



## Review article

# Transcatheter closure of post-myocardial infarction ventricular septal defect: A systematic review and single-arm meta-analysis

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## ABSTRACT

**Background:** Ventricular septal defects (VSDs) are one of the mechanical complications of acute myocardial infarction (AMI). Because of the high risks of mortality and postoperative complications, a new alternative method is needed. With the development of interventional medicine, transcatheter closure has been increasingly performed for postmyocardial infarction ventricular septal defects (PMIVSDs). The aim of this study is to explore the feasibility and safety of transcatheter closure of PMIVSDs by meta-analysis.

**Methods:** The included studies were mainly single-arm studies of transcatheter closure of PMIVSDs. We compared VSD size, device size, preoperative risk factors and interventions among PMIVSD patients. We analysed the transcatheter closure success rate, the 30-day mortality rate, and the incidence of residual shunts.

**Results:** A total of 12 single-arm articles (284 patients) were included. The combined incidences of preoperative hypertension, hyperlipidaemia, and diabetes were 66% [95% CI 0.56–0.75], 54% [95% CI 0.40–0.68], and 33% [95% CI 0.21–0.46], respectively. Multiple studies reported the combined incidences of preoperative PCI, IABP, and CABG, which were 46% [95% CI 0.15–0.80], 60% [95% CI 0.44–0.75], and 8% [95% CI 0.02–0.18]. Eleven studies reported the number of successful closures and the 30-day mortality rate; the success rate was 90% [95% CI 0.86–0.94], and the 30-day mortality rate reached 27% [95% CI 0.86–0.94].

**Conclusion:** For patients with PMIVSD, transcatheter closure in the acute phase can be used as a rescue measure, while in the chronic phase, it is more effective and has a lower mortality rate, but the effect of selection bias should be considered. Residual shunts are a long-term complication that have a high incidence and long-lasting effects on patients. More large, multicentre, randomized controlled trials are needed in the future to confirm the safety and reliability of transcatheter closure of PMIVSDs.

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## 1. Introduction

Acute myocardial infarction (AMI) is a serious consequence of coronary artery disease, and myocardial infarction is a major global health problem, affecting more than 7 million people worldwide each year [1]. Patients with extensive infarction or delayed revascularization are at risk for mechanical complications of AMI. The most common mechanical complications are acute mitral regurgitation secondary to papillary muscle rupture, ventricular septal defect (VSD), pseudoaneurysm, and free wall rupture. In contemporary cardiovascular practice, the incidence of postmyocardial infarction ventricular septal defect (PMIVSD) is approximately 0.3% [2,3]. The prognosis of PMIVSD before thrombolysis is poor, with a mortality rate of approximately 45% for surgical treatment and 90% for medical treatment [3,4]. Selecting the appropriate surgical method and optimal timing are important to reduce patient mortality and improve prognosis. To date, there are two main treatment options for the treatment of PMIVSD: surgical repair and interventional closure. Immediate surgical repair regardless of clinical status (Class I recommendation) is recommended for the management of PMIVSD in the current American College of Cardiology/American Heart Association guidelines [5]. The timing of the surgery is associated with the belief that shortly after AMI, the ruptured myocardium is too fragile to be repaired safely. Therefore, a waiting period of 3–6 weeks is required to achieve relatively firm scarring of the ischaemic necrotic muscle so that the defect can be repaired [6]. Because surgeons often avoid early surgery, patient mortality is likely increased. Lock [7] and colleagues are the first to report an interventional treatment approach for PMIVSD. Transcatheter closure of PMIVSD has become a viable treatment option since this first report. For patients with PMIVSD, haemodynamic instability is the main cause of high mortality in open surgery. Transcatheter closure may be a resolution for this problem, thereby leading to an immediate increase in patient survival. At present, transcatheter occlusion technology is gradually advancing, but the number of applications in PMIVSD is relatively small. Only a few studies have discussed postoperative complications and mortality. To explore the effect of transcatheter occlusion therapy in PMIVSD, this paper discusses the feasibility and safety of transcatheter occlusion of PMIVSD through meta-analysis.

## 2. Method

### 2.1. Document retrieval

According to the “PICOS” principle, the two researchers searched all relevant literature from the establishment of the library to December 2022, including PubMed, Embase, Cochrane Library, and Web of Science. At the same time, to prevent missing articles, we also searched the references of the included articles. Taking PubMed as an example, the search strategy was (Transcatheter OR transcatheter OR percutaneous) AND (“Heart Septal Defects, Ventricular” [Mesh] OR “Ventricular Septal Defect” OR “Ventricular Septal Defects” OR “Intraventricular Septal Defects” OR “Intraventricular Septal Defect” OR “Ventricular Septal Rupture”). We also searched several clinical trial registration platforms, including the WHO International Clinical Trials Registry Platform (WHO ICTRP) and the US Clinical Trials Registry ([ClinicalTrials.gov](https://clinicaltrials.gov)). Search results without language restrictions. To ensure detailed and accurate data, all data were extracted and analysed by two assessors, and differences were resolved through consultation between the two researchers.

