RESEARCH ARTICLE

Balloon-expandable versus self-expanding transcatheter aortic valve replacement for bioprosthetic dysfunction: A systematic review and meta-analysis

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Abstract

Background

Transcatheter aortic valve-in-valve (VIV) procedure is a safe alternative to conventional reoperation for bioprosthetic dysfunction. Balloon-expandable valve (BEV) and self-expanding valve (SEV) are the 2 major types of devices used. Evidence regarding the comparison of the 2 valves remains scarce.

Methods

A systematic review and meta-analysis was conducted to compare the outcomes of BEV and SEV in transcatheter VIV for aortic bioprostheses dysfunction. A computerized search of Medline, PubMed, Embase, and Cochrane databases was performed. English-language journal articles reporting SEV or BEV outcomes of at least 10 patients were included.

Results

In total, 27 studies were included, with 2,269 and 1,671 patients in the BEV and SEV groups, respectively. Rates of 30-day mortality and stroke did not differ significantly between the 2 groups. However, BEV was associated with significantly lower rates of postprocedural permanent pacemaker implantation (3.8% vs. 12%; $P < 0.001$). Regarding echocardiographic parameters, SEV was associated with larger postprocedural effective orifice area at 30 days (1.53 cm^2 vs. 1.23 cm^2; $P < 0.001$) and 1 year (1.55 cm^2 vs. 1.22 cm^2; $P < 0.001$).

Conclusions

For patients who underwent transcatheter aortic VIV, SEV was associated with larger post-procedural effective orifice area but higher rates of permanent pacemaker implantation. These findings provide valuable information for optimizing device selection for transcatheter aortic VIV.

1. Introduction

The use of bioprosthetic valves in surgical aortic valve replacement (AVR) has increased considerably during the last few decades [1], particularly in middle-aged patients, largely driven by patients' wish of avoiding lifelong anticoagulation. However, bioprosthesis degenerates, requiring reoperation, which remains a relatively high risk. The evolution of transcatheter aortic valve replacement (TAVR) has enabled a safe and feasible alternative, the transcatheter valve-in-valve (VIV) procedure, which is less invasive than conventional redo surgery and has comparable outcomes [2–6]. Considering the possibility of future transcatheter VIV, the trend of increasing use of bioprostheses in surgical AVR is likely to persist, and the need of aortic VIV is expected to grow exponentially in the future.

Balloon-expandable valve (BEV) and self-expanding valve (SEV) are the two major types of transcatheter heart valves (THVs). These two THV types are different in valve height, implantation depth, relative position of the valve and the annulus, radial force, deployment mechanism, and valve geometry and therefore may result in different outcomes and rates of complication, such as postprocedural transvalvular pressure gradient, conduction block, or paravalvular leak (PVL). Currently, there is no randomized study comparing the two types of THVs, and only few observational studies have been published, with the observation that SEV was associated with better postprocedural hemodynamic performance but higher rates of postprocedural permanent pacemaker (PPM) implantation and aortic regurgitation [7, 8]. However, the most recent publication is a single-center study with limited number of patients and thus may not represent the whole population well [7]. Large cohort studies exist but are relatively outdated [8, 9]. Hence, a meta-analysis of the most recent studies is warranted to guide physicians in selecting the optimal device for VIV candidates.

2. Material and methods

We conducted this systematic review and meta-analysis in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. A PRISMA checklist used for this review is provided in the **S1 Table**. The study has been registered on PROSPERO (CRD42018111178).

2.1. Literature search

We performed a computer search of the Medline, PubMed, Embase, and Cochrane databases using the following keywords: "transcatheter", "aortic", "valve", "failed", "failing", "degenerated", "degeneration", "degenerative", "deterioration", and "valve in valve". The detailed search strategy is provided in the **S1 Appendix**. All relevant studies published until April 2020 were identified. Review articles and meta-analyses were screened for additional studies from the cited references. The processes of searching and reviewing were independently performed by 2 evaluators (H.-A. Lee and S.-W. Chen). Discrepancies were discussed to achieve a consensus.

2.2. Study selection

Inclusion criteria were as follows: (1) original article with full-length content available in English, (2) at least 10 patients who underwent aortic VIV procedures for failed surgical aortic bioprosthesis using either Edwards Lifesciences or Medtronic THVs were enrolled, and (3) results of patients who underwent aortic VIV procedures with BEV or SEV were reported. Studies were excluded if they met any of the following conditions: (1) study population overlapped with another study, including subgroup studies of a main study; (2) devices other than Medtronic valves (Medtronic, Minneapolis, MN) and Edwards Lifesciences valves (Edwards Lifesciences, Irvine, CA) were used; and (3) VIV for failed THVs. If studies were suspected of involving an overlapping cohort, only data of the most recent publication were included for analysis.

