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Original Research

Transcatheter Aortic Valve Replacement in Patients With Small Aortic Annulus: An Observational Study

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ABSTRACT

Background: The Small Annuli Randomized to Evolut or SAPIEN Trial showed superior hemodynamics of self-expanding valves (SEVs) over balloon-expandable valves (BEVs) in patients with small aortic annuli (SAA). The long-term clinical implications of these hemodynamic differences are unknown.

Methods: We conducted an observational cohort study of patients with SAA, defined as an aortic valve annular area ≤430 mm^2 on cardiac computed tomography, who underwent transcatheter aortic valve replacement using BEV or SEV at a single institution between August 2013 and February 2021. Patients undergoing valve-in-valve procedures or alternative access were excluded. Patient-prosthesis mismatch (PPM) was defined as moderate when indexed effective orifice area of 0.65-0.85 cm^2/m^2 and severe when indexed effective orifice area was <0.65 cm^2/m^2 (or <0.55 cm^2/m^2 for body mass index >30 kg/m^2). The primary outcome of the study was mortality and major adverse cardiovascular events.

Results: A total of 258 patients were included. The majority were female (81%) with intermediate surgical risk (median STS risk score 4.23); 90 patients (35%) received a BEV (median age 80 years [73, 86]) and 168 (65%) received a SEV (81 years [75, 85], $p = 0.699$). Comorbidities and risk profiles were well balanced between groups. At 30 days post-transcatheter aortic valve replacement, SEV had lower aortic valve mean gradients (8 mmHg [6, 11] vs. BEV 14 mmHg [10, 18], $p < 0.001$), lower peak velocities (1.86 m/s [1.60, 2.34] vs. BEV 2.52 m/s [2.14, 2.90], $p < 0.001$), and were less likely to have PPM (SEV 18% vs. BEV 42% ($p < 0.001$). At 3 years, both groups had similar mortality (SEV 23% vs. BEV 22%, $p = 0.875$). PPM was not associated with long-term mortality.

Conclusions: In patients with SAA, we observed no difference in mortality between SEV and BEV up to 3 years after the index procedure, despite early differences in valve hemodynamics.

ABBREVIATIONS

AV, aortic valve; BEV, balloon-expandable valve; MACE, major adverse cardiovascular events; PPM, patient-prosthesis mismatch; SAA, small aortic annuli; SEV, self-expanding valve; SMART, Small Annuli Randomized to Evolut or SAPIEN Trial; STS, Society of Thoracic Surgeons; TAVR, transcatheter aortic valve replacement; THV, transcatheter heart valve.

Introduction

Patient-prosthesis mismatch (PPM) is associated with worse clinical outcomes after surgical aortic valve (AV) replacement.[1–3] Although transcatheter heart valves (THVs) do not have a sewing ring and can generally achieve larger effective orifice areas (EOAs) than surgical valves, there are anatomical subsets that are at risk of PPM, including small aortic annulus, valve-in-valve procedures, and patients with a large body surface area.[4–6]

PPM affects one in three patients undergoing commercial transcatheter aortic valve replacement (TAVR) in the United States, with most cases being of moderate severity.[4] There is conflicting information

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Table 1
Baseline characteristics of the study cohort

