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Systematic review and meta-analysis

# Valve-in-valve/valve-in-ring transcatheter mitral valve implantation vs. redo surgical mitral valve replacement for patients with failed bioprosthetic valves or annuloplasty rings: A systematic review and meta-analysis

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ABSTRACT

*Background:* Valve-in-valve (ViV)/valve-in-ring (ViR) transcatheter mitral valve implantation (TMVI) is a less invasive alternative to redo surgical mitral valve replacement (SMVR). To further verify its feasibility, we aimed to appraise early clinical outcomes after either ViV/ViR TMVI or redo SMVR for failed bioprosthetic valves or annuloplasty rings, as a comparison of long-term follow-up results are not available for these procedures.

*Methods:* We systematically searched PubMed, Cochrane Controlled Trials Register, EMBASE, and Web of Science to identify studies that compared ViV/ViR TMVI and redo SMVR. Fixed- and random-effects meta-analyses were used to compare the early clinical results between these two groups.

*Results:* A total of 3,890 studies published from 2015 to 2022 were searched, and ten articles comprising 7,643 patients (ViV/ViR TMVI, 1,719 patients; redo SMVR, 5,924 patients) were included. In this meta-analysis, ViV/ViR TMVI significantly improved in-hospital mortality (fixed-effects model: odds ratio [OR], 0.72; 95% confidence interval [CI], 0.57–0.92; $P = 0.008$) and for the matched populations (fixed-effects model: OR, 0.42; 95% CI, 0.29–0.61; $P < 0.00001$). ViV/ViR TMVI also outperformed redo SMVR in 30-day mortality and in rates of early postoperative complications. ViV/ViR TMVI resulted in less time spent in the ICU and hospital, whereas it showed no significant difference in one-year mortality. A lack of comparison of long-term clinical outcomes and postoperative echocardiographic results are important limitations of our results.

*Conclusions:* ViV/ViR TMVI is a reliable alternative to redo SMVR for failed bioprosthetic valves or annuloplasty rings as a result of lower in-hospital mortality, higher 30-day survival, and lower early postoperative complication rates, although there is no significant difference in 1-year mortality.

*Abbreviations:* ViV, valve-in-valve; ViR, valve-in-ring; TMVI, transcatheter mitral valve implantation; SMVR, surgical mitral valve replacement; CCTR, Cochrane controlled Trials Register; OR, odds ratio; CI, confidence interval; TAVR, transcatheter aortic valve replacement; NOS, Newcastle-Ottawa scale; WMD, weighted mean difference; SMD, standardized mean difference; PPM, postoperative prosthesis-patient mismatch; EOA, effective orifice area; MAC, mitral annulus calcification; LVOTO, Left ventricular outflow tract obstruction.

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## 1. Background

The success of valve-in valve transcatheter aortic valve replacement (TAVR) has prompted the exploration for a mitral equivalent. Studies [1,2] have shown that patients receiving SMVR or annuloplasty were nearly 10-years younger than those who underwent surgical aortic valve replacement. Furthermore, the mitral valve endures a higher-pressure gradient during systole than the aortic valve in diastole, and bioprosthetic valves and annuloplasty rings in the mitral position deteriorate more easily as a result. Therefore, future re-interventions are inevitable. Although transcatheter mitral valve repair has been adopted rapidly, it is still in its infancy [3]. Undeniably, especially for high-risk patients, ViV/ViR TMVI has emerged as a less invasive alternative to conventional redo SMVR when dealing with failed bioprosthetic valves or annuloplasty rings [4–7]. Although the feasibility of ViV/ViR TMVI has been confirmed through several observational studies, there is a paucity of randomised controlled trials comparing ViV/ViR TMVI and redo SMVR. As long-term clinical results were not available, this meta-analysis was performed to evaluate the current situation and compare the early clinical outcomes between these two groups.

## 2. Methods

The internationally accepted epidemiological protocol for meta-analyses of observational studies was followed [8]. Ethical approval was not required for this systematic review and meta-analysis.

### 2.1. Databases and search strategy

We systematically searched for literature published between January 2015 and August 2022 in the following databases: PubMed, Cochrane Controlled Trials Register, Embase, and Web of Science. The following terms were searched: 'transcatheter mitral valve implantation', 'transcatheter mitral valve replacement', 'valve-in-valve', 'valve-in-ring', 'redo surgical mitral valve replacement', 'reoperation', 'reoperative', 'failed annuloplasty rings', 'failed bioprosthesis', 'failed bioprosthetic valves', 'structural valve deterioration', 'structural valve degeneration', and 'mitral'.

