Meta-Analysis Comparing Transcatheter Aortic Valve Implantation With Balloon Versus Self-Expandable Valves

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Two transcatheter aortic valve systems are currently in use in the United States; balloon-expandable valves (BEV) and the self-expanding valve (SEV). However, comparative data outcomes between the 2 systems are limited, as only one randomized trial (RCT) performed a head-to-head comparison between BEVs and SEVs. However, there are several RCTs comparing BEV or SEV to surgical valve replacement. In this analysis, we used Bayesian network meta-analysis techniques to compare BEVs and SEVs. The primary outcome was all-cause mortality at maximum follow-up. Secondary outcomes were cardiovascular mortality, stroke, pacemaker implantation, reintervention, heart failure hospitalization, and moderate-severe paravalvular leak (PVL.). Eight RCTs with 8,095 patients were included. With the exception of less pacemaker implantation in BEV versus SEV (odds ratio [OR] 0.29, 95% confidence interval [CI] 0.11 to 0.77, $I^2 = 51\%$), there was no difference between BEV and SEV in 30-day outcomes. During long-term follow-up (mean 3 ± 2 years); there was no difference between BEV and SEV in all-cause mortality (hazard ratio [HR] 1.1, 95% CI 0.87 to 1.5, $I^2 = 19.6\%$), cardiovascular mortality (HR 1.1, 95% CI 0.73 to 1.6, $I^2 = 18.5\%$), stroke (HR 1.3, 95% CI 0.73 to 2.1, $I^2 = 16.9\%$), hospitalization (HR 0.87, 95% CI 0.41 to 1.6, $I^2 = 62\%$), and reintervention (HR 0.68, 95% CI 0.2 to 2.3, $I^2 = 62\%$). New pacemaker implantation and PVL were significantly less in BEV group (HR 0.45, 95% CI 0.24 to 0.80, $I^2 = 38.2\%$), and (HR 0.03, 95% CI 0.0004 to 0.28, $I^2 = 79\%$), respectively. In conclusion, similar outcomes were seen following transcatheter aortic valve implantation with BEV and SEV with the exception of higher rates of pacemaker implantation and PVL in SEV group.
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Transcatheter aortic valve implantation (TAVI) has been shown to be at least comparable to surgical aortic valve replacement (SAVR) in patients with aortic stenosis regardless of the surgical risk.[1−3] In 2014, the Comparison of Balloon-Expandable versus Self-expandable Valves in Patients Undergoing Transcatheter Aortic Valve Replacement (CHOICE) randomized clinical trial compared for the first time the self-expanding (SEV) and the balloon expandable (BEV) transcatheter heart valves in patients undergoing TAVI.[4] However, since then no other randomized head-to-head comparison between the BEVs and SEVs has been performed and consequently no high-quality evidence could be synthesized. Hence, in the current study we used the unique properties of Bayesian network meta-analysis to indirectly compare BEV (SAPIEN, SAPIEN XT, and SAPIEN-S3; Edwards, Irvine, CA), with SEV (CoreValve, Evolute-R, and Evolute-PRO; Medtronic, Minneapolis, MN) from randomized clinical trials (RCTs).

Methods

We conducted a literature search of PubMed, EMBASE, and Cochrane library from inception through March 31, 2019. Our search strategy is presented in the online supplement. We utilized the "related articles" function in PubMed to find relevant articles which were missed by the initial search. In addition, reference lists of included studies were hand searched to further locate relevant articles that were missed by keyword searches and the "related articles" function. Our search and network meta-analysis were conducted and reported according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA) Statement 2015.[5] Titles and abstracts of studies retrieved by the initial search were screened by 2 authors (KO and MBM). Consequently, the full texts of the potentially relevant articles were reviewed to determine if the study fulfill the inclusions criteria. Any discrepancies or disagreements were resolved by a third author (MO). We only included randomized controlled trials meeting the following criteria: (1) The trial compared BEV with SEV directly or BEV to SAVR or SEV to SAVR, (2) The trial reported the primary outcome of all-cause mortality at the maximum follow-up, (3) Follow-up duration was at least 12 months. The prespecified primary outcome of interest was all-cause mortality at maximum follow-up. Secondary long-term outcomes included cardiovascular mortality, stroke, new pacemaker

