Meta-Analysis of Valve-in-Valve Transcatheter Aortic Valve Implantation Versus Redo-surgical Aortic Valve Replacement in Failed Bioprosthetic Aortic Valve

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This meta-analysis was conducted to compare clinical outcomes of valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) versus redo-surgical aortic valve replacement (Redo-SAVR) in failed bioprosthetic aortic valves. We conducted a comprehensive review of previous publications of all relevant studies through August 2020. Twelve observational studies were included with a total of 8,430 patients, and a median-weighted follow-up period of 1.74 years. A pooled analysis of the data showed no significant difference in all-cause mortality (OR 1.15; 95% CI 0.93 to 1.43; p = 0.21), cardiovascular mortality, myocardial infarction, permanent pacemaker implantation, and the rate of moderate to severe paravalvular leakage between ViV-TAVI and Redo-SAVR groups. The rate of major bleeding (OR 0.36; 95% CI 0.16 to 0.83, p = 0.02), procedural mortality (OR 0.41; 95% CI 0.18 to 0.96, p = 0.04), 30-day mortality (OR 0.58; 95% CI 0.45 to 0.74, p <0.0001), and the rate of stroke (OR 0.65; 95% CI 0.52 to 0.81, p = 0.0001) were significantly lower in the ViV- TAVI arm when compared with Redo-SAVR arm. The mean transvalvular pressure gradient was significantly higher post-implantation in the ViV-TAVI group when compared with the Redo-SAVR arm (Mean difference 3.92; 95% CI 1.97 to 5.88, p < 0.0001). In conclusion, compared with Redo-SAVR, ViV-TAVI is associated with a similar risk of all-cause mortality, cardiovascular mortality, myocardial infarction, permanent pacemaker implantation, and the rate of moderate to severe paravalvular leakage. However, the rate of major bleeding, stroke, procedural mortality and 30-day mortality were significantly lower in the ViV-TAVI group when compared with Redo-SAVR. **(Am J Cardiol 2021;146:74−81)**

Conventional re-operative surgical aortic valve replacement (redo-SAVR) is the gold standard approach for patients with degenerated aortic bioprosthesis.[1,2] Several studies have demonstrated the feasibility and safety of valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) in appropriately selected patients with high surgical risk.[3] Short-term outcomes were promising with excellent functional outcomes. Subsequently in 2015, the United States Food and Drug Administration approved the use of ViV-TAVI in failed aortic bioprosthetic valves.[4] Given that redo-SAVR has a reported operative mortality ranging from 4% to as high as 9%, a comprehensive analysis to understand contemporary outcomes of ViV-TAVI versus redo-SAVR is key to provide data to help in decision-making, patient counseling, and risk-stratification.[1,2] Hence, we performed this meta-analysis to compare clinical outcomes between the 2 treatment modalities.

Methods

We conducted a comprehensive review of previous publications of all relevant studies through August 2020. We searched PUBMED, EMBASE, and COCHRANE databases. We included studies that met our criteria of: (1) the study compared clinical outcomes between ViV- TAVI versus Redo-SAVR in patients with failed bioprosthetic aortic valve, (2) the study reported more than one clinical outcome. The meta-analysis was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.

The search included the following keywords: Valve in valve transcatheter aortic valve implantation, or valve in valve transcatheter aortic valve implantation; Redo-surgical aortic valve replacement, or re-operative surgical aortic valve replacement, or surgical aortic valve re-replacement; Failed bioprosthetic aortic valve, or failed aortic bioprostheses, or failing aortic biological valve. Two authors (AA and YS) independently reviewed the search results, extracted potential articles, and assessed their eligibility. The Cochrane Collaboration risk-of-bias tool was used by 2 different authors (AA and YS) to assess the quality of the included studies.

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The primary outcome of this meta-analysis was all-cause mortality, which was defined as reported mortality after a follow-up period of at least 1 year. We collected the following characteristics of each study: first author's name, year of publication, single vs multicenter, number of participants in each arm, follow-up duration, mean age, and type of valve used in the ViV-TAVI arm. Secondary outcomes included cardiovascular mortality, in-hospital mortality, 30-day mortality, in-hospital myocardial infarction, stroke, major bleeding, permanent pacemaker implantation, paravalvular leakage, acute kidney injury, and hospital readmission. cardiovascular mortality was defined as reported cardiovascular mortality after a follow-up period of at least 1 year.

