ORIGINAL ARTICLE

Self-Expanding or Balloon-Expandable TAVR in Patients with a Small Aortic Annulus

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ABSTRACT

BACKGROUND

Patients with severe aortic stenosis and a small aortic annulus are at risk for impaired valvular hemodynamic performance and associated adverse cardiovascular clinical outcomes after transcatheter aortic-valve replacement (TAVR).

METHODS

We randomly assigned patients with symptomatic severe aortic stenosis and an aortic-valve annulus area of 430 mm^2 or less in a 1:1 ratio to undergo TAVR with either a self-expanding supraannular valve or a balloon-expandable valve. The coprimary end points, each assessed through 12 months, were a composite of death, disabling stroke, or rehospitalization for heart failure (tested for noninferiority) and a composite end point measuring bioprosthetic-valve dysfunction (tested for superiority).

RESULTS

A total of 716 patients were treated at 83 sites in 13 countries (mean age, 80 years; 87% women; mean Society of Thoracic Surgeons Predicted Risk of Mortality, 3.3%). The Kaplan–Meier estimate of the percentage of patients who died, had a disabling stroke, or were rehospitalized for heart failure through 12 months was 9.4% with the self-expanding valve and 10.6% with the balloon-expandable valve (difference, –1.2 percentage points; 90% confidence interval [CI], –4.9 to 2.5; P<0.001 for noninferiority). The Kaplan–Meier estimate of the percentage of patients with bioprosthetic-valve dysfunction through 12 months was 9.4% with the self-expanding valve and 41.6% with the balloon-expandable valve (difference, –32.2 percentage points; 95% CI, –38.7 to –25.6; P<0.001 for superiority). The aortic-valve mean gradient at 12 months was 7.7 mm Hg with the self-expanding valve and 15.7 mm Hg with the balloon-expandable valve, and the corresponding values for additional secondary end points through 12 months were as follows: mean effective orifice area, 1.99 cm^2 and 1.50 cm^2; percentage of patients with hemodynamic structural valve dysfunction, 3.5% and 32.8%; and percentage of women with bioprosthetic-valve dysfunction, 10.2% and 43.3% (all P<0.001). Moderate or severe prosthesis–patient mismatch at 30 days was found in 11.2% of the patients in the self-expanding valve group and 35.3% of those in the balloon-expandable valve group (P<0.001). Major safety end points appeared to be similar in the two groups.

CONCLUSIONS

Among patients with severe aortic stenosis and a small aortic annulus who underwent TAVR, a self-expanding supraannular valve was noninferior to a balloon-expandable valve with respect to clinical outcomes and was superior with respect to bioprosthetic-valve dysfunction through 12 months. (Funded by Medtronic; SMART ClinicalTrials.gov number, NCT04722250.)

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On the basis of multiple prospective randomized trials comparing transcatheter aortic-valve replacement (TAVR) with surgery, TAVR has emerged as the dominant treatment method for most patients with symptomatic severe aortic stenosis.[1-6] Despite differences in their design, hemodynamic characteristics, and implantation techniques, different types of TAVR prostheses have been compared in relatively few randomized trials.[7-10] In observational studies and randomized trials, the self-expanding supraannular valve has been shown to have better hemodynamic properties than balloon-expandable valves.[11-14]

The hemodynamic differences between these two valve platforms may be particularly important in patients with a small aortic annulus, who account for up to one third of the patients in randomized trials, with a marked preponderance of women.[2-5,15] These patients are at greater risk for impaired valve hemodynamics, including high gradients, prosthesis–patient mismatch, reduced exercise capacity, and impaired prosthesis durability.[15-21] For these reasons, we designed a prospective, international, randomized trial (the Small Annuli Randomized to Evolut or SAPIEN Trial [SMART]) to evaluate the clinical outcomes and valve performance of the self-expanding supraannular valve as compared with the balloon-expandable valve in patients undergoing TAVR who have symptomatic severe aortic stenosis and a small aortic-valve annulus.[22] Here we report the results for the coprimary and secondary end points through 1 year.

Methods

Trial Design and Oversight

In this international, prospective, postmarket, randomized, controlled trial, we evaluated the safety and performance of the self-expanding supraannular valve as compared with the balloon-expandable valve in patients with symptomatic severe aortic stenosis and a small aortic annulus who were undergoing TAVR. Patients were treated at 83 sites in Canada, Europe, the Middle East, and the United States. The trial investigators and clinical trial sites are listed in the Supplementary Appendix, available with the full text of this article at NEJM.org.