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implantation, reintervention, heart failure hospitalization, and moderate-to-severe paravalvular leak (PVL). Secondary short-term outcomes included 30-day all-cause and cardiovascular mortality, new pacemaker implantation, major vascular complications, major and life-threatening bleeding (defined based on the individual study), stroke, and PVL. We assessed the methodological quality of the studies independently by 2 authors (KO and MBM) using the Cochrane Collaboration tool for assessing the quality of RCTs, the risk of bias graph and summary are shown in the online supplement (eFigure-1). Disagreements were solved by a third author (MO), as recommended by PRISMA.[5] For statistical analysis, we followed a Bayesian framework using the Markov Chain Monte Carlo simulation to derive the posterior distribution of the parameter estimates. Convergence was assessed using the Brooks-Gelman-Rubin method. We utilized random effects model on data presentation and interpretation due to the high heterogeneity. We used vague priors for the analysis and inconsistency between the direct and indirect comparison was investigated using node splitting method. Data were reported as odds ratios (ORs) for the 30-day outcomes and hazard ratios (HR) for the long-term outcomes. Analysis was performed using NetMetaXL version 1.6.1, WinBUGS version 1.4.3 and Gemtc package (version 0.8-2)13 in R, version 3.5.1 (The R Foundation).

Results

The initial database search retrieved 8,356 articles. After excluding duplicates, a total of 4,966 studies were screened for eligibility by reading the title and abstract of the study. A total of 50 studies were then screened using the predetermined inclusions criteria to assess eligibility. Details of the study selection process are reported following the PRISMA guidelines (Figure 1). Eight RCTs with 8,095 patients were included in our network meta-analysis.[4,6−12] Among the total network population 1,976, 2,256, and 3,863 patients were randomized to BEV, SEV, and SAVR, respectively. Among the included trials, 3 compared BEV with SAVR,[7−9] 4 compared SEV with SAVR[6,10−12] and only the CHOICE trial compared BEV with SEV directly.[4] The risk of publication bias was assessed by inspecting the funnel plot (eFigure-2). The network geometry is presented in the online supplement (eFigure-3). The details of the included RCTs and their study design and baseline characteristics and types of valves included are shown in Table 1 and eTable 2.

There was no difference between BEV and SEV in 30-day all-cause mortality (OR 0.85, 95% CI 0.34 to 1.99, $I^2 = 35\%$), cardiovascular mortality (OR 1.3, 95% CI 0.58 to 2.50, $I^2 = 22\%$), stroke (OR 1.59, 95% CI 0.37 to 6.71, $I^2 = 69\%$), bleeding (OR 0.85, 95% CI 0.34 to 1.99, $I^2 = 80\%$), and major vascular complications (OR 1.30, 95% CI 0.58 to 2.50, $I^2 = 72\%$). The need for new pacemaker implantation within 30-days was less in BEV compared with SEV group (OR 0.29, 95% CI 0.11 to 0.77, $I^2 = 51\%$). There was no difference in the rate of 30-day moderate to severe PVL between the BEV and SEV groups, (OR 0.28, 95% CI 0.06 to 1.22, $I^2 = 44\%$) (Figure 2).

There was no difference in long-term outcomes including all-cause mortality (HR 1.1, 95% CI 0.87 to 1.5, $I^2 = 19.6\%$), cardiovascular mortality (HR 1.1, 95% CI 0.73