Variable	Overall (N = 258)	Balloon-expandable valve (N = 90)	Self-expanding valve (N = 168)	*p* value
Sex–female, n (%)	210 (81)	65 (72)	145 (86)	**0.006**
Age, median (IQR)	80.8 (74.8, 86.2)	80.0 (73.6, 86.5)	81.0 (75.5, 85.8)	0.699
Caucasian race, n (%)	242 (94)	85 (94)	157 (93)	0.753
Atrial fibrillation, n (%)	111 (43)	32 (36)	79 (47)	0.076
Prior stroke, n (%)	29 (11)	13 (14)	16 (10)	0.233
Chronic lung disease, n (%)	106 (41)	34 (38)	72 (43)	0.429
Diabetes, n (%)	93 (36)	35 (39)	58 (35)	0.486
Prior endocarditis, n (%)	5 (2)	1 (1)	4 (2)	0.661
Heart failure, n (%) Within 2 weeks of procedure	233 (90)	81 (90)	152 (90)	0.902
Hostile chest, n (%)	18 (7)	3 (3)	15 (9)	0.124
Hypertension, n (%)	222 (86)	78 (87)	144 (86)	0.833
Prior MI, n (%)	94 (36)	33 (37)	61 (36)	0.955
Peripheral artery disease, n (%)	90 (35)	30 (33)	60 (36)	0.702
Porcelain aorta, n (%)	8 (3)	2 (2)	6 (4)	0.717
Prior TIA, n (%)	32 (12)	13 (14)	19 (11)	0.467
Home oxygen, n (%)	24 (9)	5 (6)	19 (11)	0.129
Dialysis, n (%)	11 (4)	6 (7)	5 (3)	0.162
Tobacco use, n (%)	22 (9)	8 (9)	14 (8)	0.879
Prior CABG, n (%)	55 (21)	25 (28)	30 (18)	0.064
Prior ICD, n (%)	17 (7)	3 (3)	14 (8)	0.187
Mitral valve procedure, n (%)	12 (5)	2 (2)	10 (6)	0.224
Prior PCI, n (%)	91 (35)	36 (40)	55 (33)	0.245
Prior PPM, n (%)	34 (13)	12 (13)	22 (13)	0.957
Pre-NYHA class, n (%)				0.185
I	1 (0)	0 (0)	1 (1)	
II	51 (20)	17 (19)	34 (20)	
III	152 (59)	60 (67)	92 (55)	
IV	53 (21)	13 (14)	40 (24)	
Cardiogenic shock, n (%)	12 (5)	2 (2)	10 (6)	0.225
STS risk score, median (IQR)	4.23 (2.57, 6.19)	4.46 (2.55, 6.53)	4.20 (2.61, 5.97)	0.620

Abbreviations: CABG, coronary artery bypass graft; ICD, implantable cardioverter defribrillator; IQR, interquartile range; MI, myocardial infarction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; PPM, patient-prosthesis mismatch; STS, Society of Thoracic Surgeons; TIA, transient ischemic attack.

regarding the prognosis of PPM after TAVR.[4,7] In the Society of Thoracic Surgeons (STS)/American College of Cardiology Transcatheter Valve Therapy (TVT) registry, severe PPM was associated with an increased risk of death and heart failure rehospitalization at 1-year.[4] In a subsequent analysis by Tang et al.[7] focusing on supra-annular THV devices, PPM was significantly less common (5.3%) and not associated with worse clinical outcomes. To better understand the role of THV design (self-expanding and supra-annular vs. balloon expandable and intra-annular) on PPM after TAVR and its clinical implications, we conducted an observational study comparing both platforms in patients with small aortic annulus.

Methods

We conducted an observational cohort study of consecutive patients with small aortic annulus, defined as an AV annular area $\leq$430 mm^2 on cardiac computed tomography, who underwent TAVR using commercially available THV at a single institution (The Christ Hospital, Cincinnati, OH) between August 2013 and February 2021. Patients undergoing valve-in-valve procedures or alternative access were excluded.

We compared the Edwards SAPIEN 3/Ultra balloon-expandable valve (BEV group) vs. the Medtronic Evolut R/PRO self-expanding valve (SEV group) in patients with small aortic annulus (SAA). PPM was considered moderate when the indexed effective orifice area was between 0.65 and 0.85 cm^2/m^2 and severe when $<$0.65 cm^2/m^2 (or *indexed effective orifice area* $< 0.55\ cm^2/m^2$ *if body mass index is* $> 30\ kg/m^2$).[8] Demographic and clinical variables were captured from electronic medical records using Transcatheter Valve Therapy data collection forms. Clinical outcomes were defined according to the Valve Academic Research Consortium-3 definitions.[9] The primary outcome of the study was mortality and major adverse cardiovascular events (MACE), defined as a composite of death, stroke, and myocardial infarction at 3 years. Secondary outcomes included the incidence and prognosis of moderate/severe PPM.

Statistical Analysis

Continuous variables are presented as mean $\pm$ standard deviation if normally distributed or median (interquartile range) if skewed. Differences in continuous variables were assessed using a student's t-test or Wilcoxon rank-sum test, depending on the distribution. Discrete variables are presented as counts and percentages, with differences assessed using the chi-square test or Fisher's exact test, where appropriate. Kaplan-Meier curves were used to present survival free of mortality and survival free of MACE. Differences in survival distributions were tested using the log-rank test. To minimize the risk of bias, propensity score matching using four pretreatment variables (age, gender, STS score, and bicuspid valve) was performed. All analyses were performed in Stata version 17.0 (College Station, TX). The study was approved by the local institutional review board, and informed consent was waived.