### 2.2. Inclusion criteria

Employing the population, interventions, comparison, outcome, and study design strategy, studies were chosen when meeting the following principles: 1) the population was composed of patients with failed mitral bioprosthetic valves or annuloplasty rings; 2) an intervention group received ViV/ViR TMVI and a control group received redo SMVR; 3) the outcomes were composed of any of the following endpoints: in-hospital mortality, 30-day mortality, 1-year mortality, acute kidney injury, stroke, cardiac arrest, cardiogenic shock, low cardiac output, myocardial infarction, new atrial fibrillation, new complete heart block, postoperative pacemaker implantation, bleeding complication, transfusion, length of hospitalisation, or ICU time; and 4) the studies were observational in nature.

### 2.3. Study selection

We identified records after searching databases and removed duplicates, reviews, case reports, and animal trials. Next, screening and exclusion through reading titles and through abstract analysis were performed. Eligibility was appraised by retrieving full texts. Finally, we determined the ultimate inclusion for quantitative synthesis. This process was completed by two independent reviewers. Divergence was resolved by third-party adjudication.

### 2.4. Evaluation of risk for bias

The Newcastle-Ottawa scale (NOS) was used as the risk of bias tool in nonrandomised observational studies to assess the quality of the final citations [9]. The NOS consists of three parts (selection, comparability, and outcome) and eight evaluation items. A total of 9 points is obtained from 4 points for selection, 2 points for comparability, and 3 points for outcomes. NOS scores $\geq$7 were considered high-quality studies, scores of 4–6 were medium-quality studies, and those of 0–3 were low-quality studies. Two independent reviewers assessed the risk of bias and divergence was resolved by third-party adjudication.

### 2.5. Endpoints and statistical analysis

The main endpoint of this meta-analysis was in-hospital mortality rate. The secondary endpoints were 30-day mortality, 1-year mortality, acute kidney injury, stroke, major cardiac complications (cardiac arrest, cardiogenic shock, low cardiac output, and myocardial infarction), arrhythmia (new atrial fibrillation, new complete heart block, and even arrhythmias requiring postoperative pacemaker implantation), bleeding complications or transfusion, length of hospitalisation, and ICU unit admission. For data in the form of interquartile ranges, if the sample size was large and the data distribution was close to normal (none of the included studies met these requirements), the mean was calculated using a validated formula. In one article [10], the value of the continuity variable was given as $<$ 11. In that particular article, the larger the value, the worse the results were for the ViV/ViR TMVI group. Hence, the value was taken as 10.

Data on in-hospital mortality and other dichotomised variables were arranged to generate odds ratios (ORs) with 95% confidence intervals (CIs) and *P*-values. Continuous variables were compared using weighted mean difference or standardised mean difference to represent the effect quantity. Early clinical results were collected and analysed by creating forest plots. Statistical heterogeneity was assessed using the chi-square and $I^2$ tests [11]. If there was statistical heterogeneity among the studies ($P < 0.05$, $I^2 > 50\%$), then the random-effects model was adopted. Otherwise, the fixed-effects model was utilised. Two effect models (the Mantel–Haenszel method and the inverse variance method) were used to combine the ORs and differences in means in this meta-analysis [12]. A funnel plot was constructed for each endpoint to evaluate publication bias. Sensitivity analysis was performed by analysing the primary endpoint (in-hospital mortality) for studies using propensity-matched comparisons, as confounders in nonrandomised studies can be effectively controlled with this method. Differences were considered statistically significant at a two-tailed P value $< 0.05$. All extracted data were meta-analysed using Review Manager version 5.4.

