ISSN: 3029-0732

Research Article

Journal of Cardiovascular and Cardiology

Self-Expanding Versus Balloon-Expanding Valves 5-Years After Transcatheter Aortic Valve Replacement: Systematic Review and Meta-analysis

Jonathan Elias BA[1*], Warren Chan MS[1], Seth Spicer MS[1,2], Hanna Brancaccio BA[1,2], Usmaan Al-Shehab BS[1,2], Dylan Bagley BS[1,2], Sami Dakhel MS[1], Alissa Brotman O'Neill DO[1], Pasquale Luciano DO[3] and Stuti Jha PhD[4]

[1]*Department of Medicine, Rowan University School of Osteopathic Medicine, Stratford, NJ 08043, USA*

[2]*Futures Forward Research Institute, Toms River, NJ 08753, USA*

[3]*Department of Cardiac Surgery, Capital Health, Pennington, NJ 08534, USA*

[4]*College of Humanities and Social Science, Rowan University, Glassboro, NJ 08028, USA*

[*]Corresponding author

Jonathan Elias BA, Department of Medicine, Rowan University School of Osteopathic Medicine, Stratford, New Jersey. 08043, USA.

Received: May 29, 2024; **Accepted:** June 06, 2024; **Published:** June 11, 2024

ABSTRACT

Background: With transcatheter aortic valve replacement (TAVR) gaining dominance in the treatment for aortic stenosis, it is crucial to determine which type of valve is most superior long-term. Previous studies have compared shorter term outcomes of the two valves; however, long-term outcomes are yet to be determined.

Objectives: This systematic review and meta-analysis evaluate the five-year outcomes of self-expanding valves (SEV), in comparison to balloon-expanding valves (BEV) in an intermediate to high-risk population.

Methods: The systematic review and meta-analysis followed the 2020 PRISMA guidelines. Seven online databases (PubMed, Embase, Web Of Science, Scopus, Google Scholar, Cochrane, Rowan-Virtua SOM Library) were screened. 15 studies met the inclusion criteria (10,416 TAVR procedures). Mortality, cardiovascular-related mortality, new pacemaker implantation rates, mean aortic gradient, and aortic regurgitation rates were assessed at five years.

Results: A lower mean aortic gradient ($p < 0.0006$, Cohen's $d = 2.86$) throughout SEV procedures, and a lower number of new pacemaker implantation rates ($p < 0.0001$, Cohen's $d = 0.29$) from BEV procedures were analyzed. All other outcomes did not yield significant results.

Conclusion: TAVR using either SEV or BEV portrayed similar outcomes, with exception to new pacemaker implantation rates and mean aortic gradient. Using BEV to treat aortic stenosis in an intermediate to high-risk population may lower chances of new pacemaker implantation within 5 years, reducing the need for future procedures and their associated risks. Further studies utilizing RCTs would be beneficial in controlling confounding variables, such as surgeon experience, and patient compliance to postoperative instructions.

Keywords: Transcatheter Aortic Valve Replacement, TAVR, Aortic Stenosis, Pacemaker, Aortic Gradient, Self-Expanding Valve, Balloon-Expanding

Abbreviations List

AS	:	Aortic Stenosis
SEV	:	Self-expanding valve
BEV	:	Balloon-expanding valve
PPI	:	Permanent Pacemaker Implantation
MAG	:	Mean Aortic Gradient
LBBB	:	Left Bundle Branch Block

Introduction

The aorta is the largest artery of the human body that supplies oxygenated blood to the systemic circulation. To efficiently maintain the unidirectional flow of blood, the aortic valve is a tri-leaflet structure that rapidly opens and closes during ventricular contraction [1]. In aortic stenosis (AS), pathologic thickening and calcification of the leaflets restricts the aortic valve's ability to open which decreases the effective aortic valve area, ultimately obstructing blood flow [2]. According to the 2014 AHA/ACC VHD Guidelines, symptomatic severe high-gradient AS is identified when the obstruction results in an aortic valve velocity ≥ 4.0 m/s or the mean pressure gradient increases ≥ 40 mmHg [3].

Citation: Jonathan Elias BA, Warren Chan MS, Seth Spicer MS, Hanna Brancaccio BA, Usmaan Al-Shehab BS, et al. Self-Expanding Versus Balloon-Expanding Valves 5-Years After Transcatheter Aortic ValveReplacement: Systematic Review and Meta-Analysis. J Cardiovas Cardiol. 2024. 2(2): 1-9.
DOI: doi.org/10.61440/JCC.2024.v2.17

AS is the most common valvular heart disease, specifically in Europe, North America, and Japan [4,5]. Previous studies found severe AS in about 2% to 4% in this patient population aged 75 or greater [6-8]. Between 1990 and 2017, the number of prevalent cases for AS increased by 124% with a global estimate of 12.6 million cases in the latter [5]. If left untreated, patients with mild AS have a Kaplan-Meier estimated 4-year all-cause mortality rate of 25.0% while those with severe AS have an estimated rate of 42.0% [9]. The growing incidence and significant mortality rate of AS drives the pursuit for an effective treatment to maximize patient outcomes.

The introduction of open-heart surgery marked a new era for cardiovascular intervention. In 1960, Dr. Dwight Harken implanted a caged ball valve in the sub coronary aortic position in a patient with AS [10]. For the following decades, prosthetic valves have continued to evolve, establishing surgical aortic valve replacement (SAVR) as the standard treatment to reduce AS symptoms and improve survival rates up to 94.6% at 5 years with long-term durability extending beyond 10 years [11-13].

SAVR has shown to have a range of success depending on a patient's surgical risk - a measure based on age, sex, blood pressure, BMI, comorbidities and other variables [14,15]. In a retrospective study using the SWEDEHEART registry, Martinsson et al. demonstrated that low-risk patients had 30-day post-SAVR mortality rates as low as 1.2% while high-risk patients had mortality rates of up to 11.5% [14]. High-risk patients are still operative candidates for SAVR; however, a high-risk score may serve as a deterrent for such a procedure. In 2009, Bach et. al conducted a retrospective review and discovered that 16.5% of patients did not undergo aortic valve replacement due to being at high surgical risk [16].