Statistical analysis was conducted using Review Manager (RevMan), version 5.3 (The Cochrane Collaboration, Copenhagen, Denmark). The Mantel-Haenszel random-effects models were used to estimate the mean difference and the corresponding 95% confidence intervals (CIs). Two-sided p values of <0.05 were considered as statistical significance. I2 statistics were used to assess statistical heterogeneity. Sensitivity analysis was done with the exclusion of 1 to 2 studies to evaluate heterogeneity.

Results

Twelve retrospective observational studies were included with a total of 8,430 patients (Figure 1).[5,6,15,16,7–14] The median-weighted follow up period was 1.74 years. Characteristics of included studies and patients are described in Tables 1 and 2. A pooled analysis of the data showed no significant difference in all-cause mortality

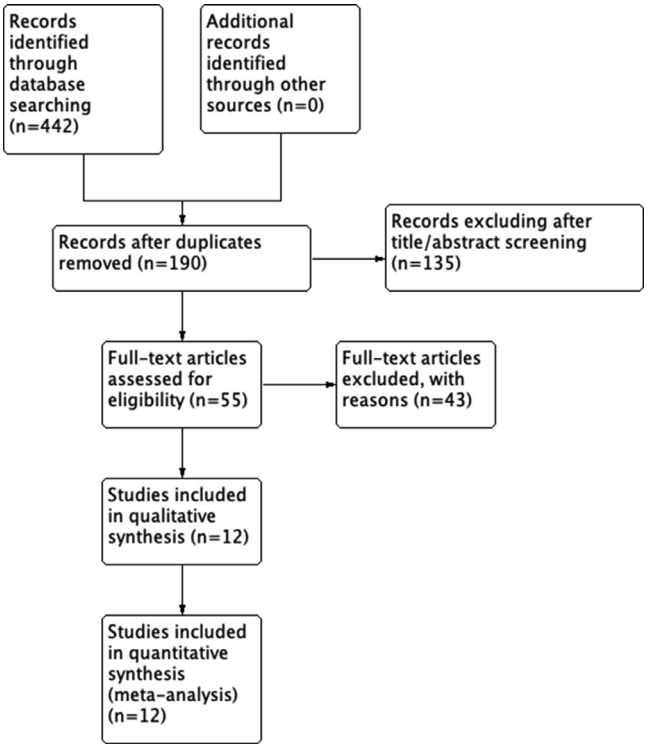

Figure 1. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram.

Table 1

Study	Study period	Location	Number of centers involved (N)	Total sample size (N)	Follow-up duration (months)	Type of failed bioprosthesis		Type of ViV-TAVI (N)			Type of prosthesis in redo-SAVR (N)
						Porcine (%)	Pericardial (%)	Sapien (N)	Evolut (N)	Corevalve (N)	
Deharo [1]	2010-2019	France	Multiple	1434	17.2	–	–	–	–	–	–
Seedek [2]	2008-2018	US	1	350	25.2	–	–	60	25	5	Mechanical: 102, Stented: 147, Stentless: 11
Santarpino [3]	2010-2012	Germany	1	74	18.9	–	–	6	–	–	Perceval M, Perceal S
Stankowski [4]	2003-2018	Germany	1	108	67.2	–	–	–	–	68	Hancock: 25, Epic Supra: 10, CoreValve/Evolut: 26, other: 4
Malik [5]	2012-2016	US	Multiple	1420	–	–	–	–	–	–	–
Woitek [6]	2006-2017	Germany	1	258	12	–	–	–	–	–	–
Spaziano [7]	2007-2015	Europe and Canada	7	156	–	–	–	32	–	46	-Stented: 77, Stentless: 1
Grubitzsch [8]	2010-2015	Germany	1	52	21	60	40	–	–	–	Mechanical: 2, Stented: 7, Stentless: 16
Erlebach [9]	2001-2014	Canada	1	102	1	30	67	32	–	17	Trifecta: 14, Perimount: 27, other: 11
Silaschi [10]	2008-2015	UK and Germany	2	130	22.5	–	–	36	–	28	Stented: 56, Stentless: 3
Ejiofor [11]	2002-2015	US	1	44	–	–	–	32	–	5	Carpentier: 14, St Jude Mechanical: 4, Other: 4
Hirji [12]	2012-2016	US	Multiple	4362	–	–	–	–	–	–	–