The sponsor (Medtronic) developed the protocol (available at NEJM.org) in collaboration with the principal investigators and executive committee, with approval from the institutional review board or medical ethics committee at each site. The trial was conducted in accordance with Good Clinical Practice guidelines and the Declaration of Helsinki. Medtronic funded the trial and was responsible for clinical site selection, data monitoring, and statistical analyses. A steering committee provided oversight with regard to the scientific content and execution of the trial. An independent clinical-events committee adjudicated end point–related adverse events, and an independent data and safety monitoring board (Baim Institute for Clinical Research) reviewed the safety results. Echocardiographic end points were based on assessment by an independent echocardiographic core laboratory (Mayo Clinic); the personnel performing the assessments were unaware of the clinical outcomes. Details of the trial oversight and the core laboratories are provided in Table S1 in the Supplementary Appendix. All the patients provided written informed consent.

The lead principal investigators (the first, second, and last authors) had full access to the data and wrote the first draft of the manuscript, and all the authors contributed to the content, critically reviewed the manuscript, and agreed to submit it for publication. An employee of Medtronic prepared earlier versions of the figures and tables and provided editorial assistance with the submitted manuscript under the direction of the first author. The authors vouch for the accuracy and completeness of the data and for the fidelity of the trial to the protocol.

Patients

An independent case planning committee made up of external physicians assessed the suitability and eligibility of the patients, including confirmation of annular sizing, before randomization.[22] In order to be eligible for participation, patients (including those with a bicuspid aortic valve) had to have an aortic-valve annulus area of 430 mm^2 or less, as determined with multidetector computed tomography, and suitable anatomy for transfemoral TAVR with the supraannular self-expanding Evolut PRO/PRO+/FX (Medtronic) and the balloon-expandable SAPIEN 3/3 Ultra (Edwards Lifesciences). Complete lists of the inclusion and exclusion criteria are provided in Table S2.

Enrolled patients were randomly assigned in a 1:1 ratio to receive a self-expanding valve or a balloon-expandable valve, and randomization was stratified according to site and sex. All treated patients are followed for 5 years.

TRIAL END POINTS

The two powered coprimary end points,[23] both of which were assessed through 12 months, were a clinical outcome composite of death, disabling stroke, or rehospitalization for heart failure and a composite end point of bioprosthetic-valve dysfunction. The bioprosthetic-valve dysfunction end point included the following components: hemodynamic structural valve dysfunction, defined as an aortic-valve mean gradient of 20 mm Hg or higher; nonstructural valve dysfunction, defined as severe prosthesis–patient mismatch or at least moderate total aortic regurgitation; clinical valve thrombosis; endocarditis; or aortic-valve reintervention.

The hypothesis-tested secondary end points were hemodynamic mean gradient as a continuous variable at 12 months, effective orifice area as a continuous variable at 12 months, hemodynamic structural valve dysfunction through 12 months, bioprosthetic-valve dysfunction in women through 12 months; and moderate or severe prosthesis–patient mismatch at 30 days. Clinical valve thrombosis and endocarditis were defined in accordance with Valve Academic Research Consortium (VARC)–2 criteria[24] and modified Duke criteria,[25] respectively. Severe prosthesis–patient mismatch was defined as an indexed effective orifice area of 0.65 cm^2 per square meter of body-surface area or less in a patient with a body-mass index (BMI, the weight in kilograms divided by the square of the height in meters) of less than 30 or of 0.55 cm^2 per square meter or less in a patient with a BMI of 30 or higher.[26] Other secondary end points included device success at 30 days according to VARC-2 criteria, Doppler velocity index through 12 months, and total aortic regurgitation. Device success at 30 days according to VARC-3 criteria, the Kansas City Cardiomyopathy Questionnaire (KCCQ) ordinal outcome according to VARC-3 criteria, which is based on the change in the overall summary score (summary scores range from 0 to 100, with higher scores indicating better health status[27]), and a composite of death or disabling stroke were exploratory end points. Full lists of end points and definitions are provided in Tables S3 and S4.

STATISTICAL ANALYSIS

The first coprimary end point, the clinical outcome composite through 12 months, was assessed in the as-treated population, defined as all patients with an attempted implantation procedure; patients were included in the analysis according to the first attempted device. The first coprimary end point was evaluated for noninferiority with the use of a z-test on the basis of event rates and Greenwood standard errors estimated by the Kaplan–Meier method with a one-sided alpha level of 0.05 and a noninferiority margin of 8 percentage points. Under the assumption that an event would occur in 16% of the patients in each group, a sample of 700 participants (350 per group) would provide 85% power with attrition taken into account (see the Supplementary Statistical Methods section). Treatment effect was summarized as the risk difference at 12 months with 90% confidence intervals.