Over the last few decades, transcatheter aortic valve replacement (TAVR) has become the new standard of care in high-risk surgical patients with severe AS [17,18]. Since the first in-human TAVR procedure in 2002, transcatheter heart valves have continued to evolve in their design and techniques, to reduce postoperative complications such as paravalvular aortic regurgitation (PAR) and disturbances to the heart conduction system [19,20] The minimally invasive treatment for high-risk patients has shown to have 30-days, 1-year and 5-year mortality rates that rivaled those of SAVR, making it a viable alternative [17,21-24]. In more recent years, TAVR has also been under consideration for intermediate-risk and low-risk surgical patients as more randomized controlled trials demonstrate comparable long-term results [25,26]

Currently, there are two main categories for TAVR valves: balloon-expanding valves (BEV) and self-expanding valves (SEV) [27]. In SEV, the valve is compressed within a sheath and self-expands when the sheath is removed, whereas in BEV, the valve is mounted and compressed onto an inflatable balloon [27]. Despite the differences in expansion design, stent frame and composition, and leaflet material, both designs portrayed comparable short-term and long-term mortality rates as observed in the UK TAVI registry, FRANCE-2 registry, and CHOICE trial [28-32]. Across the studies, patients with SEV had higher rates of PAR (17.3%, 21.5%, 18.3%, respectively) compared to those with BEV (9.6%, 13.9%, 4.1%, respectively0 [28,30,32]

In the France-2 registry and CHOICE trial, patients with SEV also had higher rates of new permanent pacemaker implantation (PPI) (24.2% and 37.6%, respectively) compared to those with BEV (11.5% and 17.3%, respectively) [30,32]. Although studies suggest BEV to have a lower incidence of postoperative complications, it is unclear whether BEV or SEV is the superior choice since both devices have similar short-term and long-term survival rates.

Evidently, there is a great amount of data comparing BEV to SEV. However, there have been no systematic reviews or meta-analyses compiling and comparing the 5-year outcomes in an intermediate to high-risk population. In this systematic review and meta-analysis, we fill in that gap in research, and compare the 5-year outcomes of BEV to SEV in an intermediate to high-risk patient population.

Methods

A systematic review and meta-analysis were conducted following the 2020 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [33]. This study determines whether utilizing either SEV or BEV in TAVR yields more superior 5-year outcomes in an intermediate to high-risk population, by comparing the primary outcome of mortality, and the secondary outcomes of cardiovascular-related mortality, new pacemaker implantation rate, moderate or greater paravalvular aortic regurgitation rates, and mean aortic gradient.

Search Procedure

A comprehensive review of seven online databases (Cochrane, Embase, Scopus, Web of Science, PubMed, Google Scholar, Rowan-Virtua School of Osteopathic Medicine Library) was conducted on October 8, 2023. Key terms were identified using MeSH, and Boolean operators were applied to yield the following search string, which was used for every database except Google Scholar: ("TAVR" OR "transcatheter aortic valve replacement" OR "transcatheter aortic valve implantation") AND ("self-expanding" OR "self-expandable" OR "Core Valve" OR "Evolut" OR "balloon expanding" OR "balloon expandable" OR "SAPIEN" OR "BEV" OR "BE" OR "SEV" OR "SE") AND ("mortality" OR "death") AND ("case-controlled" OR "cohort" OR "prospective" OR "retrospective review" OR "randomized control trial" OR "RCT") AND ("high risk" OR "high surgical risk").

The search string utilized for Google Scholar was ("TAVR" OR "transcatheter aortic valve replacement" OR "transcatheter aortic valve implantation") AND ("self-expanding balloon" OR "self-expandable balloon" OR "Core Valve" OR "Evolut" OR "balloon expanding" OR "balloon expandable" OR "SAPIEN") AND ("five-year mortality" OR "five-year death" OR "Five-year outcomes") AND ("case-controlled" OR "cohort" OR "prospective" OR "Retrospective review" OR "randomized control trials" OR "RCT") AND ("high risk patients" OR "high surgical risk").

Inclusion Criteria

Included in the analysis were randomized controlled trials, cohort studies, retrospective studies, and prospective studies that contained primary data of either SEV or BEV implantation in an intermediate to high-risk population (Mean Society of Thoracic Surgeons (STS) Score ≥ 6, Euroscore I ≥ 6, or Euroscore II ≥

15) [15]. Articles needed to include baseline and 5-year post-procedural data for at least one of the following variables: mortality, cardiovascular-related mortality, mean aortic gradient, new pacemaker implantation rates, or moderate or greater paravalvular aortic regurgitation rates. All included studies were available in English or English translation.

Exclusion Criteria

Animal studies, studies that did not stratify the data between SEV and BEV, reviews, studies that did not include 5-year post-procedural data, studies that were measuring outcomes in non-intermediate to high-risk populations, and studies that did not have an available English translation were excluded.

Study Selection

There were 3,167 studies (1 from Cochrane, 1018 from Embase, 616 from Scopus, 328 from Web of Science, 203 from PubMed, 672 from Google Scholar, and 329 from Rowan-Virtua School of Osteopathic Medicine Library) identified during the initial database search. Rayyan.ai software was used to detect duplicates. Two reviewers (JE and WC) individually reviewed each detected duplicate to ensure no mistakes were made via the use of the software, and manually excluded duplicates. Following the exclusion of 1361 duplicates, JE and WC screened the abstracts and titles of the remaining 1909 articles. After title and abstract review, 44 articles were retrieved and assessed for eligibility with full-text screening. A third reviewer (SS) was consulted for conflicting inclusion or exclusion decisions between the two reviewers. Ultimately, 15 studies met inclusion criteria and were included in the final systematic review and meta-analysis, whereas the other 29 studies were removed due to not meeting the inclusion criteria.