2.3. Data extraction

Data extracted were characteristics of the enrolled studies and characteristics of patients reported, including baseline information and outcomes. Study-level characteristics included year of publication, study period, location of the study conducted, number of hospitals, and number of patients included. Baseline patient-level information included age, Society of Thoracic Surgery (STS) score, European System for Cardiac Operative Risk Evaluation (Euro-SCORE) II, logistic EuroSCORE, comorbidities, left ventricular ejection fraction, devices used, and characteristics of previous bioprosthesis. Thirty-day and 1-year outcomes were extracted, including death of any cause, cardiovascular death, stroke, coronary artery obstruction, major vascular complications, PPM implantation, major or life-threatening bleeding, acute kidney injury, second valve required, conversion to traditional surgery, and hemodynamics of the implanted valves.

2.4. Quality assessment

The Newcastle–Ottawa Scale (NOS) [10] was used to assess the quality of included studies, with scores ranging from 0 (lowest quality) to 8 (highest quality). Two reviewers (H.-A. Lee and S.-W. Chen) assessed the scores of each study separately; disagreements between the 2 reviewers were discussed until a consensus was achieved.

2.5. Statistical analysis

The estimates of primary and secondary outcomes derived from individual studies for each arm (Medtronic or Edwards Lifesciences valves) were pooled using the random-effects model. In contrast to the fixed-effects model, a random-effects model enables the true underlying effect to vary among individual studies. I^2 values >25%, >50%, and >75% were considered to represent low, moderate, and high heterogeneity across the studies, respectively [11]. The pooled estimates between the BEV and SEV were compared using the mixed-effects model. In a further subgroup analysis, we compared outcomes between the Evolut R (Medtronic) and Sapien 3 (Edwards Lifesciences) valves. Statistical significance was set at $P < 0.05$ with a two-tailed test. Data were analyzed using the software Comprehensive Meta-Analysis (version 3.3; Biostat, Inc., Englewood, NJ, USA).

3. Results

3.1. Literature search

The literature screened, excluded, reviewed, and included for analysis is illustrated in **Fig 1**. Of the 398 articles yielded by computer search, 293 were excluded after titles and abstracts were
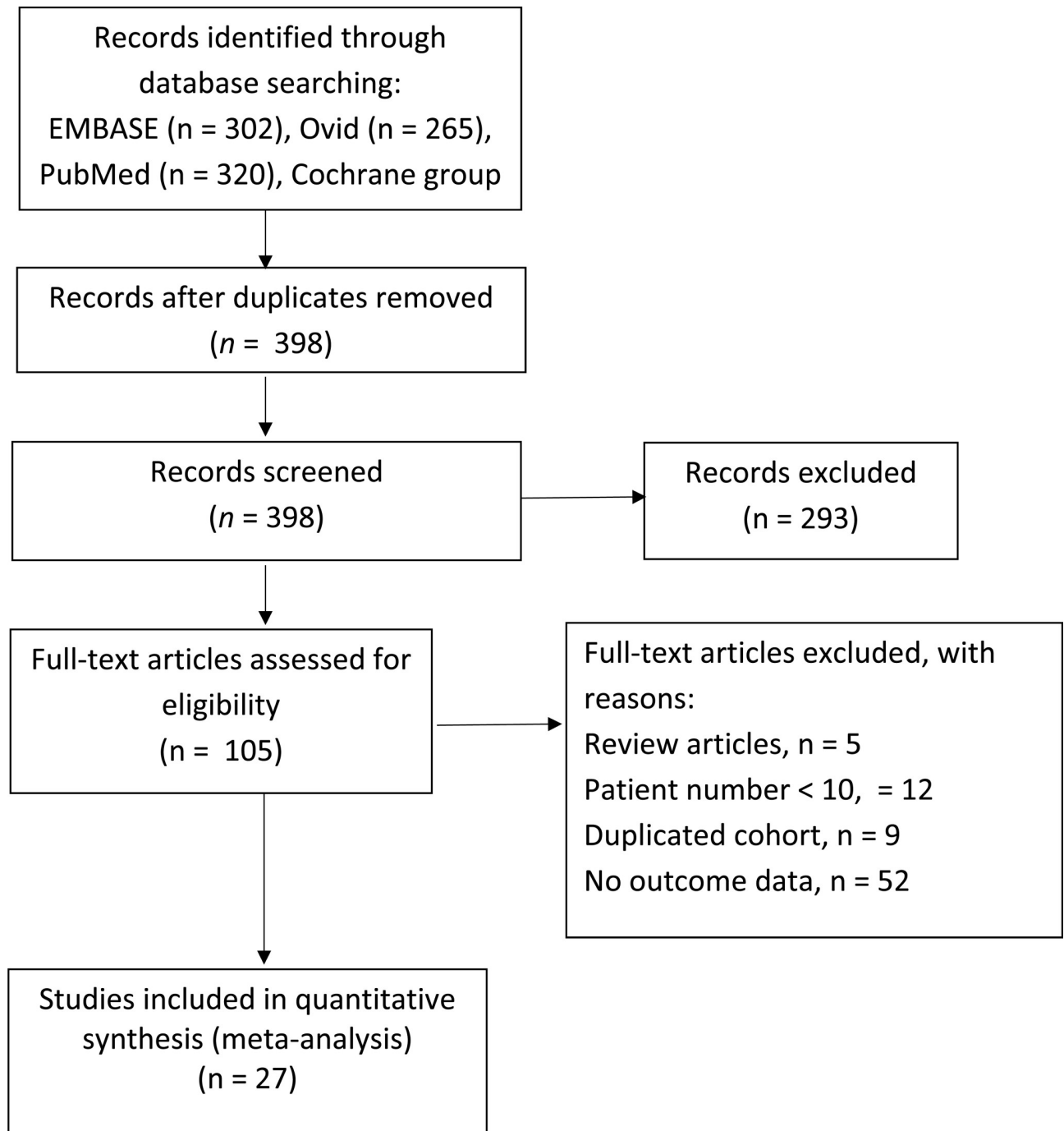
Fig 1. Flow diagram depicting study selection process.