Results

A total of 258 patients with SAA, out of 1188 TAVR procedures, underwent TAVR during the study period and were included in the study. The baseline clinical characteristics of the study cohort are presented in Table 1. There was a high preponderance of female gender (81%) with multiple comorbidities and intermediate surgical risk (median STS risk score 4.23 [2.57, 6.19]). A total of 90 patients (35%) received a BEV (median age 80 years [73, 86]) and 168 (65%) received a SEV (median age 81 years [75, 85], $p = 0.699$). The groups were well balanced in regard to comorbidities and risk profile (Table 1).

At baseline, patients with SAA had an AV area of 0.67 cm^2 (0.56, 0.80), a mean gradient of 44 mmHg (37, 50), and a peak AV velocity of 4.2 m/sec (3.9, 4.5). The median annular diameter by computed tomography angiography (CTA) was 24 mm (22, 26) with an annular area of 374 mm^2 (341,404) and a perimeter of 71 mm ($\pm$4). The baseline echocardiographic and CTA characteristics are presented in Table 2. There were no differences in CTA or echocardiographic characteristics

Table 2
Baseline comparison of echocardiographic and computed tomography data

Variable	Overall (N = 258)	Balloon-expandable valve (N = 90)	Self-expanding valve (N = 168)	*p* value
AV area, median (IQR), cm^2	0.67 (0.56, 0.80)	0.67 (0.58, 0.80)	0.66 (0.55, 0.80)	0.895
AV mean gradient, median (IQR), mmHg	44 (37, 50)	45 (37, 50)	43 (37, 54)	0.848
AV peak gradient, median (IQR), mmHg	72 (63, 84)	74 (66, 82)	70 (61, 87)	0.496
Peak AV velocity, median (IQR), m/s	4.2 (3.9, 4.5)	4.3 (4.0, 4.5)	4.1 (3.9, 4.6)	0.799
Bicuspid valve, n (%)	16 (9)	8 (12)	8 (8)	0.423
Annulus diameter, median (IQR), mm	24 (22, 26)	24 (22, 26)	24 (22, 26)	0.768
AV annulus area, median (IQR), mm^2	374 (341, 404)	376 (350, 410)	369 (331, 403)	0.193
Annulus circumference, mean ± SD, mm	71.0 ± 4.3	71.8 ± 3.9	70.5 ± 4.5	0.022

Abbreviations: AV, aortic valve; IQR, interquartile range.

between the SEV or BEV groups. Patients undergoing TAVR with SEV received larger nominal valve sizes relative to BEV (Table 3). Among patients receiving a BEV, 68% received a 23 mm and 32% a 26 mm valve size. Among patients receiving a SEV, 13% received a 23-mm valve, 55% received a 26-mm valve, and 32% received a 29-mm valve ($p < 0.001$).

Clinical Outcomes

There were no differences in hospital mortality (BEV 2.2% vs. SEV 2.4%, $p = 1.00$), proportion of patients discharged home (BEV 84% vs. SEV 80%, $p = 0.376$), or paravalvular aortic regurgitation ≥ moderate (BEV 7% vs. SEV 3%, $p = 0.092$) between valve platforms. Patients receiving a SEV had lower AV mean gradients (8 mmHg [6, 10] vs. BEV 14 mmHg [10, 18], $p < 0.001$), lower aortic peak velocities (1.86 m/s [1.60, 2.34] vs. BEV 2.52 m/s [2.14, 2.90]), and were less likely to have patient-prosthesis mismatch (PPM) (SEV 18% vs. BEV 42%, $p < 0.001$). PPM severity was graded as moderate in 15% of cases (SEV 9% vs. BEV 27%) and severe in 11% (SEV 9% vs. BEV 15%).

At 3 years, MACE occurred in 26% of patients with SAA after TAVR with no difference between SEV (25%) and BEV (27%) ($p = 0.694$). The individual components of the composite endpoint were no different at 3-years: mortality SEV 23% vs. BEV 22%, $p = 0.875$; stroke SEV 1% vs. BEV 2%, $p = 0.280$; and myocardial infarction SEV 3% vs. BEV 5%, $p = 0.723$.