Table 2
Baseline characteristics of patients in included studies for ViV-TAVI vs redo-SAVR

	Sample Size (N)	Mean age (± SD)	Males (%)	Hypertension (%)	Atrial Fibrillation (%)	Stroke (%)	Mean Pre-operative Aortic Gradient (mm Hg ± SD)	Logistic EuroSCORE (%)	STS Score
Deharo [1]	717	74.9 ± 9.7	56.1	79.4	61.2	5.3	–	4.7 ± 1.0	–
VIV-TAVR	717	4.7 ± 3.0	57.7	77.8	60.8	5.0		4.7 ± 1.0	
Redo-SAVR									
Seedek [2]	90	79	81	88	47	–	–	–	7.5
VIV-TAVR	260	72	68	73	33				3
Redo-SAVR									
Santarpino [3]	37	80.2 ± 2.3	66.7	59.5	–	–	–	20.6 ± 2.2	–
VIV-TAVR	37	78.8 ± 3.0	25.0	73				18.1 ± 1.9	
Redo-SAVR									
Stankowski [4]	68	79.2 ± 5.7	41.2	92.6	48.5	10.3	41.9 ± 19.3	10.9 ± 6.2	–
VIV-TAVR	40	72.9 ± 7.2	62.5	90.0	40.0	5.0	40.1 ± 20.9	7.8 ± 4.3	
Redo-SAVR									
Malik [5]	710	73.7 ± 10.4	52.8	83.1	52.8	–	–	–	–
VIV-TAVR	710	73.3 ± 8.6	54.9	78.2	48.6				
Redo-SAVR									
Woitek [6]	111	58.5 ± 14.4	59.9	86.5	18.9	9.0	–	–	2.76 ± 2.09
VIV-TAVR	147	76.2 ± 8.0	62.6	98.0	44.2	17.8			8.27 ± 6.12
Redo-SAVR									
Spaziano [7]	78	78.0 ± 8.0	50.0	72	–	9	–	22.0 ± 16.0	7.4 ± 4.9
VIV-TAVR	78	77.4 ± 5.0	56.4	73		12		14.0 ± 12.4	4.4 ± 4.4
Redo-SAVR									
Grubitzsch [8]	27	75.3 ± 9.9	23.1	–	39	12	–	13.0 ± 10.4	–
VIV-TAVR	25	69.0 ± 8.6						8.9 ± 6.5	
Redo-SAVR									
Erlebach [9]	50	78.1 ± 6.7	54.0	82	32	8	–	27.4 ± 18.8	–
VIV-TAVR	52	66.2 ± 13.1	73.1	73	14	0		14.4 ± 10.0	
Redo-SAVR									
Silaschi [10]	71	78.6 ± 7.5	57.7	–	–	14.1	33.0 ± 17.8	25.1 ± 18.9	–
VIV-TAVR	59	72.9 ± 6.6	61.0			10.2	37.3 ± 13.7	16.8 ± 9.3	
Redo-SAVR									
Ejiofor [11]	22	75.0 ± 9.6	63.6	95.5	–	22.7	39.8 ± 13.6	–	7.54 ± 3.0
VIV-TAVR	22	74.5 ± 10.4	59.1	90.9		13.6	46.6 ± 26.5		4.36 ± 3.1
Redo-SAVR									
Hirji [12]	2181	72.5 ± 12.0	61.1	56.3	29.6	3.5	–	–	–
VIV-TAVR	2181	72.9 ± 12.2	61.8	55.7	30.0	3.9			
Redo-SAVR									