### 2.2. Inclusion criteria

All study population should be affected by PMIVSD. The number of cases included in each study should be  $\geq 10$ . Single-arm studies should directly report transcatheter closure of PMIVSD. Randomized controlled trials should include a comparison of transcatheter and traditional transthoracic surgery. Patients’ baseline information must include transcatheter closure success rates, postoperative complications, and 30-day mortality. Other data can include residual hunt, VSD size, and device size. Postoperative follow-up data should also be included.

### 2.3. Exclusion criteria

The main contents are non-VSD studies; VSD studies related to congenital heart disease; VSD caused by causes other than myocardial infarction; studies with insufficient data and a loss to follow-up rate greater than 50%; animal experiments, literature reviews, and conference abstracts.

### 2.4. Protocol and registration

This work has been reported in line with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) and AMSTAR (Assessing the methodological quality of systematic reviews) Guidelines [8]. We registered a review protocol in PROSPERO (<https://www.crd.york.ac.uk/PROSPERO/>) on Aug 15, 2022, and it was last updated on Aug 16, 2022. The registration number is CRD 42022347358.

### 2.5. Data acquisition

To ensure the integrity and authenticity of the data, the two researchers jointly carried out data extraction work and used

standardized forms to extract research data. The data extraction table should include as detailed as possible the valuable characteristics of the included studies, such as VSD size, device size, successful occlusions, 30-day deaths, preoperative risk factors (smoking, hypertension, hyperlipidaemia, diabetes, heart failure), preoperative interventions [percutaneous coronary intervention (PCI), intra-aortic balloon pump (IABP), coronary artery bypass grafting (CABG)], and postoperative complications (residual shunts, device shedding, shock, arrhythmias).

2.6. Statistical analysis

The analysis software used in our study was Stata 14.0. Meta-analysis was performed using the “metaprop” command. Since most of the included studies were single-arm studies, there may be high heterogeneity. Therefore, the combined results were expressed as the benefit value plus 95% confidence interval (CI) under the random effects model, and the incidence of each variable was analysed. Subgroup analyses of postoperative complications were performed. For all analysis results,  $P < 0.05$  was considered statistically significant.

2.7. Risk of bias assessment

The risk of bias was assessed using quality assessment criteria for observational studies recommended by the Agency for Health care Research and Quality (AHRQ) [9]. The answers were “yes”, “no” and “unclear”, respectively. The studies were independently reviewed and cross-checked by two researchers, and disputes were discussed until consensus was reached.

3. Results

The results of the risk of bias assessment are shown in Figs. 1 and 2. The included studies were generally treated well, and no obvious bias was found. A total of 205 studies on PMIVSD were retrieved, and two researchers conducted preliminary screening by reading abstracts. We did not collect studies on transcatheter occlusion versus surgery for PMIVSD, so we screened 44 case reports related to PMIVSD. After reading the full text of these 44 studies according to the inclusion and exclusion criteria, we finally selected 12 studies for inclusion in this single-arm meta-analysis 6 10–20. The literature screening process and results are shown in Fig. 3.

A total of 284 patients with VSD after myocardial infarction were included in the 12 studies with transcatheter closure of VSD. The research was carried out from 2004 to 2018. Five studies were from China, two were from the USA, and four were from the UK, India, Canada, Poland, and Germany. Eleven studies reported successful closure and 30-day deaths. All 12 studies reported complications and causes of death in patients after transcatheter closure, with the main complication being residual defects after closure. Postoperative causes of death included cardiogenic shock, device displacement, arrhythmia, and ventricular rupture. The combined incidence rates of preoperative hypertension, hyperlipidaemia, and diabetes in 12 studies were 66% [95% CI 0.56–0.75], 54% [95% CI 0.40–0.68], and 33% [95% CI], respectively. Multiple studies reported the combined incidences of preoperative PCI, IABP, and CABG were 46% [95% CI 0.15–0.80], 60% [95% CI 0.44–0.75], and 8% [95% CI 0.02–0.18]. Eleven studies reported the number of successful closures and the 30-day mortality rate; the success rate was 90% [95% CI 0.86–0.94], and the 30-day mortality rate reached 27% [95% CI 0.18–0.37]. The average age of the study participants was older than 60 years. In terms of sex, the combined result of the female sex ratio is 46% [95% CI 0.40–0.53]. We also assessed the VSD size and the device size of the patients, and the results were 12.11 mm [95% CI 8.00–16.22] and 18.57 mm [95% CI 15.14–22.00], respectively. The combined incidence of all events and the subgroup analyses of postoperative complications are presented in Figs. S1–S8. In the included study, Xian-Yang Zhu [6] explored the short-term and long-term efficacy of transcatheter closure of VSD combined with PCI in the treatment of MI complicated with VSD. Holger Thiele [10] divided 29 patients into a cardiogenic shock group and a noncardiogenic shock group for risk stratification to explore the safety and efficacy of VSD after transcatheter closure of MI. Three studies investigated the feasibility, timing, outcomes,