Clinical outcomes according to PPM and PPM severity are presented in Figure 1 and Table 4, respectively. No difference in MACE was reported, according to PPM, at any point in time up to 3 years after TAVR. A total of 7 patients required reintervention during the study period (2 SEV and 5 BEV). Two of these procedures were TAVR surgical explants due to endocarditis (BEV) or device malpositioning (SEV) whereas five required transcatheter aortic valve in transcatheter aortic valve procedures due to structural valve deterioration (3 BEV and 1 SEV) or nonstructural valve deterioration (1 BEV).

The results of the propensity-matched analysis are in line with the unadjusted analysis and are presented in the supplementary appendix.

Discussion

We conducted a single-center, observational study of patients with small aortic annulus undergoing TAVR with commercially available platforms. Several important findings are noted. First, most patients (4 out of 5) with SAA undergoing TAVR are females with a high burden of comorbidities. Second, in our clinical practice, SEVs with a supra-annular valve design are used more often than BEVs with an intra-annular design in this cohort (64 vs. 36%). Third, SEVs are associated with lower transvalvular gradients and incidence of PPM, in particular moderate PPM. Fourth, clinical outcomes were similar between these 2 valve platforms up to 3 years. Finally, the presence of PPM had no discernible effect on MACE. Our study results suggest equipoise between SEV and BEV with regard to hard clinical outcomes up to 3 years post-TAVR, despite lower echocardiographic gradients.

The Small Annuli Randomized to Evolut or SAPIEN Trial (SMART) evaluated valve performance and clinical outcomes of a self-expanding suprannular valve design as compared with a balloon-expandable intra-annular valve design in patients with severe symptomatic aortic stenosis and small aortic annuli.[11] Similar to our study, the majority of patients with SAA in the SMART trial were women (86%). Also in concordance with SMART trial findings, SEV had lower transvalvular

Table 3
Procedural characteristics and clinical outcomes

Variable	Overall (N = 258)	Balloon-expandable valve (N = 90)	Self-expanding valve (N = 168)	*p* value
Device size, n (%)				<0.001
23	83 (32)	61 (68)	22 (13)	
26	122 (47)	29 (32)	93 (55)	
29	53 (20)	0 (0)	53 (32)	
Length of stay (d), median (IQR)	2 (1, 3)	1 (1, 3)	2 (1, 3)	0.007
In-hospital death	6 (2.3)	2 (2.2)	4 (2.4)	1.000
Discharged home, n (%)	202 (81)	74 (84)	128 (80)	0.376
AV area, median (IQR)	1.6 (1.4, 2.0)	1.5 (1.3, 1.8)	1.7 (1.4, 2.0)	<0.001
AV mean gradient, median (IQR)	10 (6, 14)	14 (10, 18)	8 (6, 11)	<0.001
AV peak velocity, median (IQR)	2.10 (1.69, 2.59)	2.52 (2.14, 2.90)	1.86 (1.60, 2.34)	<0.001
≥ Moderate AR	10 (4)	6 (7)	4 (3)	0.092
PPM, n (%)	66 (26)	36 (42)	30 (18)	<0.001
PPM severity, n (%)				<0.001
Moderate	38 (15)	23 (27)	15 (9)	
Severe	28 (11)	13 (15)	15 (9)	
3-y outcomes				
MACE, n (%)	65 (26)	24 (27)	41 (25)	0.694
Death, n (%)	57 (23)	19 (22)	38 (23)	0.875
Stroke, n (%)	3 (1)	2 (2)	1 (1)	0.280
MI, n (%)	9 (4)	4 (5)	5 (3)	0.723

Abbreviations: AR, aortic regurgitation; AV, aortic valve; IQR, interquartile range; MACE, major adverse cardiovascular events; MI, myocardial infarction; PPM, patient-prosthesis mismatch.