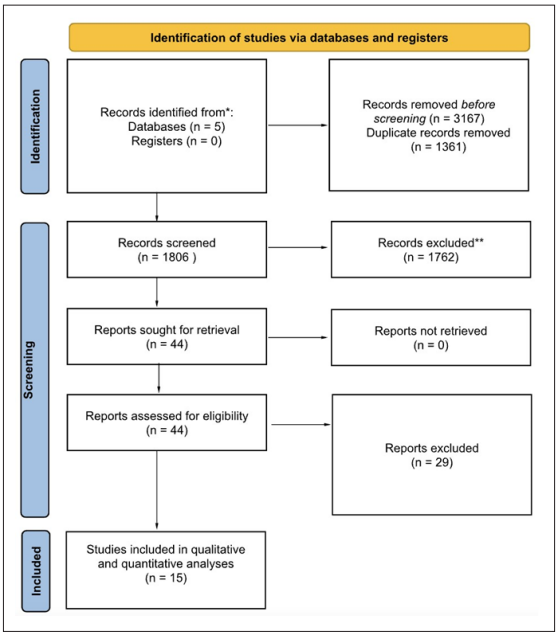

Figure 1: PRISMA flow diagram of study selection [33].

Data Extraction

2 independent reviewers extracted relevant data from each of the 15 included articles for analysis. The following study characteristics and data were extracted: author, year of publication, country in which study was conducted, sample size, intervention type (SEV or BEV), mortality, cardiovascular-related mortality, mean aortic gradient, moderate or greater paravalvular aortic regurgitation rates, and new pacemaker implantation rates. All data was measured 5-years post-TAVR. The primary outcome extracted from the studies was 5-year mortality. Secondary outcomes extracted were 5-year cardiovascular-related mortality, mean aortic gradient, moderate or greater aortic regurgitation rates, and new pacemaker implantation rates. Data was extracted as rates (mortality, cardiovascular-related mortality, new pacemaker implantation, moderate or greater paravalvular aortic regurgitation) or as the mean and standard deviation (aortic gradient).

Statistical Analysis

Multiple single-proportion meta-analyses were performed in RStudio under a random-effects model in order to compare the outcomes of patients who received SEV and patients who received BEV. The outcomes of the single-proportion meta-analyses were 5-year post-TAVR mortality, cardiovascular-related mortality, new pacemaker implantation rate, and moderate or greater paravalvular aortic regurgitation rate. An effect size was calculated between the pooled proportions using an unpaired two-sample T-test. A meta-analysis of continuous outcomes was performed in SPSS to compare the mean aortic gradient between patients who received SEV and patients who received BEV.

Risk of Bias and Certainty of Evidence Assessment

Included manuscripts underwent a rigorous critical appraisal process using modified Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria (Table 2). Bias in the included articles was assessed independently by two reviewers (JE and HB) based on study designs. Since randomized control trials and prospective cohort studies were included in our analysis, they were subjected to evaluation with ROBINS-I [34]. All studies were weighted equally in the risk of bias assessment. The data is presented in plot format (Figure 2, Figure 3).

Table 1: Summary of the data comparing mean aortic gradient between SEV and BEV.

Group	SEV	BEV
Mean (mmHg)	8.265	12.167
Standard Deviation	1.210	1495
Standard Error of Mean	0.494	0.610
N	894	541
Cohen's d	2.869	
P-value	0.0006	

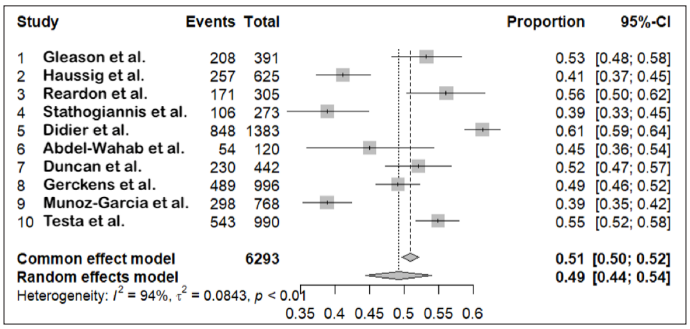

Figure 2: Single proportions meta-analysis of 5-year mortality in the SEV group [29,31,35,36,38,40,42,44-46].

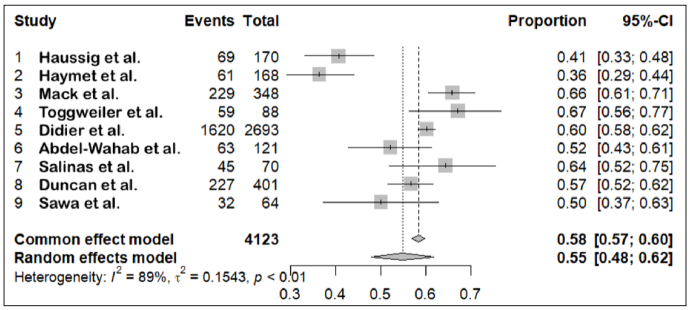

Figure 3: Single proportions meta-analysis of 5-year mortality in the BEV group [29,31,36,37,39,41-43,47].

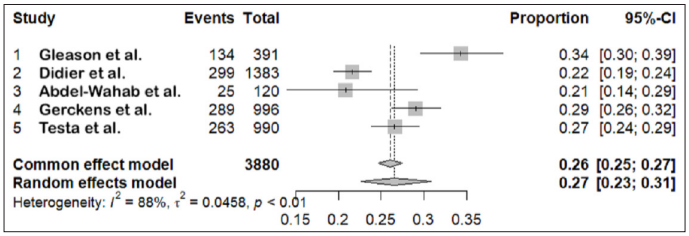

Figure 4: Single proportions meta-analysis of 5-year cardiovascular-related mortality in the SEV group [31,35,42,44,46].

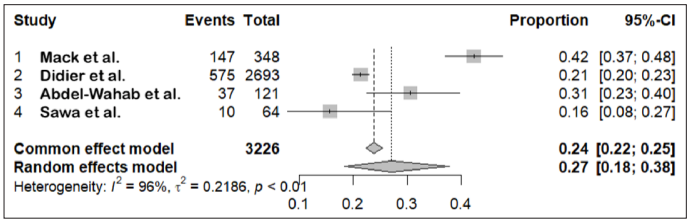

Figure 5: Single proportions meta-analysis of 5-year cardiovascular-related mortality in the BEV group [31,39,42,47].