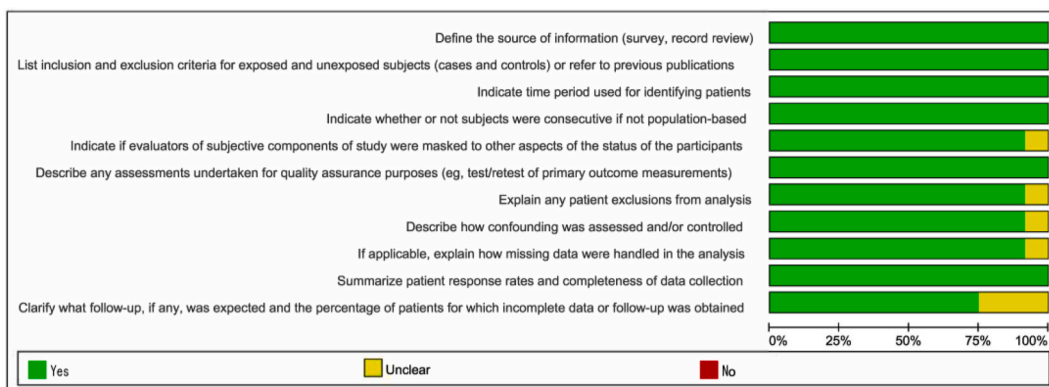


Fig. 1. Risk of bias graph on this study.

Author	Define the source of information (survey, record review)	List inclusion and exclusion criteria for exposed and unexposed subjects (cases and controls) or refer to previous publications	Indicate time period used for identifying patients	Indicate whether or not subjects were consecutive if not population-based	Indicate if evaluators of subjective components of study were masked to other aspects of the status of the participants	Describe any assessments undertaken for quality assurance purposes (eg, test/retest of primary outcome measurements)	Explain any patient exclusions from analysis	Describe how confounding was assessed and/or controlled	If applicable, explain how missing data were handled in the analysis	Summarize patient response rates and completeness of data collection	Clarify what follow-up, if any, was expected and the percentage of patients for which incomplete data or follow-up was obtained
Alexander C. Egebe 2015	●	●	●	●	●	●	●	●	●	●	●
Holger Thiele 2008	●	●	●	●	●	●	●	●	●	●	●
Liang Tang 2015	●	●	●	●	●	●	●	●	●	●	●
Marek Aggarwal 2018	●	●	●	●	●	●	●	●	●	●	●
Patrick A. Cahier 2014	●	●	●	●	●	●	●	●	●	●	●
Ralf Hoyer 2004	●	●	●	●	●	●	●	●	●	●	●
Robert Sabihovic 2017	●	●	●	●	●	●	●	●	●	●	●
Ruoxi Zhang 2017	●	●	●	●	●	●	●	●	●	●	●
Simon Malais 2009	●	●	●	●	●	●	●	●	●	●	●
Xian-Yang Zhu 2013	●	●	●	●	●	●	●	●	●	●	●
Xu-Dong Xu 2014	●	●	●	●	●	●	●	●	●	●	●
Yao-Lin Nie 2016	●	●	●	●	●	●	●	●	●	●	●

Fig. 2. Risk of bias summary on this study.

and prognostic factors of transcatheter closure of PMIVSD<sup>6 15 20</sup>. The baseline characteristics of the individual studies are shown in Table 1. The included studies also reported on patients' perioperative events, including cardiovascular risk factors, surgical interventions, and postoperative complications. The main events and combined incidence are shown in Table 2.

All patients with PMIVSD included in this study were treated with transcatheter closure surgery, and all patients were treated with transcatheter closure via the femoral artery or internal jugular vein approach. All transcatheter devices were Amplatzer devices, including ASD devices, PMIVSD devices, and multiple VSD devices. The basic surgical procedure is as follows: The right femoral artery and the right internal jugular vein are usually used for initial left ventricular angiography to establish markers to guide surgery. Different types and sizes of catheters are inserted into the left ventricular cavity through the brachial artery and then sent to the VSD orifice. The wire passes through the VSD through the catheter and then pushes the catheter into the right ventricular cavity. After pushing the catheter into the pulmonary artery, the wire is pulled out from the right internal jugular vein to form a complete arteriovenous ring. Push the appropriate conveyor sheath carefully over the wire and through the defect. The occluder is pushed through the delivery sheath, and then the sheath and device are pulled backwards until the left ventricular disc is safely secured to the left ventricular septum wall. The sheath is retracted under transthoracic echocardiography (TTE) and fluoroscopy guidance to deploy the device at the waist.

#### 4. Discussion

VSD is a serious mechanical complication of AMI. The prognosis for patients with PMIVSD is poor. Although the incidence of PMIVSD is low, mortality remains high in patients receiving both medical therapy and surgical intervention. Transcatheter occlusion of PMIVSD was introduced as a minimally invasive method that may be a better treatment for VSD to improve patient survival. However, there is a lack of consensus on the surgical procedure and management of transcatheter closure of PMIVSDs. This study included 12 related reports on transcatheter closure of PMIVSDs and discussed the clinical characteristics, timing of surgical intervention, and efficacy and safety of transcatheter closure in patients. Using the method of meta-analysis, we have reached the main conclusion that transcatheter closure can be used as a rescue measure for patients with PMIVSD in the acute phase, and closure in the chronic phase is more effective and has lower mortality. A residual shunt is a long-term postoperative complication that has a continuous impact on patients.