The second coprimary end point, bioprosthetic-valve dysfunction through 12 months, was assessed in the population with implantation, defined as all patients with a successfully implanted valve; patients were included in the analysis according to the last valve implanted during the index procedure. The second coprimary end point was evaluated for superiority with the use of a z-test based on event rates and Greenwood standard errors estimated by the Kaplan–Meier method with a one-sided alpha level of 0.025. Under the assumption that an event would occur in 14% of the patients in the self-expanding valve group and in 36% of those in the balloon-expandable valve group, on the basis of the pooled z-test, a minimum evaluable sample of 120 participants (60 per group) would provide 80% power. Treatment effect was summarized as the risk difference at 12 months with 95% confidence intervals. Sensitivity analyses were performed for both coprimary end points to evaluate the robustness of the results for different populations and definitions.

If the results for both coprimary end points were significant, hierarchical testing of secondary end points was to be performed in a prespecified order at a one-sided alpha level of 0.025 for superiority with the use of a serial

gatekeeping procedure (see the Supplemental Statistical Methods section). For the remaining end points, the results are reported as point estimates and 95% confidence intervals only. The widths of the confidence intervals have not been adjusted for multiplicity. Cox proportional-hazards models were used to estimate hazard ratios and 95% confidence intervals for clinical-event end points. All coprimary and secondary end points were analyzed according to the prespecified statistical approach outlined in the statistical analysis plan. No statistical techniques were used to impute missing data in the prespecified analyses. However, some patients had unknown status at 365 days, died before the 12-month trial visit, or were missing data on the 12-month echocardiogram. To comply with *Journal* guidelines for analysis of missing data, post hoc analyses with multiple imputation were performed for the coprimary and secondary end points as described in the Supplemental Statistical Methods section. All P values for superiority testing are reported as two-sided to comply with *Journal* reporting guidelines. Statistical analyses were performed with the use of SAS software, version 9.4 (SAS Institute), and R software, version 4.2 (R Foundation for Statistical Computing).

RESULTS

PATIENTS

From April 2021 through September 2022, a total of 737 patients underwent randomization and were included in the intention-to-treat population; 366 were assigned to receive a self-expanding valve and 371 to receive a balloon-expandable valve. Twenty-one patients (10 who had been assigned to receive a self-expanding valve and 11 who had been assigned to receive a balloon-expandable valve) exited the trial before the procedure, 3 patients crossed over between treatment groups (Table S5), 1 patient did not undergo TAVR, and 4 patients underwent attempted implantation of a self-expanding valve but received a balloon-expandable valve (3 self-expanding valves embolized, and 1 self-expanding valve could not be implanted), resulting in an as-treated population of 355 patients in the self-expanding valve group and 361 patients in the balloon-expandable valve group and a final population with implantation that consisted of 350 patients in the self-expanding valve group and 365 patients in the balloon-expandable valve group (Fig. S1). Of the 655 patients who were still alive and enrolled in the trial, 642 (98%) completed a 12-month visit.

The baseline characteristics of patients in the as-treated population are shown in Table 1. The majority of the patients were women (86.7%), with a mean age of 80 years and a mean surgical risk of 3.3% as determined by Society of Thoracic Surgeons Predicted Risk of Mortality. The mean (±SD) aortic annular area in patients in this trial was 381.9±34.1 mm^2. Baseline characteristics appeared to be balanced between the groups, with the exception of previous percutaneous coronary intervention and coronary artery disease, for which the percentages were higher in the balloon-expandable valve group than in the self-expanding valve group. The patient population in this study appeared to be consistent with the general population of patients with aortic stenosis and a small aortic annulus (Table S6). Procedural characteristics and a summary of valve sizes are shown in Tables S7 and S8, respectively. Most patients who received a self-expanding valve received a 26-mm (68.9%) or 29-mm (28.9%) valve, and most patients who received a balloon-expandable valve received a 20-mm (7.9%) or 23-mm (90.1%) valve as their last implanted valve. Device success at 30 days according to VARC-2 criteria was reported for 85.2% of patients in the self-expanding valve group and 59.2% in the balloon-expandable valve group (difference, 26.0 percentage points; 95% confidence interval [CI], 19.2 to 32.7); when device success was defined according to VARC-3 criteria, the percentages were 94.5% and 86.6%, respectively (difference, 7.9 percentage points; 95% CI, 3.5 to 12.4) (Table S9).