screened. Full texts of 105 articles were reviewed to evaluate eligibility; of them, 5 were excluded because they were meta-analysis or review articles, 12 because their case numbers were <10, 9 because they included duplicated cohorts, and 52 because they did not report outcomes of patients who underwent VIV with BEV or SEV. Hence, 27 studies were included for the final quantitative meta-analysis [7, 8, 12–36]. All 27 studies were observational. Five of the

Table 1. Study data.

First author	Year	Valve types	Study type	Locations/country	No. of centers	study period	Patient number
Woitek [34]	2020	BEV, SEV	Single center	Germany	1	2006–2017	146
Ribeiro [36]	2018	BEV, SEV	Multi-center	Global	135	2007–2014	1324
Ochiai [7]	2018	BEV, SEV	Single center	California, USA	1	2012–2017	74
Dvir [8]	2014	BEV, SEV	Multi-center	Global	55	2007–2013	459
Ihlberg [22]	2013	BEV, SEV	Multi-center	Nordic	11	2008–2012	45
Stankowski [29]	2020	SEV	Single center	Germany	1	2003–2018	68
Pascual [33]	2019	SEV	Single center	Spain	1	2012–2017	45
Schwerg [13]	2018	SEV	Single center	Germany	1	2013–2017	26
Scholtz [14]	2018	SEV	Single center	Germany	1	2009–2016	37
Sang [31]	2018	SEV	Single center	Michigan, USA	1	2014–1016	22
Deeb [17]	2017	SEV	Multi-center	USA	NA	2013–2015	227
Chhatriwalla [18]	2017	SEV	Single center	Michigan, USA	9	NA	12
Duncan [20]	2015	SEV	Single center	UK	1	2009–2014	22
Ong [23]	2012	SEV	Multi-center	Germany	3	NA	18
Linke [24]	2012	SEV	Single center	Germany	1	NA	27
Bedogni [27]	2011	SEV	Multi-center	Italy	8	NA	25
Murdoch [30]	2020	BEV	Multi-center	Global	46	2012–2015	339
Stankowski [32]	2019	BEV	Single center	Germany	1	2010–2018	27
Seiffert [12]	2018	BEV	Multi-center	Global	NA	NA	514
Webb [15]	2017	BEV	Multi-center	Worldwide	34	2012–2014	365
Nielsen-Kudsk [16]	2017	BEV	Single center	Denmark	1	2015–2017	10
Ye [19]	2015	BEV	Single center	Canada	1	2007–2013	42
Bapat [21]	2014	BEV	Single center	UK	1	2010–2014	10
Seiffert [35]	2012	BEV	Single center	Germany	1	2008–2011	11
Bapat [25]	2012	BEV	Single center	UK	1	2009–2011	23
Pasic [26]	2011	BEV	Single center	Germany	1	NA	14
Kempfert [28]	2010	BEV	Single center	Germany	1	2007–2009	11

Basic information of studies included in the meta-analysis.

BEV, balloon-expandable valve; SEV, self-expanding valve

studies reported outcomes of both BEV and SEV, while the other 22 studies enrolled only 1 of the 2 types of THV. Basic information of the 27 studies is shown in **Table 1**. Three studies derived from Valve-In-Valve International Database were included because each of them has data that was not reported in the other articles. For items that were reported by more than 1 of the studies, only those reported by the latest publication were included in our analysis. Quality assessment was performed using the NOS, with scores of the 27 studies ranging 5–9 points (**S2 Table**).