##### 4.1. Clinical features of PMIVSD patients

In the 12 studies included in this article, the combined incidence of myocardial infarction risk factors in our patients was as follows: smoking = 36% [95% CI 0.27–0.46], hypertension = 66% [95% CI 0.56–0.75], hyperlipidaemia = 54% [95% CI 0.40–0.68], and diabetes = 33% [95% CI 0.21–0.46]. These factors were not accounted for in all studies due to mixed data, but combined, we found that the majority of patients with myocardial infarction had these cardiovascular risk factors.

Patients with PMIVSD require resolution of myocardial ischaemia and haemodynamic instability as soon as possible to provide time for subsequent surgical intervention. Percutaneous coronary intervention (PCI) is currently the preferred treatment strategy for myocardial ischaemia in patients with AMI. In our study, 92 patients underwent PCI before surgery, and the combined incidence rate was 46% [95% CI 0.15–0.80]. Three articles reported coronary artery disease in patients. In the study by Xu et al. all patients underwent coronary angiography before VSD closure, and 47.6%, 33.3% and 19.1% of them suffered from single vessel, double vessel and triple vessel diseases, respectively. Among the patients included in the study by Thiele et al., 51%, 28% and 21% had single, double and triple vessel diseases, respectively. Zhu et al. described coronary artery disease in detail: the left opposite descending coronary

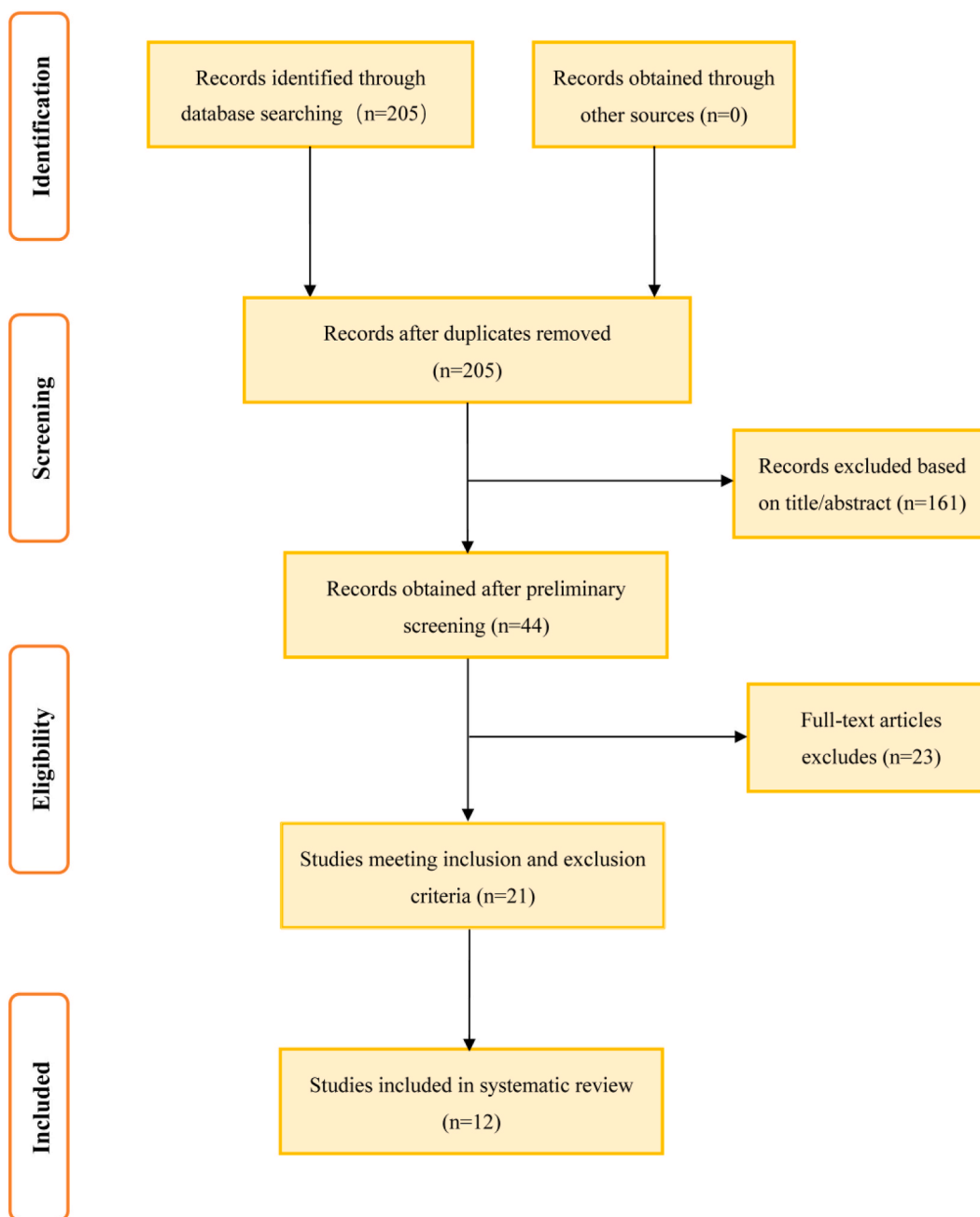


Fig. 3. Search strategy for this study in PubMed.

artery was involved in 18 (51.4%), the right coronary artery was involved in 14 (40%), and the left circumflex coronary artery was involved in 3 (8.6%). In the study reported by Xian-Yang Zhu [6], all 35 patients included in the study underwent PCI treatment. Haemodynamic instability caused by VSD often leads to cardiogenic shock.