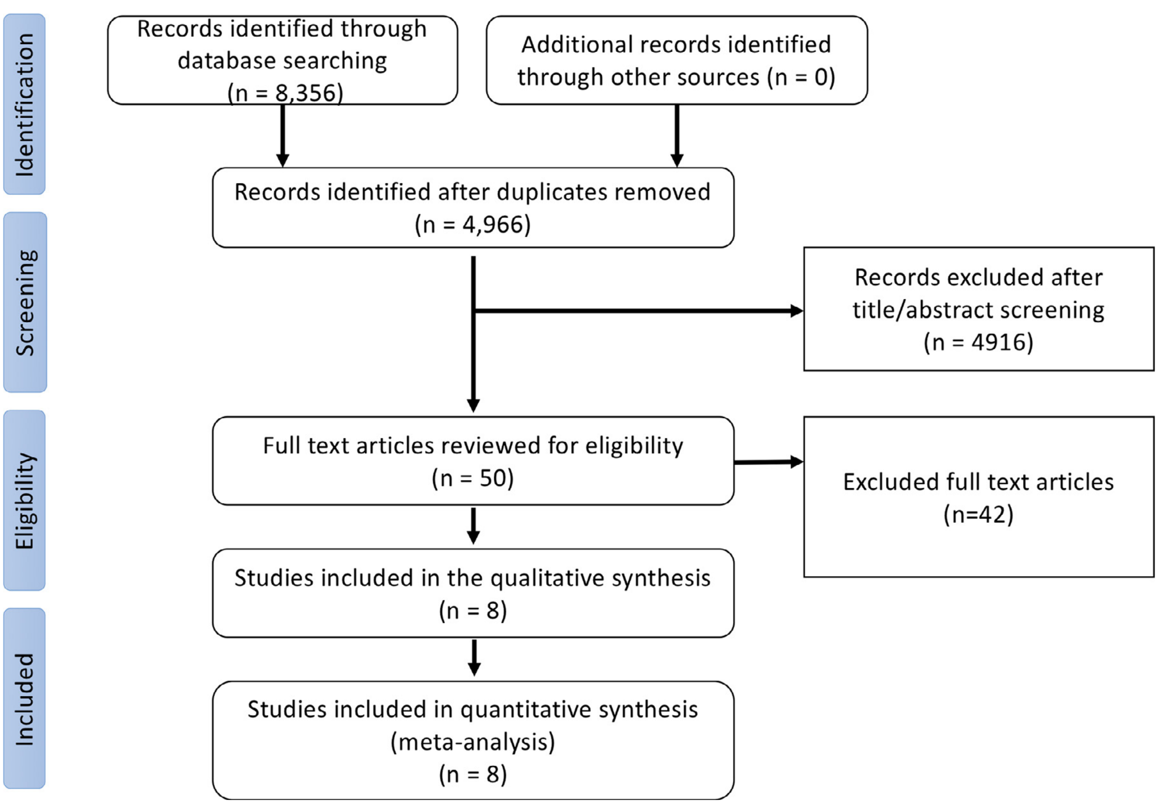

Figure 1. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram.