COPRIMARY END POINTS

The Kaplan–Meier estimate of the percentage of patients with a first coprimary end-point event (death, disabling stroke, or rehospitalization for heart failure through 12 months) was 9.4% in the self-expanding valve group and 10.6% in the balloon-expandable valve group (difference, –1.2 percentage points; 90% CI, –4.9 to 2.5; P<0.001 for noninferiority; hazard ratio, 0.90; 95% CI, 0.56 to 1.43) (Table 2 and Fig. 1A). The estimates for each component of the first coprimary end point among patients assigned to the self-expanding valve group and balloon-expandable valve group

Table 1. Characteristics of the Patients at Baseline (As-Treated Population).*

Characteristic	SEV (N=355)	BEV (N=361)
Age — yr	80.1±6.3	80.3±6.1
Body-surface area — m^2	1.8±0.2	1.8±0.2
Female sex — no. (%)	312 (87.9)	309 (85.6)
STS-PROM — %	3.3±1.9	3.2±1.7
STS-PROM category — no. (%)		
<3%	182 (51.3)	191 (52.9)
3 to <5%	122 (34.4)	123 (34.1)
≥5%	51 (14.4)	47 (13.0)
NYHA functional class — no. (%)†		
I	4 (1.1)	6 (1.7)
II	197 (55.5)	211 (58.4)
III	150 (42.3)	144 (39.9)
IV	4 (1.1)	0
Diabetes — no. (%)	104 (29.3)	123 (34.1)
Hypertension — no. (%)	293 (82.5)	313 (86.7)
COPD or chronic lung disease — no./total no. (%)	61/339 (18.0)	62/353 (17.6)
Cerebrovascular disease — no./total no. (%)	42/351 (12.0)	41/360 (11.4)
Previous CABG — no./total no. (%)	12/354 (3.4)	18/361 (5.0)
Previous PCI — no./total no. (%)	60/353 (17.0)	84/360 (23.3)
Previous myocardial infarction — no. (%)	19 (5.4)	29 (8.0)
Arrhythmia — no./total no. (%)	83/355 (23.4)	85/360 (23.6)
Atrial fibrillation or flutter — no./total no. (%)	69/349 (19.8)	65/353 (18.4)
History of right bundle-branch block — no. (%)	21 (5.9)	25 (6.9)
Site-reported LVEF at screening — %‡	61.6±7.6	61.2±8.7
Coronary artery disease — no. (%)	125 (35.2)	148 (41.0)
Preexisting pacemaker or defibrillator — no. (%)	30 (8.5)	25 (6.9)
Tricuspid aortic-valve morphology — no. (%)	341 (96.1)	346 (95.8)
Treatment with vitamin K antagonist — no. (%)	16 (4.5)	16 (4.4)
Treatment with direct oral anticoagulant — no. (%)	54 (15.2)	57 (15.8)
Aortic annulus area — mm^2	380.9±34.2	382.8±33.9

* Plus–minus values are means ±SD. The as-treated population included all patients with an attempted implantation procedure, who were included in the analysis according to the first attempted device. BEV denotes balloon-expandable valve, CABG coronary-artery bypass graft, COPD chronic obstructive pulmonary disease, LVEF left ventricular ejection fraction, NYHA New York Heart Association, PCI percutaneous coronary intervention, SEV self-expanding valve, and STS-PROM Society of Thoracic Surgeons Predicted Risk of Mortality.
† If data on the NYHA class at baseline were not available, the data from the screening assessment were used.
‡ Data were available for 353 patients in the SEV group and 360 patients in the BEV group.

through 12 months were as follows: death, 5.1% and 5.9%, respectively (difference, –0.7 percentage points; 90% CI, –3.5 to 2.1); disabling stroke, 3.1% and 2.6% (difference, 0.6 percentage points; 90% CI, –1.5 to 2.7); and rehospitalization for heart failure, 3.8% and 3.5% (difference, 0.4 percentage points; 90% CI, –2.0 to 2.7) (Table S10 and Fig. S2).

The Kaplan–Meier estimate of the percentage of patients with bioprosthetic-valve dysfunction through 12 months, the second coprimary end point, was 9.4% in the self-expanding valve group