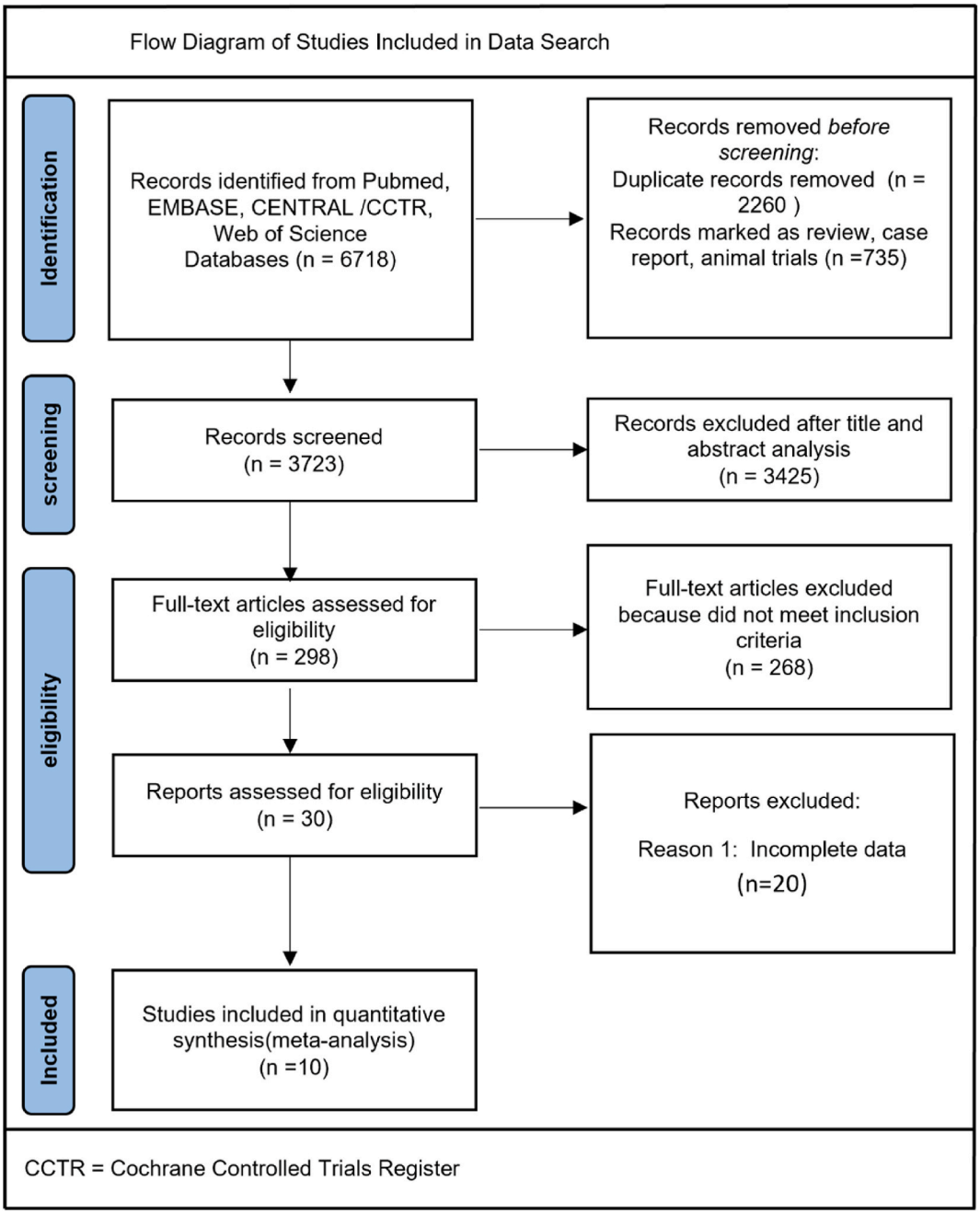


**Fig. 1.** Flow Diagram of Studies Included in data search.

## 3. Results

### 3.1. Study selection and study characteristics

A total of 3,890 articles published between January 2015 and August 2022 were initially screened by title and abstract, of which 141 publications were possibly related and retrieved as full text. Ten articles [10,13–21] satisfied our final inclusion criteria (Fig. 1). The characteristics of every study and their populations are presented in Supplemental Tables S1–S6. Across the 10 trials, 7,643 participants were enrolled (ViV/ViR TMVI, n = 1,719; redo SMVR, n = 5,924). All were observational nonrandomised studies, and