3.2. Baseline and procedural characteristics

Table 2 shows the pooled baseline and procedural characteristics of all patients in the 27 included studies. A total of 2,269 and 1,671 patients in the BEV and SEV groups were included. Mean age (78.0 ± 1.6 years in BEV vs. 75.6 ± 10.0 years in SEV), STS score (9.0 ± 2.5 in BEV vs. 9.2 ± 2.2 in SEV), left ventricular ejection fraction (50.0 ± 2.7% in BEV vs. 51.1 ± 3.0% in SEV), and other baseline echocardiographic parameters appeared to be similar between the 2 groups. The proportion of small degenerated surgical bioprostheses (≤21mm) appeared slightly lower in BEV (25.6%) than in SEV (30.7%) groups; however, the proportion of small

Table 2. Baseline and procedural characteristics of patients (number of included studies = 27).

Variable	BEV (Edwards)		SEV (Medtronic)	
	Available data, n	Weighted % or mean ± SD	Available data, n	Weighted % or mean ± SD
Age (year)	1087	78.0 ± 1.6	788	75.6 ± 10.0
Male (%)	1097	63.3%	751	55.3%
Log EuroSCORE	730	21.7 ± 9.9	586	26.2 ± 3.4
EuroSCORE II	53	19.6 ± 5.7	188	11.3 ± 2.9
STS score	1087	9.0 ± 2.5	678	9.2 ± 2.2
CAD (%)	491	65.2%	431	61.7%
Prior stroke (%)	1065	13.7%	666	11.7%
Prior Afib (%)	392	46.2%	467	42.0%
Prior PPM (%)	943	17.2%	377	22.5%
PAD (%)	1050	23.7%	674	22.7%
CKD (%)	1009	37.4%	674	34.3%
AR ≥moderate (%)	648	43.4%	509	54.0%
Bioprosthesis age (year)	732	10.5 ± 1.6	657	9.9 ± 1.3
Stented valve (%)	1078	84.2%	867	75.1%
Stentless valve (%)	809	13.6%	867	19.6%
Bioprosthesis size (%)	1097		746	
≤21 mm		25.6%		30.7%
21–24.9 mm		40.4%		37.9%
≥25 mm		31.4%		28.9%
Unknown		2.3%		3.2%
Mode of failure (%)				
AS	1126	45.8%	632	53.2%
AR	1126	28.0%	620	27.3%
Mix	1116	26.6%	583	21.8%
LVEF (%)	829	50.0 ± 2.7	527	51.1 ± 3.0
AV area (cm^2)	699	0.90 ± 0.08	671	0.95 ± 0.09
AVA index (cm^2/m^2)	900	0.53 ± 0.06	213	0.55
Max PG (mmHg)	341	62.6 ± 8.5	423	61.0 ± 9.2
Mean PG (mmHg)	1022	34.6 ± 3.8	754	36.0 ± 4.4
Fluoroscopic time (min)	436	18.3 ± 3.4	92	19.6 ± 9.8
THV size ≤23 mm (%)	1299	67.5%	490	26.9%
TF access (%)	1076	68.5%	561	95.0%

Abbreviations: Afib, atrial fibrillation; AR, aortic regurgitation; AS, aortic stenosis; AV, aortic valve; AVA, aortic valve area; CAD, coronary artery disease; CKD, chronic kidney disease; LVEF, left ventricular ejection fraction; PAD, peripheral artery disease; PG, pressure gradient; PPM, permanent pacemaker; PVL, paravalvular leak; STS, Society of Thoracic Surgery; TF, transfemoral; THV, transcatheter heart valve.

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THVs (≤23 mm) used was much higher in the BEV group (67.5%) than in the SEV group (26.9%). Transfemoral access was more frequently used in the SEV group (95%) than in the BEV group (61.3%).

3.3. Clinical and echocardiographic outcomes

The event rates of all-cause mortality, cardiovascular death, and stroke at 30 days did not differ significantly between the BEV and SEV groups (Fig 2A). However, BEV was associated with significantly lower rates of major vascular complications (4.7% vs. 8.7%; P = 0.012), PPM implantation (3.8% vs. 12%; P < 0.001), and second valve requirement (2.9% vs. 6.2%;