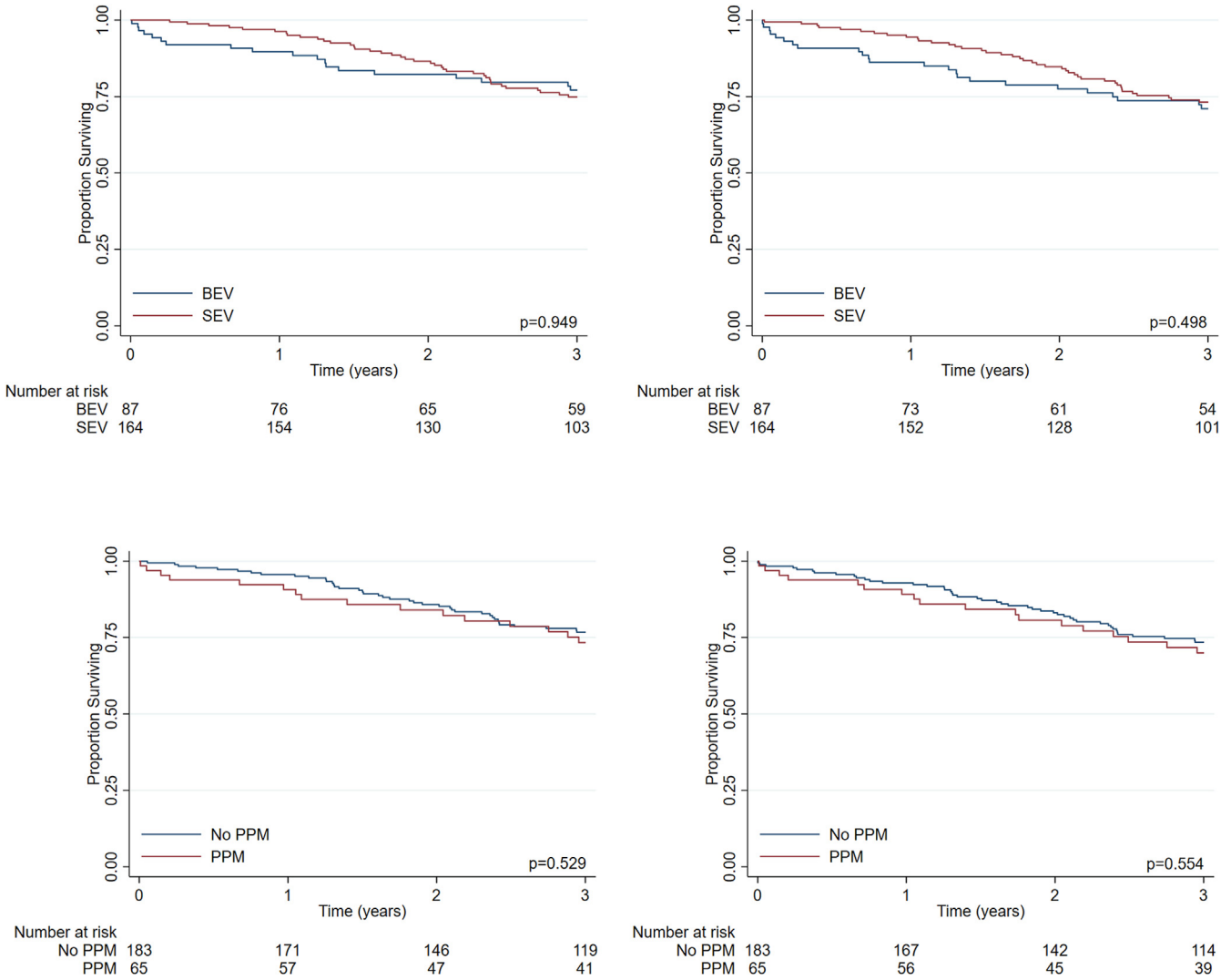

Figure 1. Time-to-event curves depicting mortality (left) and MACE (right) after TAVR in patients with small aortic annulus according to valve type (top) and patient-prosthesis mismatch (bottom).
Abbreviations: BEV, balloon-expandable valve; MACE, major adverse cardiovascular events; PPM, patient-prosthesis mismatch; SEV, self-expanding valve; TAVR, transcatheter aortic valve replacement.

gradients (SEV 7.7 mmHg vs. BEV 15.7 mmHg, $p < 0.001$), larger EOA (SEV 1.99 cm^2 vs. BEV 1.50 cm^2, $p < 0.001$), and less moderate to severe PPM (SEV 11.2% vs. BEV 35.3%, $p < 0.001$) than BEV. Clinical events up to 1 year were similar between groups. The percentage of patients who died, had a disabling stroke, or were rehospitalized for heart failure through 12 months was similar (SEV 9.4% and BEV 10.6%). Our study extends these important clinical findings up to 3 years after TAVR.