Intra-aortic balloon pump (IABP) has great advantages in stabilizing patient haemodynamics and maintaining systemic perfusion [21]. In our study, 109 people underwent IABP, with a pooled incidence of 60% [95% CI 0.44–0.75]. Pojar et al. [22] conducted a study of surgical management of PMIVSD, and 44% of patients had an IABP implanted preoperatively. In the SHOCK trial registry [23], an IABP was implanted in 75% of PMIVSD patients. Temporary preoperative interventions such as PCI and IABP can relieve myocardial ischaemia, stabilize haemodynamics, and maintain systemic catheterization, which creates opportunities for later surgery.

In our study, the average age of patients included in all studies was more than 60 years old, and the proportion of females was 46% [95% CI 0.40–0.53]. It has been confirmed that advanced age ( $>70$ , OR = 4.66;  $P = 0.007$ ) and female sex (OR = 5.73;  $P = 0.004$ ) are high-risk factors for PMIVSD [24]. This further suggests that advanced age and female sex are closely related to the PMIVSD. However,

**Table 1**

Baseline characteristics of individual studies.

Study	Year	Country	N	VSD size/mm	Device size/mm	n	30-day death	Residual Shunt	PCI	IABP	CABG	Hypertension	Hypercholesterolemia	Diabetes	Cardiogenic shock	Smoking
Xian-Yang Zhu [6]	2013	China	35	/	19.3 (4.6)	32	5	25	35	13	/	15	/	/	13	/
Manav Aggarwal [11]	2018	India	21	20.8 (6.9)	20.8 (6.7)	19	8	13	4	12	2	/	/	/	/	/
Patrick A. Calvert [12]	2014	UK	53	/	19.4 (6.1)	47	18	45	3	33	2	36	27	11	26	15
Alexander C. Egbe [13]	2015	USA	18	16.0 (6.0)	22 (7)	17	0	/	/	/	/	/	/	/	9	/
Ralf Holzer [14]	2004	USA	18	14 (12.9)	17.7 (9.7)	16	7	16	9	8	/	/	/	/	10	/
Simon Maltais [15]	2009	Canada	12	10 (2.6)	/	/	5	/	/	12	/	9	/	/	5	/
You-Lin Nie [16]	2016	Taiwan, China	10	12.8 (5.7)	20.6 (7.8)	10	4	/	/	6	2	/	/	/	/	/
Robert Sabiniewicz [17]	2017	Poland	20	/	15.8 (3.6)	16	4	/	16	/	3	15	/	11	6	11
Liang Tang [18]	2015	China	11	12.3 (7.6)	23.6 (9.0)	10	3	6/8	6	9	/	6	3	3	8	5
Holger Thiele [10]	2008	Germany	29	/	/	25	10	/	17	/	/	24	15	15	16/29	7
Xu-Dong Xu [19]	2014	China	42	/	18.0 (3.1)	39	/	32/42	2	16	/	27	21	11	16	17
Ruoxi Zhang [20]	2017	China	15	/	/	11	4	/	/	/	/	9	13	3	4	6

N: The number of subjects included in the literature; n: The number of successful closure; PCI: Percutaneous Coronary Intervention; IABP: Intra Aortic Balloon Pump; CABG: Coronary-artery-bypass-grafting.

**Table 2**

The main events and combined incidence rates.

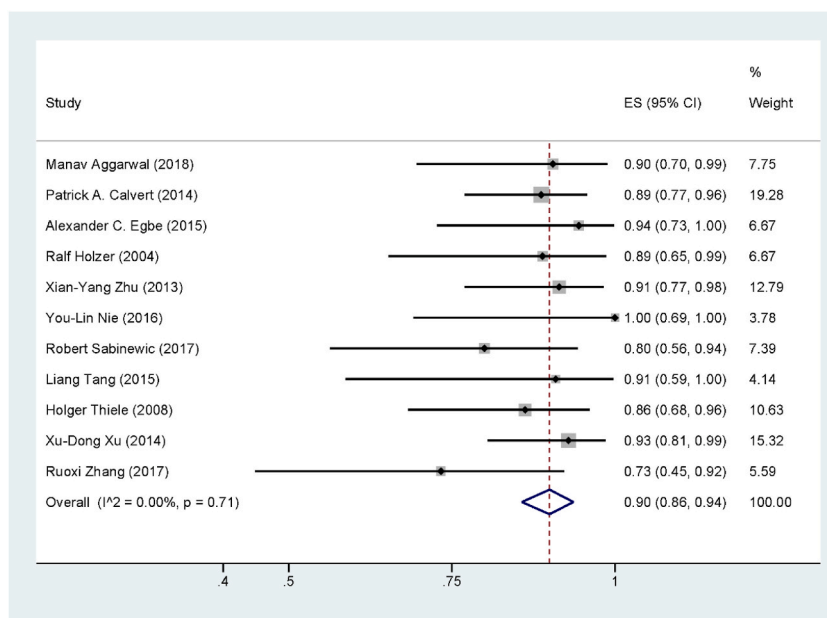
Event	Studies	Participants	Statistical method	Effect estimate (95%CI)	P value
Successful closure	11	242	Incidence (Random, 95%CI)	0.90 (0.86–0.94)	0.71
30-day mortality	11	69	Incidence (Random, 95%CI)	0.26 (0.18–0.37)	0.00
Residual shunt	6	137	Incidence (Random, 95%CI)	0.76 (0.66–0.84)	0.11
Hypertension	8	141	Incidence (Random, 95%CI)	0.66 (0.56–0.75)	0.06
Hypercholesterolemia	5	79	Incidence (Random, 95%CI)	0.54 (0.40–0.68)	0.03
Diabetes	6	54	Incidence (Random, 95%CI)	0.33 (0.21–0.46)	0.02
Smoking	6	61	Incidence (Random, 95%CI)	0.36 (0.27–0.46)	0.22
PCI	8	92	Incidence (Random, 95%CI)	0.46 (0.15–0.80)	0.00
IABP	8	109	Incidence (Random, 95%CI)	0.60 (0.44–0.75)	0.00
CABG	4	9	Incidence (Random, 95%CI)	0.08 (0.02–0.18)	0.22
Cardiogenic shock	10	113	Incidence (Random, 95%CI)	0.45 (0.37–0.52)	0.27
VSD size/mm	4	61	Incidence (Random, 95%CI)	0.12 (8.00–16.22)	0.444
Device size/mm	8	210	Incidence (Random, 95%CI)	0.16 (15.14–22.00)	0.986