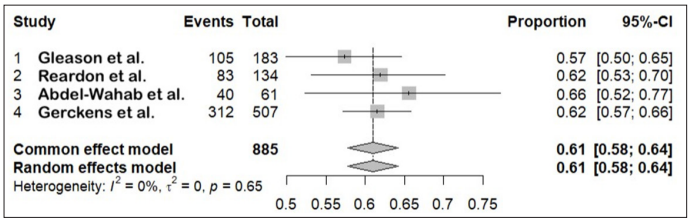

Figure 6: Single proportions meta-analysis of 5-year new pacemaker implantation rate in the SEV group [35,38,42,44].

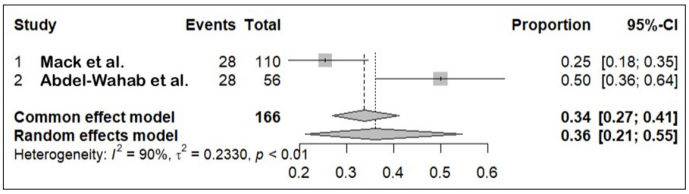

Figure 7: Single proportions meta-analysis of 5-year new pacemaker implantation rate in the BEV group [39,42].

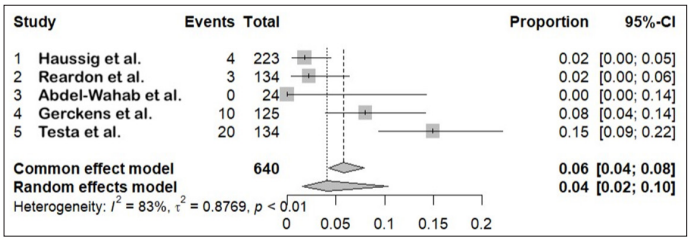

Figure 8: Single proportions meta-analysis of 5-year moderate or greater paravalvular aortic regurgitation rates in the SEV group [36,38,44,44,46].

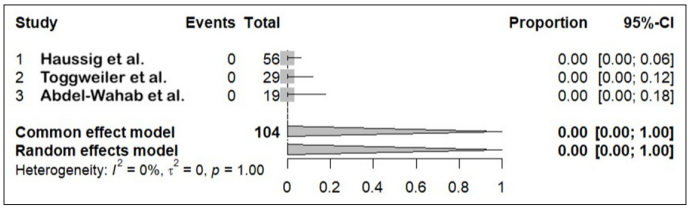

Figure 9: Single proportions meta-analysis of 5-year moderate or greater aortic regurgitation rates in the BEV group [36,41,42].

Results

Effect of Intervention

After extraction of the data, 10,416 distinct TAVR procedures were analyzed 5-years post-TAVR procedure, comprised of 4,123 BEV, and 6,293 SEV from a total of 15 studies [29,31,34-46]. A single proportions test was conducted to measure the prevalence of mortality, cardiovascular-related mortality, moderate or greater paravalvular aortic regurgitation rates, and new pacemaker implantation rates, while an unpaired t-test was conducted to analyze the significance of mean aortic gradient between the two groups. Due to the high degree of heterogeneity amongst the studies, a random-effects model was used.

The proportion of the population that received a new pacemaker within 5-years post-procedure was 0.36 (95% CI 0.21 - 0.55) in the BEV group, and 0.61 (95% CI 0.58 - 0.64) in the SEV group. The confidence intervals did not overlap in the analysis of new pacemaker implantation rates between the two groups, signifying a statistical significance. An unpaired t-test and cohen's d calculation of the new pacemaker rate proportions were conducted, yielding $p < 0.0001$, and cohen's $d = 0.29$.

The mean aortic gradient for the SEV group was 8.625 mmHg ± 1.210, and 12.167 mmHg ± 1.495 for the BEV group. Unpaired t-testing between the two groups revealed $p < 0.0006$, and further cohen's d calculations revealed cohen's $d = 2.869$. 5-year all-cause mortality and cardiovascular related mortality in the SEV group were 49% and 27%, respectively, while all-cause mortality and cardiovascular related mortality in the BEV group were 55% and 27%, respectively. Although the confidence intervals overlap between the groups in the all-cause mortality measure, SEV yielded 6% lower all-cause mortality. However, cardiovascular-related mortality measured 5-year post-procedure yielded the same proportion between the two groups. Paravalvular aortic regurgitation rates were comparable, and did not differ clinically or statistically.

Risk of Bias and Certainty of Evidence Assessment

Modified GRADE analysis revealed a moderate quality of evidence for 8 included studies and a low quality of evidence for 7 included studies. High heterogeneity calculated in the analysis contributed to the serious inconsistency reflected in each study. Other reasons for downgrading quality of evidence include low sample sizes, resulting in serious imprecision for some studies, and strongly detected publication bias for studies that were funded by valve manufacturers. The domains within GRADE and explanation for any decisions to downgrade the quality of evidence are detailed in the summary of findings chart (Table 2).

Table 2: Summary of findings of modified GRADE assessment of quality of evidence.

Modified Grading of Recommendations Assessment, Development and Evaluation Criteria for Included Articles								
Author (Year)	**Study Design**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication Bias**	**Other Factors**	**Final Grade**
Haussig (2021)	Prospective cohort study	Not serious	Serious	Not serious	Not serious	Undetected	N/A	Moderate
Haymet (2021)	Prospective cohort study	Not serious	Serious	Not serious	Not serious	Undetected	N/A	Moderate
Gleason (2018)	RCT	Not serious	Serious	Not serious	Not serious	Strongly suspected due to funding from SEV manufacturer (Medtronic)	N/A	Low
Reardon (2021)	RCT	Not serious	Serious	Not serious	Not serious	Undetected	N/A	Moderate
Mack (2015)	RCT	Not serious	Serious	Not serious	Not serious	Strongly detected due to funding from BEV manufacturer (Edwards Lifesciences)	N/A	Low
Stathogiannis (2021)	Prospective cohort study	Not serious	Serious	Not serious	Not serious	Undetected	N/A	Moderate
Toggweiler (2013)	Prospective cohort study	Not serious	Serious	Not serious	Serious due to small sample size	Undetected	N/A	Low
Didier (2018)	Prospective cohort study	Not serious	Serious	Not serious	Not serious	Undetected	N/A	Moderate
Abdel-Wahab (2020)	RCT	Not serious	Serious	Not serious	Serious due to small sample size	Undetected	N/A	Low
Salinas (2015)	Prospective cohort study	Not serious	Serious	Not serious	Not serious as small sample size is reflective of normal practice of Spanish tertiary center	Undetected	N/A	Moderate
Duncan (2015)	Prospective cohort study	Not serious	Serious	Not serious	Not serious	Undetected	N/A	Moderate
Gerckens (2017)	Prospective cohort study	Not serious	Serious	Not serious	Not serious	Strongly suspected due to funding from SEV manufacturer (Medtronic)	N/A	Low
Munoz-Garcia (2021)	Prospective cohort study	Not serious	Serious	Not serious	Not serious	Undetected	N/A	Moderate
Testa (2020)	Prospective cohort study	Not serious	Serious	Not serious	Not serious	Strongly suspected due to funding from SEV manufacturer (Medtronic)	N/A	Low
Sawa (2017)	Prospective cohort study	Not serious	Serious	Not serious	Serious due to small sample size	Strongly suspected due to study design by sponsor (Edwards Lifesciences Limited)	N/A	Low