Table 2. Coprimary and Hypothesis-Tested Secondary End Points.*

End Point	Prespecified Analyses Based on Observed Data				Analysis with Multiple Imputation of Missing Data			
	SEV	BEV	Difference (90% CI)	P Value for Inferiority	SEV	BEV	Difference (90% CI)	P Value for Inferiority
First coprimary end point: death from any cause, disabling stroke, or rehospitalization for heart failure through 12 mo — no. (Kaplan–Meier %) or %†	33 (9.4)	38 (10.6)	−1.2 (−4.9 to 2.5)	<0.001	9.8	10.8	−1.0 (−4.8 to 2.8)	<0.001
			Difference (95% CI)	P Value for Superiority			Difference (95% CI)	P Value for Superiority
Second coprimary end point: BVD composite through 12 mo — no. (Kaplan–Meier %) or %‡	28 (9.4)	131 (41.6)	−32.2 (−38.7 to −25.6)	<0.001	10.9	42.7	−31.8 (−38.5 to −25.1)	<0.001
Secondary end points								
Mean gradient at 12 months — mm Hg§	7.7±4.0	15.7±6.7	−7.9 (−8.8 to −7.0)	<0.001	7.7	15.7	−8.0 (−8.9 to −7.1)	<0.001
Mean EOA at 12 months — cm^2¶	1.98±0.47	1.50±0.35	0.48 (0.40 to 0.56)	<0.001	1.99	1.50	0.49 (0.42 to 0.56)	<0.001
HSVD through 12 months — no. (Kaplan–Meier %) or %	10 (3.2)	105 (32.2)	−29.1 (−34.6 to −23.5)	<0.001	3.5	32.8	−29.3 (−34.7 to −23.8)	<0.001
BVD in women through 12 months — no. (Kaplan–Meier %) or %‖	22 (8.4)	112 (41.8)	−33.4 (−40.4 to −26.4)	<0.001	10.2	43.3	−33.0 (−40.2 to −25.9)	<0.001
Moderate or severe PPM at 30 days — no./total no. (%) or %**	28/273 (10.3)	104/296 (35.1)	−24.9 (−31.4 to −18.4)	<0.001	11.2	35.3	−24.1 (−30.5 to −17.7)	<0.001

* Plus–minus values are means ±SD. The prespecified analysis of the first coprimary end point was performed in the as-treated population (355 patients in the self-expanding valve [SEV] group and 361 patients in the balloon-expandable valve [BEV] group); all other prespecified analyses were performed in the population with implantation (all patients with a successfully implanted valve, who were included in the analysis according to the last valve implanted during the index procedure [350 patients in the SEV group and 365 patients in the BEV group]).

† Noninferiority in the prespecified analysis was evaluated with the use of a z-test based on the event rates and Greenwood standard errors estimated by the Kaplan–Meier method against a noninferiority margin of 8 percentage points. In the multiple imputation analysis, noninferiority was evaluated with the use of a z-test based on the event rates and standard errors from a binomial proportion analysis. Multiple imputation was performed for patients without an event who had less than 365 days of confirmed event-free follow-up. Outcomes were imputed for 17 patients in the SEV group and 8 patients in the BEV group.

‡ Bioprosthetic-valve dysfunction (BVD) was a composite of hemodynamic structural valve dysfunction (HSVD), nonstructural valve dysfunction (NSVD), clinical valve thrombosis, endocarditis, or aortic-valve reintervention. Superiority in the prespecified analysis was evaluated with the use of a two-sided z-test based on the event rates and Greenwood standard

errors estimated by the Kaplan–Meier method. In the multiple imputation analysis, superiority was evaluated with the use of a z-test based on the event rates and standard errors from a binomial proportion analysis. The time of HSVD and NSVD was based on the date of echocardiography or 365 days, whichever was earlier; otherwise, data were censored at the time of the last evaluable echocardiogram free of HSVD or free of NSVD. HSVD was defined as a hemodynamic mean gradient of 20 mm Hg or greater as assessed by the core laboratory. NSVD was defined as severe prosthesis–patient mismatch (PPM) or at least moderate total aortic regurgitation as assessed by the core laboratory. Thrombosis includes clinical events committee (CEC)–adjudicated clinical valve thrombosis. Endocarditis includes CEC-adjudicated definite prosthetic-valve endocarditis.[25] Multiple imputation was performed for patients without an event who had less than 365 days of confirmed event-free follow-up. Outcomes were imputed for 91 patients in the SEV group and 82 patients in the BEV group.

§ Multiple imputation was performed for patients who were missing data for the 12-month mean gradient, excluding those who died before the 12-month trial visit (16 patients in the SEV group and 23 in the BEV group). Complete data for mean gradient at 12 months were available for 298 patients in the SEV group and 301 patients in the BEV group. Data were imputed for 36 patients in the SEV group and 41 patients in the BEV group who were not known to have died before 12 months, for a total of 334 patients and 342 patients, respectively, included in this analysis.

¶ Multiple imputation was performed for patients who were missing data for the 12-month effective orifice area (EOA), excluding those who died before the 12-month trial visit (16 patients in the SEV group and 23 in the BEV group). Complete data for EOA at 12 months were available for 267 patients in the SEV group and 266 in the BEV group. Data were imputed for 67 patients in the SEV group and 76 patients in the BEV group who were not known to have died before 12 months, for a total of 334 patients and 342 patients, respectively, included in this analysis.

‖ Data on BVD in women were available for 307 patients in the SEV group and 313 patients in the BEV group. Multiple imputation was performed for patients without an event who had less than 365 days of confirmed event-free follow-up. Outcomes were imputed for 80 patients in the SEV group and 74 patients in the BEV group.