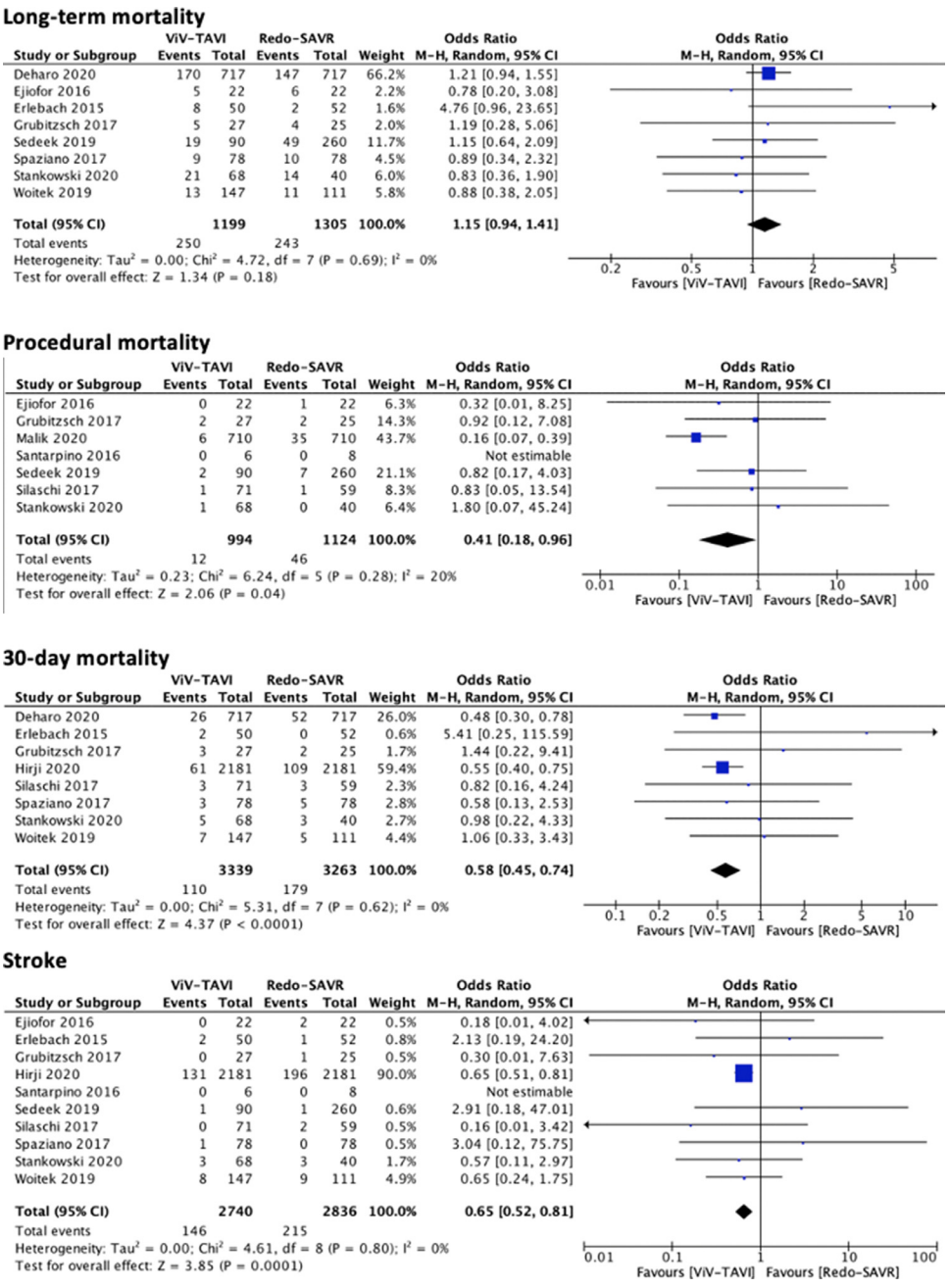

Figure 2. Forest plot of the rate of all-cause mortality, procedural mortality, 30-day mortality, and stroke.