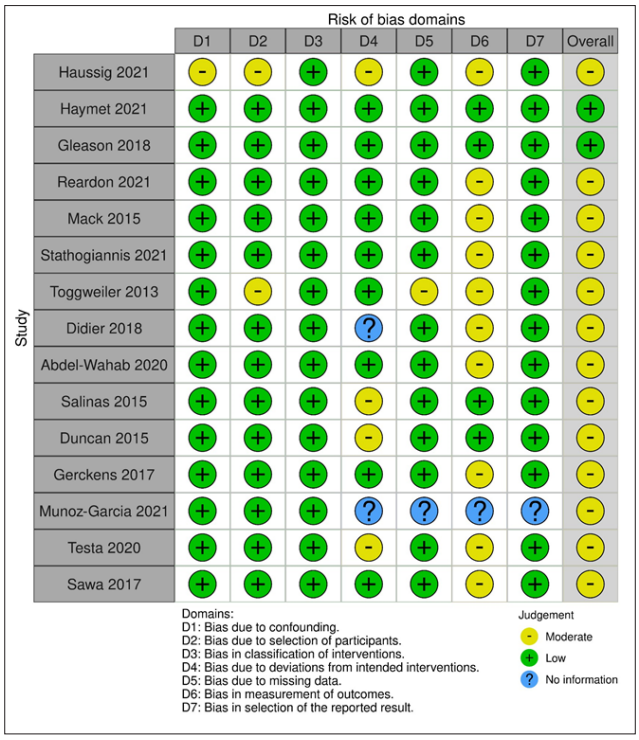

Figure 10: RoB-2 traffic-light plot [48].

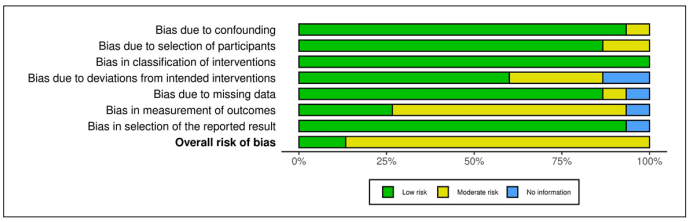

Figure 11: RoB-2 summary plot [48]

Discussion

Outcomes

This systematic review and meta-analysis provide the most current analysis of long-term outcomes comparing SEV to BEV in TAVR for an intermediate to high-risk population. As of April 2024, a consensus regarding which valve reigns supreme remains elusive.

The meta-analysis observed that utilizing SEV in the TAVR procedure in intermediate to high-risk patients led to a lower mean aortic gradient (MAG), and 6% lower all-cause mortality when compared to BEV. Furthermore, the utilization of BEV led to lower new PPI rates compared to SEV.

Table 3: Central illustration summarizing the 5-year outcomes of SEV and BEV valves. The red asterisks (*) represent statistically significant measures.

Outcome	SEV		BEV	
	Measure	95% CI	Measure	95% CI
Mortality Proportion	0.49	[0.44 - 0.54]	0.55	[0.48 - 0.62]
Cardiovascular Related Mortality Proportion	0.27	[0.23 - 0.31]	0.27	[0.18 - 0.38]
New Pacemaker Implantation Proportion*	0.61	[0.58 - 0.64]	0.36	[0.21 - 0.55]
Moderate or Greater Paravalvular Aortic Regurgitation Proportion	0.04	[0.02 - 0.10]	0.00	[0.00 - 1.00]
Mean Aortic Gradient (mmHg)*	8.265	[8.19 – 8.34]	12.167	[12.041 - 12.293]

Factors that may contribute to the decreased MAG found in patients who received the SEV during the TAVR procedure are: material utilized in the SEV, better adaptation of the SEV to the aortic annulus, and superior hemodynamic performance of the SEV valve. The framework of self-expanding valves is commonly made from nitinol, which is a nickel-titanium alloy that expands when it reaches body temperature [49]. The nitinol allows for continual expansion, even after placement, until the valve itself conforms fully to the shape of the aortic annulus [50]. Thus, the SEV allows for better sealing and a greater opening area of the aortic valve while also exhibiting less paravalvular leakage during each heartbeat [51]. Additionally, the design of the SEV allows for blood flow to mimic a more natural flow similar to what is observed in a native aortic valve [52]. These factors may play a role in improved hemodynamic performance, contributing to a reduced MAG.

Conduction system disease is a prevalent adverse outcome post-TAVR, occurring, on average, between 13-17% in a meta-analysis including more than 11,000 patients [53]. This largely pertains to the proximity of the aortic annulus to the left bundle branch, which is located distally in relation to the aortic annulus [54]. When setting the new valve into place, the force required for anchoring may disturb the ability of the left bundle branch to continue its conduction, which would result in a left bundle branch block (LBBB). BEV may have yielded lower PPI rates 5-years post-TAVR compared to SEV for two main reasons. Firstly, BEV are anchored to the existing calcified leaflets which decreases the likelihood of the new valve disrupting the distally located left bundle branch. Secondly, insufflation of the balloon in BEV can be altered intra-procedurally, whereas SEV continually expands to conform to the aortic annulus. As a result, BEV does not typically exert as much force on the interventricular septum, which contains the left bundle branch, as SEV does [54].