** Multiple imputation was performed for patients with no evaluable PPM data on the 30-day echocardiogram, excluding those who died before 30 days (6 patients in each group). Complete data for PPM at 30 days were available for 273 patients in the SEV group and 296 in the BEV group. Data were imputed for 71 patients in the SEV group and 63 in the BEV group who were not known to have died before 30 days, for a total of 344 patients and 359 patients, respectively, included in this analysis.

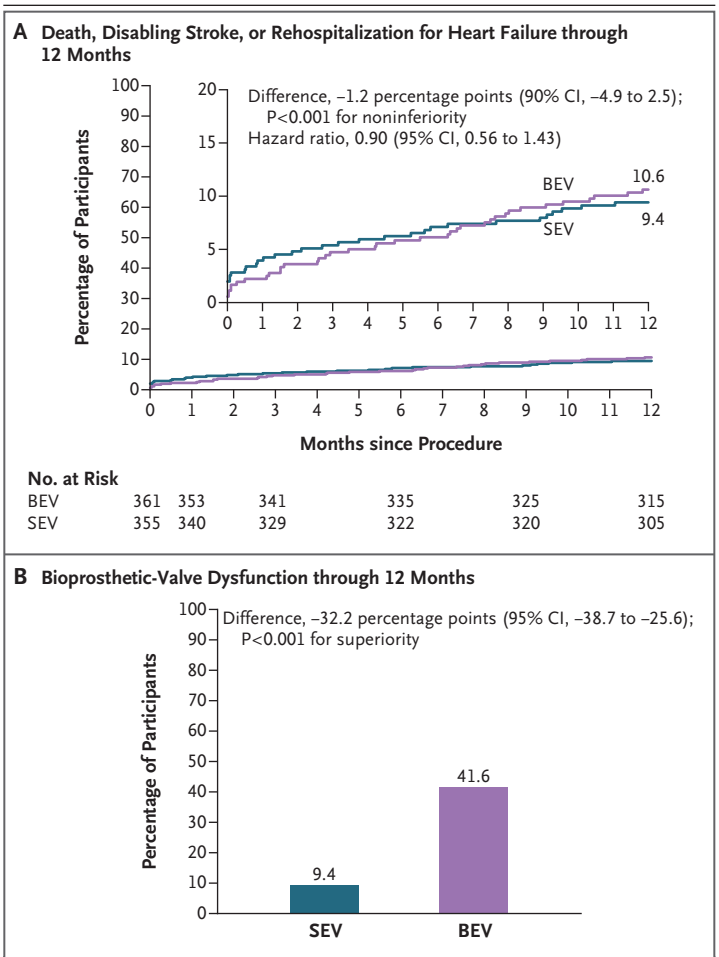


Figure 1. Coprimary End Points through 12 Months.

Panel A shows the Kaplan–Meier curve for the first coprimary end point, a clinical composite of death from any cause, disabling stroke, or rehospitalization for heart failure through 12 months, analyzed in the as-treated population (all patients with an attempted implantation procedure, who were included in the analysis according to the first attempted device). Noninferiority testing was based on the difference in the Kaplan–Meier estimates between the self-expanding valve (SEV) group and the balloon-expandable valve (BEV) group, which is reported with a two-sided 90% confidence interval. The inset shows the data on an enlarged y axis. Panel B shows the Kaplan–Meier estimates of the percentages of patients with bioprosthetic-valve dysfunction through 12 months, the second coprimary end point, a composite of hemodynamic structural valve dysfunction, nonstructural valve dysfunction, clinical valve thrombosis, endocarditis, or aortic-valve reintervention. This end point was assessed in the population with implantation (all patients with a successfully implanted valve, who were included in the analysis according to the last valve implanted during the index procedure). Superiority testing was based on the difference in the Kaplan–Meier estimates for the SEV and BEV groups, which is reported with 95% confidence intervals. The results shown are based on observed data from the prespecified analyses.

and 41.6% in the balloon-expandable valve group (difference, −32.2 percentage points; 95% CI, −38.7 to −25.6; P<0.001) (Table 2 and Fig. 1B). The estimates for each component of the second coprimary end point in the self-expanding valve group and the balloon-expandable valve group were as follows: hemodynamic structural valve dysfunction, 3.2% and 32.2%, respectively (difference, −29.1 percentage points; 95% CI, −34.6 to −23.5); nonstructural valve dysfunction, 5.9% and 18.2% (difference, −12.3 percentage points; 95% CI, −17.6 to −7.0); clinical valve thrombosis, 0.3% and 0.3% (difference, 0.0 percentage points; 95% CI, −0.8 to 0.8); endocarditis, 0.6% and 2.3% (difference, −1.7 percentage points; 95% CI, −3.5 to 0.1); and aortic-valve reintervention, 0.9% and 0.6% (difference, 0.3 percentage points; 95% CI, −1.0 to 1.6) (Table S10).

