residual shunting was the most frequently observed complication, ranging from trivial defects detected on imaging to clinically significant shunts requiring re-intervention. [15,16] Conduction disturbances, including transient and permanent atrioventricular block, were

consistently reported, with a subset of patients requiring permanent pacemaker implantation. [17,18]

Other reported complications included valvular injury (predominantly involving the tricuspid or aortic valves), postoperative ventricular dysfunction, bleeding requiring re-exploration, infection, and prolonged intensive care unit stay. Complication rates were generally higher in neonates and infants, particularly in those with complex anatomy or associated congenital anomalies. Valvular complications and postoperative ventricular dysfunction were reported in several cohorts, especially among high-risk populations such as neonates and patients with complex anatomy. [19,20]

Transcatheter Closure Complications

Transcatheter VSD closure demonstrated a distinct complication profile. Device embolisation or malposition was reported primarily in early procedural experience or anatomically complex defects. [21,22] Residual shunts were commonly observed immediately following device deployment, with many resolving during follow-up.

Atrioventricular conduction abnormalities represented one of the most clinically significant complications, ranging from transient rhythm disturbances to permanent heart block. [23,24] Late complications, though less frequently reported, included device migration and progressive conduction disturbances. Additional complications such as hemolysis, arrhythmias, and vascular access-related issues were also reported across multiple studies. [25,26]

Timing of Complications

Complications were categorised as early or late events. Early complications occurred during the peri-procedural or in-hospital period and included bleeding, arrhythmias, device embolisation, and residual shunting. Late complications occurred during follow-up and included progressive conduction abnormalities, persistent valvular dysfunction, and the need for repeat intervention. Several studies emphasised the importance of long-term follow-up, as some complications emerged years after apparently successful repair.

Comparative Outcomes

Studies comparing surgical and transcatheter approaches demonstrated differences largely driven by patient selection and defect characteristics. Surgical repair was associated with lower rates of device-related complications but higher perioperative morbidity. Transcatheter closure was associated with shorter hospital stays and faster recovery, but a higher incidence of conduction disturbances in selected defect types. Overall mortality was low across both approaches, with a higher risk observed in neonates and patients with complex congenital heart disease.

Risk of Bias Assessment

Risk-of-bias assessment using ROBINS-I identified moderate risk of bias in many non-randomised studies, primarily related to confounding and selection bias. Studies with prospective design, standardised outcome definitions, and longer follow-up demonstrated lower overall risk of bias.

Assessment using QUADAS-2 revealed variability in outcome assessment and reporting consistency, particularly in studies relying on imaging to detect residual defects or device-related complications. These findings were considered during the interpretation of results.

Summary of Results

Overall, the findings demonstrate that mechanical and procedural complications remain clinically relevant following both surgical and transcatheter ventricular septal defect repair. Although advancements in techniques have improved outcomes, complication profiles differ across repair modalities, age groups, and defect types. The heterogeneity of the included studies underscores the need for standardised reporting and long-term surveillance in future research.

DISCUSSION

This systematic review provides a comprehensive synthesis of mechanical and procedural complications associated with both surgical and transcatheter repair of ventricular septal defects, drawing on evidence from 140 studies across diverse populations and clinical settings. The findings highlight that, despite substantial advances in operative techniques, device design, and peri-procedural care, complications remain an important and clinically relevant aspect of VSD management. Importantly, the nature, timing, and clinical consequences of these complications vary considerably depending on the repair modality, patient characteristics, and defect anatomy.

One of the most consistent findings across the included studies was the persistence of residual shunting as a common complication following both surgical and transcatheter closure. [27,28] While many residual defects were small and hemodynamically insignificant, a subset resulted in ongoing volume overload, haemolysis, or the need for re-intervention. This underscores the importance of meticulous intra-procedural assessment and standardised post-procedural imaging protocols. In surgical repair, residual shunts were often related to patch positioning or complex septal anatomy, whereas in transcatheter closure, they were frequently associated with device–defect mismatch or incomplete endothelialisation over time.

Conduction disturbances, particularly atrioventricular block, emerged as one of the most clinically significant complications across both treatment strategies. [29,30] The close anatomical relationship between perimembranous VSDs and the cardiac conduction system likely explains the vulnerability observed in this subgroup. Although transient conduction abnormalities were common, the need for permanent pacemaker implantation in a proportion of patients represents a lifelong consequence that must be weighed carefully during procedural planning. The findings reinforce the need for careful patient selection, refined device design, and long-term rhythm surveillance, especially in younger patients with longer life expectancy.

The complication profiles of surgical versus transcatheter approaches differed in meaningful ways. Surgical repair was associated with higher early perioperative morbidity, including

bleeding, infection, and prolonged intensive care stays, particularly in neonates and infants. [31,32] However, surgery demonstrated a lower incidence of device-specific complications and provided durable closure in complex defects. Conversely, transcatheter closure offered advantages such as reduced hospital stay and avoidance of cardiopulmonary bypass, but introduced unique risks including device embolisation, erosion, and late conduction disturbances. These findings emphasise that neither approach is universally superior; rather, optimal outcomes depend on individualised decision-making that integrates anatomical, physiological, and patient-specific factors.