Table 4
Clinical outcomes according to patient prosthesis mismatch (PPM)

Variable	Overall (N = 248)	No PPM (N = 183)	Moderate PPM (N = 38)	Severe PPM (N = 27)	*P* value
30-d outcomes					
MACE, n (%)	5 (2)	3 (2)	2 (5)	0 (0)	0.256
Death, n (%)	3 (1)	1 (1)	2 (5)	0 (0)	0.094
Stroke, n (%)	2 (1)	2 (1)	0 (0)	0 (0)	1.000
MI, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	—
1-y outcomes					
MACE, n (%)	20 (8)	13 (7)	4 (11)	3 (11)	0.533
Death, n (%)	14 (6)	8 (4)	3 (8)	3 (11)	0.160
Stroke, n (%)	3 (1)	3 (2)	0 (0)	0 (0)	1.000
MI, n (%)	4 (2)	3 (2)	1 (3)	0 (0)	0.706
3-y outcomes					
MACE, n (%)	64 (26)	46 (25)	11 (29)	7 (26)	0.887
Death, n (%)	56 (23)	40 (22)	10 (26)	6 (22)	0.835
Stroke, n (%)	3 (1)	3 (2)	0 (0)	0 (0)	1.000
MI, n (%)	9 (4)	6 (3)	2 (5)	1 (4)	0.732

Abbreviations: MACE, major adverse cardiovascular events; MI, myocardial infarction; PPM, patient-prosthesis mismatch.

A survival analysis of a large national echocardiographic database showed that impaired valvular hemodynamics after AV replacement was associated with increased 5-year mortality. A mortality threshold above a mean gradient of 22.5 mmHg was noted.[10] Despite improved hemodynamics, SMART and other trials comparing SEV and BEV have failed to demonstrate differences in clinical outcomes thus far. The CHOICE trial compared early generations of SEV and BEV in 241 high-risk patients and showed superior valve hemodynamic performance for SEV with no significant differences in clinical outcome up to 5 years.[12] The SOLVE-TAVI trial used a 2 x 2 factorial design to compare SEV vs. BEV in 447 moderate-to-high-risk patients with severe symptomatic aortic stenosis.[13] The combined endpoint of mortality, stroke, moderate or severe paravalvular regurgitation, and permanent pacemaker were similar in the two groups. The SMART trial will continue to follow-up patients for clinical events for up to 5 years to determine if the early superior hemodynamic results will translate into clinical benefits, including long-term valve durability.

An important difference between our study and SMART is that 33% of our patients with SAA received a 26 mm BEV vs. only 1.3% in the SMART trial. In contrast, both SMART and our study reported a similar proportion of 29 mm SEV (SMART 28.9% vs. our study 32%). The nominal area of a 23 mm BEV is 409 mm^2, so patients with annulus areas between in the "grey zone" (410-430 mm^2) could be treated with either a 23 mm or a 26 mm BEV using different strategies of volume manipulation.[14]

Limitations

Our study has intrinsic limitations common to observational, single-center studies including unmeasured confounders, small sample size, and lack of an independent committee for event adjudication. However, it should be noted that both groups were well balanced with regard to comorbidities and surgical risk and the hemodynamic findings are strikingly similar to the randomized SMART trial. Valve selection was not randomly assigned. Although we cannot completely exclude selection bias, the two groups appear well balanced with regard to measured baseline characteristics. Invasive hemodynamics were not routinely collected in our study. Invasive and echocardiographic measures may differ after TAVR. Finally, longer follow-up (5-10 years) may be required to determine if hemodynamic differences translate into clinical events, including valve reintervention.

Conclusions

In patients with SAA, SEV had better hemodynamic performance and less PPM after TAVR. However, we observed no difference in mortality between SEV and BEV up to 3-years after the index procedure. PPM is common in patients with SAA but has no effect on intermediate clinical outcomes.

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Ethics Statement

This research was carried out in accordance with the appropriate ethical guidelines and regulations. For studies involving human subjects, ethics committee approval was obtained, and informed consent was secured from all participants. All procedures performed were in accordance with the ethical standards of the institutional and national research committees.

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Disclosure Statement

The authors report no conflict of interest.

Supplementary Data

Supplemental data for this article can be accessed on the publisher's website

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