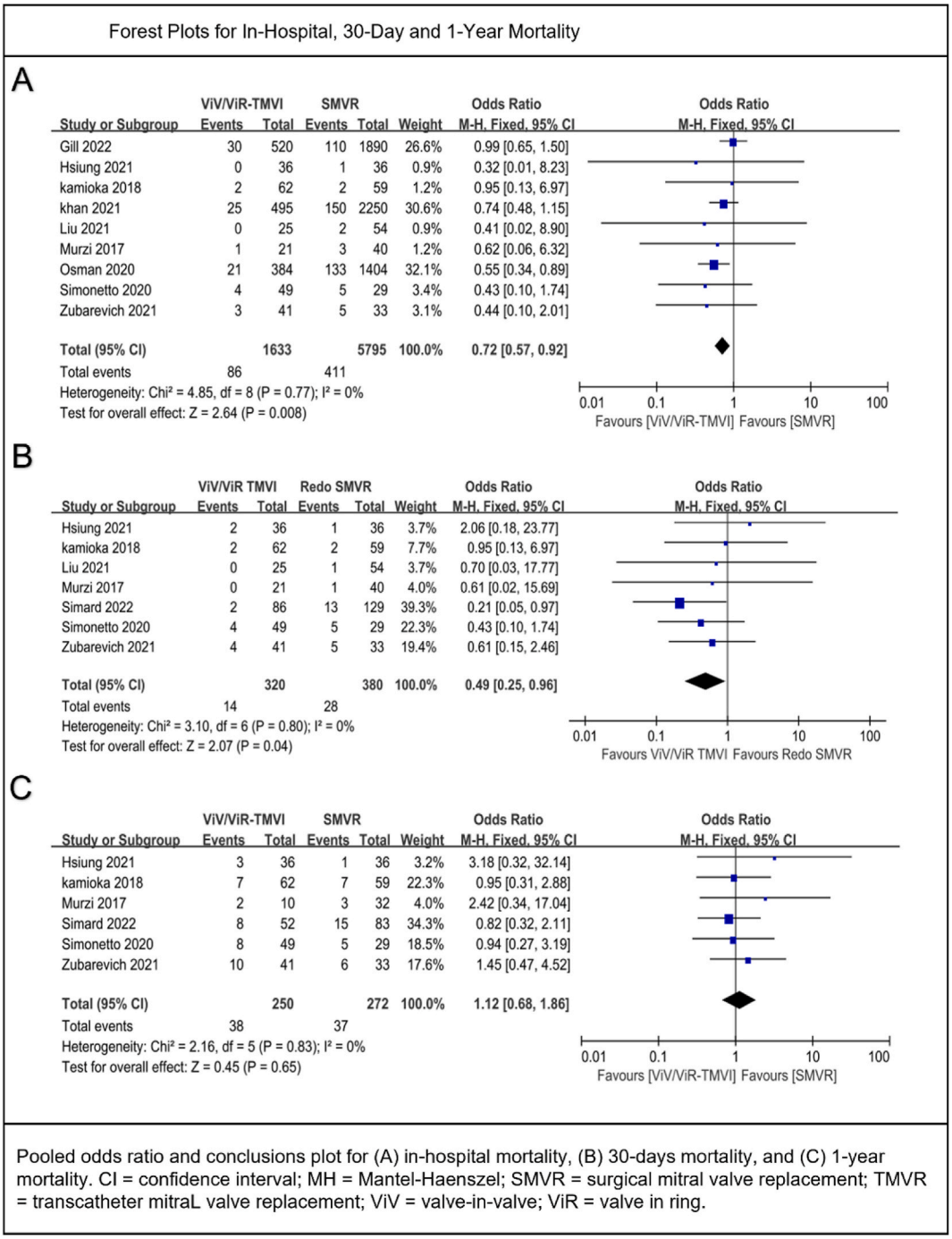


**Fig. 2.** Forest plots for in-hospital,30-day and 1-year mortality.

three applied propensity patient matching. In most trials, patients undergoing ViV/ViR TMVI experienced more physical illnesses, such as hypertension, diabetes mellitus, atrial fibrillation, and coronary artery disease. These patients were older, more symptomatic, presented with New York Heart Association class III/IV status, and had a higher surgical risk according to the Society of European System for Cardiac Operative Risk Evaluation, thoracic surgeons, or Charlson Comorbidity Index scores. According to NOS scores (Supplemental Table S7), all 10 studies were defined as low or moderate quality, resulting in a high risk for bias upon overall internal effectiveness of the analysis. Confounding factors such as discrepancy in the unmatched populations, inadequate sample size, and follow-up might explain the low quality of the studies.