Table 1
Baseline characteristic of the studies included in the meta-analysis

Study Name	CoreValve US pivotal[6]		Evolut low risk[10]		Notion[12]		PARTNER 1A[8]		PARTNER 2[7]		PARTNER 3[9]		SURTAVI[11]		CHOICE[4]	
Procedure	TAVR (n = 391)	SAVR (n = 359)	TAVR (n = 725)	SAVR (n = 678)	TAVR (n = 145)	SAVR (n = 135)	TAVR (n = 348)	SAVR (n = 351)	TAVR (n = 1011)	SAVR (n = 1021)	TAVR (n = 496)	SAVR (n = 454)	TAVR (n = 864)	SAVR (n = 796)	TAVR BEV (n = 121)	TAVR SEV (n = 120)
Age (Years)	83.1 ± 7.1	83.2 ± 6.4	74.1 ± 5.8	73.6 ± 5.9	79.2 ± 4.9	79.0 ± 4.7	83.6 ± 6.8	84.5 ± 6.4	81.5 ± 6.7	81.7 ± 6.7	73.3 ± 5.8	73.6 ± 6.1	79.9 ± 6.2	79.7 ± 6.1	81 ± 6.7	79 ± 15.8
Female	183 (46.9%)	170 (47.6%)	261 (36.0%)	229 (33.8%)	67 (42.2%)	64 (47.4%)	147 (42.2%)	153 (43.5%)	463 (45.9%)	460 (45.5%)	161 (32.4%)	131 (28.8%)	366 (42.3%)	358 (44.9%)	69 (57%)	86 (71.7%)
STS score	7.3 ± 3.0	7.5 ± 3.4	1.9 ± 0.7	1.9 ± 0.7	2.9 ± 1.6	3.1 ± 1.7	11.8 ± 3.3	11.7 ± 3.5	5.8 ± 2.1	5.8 ± 1.9	1.9± 0.7	1.9 ± 0.6	4.4 ± 1.5	4.5 ± 1.6	5.6 ± 2.9	6.2 ± 3.9
DM	136 (34.9%)	162 (45.4%)	228 (31.4%)	207 (30.5%)	26 (17.9%)	28 (20.7%)	-	-	381 (37.7%)	349 (34.2%)	155 (31.2%)	137 (30.2%)	295 (34.1%)	277 (34.8%)	38 (31.4%)	32 (26.7%)
Hypertension	371 (95.1%)	343 (96.1%)	614 (84.8%)	559 (82.6%)	103 (71.0%)	103 (76.3%)	-	-	-	-	-	-	801 (92.7%)	719 (90.3%)	-	-
Prior Stroke	49 (12.6%)	50 (14.0%)	74 (10.2%)	80 (11.8%)	24 (16.6%)	22 (16.3%)	95 (29.3%)	87 (27.4%)	325 (32.1%)	317 (31.0%)	17 (3.4%)	23 (5.1%)	57 (6.6%)	57 (7.2%)	-	-
Prior MI	99 (25.4%)	9 (25.2%)	48 (6.6%)	33 (4.9%)	8 (5.5%)	6 (4.4%)	92 (26.8%)	103 (30.0%)	185 (18.3%)	179 (17.5%)	28 (5.7%)	26 (5.8%)	125 (14.5%)	111 (13.9%)	14 (11.6%)	16 (13.3%)
PAD	159 (41.1%)	148 (41.7%)	54 (7.5%)	56 (8.3%)	6 (4.1%)	9 (6.7%)	148 (43.0%)	142 (41.6%)	282 (27.9%)	336 (32.9%)	34 (6.9%)	33 (7.3%)	266 (30.8%)	238 (29.9%)	20 (16.5%)	22 (18.3%)
Prior CABG	115 (29.5%)	111 (31.1%)	18 (2.5%)	14 (2.1%)	-	-	147 (42.6%)	152 (44.2%)	239 (23.6%)	261 (25.6%)	-	-	138 (16.0%)	137 (17.2%)	19 (15.7%)	15 (12.5%)
Prior PCI	133 (34.1%)	134 (37.5%)	103 (14.2%)	87 (12.8%)	11 (7.6%)	12 (8.9%)	116 (34.0%)	110 (32.5%)	274 (27.1%)	282 (27.6%)	-	-	184 (21.3%)	169 (21.2%)	44 (36.4%)	51 (42.5%)

Values are mean ± SD, or n (%). Abbreviations: DM = diabetes mellitus; BEV = balloon expandable valve; SEV = self-expanding valve; STS = society of thoracic surgeon risk score; PCI = percutaneous intervention; CABG = coronary artery bypass grafting; TAVR = transcatheter aortic valve replacement; SAVR = surgical aortic valve replacement; MI = myocardial infarction; PAD = peripheral arterial disease.

to 1.6, $I^2 = 18.5\%$), stroke (HR 1.3, 95% CI 0.73 to 2.1, $I^2 = 16.9\%$), hospitalization (HR 0.87, 95% CI 0.41 to 1.6, $I^2 = 62\%$), and reintervention (HR 0.68, 95% CI 0.2 to 2.3, $I^2 = 62\%$) between BEV and SEV. The need for new pacemaker implantation was less in BEV compared with SEV group (HR 0.45, 95% CI 0.24 to 0.80, $I^2 = 38.2\%$). Similarly, moderate-to-severe PVL was significantly less prevalent in BEV compared with SEV (HR 0.03, 95% CI 0.0004 to 0.28, $I^2 = 79\%$) (Figure 3). The results of the long-term outcomes among the different treatment arms included in the current network meta-analysis are shown in the online supplement (eTable 3). Applying node splitting showed consistent results from both the direct and indirect analysis for the BEV versus SEV comparison for all the long-term outcomes (eTable 4).