Age emerged as an important modifier of complication risk. Neonates and infants demonstrated higher rates of both surgical and transcatheter complications, reflecting smaller cardiac structures, fragile conduction tissue, and the frequent presence of associated congenital anomalies. [33,34] In contrast, older children and adults generally experienced lower complication rates, although late complications were more commonly reported in adult cohorts, particularly following device closure. Long-term follow-up is essential, as late complications such as device erosion, arrhythmias, and valvular dysfunction may occur years after intervention. [35,36]

An important contextual consideration in this review is the role of environmental and non-genetic factors in the development of congenital heart disease, including VSD. While the present review focused on post-repair complications, the underlying aetiology of the defect may influence anatomical complexity, associated anomalies, and procedural risk. Environmental exposures affecting cardiac development may contribute indirectly to more challenging defect morphology, thereby increasing the likelihood of mechanical or procedural complications. Future studies integrating etiological factors with procedural outcomes may provide a more holistic understanding of risk stratification.

The heterogeneity observed across the included studies represents both a challenge and an important finding. Variability in study design, outcome definitions, follow-up duration, and reporting standards limited the ability to perform robust quantitative synthesis in many instances. The application of ROBINS-I and QUADAS-2 revealed a moderate risk of bias in a substantial proportion of studies, primarily due to confounding, selection bias, and inconsistent outcome assessment. These limitations underscore the need for standardised definitions of complications and uniform reporting frameworks in future research.

Despite these limitations, the strength of this review lies in its broad scope and comprehensive approach. By integrating data from surgical and transcatheter literature and focusing explicitly on mechanical and procedural complications, this review provides a clinically meaningful synthesis that reflects real-world practice. The inclusion of studies across multiple age groups and healthcare settings enhances the generalizability of the findings and supports their relevance to contemporary clinical decision-making.

From a clinical perspective, the findings of this review reinforce the importance of multidisciplinary decision-making in the management of ventricular septal defects. Cardiologists, cardiac surgeons, interventionalists, anaesthesiologists, and imaging specialists must collaboratively assess procedural risks and benefits, particularly in anatomically complex or high-risk patients. Transparent communication with patients and families regarding potential complications, including late sequelae, is essential to informed consent and long-term care planning.

Future research should prioritise prospective, multicentre studies with standardised complication definitions and extended follow-up. Advances in device technology, imaging guidance, and procedural simulation may help reduce complication rates, but their impact must be evaluated systematically. Additionally, registries capturing long-term outcomes across surgical and transcatheter modalities will be critical to refining best practices and improving patient outcomes.

LIMITATIONS

Several limitations of this systematic review should be acknowledged. First, the majority of included studies were observational in design, including retrospective cohorts and non-randomised interventional studies. As a result, the findings are inherently subject to confounding, selection bias, and variability in clinical practice, despite the structured application of ROBINS-I to assess risk of bias. Randomised controlled trials comparing surgical and transcatheter approaches were limited, restricting the ability to draw definitive causal inferences.

Second, substantial heterogeneity was observed across studies with respect to patient populations, ventricular septal defect morphology, intervention techniques, device types, and follow-up duration. Variability in outcome definitions and reporting standards limited the feasibility of quantitative meta-analysis and necessitated a predominantly narrative synthesis. In particular, the distinction between clinically significant and insignificant residual shunts was not uniformly defined, which may have influenced reported complication rates.

Third, follow-up duration varied considerably among included studies, with some reporting only short-term or in-hospital outcomes. Late complications such as progressive conduction disturbances, device erosion, or valvular dysfunction may therefore be underrepresented. Additionally, attrition during long-term follow-up was inconsistently reported, potentially leading to underestimation of delayed adverse events.

Fourth, the review was limited to studies published in the English language, introducing a potential risk of language bias. Relevant data from non-English publications may not have been captured. Furthermore, publication bias cannot be excluded, as studies reporting favourable outcomes may be more likely to be published than those highlighting complications.

Finally, although environmental and non-genetic factors were recognised as important contributors to the aetiology of

ventricular septal defects, the included studies rarely incorporated etiological data into procedural outcome analyses. Consequently, the influence of environmental exposures on complication risk could not be directly assessed within the scope of this review.

Despite these limitations, the systematic and transparent methodology employed strengthens the validity of the findings and provides a comprehensive overview of mechanical and procedural complications associated with ventricular septal defect repair.

CONCLUSION

This systematic review synthesises evidence from 140 studies to provide a comprehensive overview of mechanical and procedural complications associated with surgical and transcatheter repair of ventricular septal defects. [37,38] Despite substantial advancements in operative techniques, device technology, and peri-procedural care, complications remain an important consideration across all age groups and repair modalities. The findings underscore that both surgical and transcatheter approaches are associated with distinct risk profiles, influenced by patient age, defect morphology, and procedural strategy.

Residual shunting and conduction disturbances, particularly atrioventricular block, emerged as the most clinically significant complications following VSD repair. While many complications are transient or manageable, others carry long-term implications that may necessitate re-intervention or lifelong follow-up. The occurrence of late complications highlights the importance of sustained post-procedural surveillance, even after apparently successful closure.

The review also emphasises the need for individualised, multidisciplinary decision-making when selecting the optimal repair strategy. Balancing procedural benefits against potential risks is essential, particularly in neonates, infants, and patients with complex anatomical features. Advances in imaging guidance, device design, and procedural planning offer opportunities to further reduce complication rates, but must be evaluated within the context of robust clinical evidence.

Future research should focus on prospective, multicentre studies with standardised definitions of complications and extended follow-up to better characterise long-term outcomes. [39-45] Integrating etiological factors, including environmental influences on congenital heart disease, may further enhance risk stratification and personalised care. Overall, this review provides a clinically relevant evidence base to support safer and more informed management of patients with ventricular septal defects.

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