A. 30-day clinical outcomes	No. of study		Event/Total	Percentage (95% CI)	I^2(%)	P
Any-cause death						0.117
BEV	12		19/727	3.6 (2.4, 5.4)	0.0	
SEV	14		33/788	5.5 (4.0, 7.5)	0.0	
Cardiovascular death						0.789
BEV	7		28/683	4.5 (2.6, 7.9)	29.3	
SEV	6		19/551	4.1 (2.7, 6.3)	0.0	
Stroke						0.907
BEV	8		14/497	3.3 (2.0, 5.4)	0.0	
SEV	9		11/492	3.5 (1.9, 6.2)	9.4	
Coronary artery obstruction						0.526
BEV	7		18/1048	4.6 (3.2, 6.6)	0.0	
SEV	9		22/986	8.2 (6.3, 10.7)	0.0	
Major vascular complication						0.012
BEV	6		27/662	4.7 (3.2, 6.7)	0.0	
SEV	8		48/639	8.7 (6.6, 11.3)	0.0	
Permanent pacemaker implantation						<0.001
BEV	11		25/818	3.8 (2.6, 5.5)	0.0	
SEV	14		86/788	12.0 (8.4, 16.9)	55.7	
Major or life-threatening bleeding						0.878
BEV	5		84/615	5.9 (1.7, 18.4)	85.9	
SEV	6		58/539	6.6 (2.4, 16.7)	81.5	
Acute kidney injury						0.072
BEV	2		29/402	7.2 (5.1, 10.2)	0.0	
SEV	2		10/264	3.8 (2.1, 6.9)	0.0	
Acute kidney injury stage 2 or 3						0.329
BEV	3		32/536	4.1 (0.6, 21.9)	5.6	
SEV	1		9/213	7.4 (1.9, 25.2)	0.0	
Device unsuccess						0.346
BEV	2		2/60	3.3 (12.4, 0.8)	0.0	
SEV	6		19/355	6.6 (10.0, 4.3)	0.0	
Second valve required						0.004
BEV	8		21/885	2.9 (1.9, 4.4)	0.0	
SEV	9		34/598	6.2 (4.5, 8.6)	0.0	
Conversion to traditional surgery						0.347
BEV	4		5/467	1.6 (0.6, 4.1)	16.7	
SEV	5		1/103	3.2 (1.0, 9.6)	0.0	

Percentage (95% CI)
0   10   20   30

B. 1-year clinical outcomes	No. of study		Event/Total	Percentage (95% CI)	I^2(%)	P
Any-cause death						0.505
BEV	4		90/649	15.6 (11.1, 21.5)	52.0	
SEV	5		60/502	13.3 (9.3, 18.6)	35.6	
Stroke						0.937
BEV	2		16/392	4.3 (2.6, 6.8)	0.0	
SEV	2		7/245	4.6 (0.9, 20.2)	73.9	