between ViV-TAVI and Redo-SAVR groups (OR 1.15; 95% CI 0.93 to 1.43; p = 0.21, I2=0%) (Figure 2).Meanwhile, procedural mortality (OR 0.41; 95% CI 0.18 to 0.96; p = 0.04, I2=20%), 30-day mortality (OR 0.58; 95% CI 0.45 to 0.74; p <0.0001, I2=0%) and the rate of stroke (OR 0.65; 95% CI 0.52 to 0.81; p = 0.0001, I2=0%) were significantly lower in the ViV-TAVI arm when compared with Redo-SAVR (Figure 2). The rate of major bleeding was also significantly lower in the ViV-TAVI arm when compared with Redo-SAVR (OR 0.36; 95% CI 0.16 to 0.83; p = 0.03, I2=68%) (Figure 3). Sensitivity analysis showed that heterogeneity was the lowest (I^2=0%) when studies conducted by Sedeek et al[6] and Silaschi et al[12] were excluded (OR 0.56, 95% CI 0.50 to 0.63; p <0.00001). The rate of AKI was significantly lower in the ViV-TAVI arm when compared with Redo-SAVR (OR 0.48; 95% CI 0.30 to 0.75; p = 0.001, I2=70%) (Figure 3). Sensitivity analysis showed that heterogeneity was the lowest (I^2=15%) when Ejiofor et al[13] and Hirji et al[14] were excluded (OR 0.39, 95% CI 0.27 to 0.57; p <0.00001).

There was no statistically significant difference in the rate of cardiovascular mortality (OR 1.06; 95% CI 0.78 to 1.43; p = 0.71, I2=0%), myocardial infarction (OR 0.76; 95% CI 0.38 to 1.50; p = 0.43, I2=0%), hospital readmission rate (OR 1.27; 95% CI 0.87 to 1.84; p = 0.21, I2=61%), and the rate of moderate to severe paravalvular leakage (OR

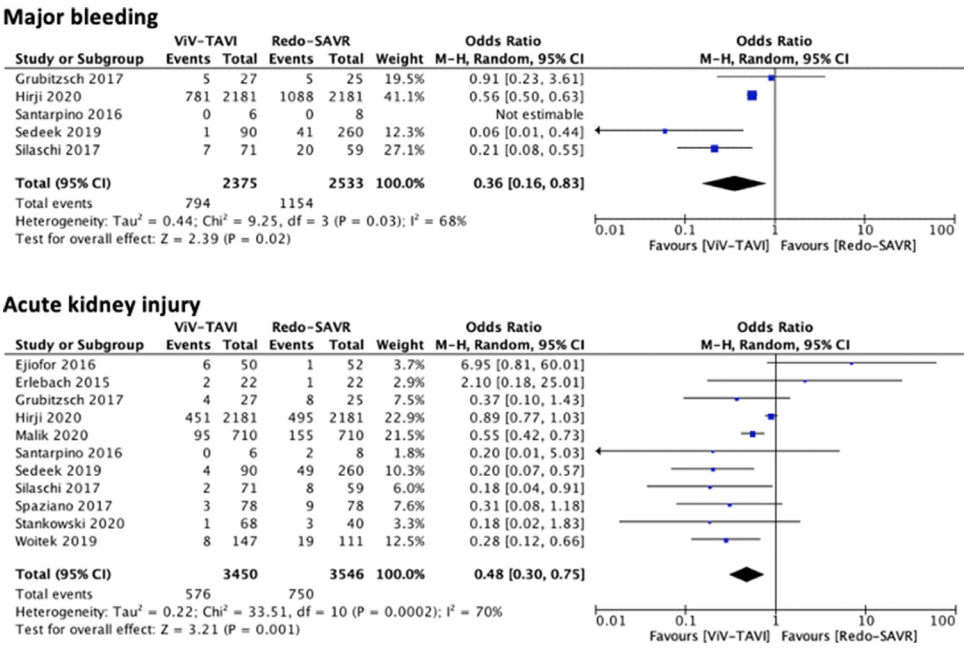

Figure 3. Forest plot of risk of major bleeding, and acute kidney injury.

3.80; 95% CI 0.42 to 34.32; p = 0.24, I2=0%) between the 2 treatment arms (Figure 4). The risk of permanent pacemaker implantation was not statistically different between the 2 groups (OR 0.75; 95% CI 0.42 to 1.34; p = 0.34, I2=85%) (Figure 5). Sensitivity analysis showed that heterogeneity was the lowest (I^2=20%) when Deharo et al[5] and Hirji et al[14] were excluded (OR 0.52, 95% CI 0.35 to 0.77; p = 0.001).

On the contrary, the mean transvalvular pressure gradient was significantly higher post-implantation in the ViV-TAVI arm when compared with Redo-SAVR (Mean difference (MD) 3.92; 95% CI 1.97 to 5.88; p <0.0001, I2=73%) (Figure 5). Sensitivity analysis showed that heterogeneity was the lowest (I^2=25%) when Silaschi et al[12] and Stankowski et al[16] were excluded (MD 4.42, 95% CI 3.13 to 5.72; p <0.00001).