While not a statistically significant difference, there was a 6% higher incidence of all-cause mortality in BEV compared to SEV. The exact cause of this finding has not yet been determined, but there are a few possible theories. One is that bioprosthetic valves are more prone to deteriorating more quickly than mechanical valves and could necessitate a second TAVR, which carries its own risks [55]. In addition, patients with reduced left ventricular ejection fraction (LVEF) who receive BEV have been shown to have increased incidence of symptoms following TAVR compared to SEV [56].

Given that there is no statistically significant difference in all-cause mortality or cardiovascular-related mortality, the use of BEV or SEV is determined by mainly clinical factors: some of which include physician preference and patient comorbidities. Furthermore, there is an increased incidence of paravalvular leak in patients receiving a mechanical valve, necessitating indefinite anticoagulation via the drug warfarin [56]. With this comes an increased risk of bleeding and the difficulty of constantly managing their anticoagulation status via international normalized ratio (INR) [58]. One advantage to using a bioprosthetic valve is that there is no need for indefinite anticoagulation [59-60].

Limitations

Possible limitations to our current study include not assessing age or diagnosis as a moderator variable and not ruling out confounding variables based on high heterogeneity. This high degree of heterogeneity may be due to the different comorbidities between patients, such as diabetes, and chronic kidney disease. It may also be due to the different manufacturers and models of the valves used in the studies. Further studies should assess these factors as possible sources of variance in patient outcomes. Additionally, we did not have access to individual patient data, and relied on the compiled data presented by the authors of the studies. Access to the full text for Reardon et al. and Munoz-Garcia et al. we're not available so only the abstract was utilized. In Gleason et al. and Haymet et al., next generation prostheses supersede the prostheses that were used in the trials that were included in the study which limits their translatability to new patients. Additionally, in Toggweiler et al, the experience of a single center rather than outcomes of a clinical trial and the small patient sample size reduces the generalizability of the data reported. Abdel-Wahab et al. and Salinas et al. faced a similar problem of a small sample size and the lack of statistical power needed to declare differences in clinical outcomes. Similarly, Sawa et al. had a small sample size along with utilizing inexperienced surgeons and interventional cardiologists for the TAVR procedure. Gerckens et al. had only 56% of echo visit compliance leading to an assessment of hemodynamic valve function being underestimated at five years. Additionally, in some studies, older generation valves were utilized and may not represent the valves currently being used.

Conclusion

While not statistically significant, utilizing the SEV yielded 6% less mortality than BEV. However, as that outcome was not statistically significant, it is difficult to truly come to that conclusion. Future randomized controlled trials are needed in order to control for confounding variables, and to expand the sample size even further. However, we can conclude that SEV yields lower mean aortic gradients in an intermediate to high-risk population, as our results for that outcome were both clinically and statistically significant. On the other hand, BEV yielded significantly lower new pacemaker implantations in this population. One way that this can be used clinically is if a patient already has a pacemaker implantation, then using the SEV may be their best choice, considering its superiority in the aforementioned outcomes. Future randomized controlled trials comparing 5-year outcomes of utilizing SEV versus BEV in patients already implanted with pacemakers would be beneficial in coming to such a conclusion.

Highlights

- No systematic reviews or meta-analysis compared 5-year outcomes of SEV to BEV in TAVR
- To determine which valve is has more superior long-term outcomes
- Future 5-year RCTs comparing the valves in those with existing pacemakers are needed

Funding: No funding was received for this review.

Disclosures: Rayyan.ai was utilized to detect the duplicates. Its detection was checked by two independent reviewers before deletion of the detected duplicates.

Acknowledgements: There are no acknowledgements.

References

1. Misfeld M, Sievers HH. Heart valve macro- and microstructure. Philos Trans R Soc Lond B Biol Sci. 2007. 362: 1421-1436.
2. Nightingale AK, Horowitz JD. Aortic sclerosis: not an innocent murmur but a marker of increased cardiovascular risk. Heart. 2005. 91: 1389-1393.
3. Nishimura RA, Otto CM, Bonow RO, Carabello BA, Erwin JP III, et al. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2014. 129: 2440–2492.
4. Lung B, Delgado V, Rosenhek R, Price S, Prendergast B, et al. Contemporary Presentation and Management of Valvular Heart Disease: The EURObservational Research Programme Valvular Heart Disease II Survey. Circulation. 2019. 140: 1156-1169.
5. Yadgir S, Johnson CO, Aboyans V, Adebayo OM, Adedoyin RA, et al. Global, Regional, and National Burden of Calcific Aortic Valve and Degenerative Mitral Valve Diseases, 1990-2017. Circulation. 2020. 141: 1670-1680.
6. Stewart BF, Siscovick D, Lind BK, Gardin JM, Gottdiener JS, et al. Clinical factors associated with calcific aortic valve disease. Cardiovascular Health Study. J Am Coll Cardiol. 1997. 29: 630-634.
7. Otto CM, Lind BK, Kitzman DW, Gersh BJ, Siscovick DS. Association of aortic-valve sclerosis with cardiovascular mortality and morbidity in the elderly. N Engl J Med. 1999. 341: 142-147.
8. Osnabrugge RL, Mylotte D, Head SJ, Van Mieghem NM, et al. Aortic stenosis in the elderly: disease prevalence and number of candidates for transcatheter aortic valve replacement: a meta-analysis and modeling study. J Am Coll Cardiol. 2013. 62: 1002-1012.
9. Généreux P, Sharma RP, Cubeddu RJ, Aaron L, Abdelfattah OM, et al. The Mortality Burden of Untreated Aortic Stenosis. J Am Coll Cardiol. 2023. 82: 2101-2109.
10. Alivizatos PA. Dwight Emary Harken, MD, an all-American surgical giant: Pioneer cardiac surgeon, teacher, mentor. Proc (Bayl Univ Med Cent). 2018. 31: 554-557.
11. Johnston DR, Soltesz EG, Vakil N, Rajeswaran J, Roselli EE, et al. Long-term durability of bioprosthetic aortic valves: implications from 12,569 implants. Ann Thorac Surg. 2015. 99: 1239-1247.