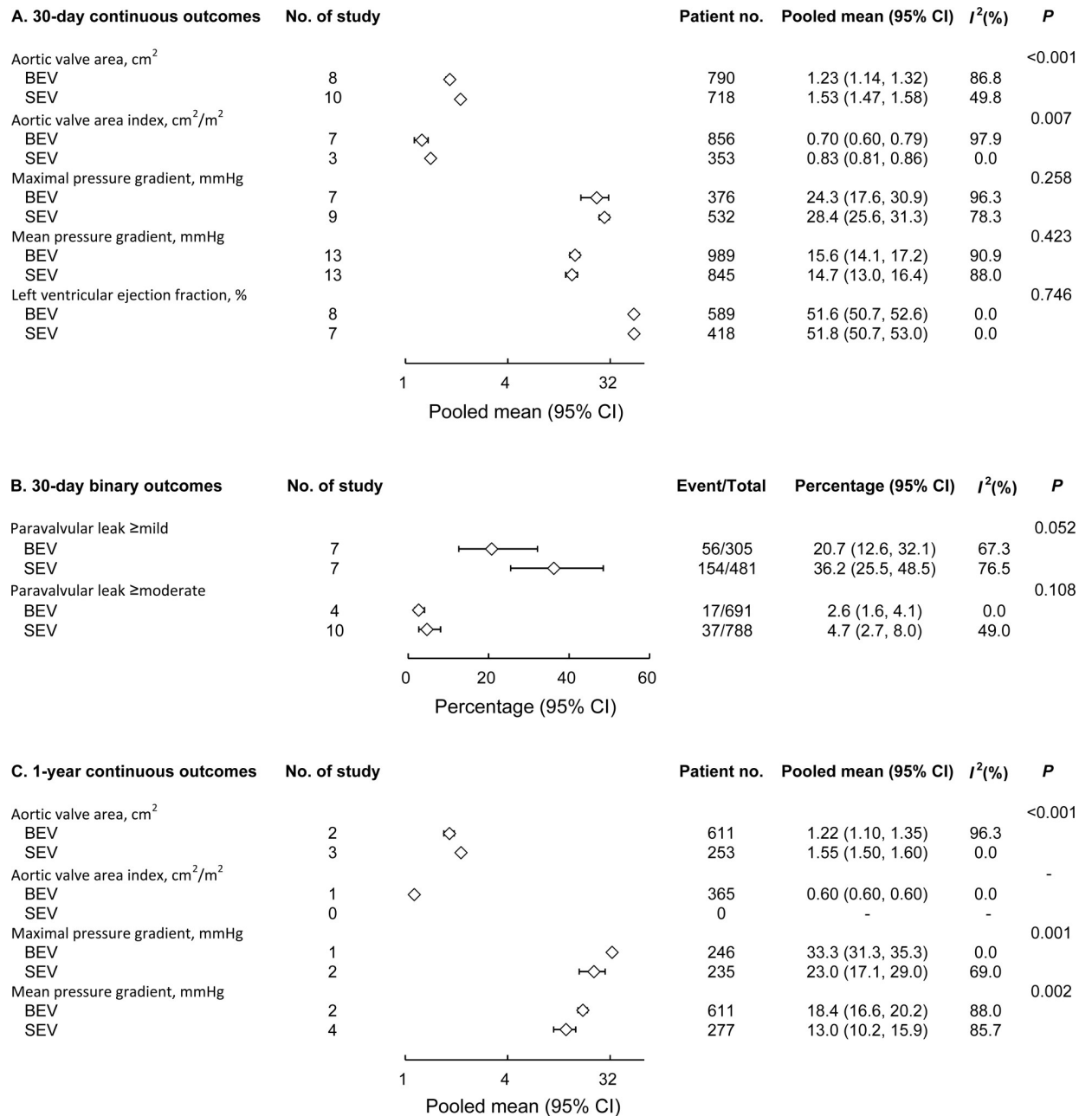Percentage (95% CI)
0   10   20   30

Fig 2. Forest plot comparing 30-day (A) and 1-year (B) clinical outcomes between BEV and SEV. BEV = balloon-expandable valve; SEV = self-expanding valve.

P = 0.004). One-year all-cause mortality and stroke rates were similar between the 2 groups (**Fig 2B**).

Regarding echocardiographic outcomes, SEV was associated with better hemodynamic performance than BEV, with significantly larger postoperative effective orifice area (EOA) at 30 days (1.53 cm² vs. 1.23 cm²; $P < 0.001$) and 1 year (1.55 cm² vs. 1.22 cm²; $P < 0.001$; **Fig 3A and 3C**) and lower maximal and mean pressure gradients at 1 year (respectively, 23.0 mm Hg vs. 33.3 mm Hg, $P = 0.001$; and 13 mm Hg vs. 18.4 mm Hg, $P = 0.002$; **Fig 3C**).

A. 30-day continuous outcomes

	No. of study	Patient no.	Pooled mean (95% CI)	I^2(%)	P
Aortic valve area, cm^2					<0.001
BEV	8	790	1.23 (1.14, 1.32)	86.8	
SEV	10	718	1.53 (1.47, 1.58)	49.8	
Aortic valve area index, cm^2/m^2					0.007
BEV	7	856	0.70 (0.60, 0.79)	97.9	
SEV	3	353	0.83 (0.81, 0.86)	0.0	
Maximal pressure gradient, mmHg					0.258
BEV	7	376	24.3 (17.6, 30.9)	96.3	
SEV	9	532	28.4 (25.6, 31.3)	78.3	
Mean pressure gradient, mmHg					0.423
BEV	13	989	15.6 (14.1, 17.2)	90.9	
SEV	13	845	14.7 (13.0, 16.4)	88.0	
Left ventricular ejection fraction, %					0.746
BEV	8	589	51.6 (50.7, 52.6)	0.0	
SEV	7	418	51.8 (50.7, 53.0)	0.0	

Pooled mean (95% CI)

B. 30-day binary outcomes

	No. of study	Event/Total	Percentage (95% CI)	I^2(%)	P
Paravalvular leak ≥mild					0.052
BEV	7	56/305	20.7 (12.6, 32.1)	67.3	
SEV	7	154/481	36.2 (25.5, 48.5)	76.5	
Paravalvular leak ≥moderate					0.108
BEV	4	17/691	2.6 (1.6, 4.1)	0.0	
SEV	10	37/788	4.7 (2.7, 8.0)	49.0	

Percentage (95% CI)