### 3.2. Short-term mortality

The final resultant effect quantity of in-hospital mortality indicated that ViV/ViR TMVI significantly outperformed redo SMVR in reducing in-hospital mortality (fixed-effects model: OR, 0.72; 95% CI, 0.57–0.92; P = 0.008; Fig. 2A) and 30-day mortality (fixed-effects model: OR, 0.49; 95% CI, 0.25–0.96; P = 0.04; Fig. 2B) with evidence of low heterogeneity. However, for 1-year mortality, there was no statistical evidence to prove marked variance between the two groups (fixed-effects model: OR, 1.03; 95% CI, 0.65–1.63; P = 0.91; Fig. 2C) with evidence of low heterogeneity.

### 3.3. Early postoperative complications

Different surgical approaches have been associated with different rates of early postoperative complications. ViV/ViR TMVI was significantly superior to redo SMVR with respect to acute kidney injury (fixed-effects model: OR, 0.50; 95% CI, 0.43–0.58; P < 0.00001; Fig. 3A), stroke (fixed-effects model: OR, 0.61; 95% CI, 0.43–0.85; P = 0.003; Fig. 3B), and major cardiac complications (fixed-effects model: OR, 0.40; 95% CI, 0.32–0.49; P < 0.00001; Fig. 3C). The heterogeneity of the above three findings was low. The risk for arrhythmia (random-effects model: OR, 0.24; 95% CI, 0.10–0.56; P = 0.0009; Fig. 3D) and bleeding complication/transfusion (random-effects model: OR, 0.23; 95% CI, 0.15–0.33; P < 0.00001; Fig. 3E) in the ViV/ViR TMVI group was observably outperformed by the redo SMVR group, with high evidence of heterogeneity. As shown in Fig. 5, ViV/ViR TMVI was associated with a marked decrease in length of hospitalisation (fixed-effects model: absolute difference of −5.50 days; 95% CI, −5.57 to −5.42; P < 0.00001; Fig. 4A), and ICU time (fixed-effects model: absolute difference of −2.83 days; 95% CI, −3.85 to −1.81; P < 0.00001; Fig. 4B), with low heterogeneity for both.

### 3.4. Publication bias analysis

A funnel plot analysis was performed to reflect the publication bias of the included studies. The results showed that some of the included studies were asymmetrically distributed on both sides of the effective line and that the figures were irregularly shaped, indicating that publication bias could not be ignored, as shown in Supplemental Figs. S1–S2.

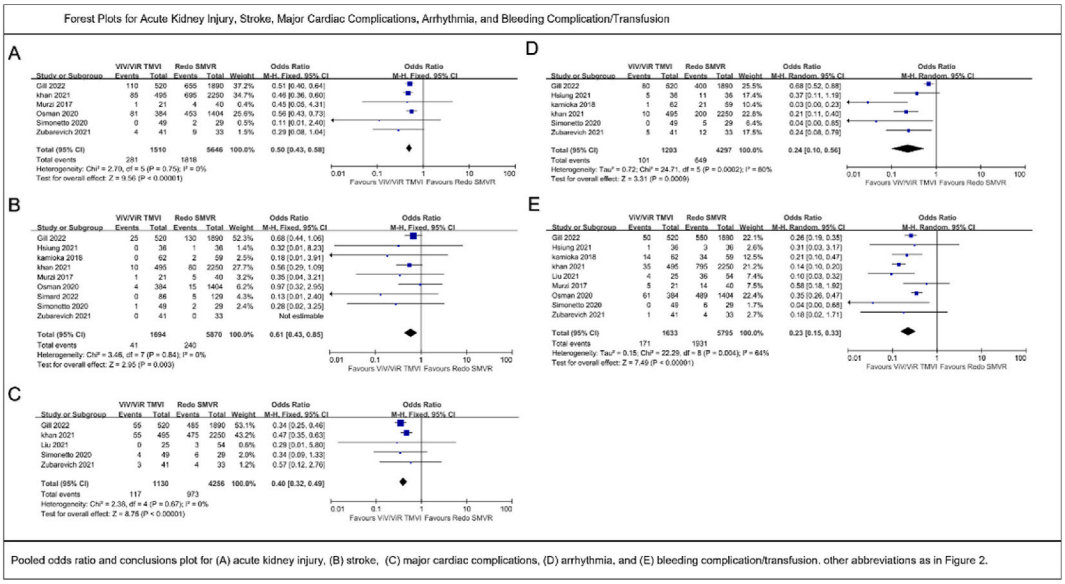


**Fig. 3.** Forest plots for acute kidney Injury, Stroke, Major cardiac Complications, Arrhythmia, and bleeding complication/transfusion.