12. Kvidal P, Bergström R, Hörte LG, Ståhle E. Observed and relative survival after aortic valve replacement. J Am Coll Cardiol. 2000. 35: 747-756.
13. Rodriguez-Gabella T, Voisine P, Dagenais F, Mohammadi S, Perron J, et al. Long-Term Outcomes Following Surgical Aortic Bioprosthesis Implantation. J Am Coll Cardiol. 2018. 71: 1401-1412.
14. Martinsson A, Nielsen SJ, Milojevic M, Redfors B, Omerovic E, et al. Life Expectancy After Surgical Aortic Valve Replacement. J Am Coll Cardiol. 2021. 78: 2147-2157.
15. Ad N, Holmes SD, Patel J, Pritchard G, Shuman DJ, et al. Comparison of EuroSCORE II, Original EuroSCORE, and The Society of Thoracic Surgeons Risk Score in Cardiac Surgery Patients. Ann Thorac Surg. 2016. 102: 573-579.
16. Bach DS, Siao D, Girard SE, Duvernoy C, McCallister BD Jr, et al. Evaluation of patients with severe symptomatic aortic stenosis who do not undergo aortic valve replacement: the potential role of subjectively overestimated operative risk. Circ Cardiovasc Qual Outcomes. 2009. 2: 533-539.
17. Leon MB, Smith CR, Mack M, Miller DC, Moses JW, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med. 2010. 363: 1597-1607.
18. Smith CR, Leon MB, Mack MJ, Miller DC, Moses JW, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med. 2011. 364: 2187-2198.
19. Cribier A, Eltchaninoff H, Bash A, Borenstein N, Tron C, et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. Circulation. 2002. 106: 3006-3008.
20. Tamm AR, Hell MM, Geyer M, Kreidel F, da Rocha E Silva JG, et al. Minimizing Paravalvular Regurgitation with the Novel SAPIEN 3 Ultra TAVR Prosthesis: A Real-World Comparison Study. Front Cardiovasc Med. 2021. 8: 623146.
21. Lin PH, Wei HJ, Hsieh SR, Tsai HW, Yu CL, et al. One-Year and Five-Year Outcomes of Transcatheter Aortic Valve Replacement or Surgical Aortic Valve Replacement in a Taiwanese Elderly Population. J Clin Med. 2023. 12: 3429.
22. Abdelgawad AME, Hussein MA, Naeim H, Abuelatta R, Alghamdy S. A Comparative Study of TAVR versus SAVR in Moderate and High-Risk Surgical Patients: Hospital Outcome and Midterm Results. Heart Surg Forum. 2019. 22: E331-E339.
23. Kodali SK, Williams MR, Smith CR, Svensson LG, Webb JG, et al. Two-year outcomes after transcatheter or surgical aortic-valve replacement. N Engl J Med. 2012. 366: 1686-1695.
24. Kapadia SR, Leon MB, Makkar RR, Tuzcu EM, Svensson LG, et al. 5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial. Lancet. 2015. 385: 2485-2491.
25. Leon MB, Smith CR, Mack MJ, Makkar RR, Svensson LG, et al. Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients. N Engl J Med. 2016. 374: 1609-1620.
26. Mack MJ, Leon MB, Thourani VH, Pibarot P, Hahn RT, et al. Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years. N Engl J Med. 2023. 389: 1949-1960.
27. Luis Ortega-Paz, Giuseppe Giacchi, Salvatore Brugaletta, Manel Sabaté. Percutaneous Transcatheter Aortic Valve Implantation: A Review Focus on Outcomes and Safety. AIMS Medical Science. 2015. 2: 200-221.
28. Moat NE, Ludman P, de Belder MA, Bridgewater B, Cunningham AD, et al. Long-term outcomes after transcatheter aortic valve implantation in high-risk patients with severe aortic stenosis: the U.K. TAVI (United Kingdom Transcatheter Aortic Valve Implantation) Registry. J Am Coll Cardiol. 2011. 58: 2130-2138.
29. Duncan A, Ludman P, Banya W, Cunningham D, Marlee D, et al. Long-term outcomes after transcatheter aortic valve replacement in high-risk patients with severe aortic stenosis: The U.K. Transcatheter Aortic Valve Implantation Registry. JACC Cardiovascular interventions. 2015. 8: 645-653.
30. Gilard M, Eltchaninoff H, Iung B, Donzeau-Gouge P, Chevreul K, et al. Registry of transcatheter aortic-valve implantation in high-risk patients. N Engl J Med. 2012. 366: 1705-1715.
31. Didier R, Eltchaninoff H, Donzeau-Gouge P, Chevreul K, Fajadet J, et al. Five-Year Clinical Outcome and Valve Durability After Transcatheter Aortic Valve Replacement in High-Risk Patients. Circulation. 2018. 138: 2597-2607.
32. Abdel-Wahab M, Mehilli J, Frerker C, et al. Comparison of balloon-expandable vs self-expandable valves in patients undergoing transcatheter aortic valve replacement: the CHOICE randomized clinical trial. JAMA. 2014. 311: 1503-1514.
33. Haddaway NR, Page MJ, Pritchard CC, McGuinness LA. PRISMA2020: An R package and Shiny app for producing PRISMA 2020-compliant flow diagrams, with interactivity for optimised digital transparency and Open Synthesis. Campbell Systematic Reviews. 2022. 18.
34. Sterne JA, Hernán MA, Reeves BC, Savović J, Berkman ND, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. BMJ. 2016. 355: i4919.
35. Gleason TG, Reardon MJ, Popma JJ, Deeb GM, Yakubov SJ, et al. 5-Year Outcomes of Self-Expanding Transcatheter Versus Surgical Aortic Valve Replacement in High-Risk Patients. J AmColl Cardiol. 2018. 72: 2687-2696.
36. Haussig S, Pleissner C, Mangner N, Woitek F, Zimmer M, Kiefer P, et al. Long-term Follow-up After Transcatheter Aortic Valve Replacement. CJC Open. 2021. 3: 845-853.
37. Haymet AB, Seco M, Brown C, Cristoloveanu C, Murray S, et al. Five-Year Survival of Transcatheter Aortic Valve Implantation in High-Risk Patients. Heart Lung Circ. 2021. 30: 1901-1909.
38. Reardon M, Rajagopal V, Makkar R, Bajwa T, Kleiman N, et al. TCT-394 Late Outcomes After Transcatheter Aortic Valve Replacement with a Mechanically Expanded Versus Self-Expandable Valve: Final 5-Year Results from the REPRISE III Randomized Trial. J Am Coll Cardiol. 2021. 78: B162.
39. Mack MJ, Leon MB, Smith CR, Miller DC, Moses JW, et al. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial. Lancet. 2015. 385: 2477-2484.
40. Stathogiannis K, Synetos A, Latsios G, Karanasos A, Trantalis G, et al. Long-Term Outcomes and Valve Performance in Patients Undergoing Transcatheter Aortic Valve Implantation. Am J Cardiol. 2021. 147: 80-87.