PCI: Percutaneous Coronary Intervention; IABP: Iabp intra Aortic Balloon Pump; CABG: Coronary-artery-bypass-grafting.

their study does not elaborate on the relationship between these two important risk factors and the rates of success, complications and surgical mortality, and we also cannot give quantitative conclusions based on our research data. We hope that future high-quality randomized controlled studies or meta-analyses can clarify their relationship.

#### 4.2. Intervention timing and measures

The evolution of PMIVSD can be roughly divided into two phases: acute phase and chronic phase. The acute phase occurs within the first 2 weeks after infarction and is characterized by coagulative necrosis and the release of lytic enzymes from neutrophils, leading to myocardial necrosis. As necrosis progresses, resorption and retraction of the infarcted tissue often results in an enlarged defect size. The chronic phase begins after 2 weeks and is characterized by fibrosis and scarring around the edge of the defect [13]. Interventions in the acute or chronic phase are the focus of discussion. In the American College of Cardiology/American Heart Association guidelines, immediate surgical intervention is recommended for patients with acute PMIVSD, regardless of their haemodynamic status, to avoid further haemodynamic deterioration [5]. There is some evidence that the acute myocardium in patients with PMIVSD is too fragile to be repaired safely [6]. The short waiting time after diagnosis results in firmer scarring of the edges of the infarcted muscle, thus facilitating surgical repair and reducing the risk of VSD recurrence. Many surgeons also recommend surgical VSD closure after a delay of 3–4 weeks to allow for scarring of the VSD margins [25–27]. While helping to stabilize the patient's haemodynamic and perfusion changes, it can also determine the size of the VSD after it has progressed thereby reducing device shedding or changes in residual shunts. Emergency/rescue surgery is a risk factor for surgical mortality, according to Artemiou [21] data and the JCVSD database [28]. It is clear from the published surgical series that delayed surgery reduces operative mortality [29–31].



**Fig. 4.** The combined incidence rates of the number of successful closure.

The same conclusion was also obtained in our included study of transcatheter closure of PMIVSDs. In the study by Xu-Dong Xu et al. [19], emergency closure was associated with higher in-hospital mortality than elective closure (66.7% vs. 6.1%,  $p < 0.01$ ). In the You-Lin Nie [16] study, all patients with AMI with a time to device closure  $>12$  days survived. Mortality was high (67%) in patients with streak intervals  $\leq 12$  days. This suggests that an intervention is high risk in the acute phase. In Robert Sabinewic's [17] study, patients were divided into acute-phase and chronic-phase groups according to the time from diagnosis to closure of PMIVSD, and the 30-day survival rate of the entire cohort was 70% (acute group = 57.1%, chronic group = 76.9%). In another study [19], the majority of patients (6/9) who underwent emergency percutaneous VSD closure died in the catheterization room or during hospitalization. However, of the 33 patients who underwent elective closure approximately 3 weeks after VSD, only 2 died. The success rate of surgery in the chronic phase also increased accordingly<sup>16 19</sup>.

Notably, the reduced mortality associated with delayed VSD closure was an inherent selection bias. That is, patients with severe disease or haemodynamic instability have died before, and patients with relatively stable haemodynamics experience delayed operation and choose the best surgical method to close the VSD. Transcatheter occlusion or surgical repair of the VSD in the acute phase is the only option to stabilize the patient's haemodynamics and to restore cardiac function. Despite the high risk and high mortality, interventions cannot be performed in the acute phase. It has been suggested that transcatheter closure may be a salvage modality for acutely critically ill patients and that transcatheter closure may stabilize haemodynamics after AMI for surgical correction of VSD after myocardial fibrosis has occurred. It is suggested that transcatheter closure may be a rescue method for acute critically ill patients. Transcatheter closure can stabilize haemodynamics after AMI so that surgical correction of VSD can be performed after myocardial fibrosis [32].