Discussion

Over the past 2 decades, more bioprosthetic valves have been utilized in comparison to mechanical valves.[17] Since bioprosthetic valves degenerate within 10 years and the general population is getting older, managing degenerating bioprosthetic valves is currently a common entity and it is expected to increase exponentially. TAVI for native aortic stenosis has been studied extensively and has been proven to be non-inferior to SAVR in patients with all surgical risks. However, the data that supports TAVI in failed bioprosthetic valves are limited to retrospective observational studies. Hirji et al[14] utilized the United States National Readmission Database (NRD) to include a total of 4,362 propensity-matched patients from 2012 to 2016. On multivariate analysis, ViV- TAVI was associated with a lower risk of 30-day morbidity and mortality.[14] Additionally, Malik et al[7] analyzed the National Inpatient Sample data. A total of 1,420 patients were included from 2012 to 2016. The primary composite outcome of in-hospital all-cause mortality, myocardial infarction, stroke, and acute kidney injury was significantly lower in the ViV-TAVI group when compared with Redo-SAVR (14.1% vs 25.4%, p = 0.018).[7] Deharo et al[5] analyzed the French administrative database and included a total of 1,434 patients from 2010 to 2019. At a median follow-up of 516 days, ViV-TAVI and Redo-SAVR were associated with a similar risk of mortality, stroke, and myocardial infarction.[5] Stankowski et al[16] included 108 patients with degenerative bioprosthetic aortic valves between 2003 and 2018. Patients underwent ViV-TAVI had similar all-cause mortality compared with Redo-SAVR at 30-day (7.4% vs 7.5%), 1-year (14.8% vs 15%), and 5-years (37.1% vs 27.5%, p = 0.287).[16] Sedeek et al[6] reviewed the records of 350 patients between 2008 and 2018, ViV- TAVI was associated with less procedure-related complications when compared with Redo-SAVR (23% vs 59%, p <0.001).[6] At a median follow-up of 2.1 years, ViV-TAVI was associated with similar all-cause mortality when compared with Redo-SAVR (21% vs 19%).[6] Woitek et al[8] retrospectively included 258 patients between 2006 and 2017 in a single tertiary center in Germany. Stroke, 30-day myocardial infarction and 1-year all-cause mortality were similar in ViV-TAVI when compared with Redo-SAVR (8.8% vs 9.9%, p = 0.84).[8]

Our pooled data showed a lower rate of procedural mortality and 30-day mortality in the ViV-TAVI when compared with Redo-SAVR. However, all-cause mortality at 1.74 years follow-up was similar between the 2 groups. The higher early mortality in the Redo-SAVR group is expected as Redo-SAVR is a more invasive procedure compared with ViV-TAVI, and the included patients are old with multiple co-morbidities and high surgical risk. Although the results are in favor of ViV-TAVI, several technical limitations should be highlighted. One of the main concerns is left main occlusion which depends on the type of initial