41. Toggweiler S, Humphries KH, Lee M, Binder RK, Moss RR, et al. 5-year outcome after transcatheter aortic valve implantation. J Am Coll Cardiol. 2013. 61: 413-419.
42. Abdel-Wahab M, Landt M, Neumann FJ, Massberg S, Frerker dC. et al. 5-Year Outcomes After TAVR With Balloon-Expandable Versus Self-Expanding Valves: Results from the CHOICE Randomized Clinical Trial. JACC Cardiovascular interventions. 2020. 13: 1071-1082.
43. Haussig S, Pleissner C, Mangner N, Woitek F, Zimmer M, et al. Long-term Follow-up After Transcatheter Aortic Valve Implantation for Severe Aortic Stenosis. Revista española de cardiología (English ed). 2016. 69: 37-44.
44. Gerckens U, Tamburino C, Bleiziffer S, Bosmans J, Wenaweser P, et al. Final 5-year clinical and echocardiographic results for treatment of severe aortic stenosis with a self-expanding bioprosthesis from the ADVANCE Study. European heart journal. 2017. 38: 2729-2738.
45. M Munoz-Garcia, E Munoz-Garcia, AJ Munoz Garcia, AJ Dominguez-Franco, JH Alonso-Briales, et al. Long-term outcomes in patients undergoing transcatheter aortic valve implantation: insights on clinical outcomes and prognostic markers from a large cohort of patients. European heart journal. 2021. 42.
46. Testa L, Latib A, Brambilla N, De Marco F, Fiorina C, et al. Long-term clinical outcome and performance of transcatheter aortic valve replacement with a self-expandable bioprosthesis. European heart journal. 2020. 41: 1876-1886.
47. Sawa Y, Takayama M, Goto T, Takanashi S, Komiya T, et al. Five-Year Outcomes of the First Pivotal Clinical Trial of Balloon-Expandable Transcatheter Aortic Valve Replacement in Japan (PREVAIL JAPAN). Circ J. 2017. 81: 1102-1107.
48. McGuinness, LA, Higgins, JPT. Risk-of-bias VISualization (robvis): An R package and Shiny web app for visualizing risk-of-bias assessments. Res Syn Meth. 2020. 1- 7.
49. van Nieuwkerk AC, Santos RB, Andraka L, Tchetche D, de Brito FS, et al. Balloon-Expandable versus Self-Expandable Valves in Transcatheter Aortic Valve Implantation: Complications and Outcomes from a Large International Patient Cohort. J Clin Med. 2021. 10: 4005.
50. Reichenspurner H, Schaefer A, Schäfer U, Tchétché D, Linke A, et al. Self-Expanding Transcatheter Aortic Valve System for Symptomatic High-Risk Patients With Severe Aortic Stenosis. J Am Coll Cardiol. 2017. 70: 3127-3136.
51. Jin Q, Li W, Chen S, Li M, Zhou D, et al. Aortic valve morphology and paravalvular leak regression after a self-expandable transcatheter aortic valve replacement. Front Physiol. 2023. 13: 1088681.
52. Takahashi Y, Kamiya K, Nagai T, Tsuneta S, Oyama-Manabe N, et al. Differences in blood flow dynamics between balloon- and self-expandable valves in patients with aortic stenosis undergoing transcatheter aortic valve replacement. J Cardiovasc Magn Reson. 2023. 25: 60.
53. Chen S, Chau KH, Nazif TM. The incidence and impact of cardiac conduction disturbances after transcatheter aortic valve replacement. Ann Cardiothorac Surg. 2020. 9: 452-467.
54. Ravaux JM, Di Mauro M, Vernooy K, Kats S, Mariani S, et al. Permanent pacemaker implantation following transcatheter aortic valve implantation using self-expandable, balloon-expandable, or mechanically expandable devices: a network meta-analysis. Europace. 2021. 23: 1998-2009.
55. Tillquist MN, Maddox TM. Cardiac crossroads: deciding between mechanical or bioprosthetic heart valve replacement. Patient Prefer Adherence. 2011. 5: 91-99.
56. Kodra A, Cinelli M, Alexander R, Hamfreth R, Wang D, et al. Comparison of Periprocedural and Intermediate-Term Outcomes of TAVI in Patients with Ejection Fraction ≤ 20% vs. Patients with 20% < EF ≤ 40. J Clin Med. 2023. 12: 2390.
57. Guedeney P, Mehran R, Collet JP, Claessen BE, ten Berg J, et al. Antithrombotic Therapy After Transcatheter Aortic Valve Replacement. Circ: Cardiovascular Interventions. 2019. 12.
58. Granger C, Guedeney P, Collet JP. Antithrombotic Therapy Following Transcatheter Aortic Valve Replacement. J Clin Med. 2022. 11: 2190.
59. Verstraete A, Herregods MC, Verbrugghe P, Lamberigts M, Vanassche T, et al. Antithrombotic Treatment After Surgical and Transcatheter Heart Valve Repair and Replacement. Front Cardiovasc Med. 2021. 8: 702780.
60. Sammour Y, Krishnaswamy A, Kumar A, Puri R, Tarakji KG, et al. Incidence, Predictors, and Implications of Permanent Pacemaker Requirement After Transcatheter Aortic Valve Replacement. JACC Cardiovasc Interv. 2021. 14: 115-134.