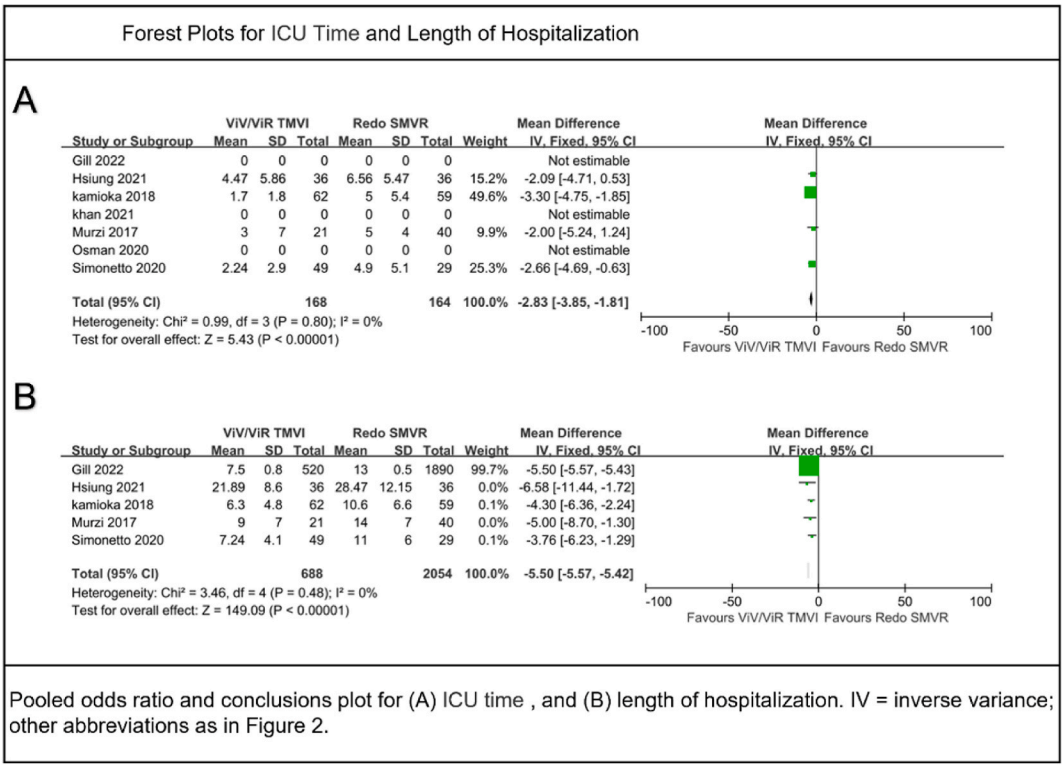


**Fig. 4.** Forest plots for ICU time and length of hospitalisation.

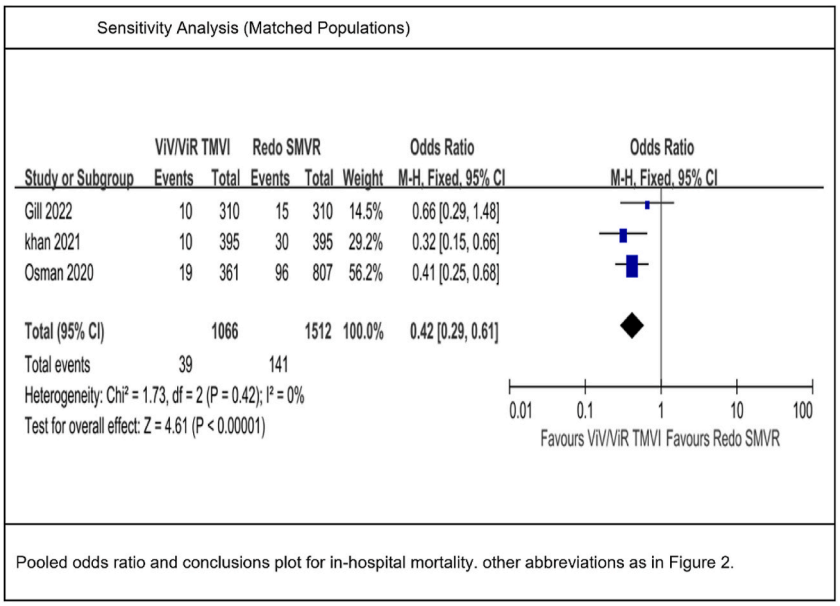


**Fig. 5.** Sensitivity Analysis (Matched populations).

### *3.5. Sensitivity analysis*

As shown in Fig. 5, studies using propensity population matching were used to calculate the OR for in-hospital mortality between the ViV/ViR TMVI and redo SMVR groups. Only three studies [10,13,19], which included a total of 2,578 matched patients, compared ViV/ViR TMVI with redo SMVR in terms of in-hospital mortality. These results showed a statistically marked variance between the two

groups (fixed-effects model: OR, 0.42; 95% CI, 0.29–0.61; P < 0.00001), with evidence of low heterogeneity.