Discussion

The key findings of current analysis are: (1) there was no difference in hard clinical end-points of all-cause mortality, cardiovascular mortality, stroke, hospitalization and reintervention at 30 days and maximum follow-up between BEV and SEV groups. (2) Although rate of PVL at 30 days was similar between BEV and SEV, in the long-term follow-up PVL was more frequent in the SEV group. (3) High rate of pacemaker implantation was observed in SEV group both in the 30-day and long-term follow-up.

The management of severe AS patients has seen a paradigm shift due to rapidly evolving indications for TAVI. The current literature on post-TAVI outcomes remains imprecise and heterogeneous when assessed based on TAVI valve types. This calls into question the need for large RCTs comparing the safety and efficacy of these valves head-to-head. We tried to address this emerging need by our meta-analysis which showed that BEV is consistently better than SEV in terms of PVL and the need for new permanent pacemaker.

Till to date, the CHOICE trial is the only RCT comparing BEV to SEV head-to-head and to report 1-year of follow-up.[4] At 12 months the rate of PVL was 1.1% in the BEV group and 12.1% in the SEV group (p = 0.005). Interestingly, 20% of the patients in SEV group with mild aortic regurgitation at discharge progressed to a moderate leak at 1 year.[4] Our current analysis confirms these findings, as we observed similar 30-day PVL rates among the 2 groups and high rate of PVL in SEV group in the long run compared with BEV. PVL is the Achilles' heel for TAVI and is a predictor for increased mortality.[13] This could be partially explained by lower radial strength of the nitinol frame of SEV, an increased angulation between the left ventricular outflow tract (LVOT) and the ascending aorta and a deep implantation, characteristic of SEV valve implantation.[14] However, the new generation TAVI valves offer a potentially better performance with the possibility of reduced incidence of PVL due to the improvement in the design.[15]

New pacemaker implantation due to post-TAVI conduction abnormalities is a well-known complication. The 2016 annual report of the Transcatheter Valve Therapy registry reported 12% incidence of post-TAVI pacemaker implantation.[16] Moreover, data from a large registry which compared more than 12,000 patients undergoing TAVI with