The results for the two coprimary end points remained consistent when analyzed with a multiple imputation approach to account for missing data (Table 2). Subgroup analyses of the coprimary end points are shown in Figure 2. The results of sensitivity analyses according to treatment group and analysis population for each coprimary end point were similar to those of the primary analysis (Tables S11 and S12 and Fig. S3).

SECONDARY END POINTS

Results for the hypothesis-tested secondary end points that were analyzed with the use of multiple imputation to account for missing data are shown in Table 2 and Figure 3. The mean gradient at 12 months was 7.7 mm Hg in the self-expanding valve group and 15.7 mm Hg in the balloon-expandable valve group (difference, −8.0; 95% CI, −8.9 to −7.1; P<0.001), and the mean effective orifice area at 12 months was 1.99 cm^2 and 1.50 cm^2, respectively (difference, 0.49; 95% CI, 0.42 to 0.56; P<0.001). Hemodynamic structural valve dysfunction occurred in 3.5% of the patients in the self-expanding valve group and 32.8% of those in the balloon-expandable valve group (difference, −29.3 percentage points; 95% CI, −34.7 to −23.8; P<0.001). In an analysis involving women only, the percentage of patients with bioprosthetic-valve dysfunction through 12 months was 10.2% with the self-expanding valve and 43.3% with the balloon-expandable valve (difference, −33.0 percentage points; 95% CI, −40.2 to −25.9; P<0.001). Moderate or severe prosthesis–patient mismatch at 30 days occurred in 11.2% of the patients in the self-expanding valve group and 35.3% of those in the balloon-expandable valve group (difference, −24.1 percentage points; 95% CI, −30.5 to −17.7; P<0.001). The results were consistent when the analysis was performed with the prespecified statistical approach based on observed data (Table 2 and Fig. S4).

Additional echocardiographic findings are shown in Table S13. The percentage of patients with severe prosthesis–patient mismatch at 30 days was 1.8% in the self-expanding valve group and 7.1% in the balloon-expandable valve group (difference, −5.3 percentage points; 95% CI, −8.6 to −1.9). Mild or greater total aortic regurgitation at 12 months was present in 14.1% of patients in the self-expanding valve group and 20.3% of patients in the balloon-expandable valve group (difference, −6.2 percentage points; 95% CI, −12.3 to −0.2). The mean Doppler velocity index was 0.63 in the self-expanding valve group and 0.44 in the balloon-expandable valve group (difference, 0.19; 95% CI, 0.17 to 0.21) (Fig. S5). The quality-of-life KCCQ ordinal outcomes according to VARC-3 criteria are shown in Figure S6. The percentage of patients with improved scores at 12 months was 74.9% in the self-expanding valve group and 67.8% in the balloon-expandable valve group (difference, 7.2 percentage points; 95% CI, 0.3 to 14.1).

SAFETY

Additional procedural and clinical outcomes are shown in Tables S7 and S14. Death from any cause or disabling stroke through 12 months (a composite end point) occurred in 6.8% of patients in the self-expanding valve group and 7.5% of those in the balloon-expandable valve group (hazard ratio, 0.92; 95% CI, 0.53 to 1.59). At 30 days, implantation of a new permanent pacemaker had occurred in 12.1% of the patients in the self-expanding valve group and 7.8% of those in the balloon-expandable valve group (hazard ratio, 1.61; 95% CI, 0.98 to 2.65). We found no apparent difference between the groups with respect to several 30-day outcomes (coronary obstruction, conversion to surgery, major bleeding, acute kidney injury, and hospital readmission) and 12-month outcomes (cardiovascular death, reintervention, valve thrombosis, and hospital readmission).

DISCUSSION

In this head-to-head, real-world, international, randomized comparison of the two most currently used TAVR prostheses, we enrolled patients with symptomatic severe aortic stenosis and a small aortic annulus — most of whom were women — across all surgical risk categories, including those with bicuspid aortic valves. The self-expanding valve was noninferior to the balloon-expandable valve with respect to the clinical composite end point of death, disabling stroke, or rehospitalization for heart failure through 12 months. The self-expanding valve was superior to the balloon-expandable valve with respect to bioprosthetic-valve dysfunction (a composite end point). The self-expanding valve was also superior to the balloon-expandable valve with respect to several hypothesis-tested secondary end points: mean gradient, effective orifice area, hemodynamic structural valve dysfunction, and bioprosthetic-valve dysfunction in women through 12 months, as well as moderate or severe prosthesis–patient mismatch at 30 days. No apparent differences in safety outcomes were found between the groups.