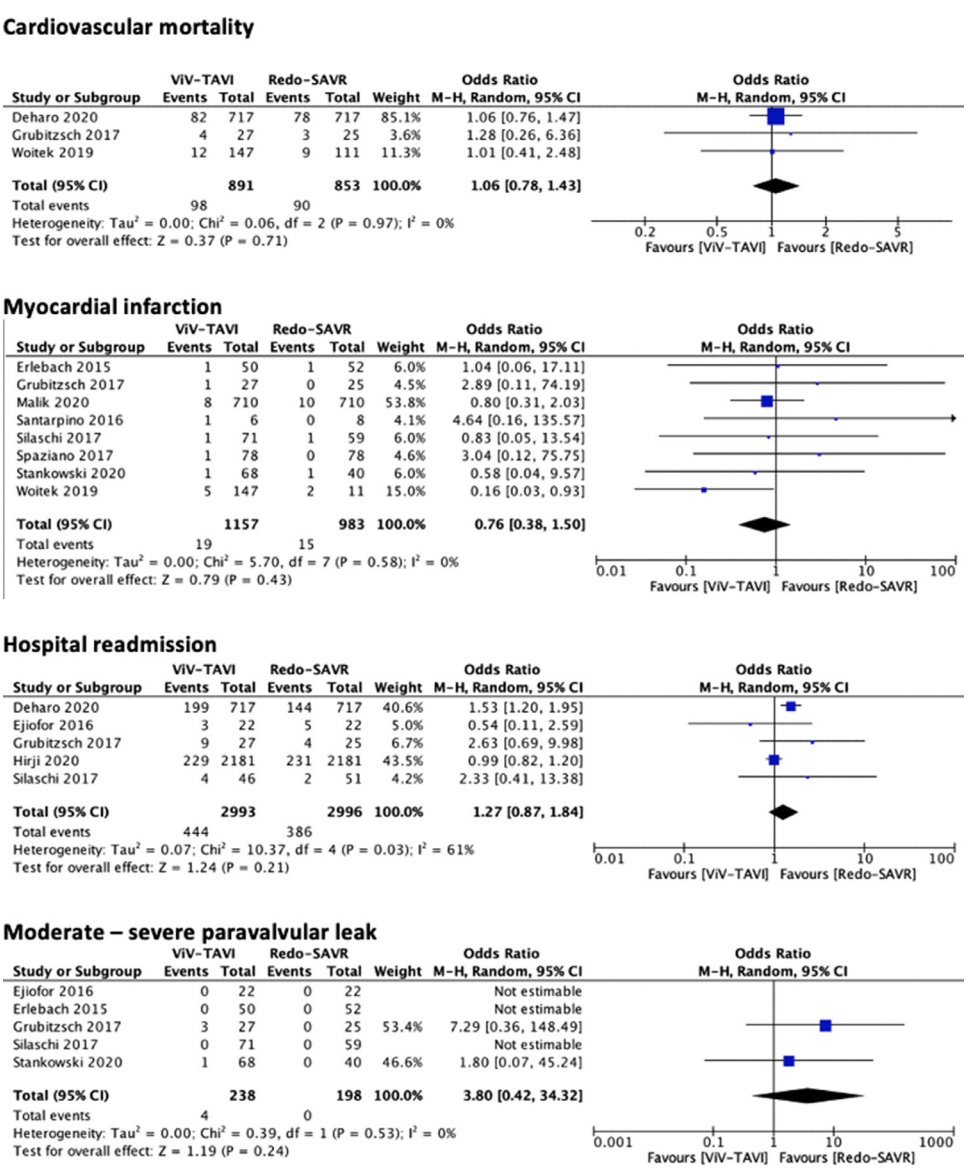

Figure 4. Forest plot of risk of cardiovascular mortality, myocardial infarction, hospital readmission rate, and moderate to severe paravalvular leak.

bioprosthesis. Although it is extremely rare, it is a life-threatening event that occurs threefold to fourfold more common after ViV-TAVI compared with native valve TAVI.[18,19] In our pooled analysis, 4 of the studies reported the rate of coronary obstruction with a total incidence rate of 3% (5/188).[10,12,13,16] Grubitzsch et al[10] reported the highest incidence of coronary obstruction with 4 out of the 5 total events and all occurred in stentless bioprosthetic valves with sub-coronary implantation. Interestingly, our pooled analysis showed a similar rate of myocardial infarction in both groups. The higher rate of coronary obstruction in the stentless valves is attributed to the possible outward expansion of the leaflets post ViV-TAVI.[20] We hypothesize that better patient screening for ViV-TAVI by measuring aortic valve diameter, and distance from the surgical frame and left main coronary artery has decreased the rate of coronary occlusion.[21] Moreover, BASILICA (bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction) which is a tool that effectively decreases the risk of coronary occlusion by lacerating the leaflet close to the coronary artery in patients with high-risk anatomy, is more utilized nowadays.[22] Another technical point in ViV-TAVI is the gradient across the valve postoperatively, our analysis showed that the post-procedural mean pressure gradient was significantly higher in the ViV-TAVI arm when compared with Redo-SAVR. The higher gradient in the ViV-TAVI group is likely driven by under-expansion of the transcatheter valve within the surgical ring of the bioprosthetic valve.[23] Proposed solutions to lower the mean pressure gradient is supra-annular valve placement and bioprosthetic valve fracture.[22] Lastly, the longevity of the TAVI valves remains to be an unanswered question. But since the limited results from the long-term outcomes of TAVI trials in native valves are promising,[24] it is reasonable to assume similar durability in ViV-TAVI.