## 4. Discussion

The findings of this meta-analysis using 10 observational comparative studies of ViV/ViR TMVI versus redo SMVR are as follows:

(1) ViV/ViR TMVI was associated with a low incidence of in-hospital and 30-day mortality. When the comparison was carried out for the matched population, ViV/ViR TMVI was still statistically superior in terms of in-hospital mortality.
(2) Patients in the ViV/ViR TMVI group were less likely to suffer from postoperative complications (acute kidney injury, stroke, major cardiac complications, arrhythmia, and bleeding complications/transfusions) and spent less time in the ICU and hospital.
(3) There was no statistically significant difference in the occurrence of 1-year mortality.

Patients with severe mitral valve disease are increasingly being treated with bioprosthetic valves and annuloplasty rings [22]. Therefore, redo mitral valve surgery is continually required. Surgical treatment remains the gold standard for structural mitral valve pathology, including three surgical approaches: right anterolateral thoracotomy, complete sternotomy, and partial sternotomy [23], all of which require cardiac arrest and extracorporeal circulation. However, the complexity of re-entering the heart, dense adhesions, difficulties in exposing the valve, and high surgical risk necessitate the urgent need for a less invasive treatment. Considering the success of ViV TAVR, scientists began to focus on ViV/ViR TMVI. The feasibility of ViV/ViR TMVI has already been confirmed by some observational studies [4–7].

Predictably, owing to the higher preoperative risk scores and incidence of comorbidities among patients undergoing ViV/ViR TMVI, this group was expected to produce worse early postoperative outcomes. Surprisingly, in this meta-analysis, we observed that the rates of in-hospital mortality and early postoperative complications in the ViV/ViR TMVI group were markedly lower than those in the redo SMVR group. In addition, higher preoperative risk scores did not show marked variance in 1-year mortality. Lower trauma and invasiveness seem to be key factors. In three large nationwide studies comparing ViV/ViR TMVI with redo SMVR, Gill et al. [13], Khan et al. [10], and Osman et al. [19] investigated nearly two thousand American adult patients with deteriorated mitral bioprostheses undergoing either ViV/ViR TMVI or redo SMVR. Using propensity score matching, ViV/ViR TMVI significantly outperformed redo SMVR in terms of in-hospital mortality, acute renal failure, length of hospitalisation, and other common early postoperative complications. This further confirmed the feasibility of ViV/ViR TMVI. However, data on long-term outcomes were not reported in these three studies. To some extent, this helps us explain why there is no obvious discrepancy in the 1-year mortality in our results. More comparative studies between ViV/ViR TMVI and redo SMVR with larger sample sizes and long-term follow-up are needed.

Left ventricular outflow tract obstruction (LVOTO), and postoperative prosthesis-patient mismatch (PPM) are the main challenges, along with ViV/ViR TMVI. However, comparisons of them between ViV/ViR TMVI and redo SMVR were missing from our results. Sufficient preoperative clinical and imaging evaluations can make high-risk patients for ViV/ViR TMVI convert to redo SMVR, which may prevent the occurrence of postoperative PPM and LVOTO associated with the ViV/ViR TMVI device.

PPM in the mitral position may identify residual mitral stenosis with similar consequences (i.e. abnormally elevated transvalvular gradient, delayed regression of left atrial pressure, higher pulmonary arterial pressure, and right ventricular failure) [24]. A large meta-analysis [25] involving 19 cohort studies with a total of 9,302 patients reported that PPM had a significantly negative impact on poorer postoperative haemodynamics and was associated with a worse early and late prognosis after mitral replacement. When focusing on ViV/ViR TMVI, Werner et al. [26] reported that no patient-prosthesis mismatch occurred after TMVI (Valve-in-valve: 3; Valve-in-ring: 3; and Valve-in-mitral annulus calcification: 3) at the 1-year follow-up. Simonato et al. [27] investigated 1,079 patients (ViV: 857; ViR: 222) and demonstrated that severe postprocedural PPM was not associated with four-year survival, four-year repeat MVR, or postprocedural NYHA III/IV functional class. In our meta-analysis, one citation [14] reporting the postprocedural effective orifice area (EOA), which could represent PPM, demonstrated that transcatheter heart valve durability appeared excellent with consistent EOA during the 3-year follow-up. In short, there are few studies directly comparing PPM between ViV/ViR TMVI and redo SMVR in the database.