C. 1-year continuous outcomes

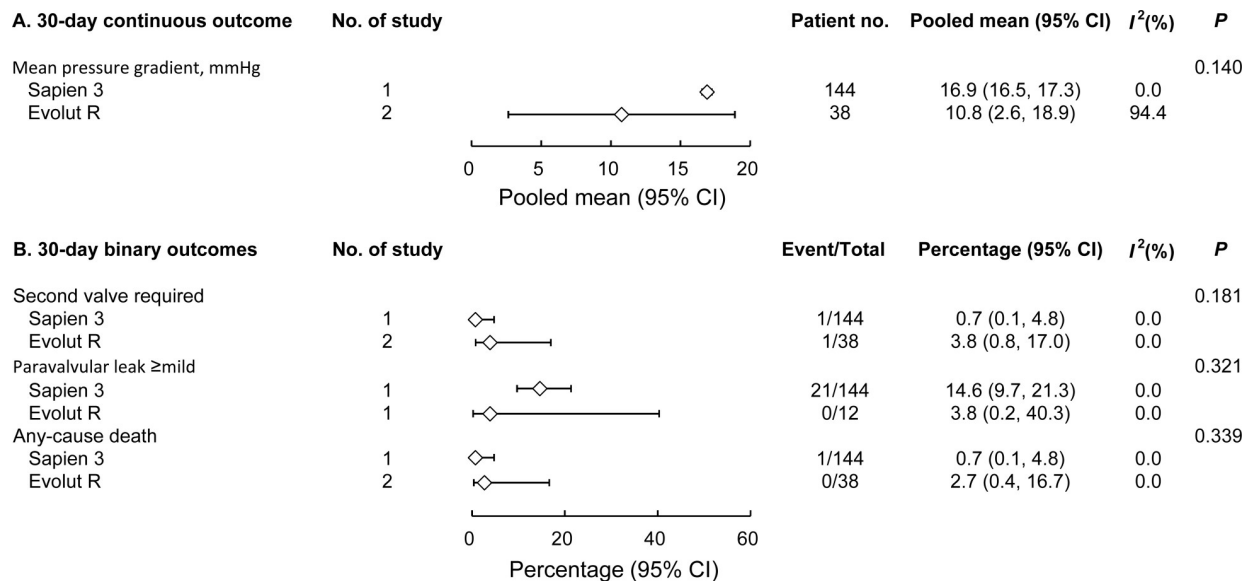|	No. of study	Patient no.	Pooled mean (95% CI)	I^2(%)	P
Aortic valve area, cm^2					<0.001
BEV	2	611	1.22 (1.10, 1.35)	96.3	
SEV	3	253	1.55 (1.50, 1.60)	0.0	
Aortic valve area index, cm^2/m^2					-
BEV	1	365	0.60 (0.60, 0.60)	0.0	
SEV	0	0	-	-	
Maximal pressure gradient, mmHg					0.001
BEV	1	246	33.3 (31.3, 35.3)	0.0	
SEV	2	235	23.0 (17.1, 29.0)	69.0	
Mean pressure gradient, mmHg					0.002
BEV	2	611	18.4 (16.6, 20.2)	88.0	
SEV	4	277	13.0 (10.2, 15.9)	85.7	

Pooled mean (95% CI)

Fig 3. Forest plot comparing echocardiographic outcomes between BEV and SEV. Thirty-day continuous outcomes (A), 30-day binary outcomes (B), and 1-year continuous outcomes (C) of BEV and SEV were compared.

3.4. Subgroup analysis for newer devices

We also compared the outcomes with the Sapien 3 (Edwards Lifesciences) and Evolut R (Medtronic) valves. These are the newest generation of the 2 types of THVs with published data available for analyses. Although no statistical significance was found, Evolut R seemed to be associated with a lower mean pressure gradient than Sapien 3 (**Fig 4**).

A. 30-day continuous outcome

	No. of study		Patient no.	Pooled mean (95% CI)	I^2(%)	P
Mean pressure gradient, mmHg						0.140
Sapien 3	1		144	16.9 (16.5, 17.3)	0.0	
Evolut R	2		38	10.8 (2.6, 18.9)	94.4	

B. 30-day binary outcomes

	No. of study		Event/Total	Percentage (95% CI)	I^2(%)	P
Second valve required						0.181
Sapien 3	1		1/144	0.7 (0.1, 4.8)	0.0	
Evolut R	2		1/38	3.8 (0.8, 17.0)	0.0	
Paravalvular leak ≥mild						0.321
Sapien 3	1		21/144	14.6 (9.7, 21.3)	0.0	
Evolut R	1		0/12	3.8 (0.2, 40.3)	0.0	
Any-cause death						0.339
Sapien 3	1		1/144	0.7 (0.1, 4.8)	0.0	
Evolut R	2		0/38	2.7 (0.4, 16.7)	0.0	

Fig 4. Subgroup analysis comparing 30-day outcomes of Sapien 3 and Evolut R valves for 30-day continuous outcomes (A) and 30-day binary outcomes (B).

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4. Discussion

4.1. Major findings

With nearly 4000 patients included, the present meta-analysis is the largest sample used for comparing BEV and SEV outcomes in patients with failed aortic valve bioprostheses thus far. Our major findings were as follows: (1) all-cause mortality and cardiovascular death did not differ significantly between the 2 groups; (2) BEV was associated with lower rates of new PPM implantation and major vascular complications; and (3) SEV was associated with larger post-procedural EOA than BEV, both at 30 days and at 1 year.