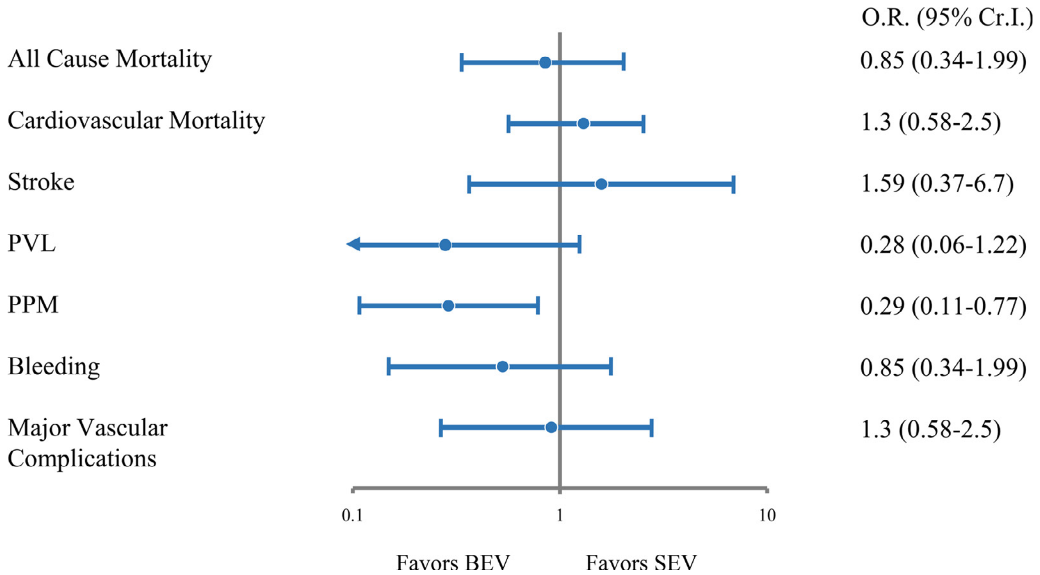

Figure 2. Forest plot comparing 30-day outcomes among BEV and SEV groups.
Abbreviations: BEV = balloon expandable valve; SEV = self-expanding valve; PVL = moderate-to-severe paravalvular leak; PPM = new permanent pacemaker.

either BEV or SEV demonstrated 3-fold low risk of pacemaker implant among BEV group compared with SEV group.[17] The differences between these 2 valves are attributed to difference in stent design, ideal depth of implantation for each valve type and the radial force exerted on the tissue especially in LVOT, all of which have the potential to injure the conduction system.[18,19]

Our meta-analysis has several limitations that need to be acknowledged. First, the trials included different patients with different risk profile which contributed to the heterogeneity among the trials. Second, this was a study level meta-analysis since there was no access to patient level data and consequently there was no possibility for detailed patients level adjustment. Third, only the CHOICE trial compared BEV with SEV directly and all the other trials compared BEV or SEV with SAVR, hence the only direct comparison is coming from one trial, however the Bayesian frame of analysis consider both direct and indirect comparison in pooling the data. Third, the longest follow up to date is only 5 years and consequently no recommendation on the long-term outcomes can be driven from the current analysis.

In the current Bayesian network meta-analysis, there was no difference in all-cause mortality, cardiovascular mortality, stroke, hospitalization, and reintervention at 30 days and maximum follow-up between BEV and SEV groups. Long-term moderate-to-severe PVL and new pacemaker

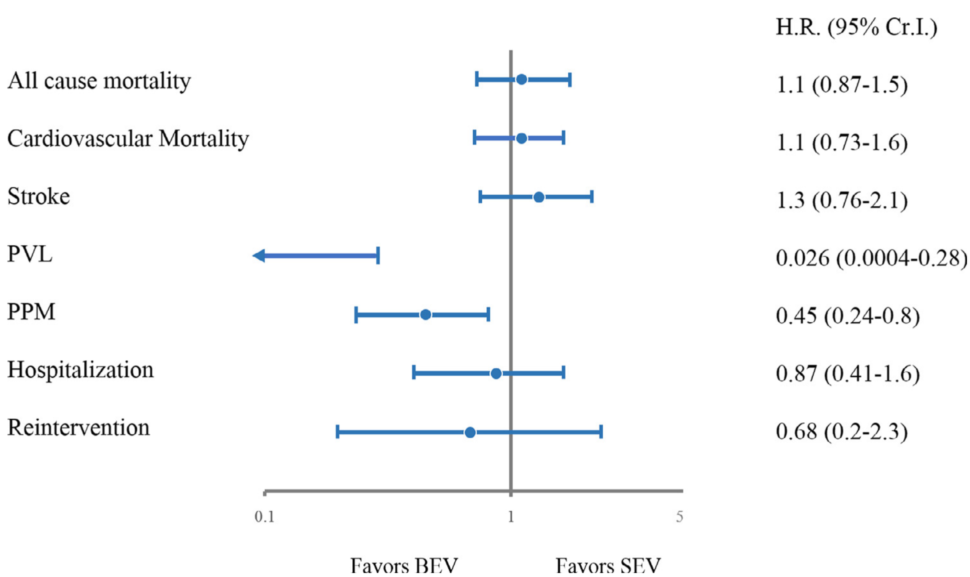

Figure 3. Forest plot comparing long-term outcomes among BEV and SEV groups.
Abbreviations: BEV = balloon expandable valve, SEV = self-expanding valve; PVL = moderate-to-severe paravalvular leak; PPM = new permanent pacemaker.

implantation for conduction abnormalities were more prevalent among the SEV group.

Disclosures

None.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.amjcard.2019.07.028.

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