The more frightening and potentially fatal complication associated with ViV/ViR TMVI and redo SMVR is LVOTO, which is defined as outflow mean gradient $\geq$10 mmHg [28]. Its occurrence was considered an independent predictor of poor early prognosis in patients undergoing TMVI [29]. Historically, TMVI has been related to a higher incidence of LVOTO than redo SMVR [30,31]. Studies [17,18,20] reported no marked variance in the risk of postoperative LVOTO between the ViV/ViR TMVI group and the redo SMVR group. Simard et al. [14] reported that transcatheter heart valve durability was excellent, with a consistent mean left ventricular outflow gradient during a 3-year follow-up. The application of cardiac computed tomography angiography to reconstruct the anatomical neo-left ventricular outflow tract and the exclusion of high-risk patients [32,33] might result in a low incidence of LVOTO after ViV/ViR TMVI. In recent years, prophylactic laceration of the anterior mitral leaflet (LAMPOON) has been used to prevent LVOTO and is regarded as rescue therapy [34]. This demonstrated the feasibility of this technology.

A valve annulus larger than the aortic annulus, a dynamic configuration with restricted rigidity, a D-shaped construction, and the distance and angle between the mitral valve annulus and the left ventricular outflow tract make securing transcatheter mitral therapies more challenging, and the incidence of oppression and deformation of other adjacent structures is increased accordingly [35]. The unique anatomical, physiological, and haemodynamic characteristics limit the use of TMVI. Given the lower incidence of early postoperative complications in the ViV/ViR TMVI group in our study and the higher preoperative risk in patients with failed annuloplasty rings or bioprosthetic valves, ViV/ViR TMVI remains promising. Apart from clinical evaluation, transthoracic and 2- and 3-dimensional transesophageal echocardiograms along with contrast CT are obligatory [36,37]. ViV/ViR TMVI may be preferred in

high-risk patients with comorbidities, whereas redo SMVR is expected to be the norm in patients with disadvantageous anatomy. Before reintervention, individualised plans based on a punctilious evaluation of clinical conditions and technical aspects by a multidisciplinary cardiac team are essential.

### *4.1. Study limitation*

Although our results provide convincing evidence that ViV/ViR TMVI has unique advantages over redo SMVR when dealing with failed bioprosthetic valves or annuloplasty rings, there are still some points worth considering when explaining our results.

All included articles were retrospective nonrandomised trials with moderate to low quality according to the NOS, as well as objectively existing publication bias, impairing the reliability of the results. A subgroup analysis examining the type of previous biological valve and annuloplasty ring, the mechanism of deterioration (regurgitation, stenosis, or mixed), and specific surgical pathways (median thoracotomy, right anterior thoracotomy, thoracoscopic SMVR, and transapical, transfemoral TMVI) was hampered by the insufficient data on each patient.

TMVI for failed bioprosthetic valves or annuloplasty rings is still emerging. Hence, making any judgement on long-term results seems impossible, as long-term follow-up results are not available. The most important aspect for creating a more comprehensive model of comparison is a randomised controlled clinical trial. Paradoxically, the selection of patients makes it difficult to perform randomised trials of ViV/ViR TMVI and redo SMVR. Therefore, propensity score matching should be used in certain studies to rectify the heterogeneity in population characteristics between the two groups.

## 5. Conclusions

ViV/ViR TMVI is a reliable alternative to redo SMVR for failed bioprosthetic valves or annuloplasty rings as a result of lower in-hospital mortality, higher 30-day survival, and lower early postoperative complication rates, although there is no significant difference in 1-year mortality.

## Ethics approval and consent to participate

Not applicable.

## Consent for publication

Not applicable.

## Availability of data and materials

This article consists of all data generated or analysed during this study.

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## Production notes

*Author contribution statement*

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

*Data availability statement*

Data included in article/supp. material/referenced in article.

## 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.e16078.

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