4.2. New PPM implantation

SEV use is an independent risk factor for PPM implantation in the overall TAVR population [37–39]. However, previous aortic valve procedures, including surgical AVR, seemed to be protective against post-TAVR PPM implantation [37, 39], possibly because the previously implanted bioprosthesis restricted the expansion of the THV. In the present meta-analysis, the pooled PPM implantation rate after SEV implantation was 10.7%, which is nearly 3-fold that in the BEV group (3.6%; $P < 0.001$). In other words, even under the potential protection of the old bioprosthesis, SEV is still associated with significantly higher risk of postprocedural PPM implantation. This finding is consistent with previous studies focusing on aortic VIV procedure [8, 9].

4.3. EOA

A major concern of the aortic VIV procedure is the relatively small postprocedural aortic valve area and high transvalvular pressure gradient, mainly resulting from restricted expansion of the THVs by the old valves. Several publications, including studies using an *in vitro* model [40, 41], large cohort studies [8, 9], and propensity-matched analysis [7], reported that SEV was associated with larger postprocedural aortic valve area and lower transvalvular gradient than

BEV after aortic VIV procedures. The current meta-analysis further supported these findings in the largest sample size to date.

In the SEV we analyzed, the functioning part is positioned above the aortic annulus (i.e., the "supra-annular design," which is thought to lessen the detrimental impact on postprocedural EOA by the old valve). The theory was supported by a study using *in vitro* model in which researchers found that when the CoreValve was positioned deeper than normal, the leaflets were more constrained, and EOA decreased; and when the SAPIEN was placed more supra-annularly, the leaflets expanded more completely, and postprocedural EOA became larger [41].

One may argue that the higher percentage of small THVs (≤23mm) used in the BEV group alone can explain the smaller postprocedural EOA in BEV. However, the proportions of small degenerated surgical bioprostheses (≤21mm) were similar between the 2 groups (**Table 2**), so why were small THVs more often used in the BEV group? We believe that the supra-annular design of Medtronic SEV allows a relatively larger size, while the intra-annular design of Edward BEV results in marked leaflet distortion if the size is too large [41]. According to the ViV Aortic app, for 19 or 21mm degenerated bioprostheses, a 23mm Medtronic THV, or a 20mm Edward THV is suggested. A study using the Valve-in-Valve International Data Registry also found that elevated postprocedural pressure gradient were more common after BEV--VIV implantation than after SEV-VIV; for small surgical valves (internal diameter < 20mm) and intermediate-sized valves (internal diameter ≥20mm and <23mm) [8].

Insufficient EOA and elevated transvalvular pressure gradient not only diminish patients' physical activity and quality of life but also predict early structural valve degeneration in bioprosthetic heart valves [42]. In addition, incomplete THV expansion itself leads to localized high stress within the leaflets, which may accelerate valve degeneration [43].

4.4. SEV versus BEV

According to the present meta-analysis, SEV was associated with significantly better postprocedural EOA, which can reduce the risk of patient–prosthesis mismatch and improve quality of life, particularly in patients with larger body size or whose old bioprosthesis is small. Lower transvalvular gradient and better THV expansion may also lead to superior durability of the THV, which is important in patients with life expectancy of 20 years or longer. Nevertheless, higher EOA and lower gradient of SEV did not translate in to lower mortality. Moreover, SEV was associated with higher rates of postprocedural PPM implantation, which is detrimental to late outcome [37, 44].

Therefore, CoreValve may be beneficial in patients whose previous surgical valve is small and those at high risk of patient–prosthesis mismatch. However, Edwards valves may be preferred to Medtronic valves for patients with adequate surgical valve size, particularly those who are prone to encounter postprocedural PPM implantation or PVL, including patients who are older [37] and those who have prior conduction disturbances [38] or a prolonged PR interval [45]. For every transcatheter aortic VIV candidate, particularly younger patients, the valve selection decision should be made carefully after thorough consideration of device characteristics and patient condition and preference, as well as detailed explanation and discussion.

4.5. Study limitations

The study has several limitations. First, this meta-analysis was based on published articles; therefore, data quality and availability are limited. Second, owing to a lack of randomized controlled trials in this area, all studies included were observational, so our results can only be

interpreted as "associations," rather than as "causations." However, the absence of randomized studies warrants the present meta-analysis to help in optimizing device selection. Third, THV devices continue advancing rapidly, so the outcomes of the present study may differ from those of the newest device.

5. Conclusion

The present systematic review and meta-analysis found that for patients who underwent transcatheter aortic VIV, SEV was associated with significantly larger postprocedural EOA but higher rates of PPM implantation and PVL of moderate or higher degree. These findings provide valuable information in guiding proper management for patients with degenerated aortic bioprostheses.

Supporting information

S1 Appendix. Detailed search strategy.
(DOCX)

S1 Table. Prisma 2009 checklist.
(DOC)

S2 Table. Newcastle-Ottawa Scale quality assessment of included studies.
(DOCX)

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