In terms of interventions, we combined the success rate and the 30-day mortality rate of patients transcatheter closure of PMIVSD, which were 90% [95% CI 0.86–0.94] and 27% [95% CI 0.18–0.37], respectively (Figs. 4 and 5). Findings from the AHA show that surgical treatment of PMIVSD has a mortality rate of approximately 40% [33]. Because of our relatively small sample size and selection bias, transcatheter closure success and mortality rates cannot be directly compared with those of the surgical series. However, from our pooled results, transcatheter occlusion has better short-term outcomes than surgery, and overall mortality is lower than that of the surgical series. For patients who are not candidates for surgery, have frequent haemodynamically tolerable deficits, and survive a period of watchful waiting, transcatheter closure of PMIVSD may be more effective based on current evidence.

#### 4.3. Residual shunt

Residual shunting is a common complication after transcatheter closure of PMIVSDs. The ventricular septal occluder is a double-disc occluder consisting of a self-expanding double-disc and a "waist" connecting the two discs. The "waist" is a short cylindrical, self-expanding double disc consisting of a nitinol mesh coated with polyester fabric that provides the basis for tissue growth on the device after deployment. The diameter of the "waist" determines the size of the VSD that can be occluded. VSD notch margins are usually incomplete, and in most cases, there is residual shunt to varying degrees after successful placement of the occluder, and it takes hours to days for tissue growth to complete closure. Some suggest that if shunts are not reduced by at least two-thirds, patients are least likely to survive surgery or discharge [12].

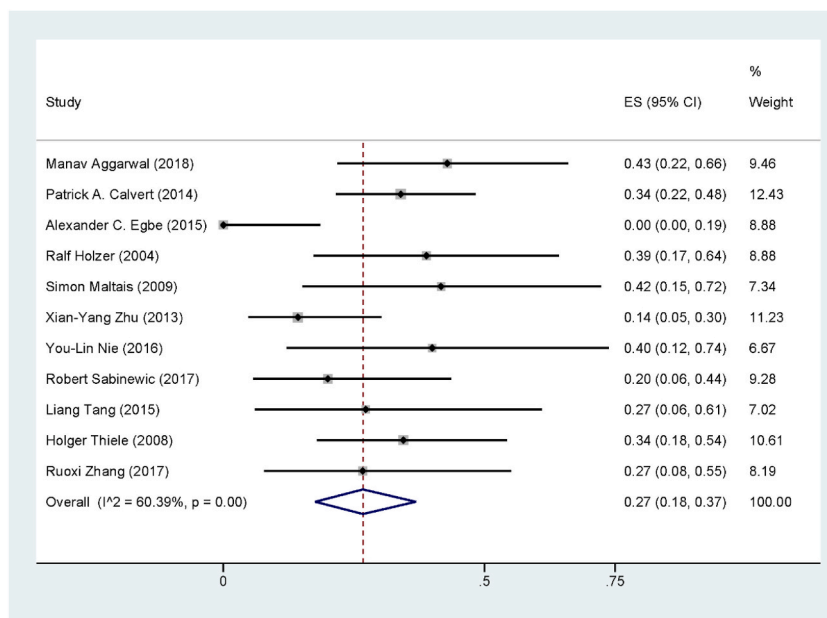


Fig. 5. The combined incidence rates of 30-day mortality.



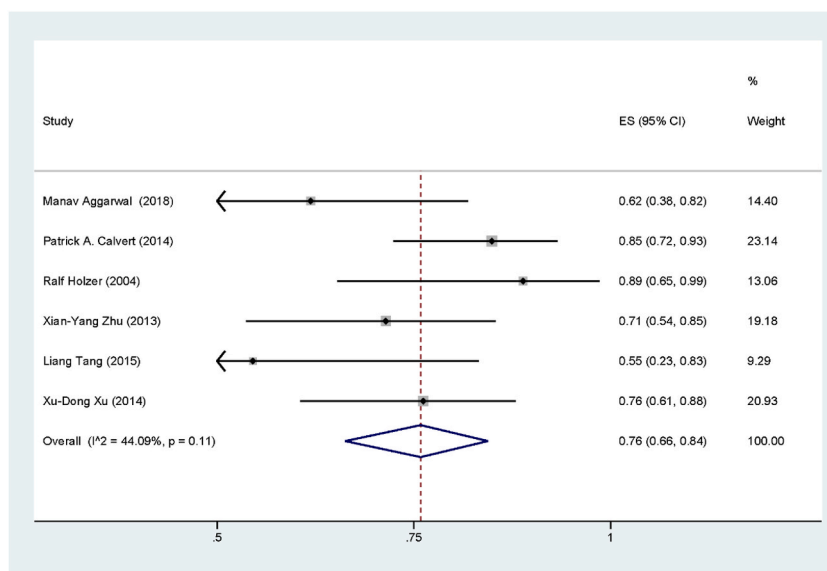


Fig. 6. The combined incidence rates of residual shunts.