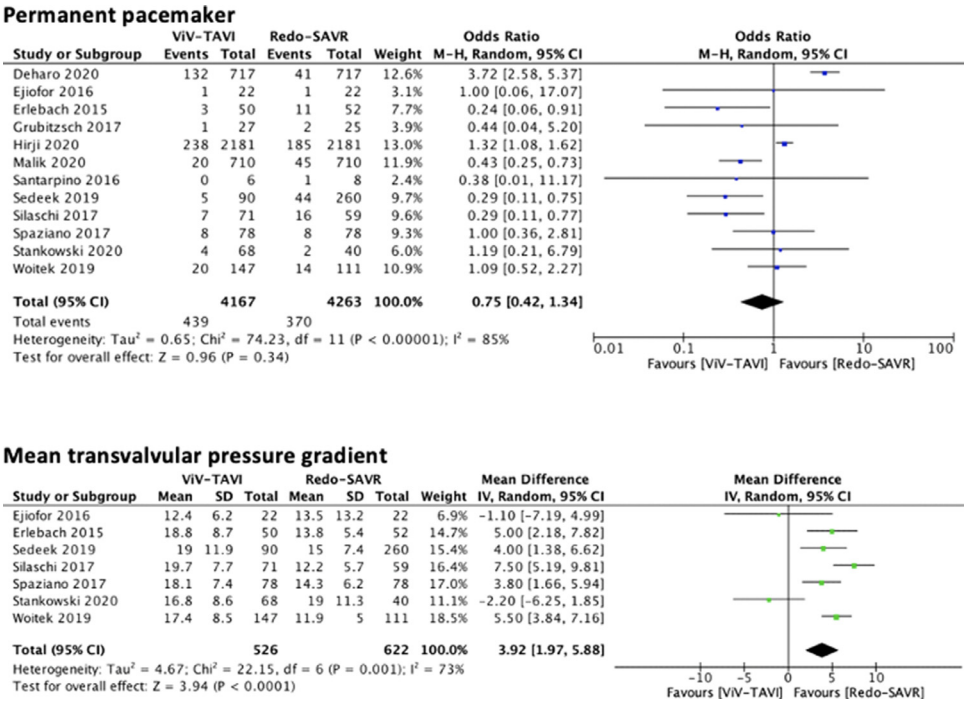

Figure 5. Forest plot of the rate of permanent pacemaker implantation, and mean transvalvular pressure gradient.

This study has some limitations. First, there is discrepancy in baseline characteristics of the patients included in the studies. Secondly, none of the studies reported outcomes depending on the type of failed prosthesis (stented versus stentless, porcine versus pericardial) or the type of implanted TAVI, thus we are unable to report safety and efficacy based on the type of the failed prosthesis or implanted valves.[25] Thirdly, a few of the included studies collected data over a very long period, and with different types and generations of transcatheter valves and operator experience. Lastly, the pooled analysis was derived from the aggregate data from all the studies, and not from an individual level patient data, and all the included studies are retrospective observational studies with a high risk of bias.

In conclusion, our metanalysis showed no significant difference in all-cause mortality, cardiovascular mortality, myocardial infarction, permanent pacemaker implantation, and the rate of moderate to severe paravalvular leakage between ViV-TAVI and Redo-SAVR. However, the rate of major bleeding, stroke, procedural mortality and 30-day mortality were significantly lower in the ViV-TAVI arm when compared with Redo-SAVR. Randomized clinical trials are needed to confirm the safety and efficacy of ViV-TAVI in patients with failed bioprosthetic aortic valve.

Author Agreement Statement

We the undersigned declare that this manuscript is original, has not been published before and is not currently being considered for publication elsewhere.

We confirm that the manuscript has been read and approved by all named authors and that there are no other persons who satisfied the criteria for authorship but are not listed. We further confirm that the order of authors listed in the manuscript has been approved by all of us.

We understand that the Corresponding Author is the sole contact for the Editorial process. He/she is responsible for communicating with the other authors about progress, submissions of revisions and final approval of proofs

On behalf of all authors

Abdullah Al-abcha (Corresponding Author)

Declaration of Interests

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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