In this study, the combined incidence of residual shunts was 76% [95% CI 0.66–0.84] (Fig. 6). Five studies detailed the residual shunts in patients<sup>6 11 13 17 19</sup>. The extent of the residual shunt was assessed using echocardiography by measuring the width of the coloured jet as it passed through the VSD. It is classified as trivial with a width of <1 mm, small with a width of 1–2 mm, moderate with a width of 2–4 mm, and large with a width of >4 mm [34]. Patrick A. Calvert et al. [12] calculated immediate shunt reduction: complete was 11 (22%), partial was 32 (63%) and none was 8 (16%), and the analysis confirmed that immediate shunt reduction was associated with patient survival. In a retrospective study by Xu-Dong Xu et al. [19], who divided patients into acute-phase and chronic-phase groups, 32 patients had residual shunts found at the time of surgery. Twenty-six patients had mild residual shunts, of which 8 disappeared at discharge, while 4 patients had moderate residual shunts. Two other patients had failed closure of one of the multiple defects with severe residual shunts. During follow-up, Ralf Holzer [14], Xian-Yang Zhu [6] and Liang Tang [18] performed detailed staging of residual shunts, namely, immediate results, 24-h results, at discharge and follow-up results. Due to incomplete data and different staging criteria for residual shunts in most studies, we only combined the incidence of residual shunts and could not analyse the results of different periods.

In a study of surgical management of PMIVSD, 5 (13%) patients developed residual defects after surgery; these residual VSDs were mild, and these patients were treated conservatively without reoperation [22]. In another surgical study, 6 patients (7.8%) had residual shunts after surgery, 13 patients (16.9%) had residual shunts at discharge, and 9 patients (11.7%) had persistent large shunts that required reoperation [35]. This also indirectly shows that the long-term outcome of transcatheter closure is poor; that is, the incidence of residual shunt is higher than that of surgery. According to our analysis, the combined result of VSD size was 12.11 mm [95% CI 8.00–16.22], the combined result of device size was 18.57 mm [95% CI 15.14–22.00], and the device size/VSD size ≈ 1.5. Due to the dissolution and continuous necrosis of the surrounding tissue of the VSD, the size of the VSD has been increased. Therefore, we believe that a device larger than the measured VSD diameter can be used for closure, that is, an occluder approximately 1.5 times larger than the VSD diameter is used for closure, thereby reducing the incidence of residual shunts. Ralf Holzer et al. [14] used a device 1.5 times the diameter of the VSD for occlusion, which is consistent with our conclusions. Attia et al. [35] concluded that a VSD size <15 mm can be treated with transcatheter occlusion. Based on our combined results, transcatheter occlusion can treat a VSD size = 12.11 mm [95% CI 8.00–16.22], which was consistent with their study. However, some patients in our study also underwent transcatheter closure despite the VSD size being >15 mm, which also means that whether transcatheter closure is an option for patients with PMIVSD should be determined on a case-by-case basis.

Based on the short-term and long-term results of transcatheter closure of PMIVSDs, we believe that the choice of surgical method should be determined according to the development of the patient's own disease. Transcatheter closure may be considered if the patient refuses surgical treatment, has contraindications to surgery, a residual shunt after surgery or a VSD size < 12 mm. In addition, some patients with poor surgical tolerance in the acute stage can also consider transcatheter occlusion to stabilize haemodynamics to create an opportunity for surgery.

## 5. Limitations

In the process of screening previous literature, no randomized controlled studies investigating surgical repair and transcatheter occlusion for the treatment of PMIVSD were found, so we only conducted a single-arm meta-analysis to discuss the safety and efficacy of transcatheter occlusion for PMIVSD. The sample size of our included literature was small, most of them were retrospective studies,

and selection bias played a role in the results. For patients with AMI, the probability of VSD is very low, and the number of patients who can undergo an intervention is very small. The small number of patients and inherent selection bias in almost all such studies make it difficult to compare the results of transcatheter closure with those of published surgical series. This article included 12 multicase studies. We considered comparing the studies of transcatheter closure in the acute phase and chronic phase of PMIVSD and considered the comparison of residual shunts in different periods after transcatheter closure. Comparisons could not be made due to variable baseline information, which may be due to individual differences among patients in such studies, with greater heterogeneity between patients. This also suggests that whether patients with PMIVSD can undergo transcatheter closure needs to be decided according to individual circumstances.

## 6. Conclusion

Since transcatheter occlusion of PMIVSD was first reported, there have been fewer case reports on PMIVSD. Due to the lack of large-scale randomized controlled studies on transcatheter closure of PMIVSDs and surgical repair, surgical repair remains the preferred method in the current guidelines. For patients with PMIVSD, transcatheter closure in the acute phase can be used as a rescue measure, and closure in the chronic phase is more effective and has a lower mortality rate, but the effect of selection bias should be considered. A residual shunt is a long-term complication after transcatheter occlusion, with a high incidence rate and a persistent impact on patients. Considering the large individual differences in PMIVSD patients, doctors should choose the surgical method and timing according to the patient's own situation. Although people have formed a certain understanding of PMIVSD, large multicentre randomized controlled trials are still needed to confirm the safety and reliability of transcatheter occlusion of PMIVSD.

## Production notes

### *Author contribution statement*

All authors listed have significantly contributed to the development and the writing of this article.

### *Data availability statement*

Data will be made available on request.

## Registration number

CRD 42022347358.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.heliyon.2023.e16708>.

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