Patients with a small aortic annulus are an important subgroup of symptomatic patients with aortic stenosis, predominantly women, who undergo TAVR.[28] In surgical series, the reported prevalence of a small annulus has been as high as 44%.[28] In randomized trials of TAVR that enrolled intermediate- and low-risk patients, those with a small aortic annulus accounted for 21% to 36% of the patient population.[2-5,29] Most patients with a small annulus in randomized trials are women.[16] In our trial, the mean age of enrolled patients was 80 years, and 87% of the patients were women; our trial population included patients who were at low (52.1%), intermediate (34.2%), or high or prohibitive (13.7%) surgical risk.

Patients with a small annulus are at particular risk for high residual gradients and prosthesis–patient mismatch, which are associated with major adverse cardiovascular events, including death, heart failure, and reduced quality of life.[30] Findings from a large national database showed that a mean echocardiographic gradient of greater than 22.5 mm Hg was associated with increased 5-year mortality.[31] Severe prosthesis–patient mismatch after TAVR is also associated with reduced survival.[18,32] Finally, impaired hemodynamic performance is associated with reduced valve durability.[19,33]

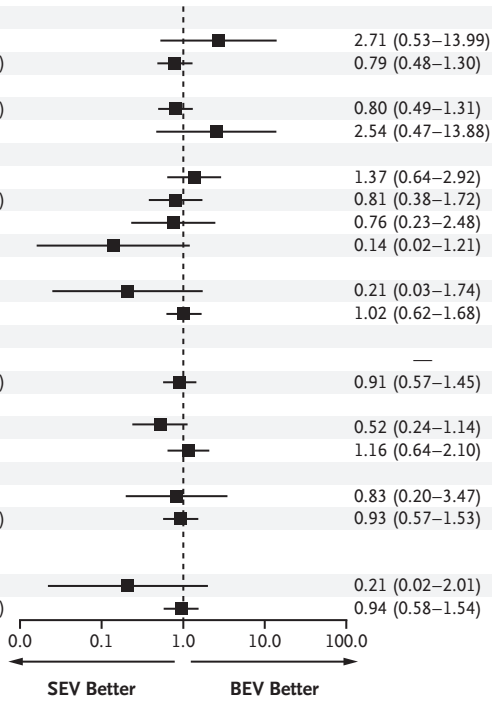
Few prospective randomized comparisons of TAVR prostheses have been performed. The CHOICE trial compared older generations of self-expanding valves and balloon-expandable valves in 241 high-risk patients and showed superior valve hemodynamic performance for self-expanding valves with no significant difference in clinical outcomes at 5 years.[14] The SOLVE-TAVI trial compared self-expanding valve and balloon-expandable valve prostheses of any size in high-risk patients and showed no clinical differences at 30 days[10] or at 1 year.[34] In contrast, our trial was designed to confirm the differences in valve hemodynamic outcomes that have been observed in other trials[11-14,35,36] and to be able to compare meaningful clinical and hemodynamic outcomes up to 5 years.

Our trial has limitations. We used core laboratory echocardiographic measures to identify hemodynamic structural valve dysfunction. Although invasive and echocardiographic hemodynamic measures may differ and both have potential pitfalls,[30] the differences, particularly after TAVR, are small, and invasive assessments have not been correlated with outcomes, nor are they easily repeated over time.[36,37] Nonstructural valve dysfunction included measured prosthesis–patient mismatch as opposed to predicted prosthesis–patient mismatch. The latter can reduce the contribution of low flow to the measurement in an individual patient but has several disadvantages, including the application of a group mean to an individual patient and an inability to adequately account for underexpansion and noncircular valve deployment, differences in leaflet material within the stent frame, frame recoil, and the interaction between valve size and its effects on flow.[30]

In addition, multiple definitions of bioprosthetic-valve dysfunction have been proposed.[19,26,31,32,38] Some require a change in gradient or valve area,[19,26] but only a few have been correlated with outcomes.[19,31,32] Our goal was to compare two prostheses with respect to hemodynamic performance because we did not anticipate significant differences in the rates of valve deterioration or failure by 1 year. We therefore initially designed the trial on the basis of the European standard[38]

A Subgroup Analysis of First Coprimary End Point through 12 Months

Subgroup	SEV	BEV
	no. of patients with an event/total no. (Kaplan–Meier % at 12 mo)	
Age		
<75 yr	5/62 (8)	2/64 (3)
≥75 yr	28/293 (10)	36/297 (12)
Sex		
Female	29/312 (9)	36/309 (12)
Male	4/43 (9)	2/52 (4)
STS-PROM		
<3%	15/182 (8)	12/191 (6)
≥3 to <5%	12/122 (10)	15/123 (12)
≥5 to <8%	5/37 (14)	6/35 (18)
≥8%	1/14 (8)	5/12 (42)
Left ventricular ejection fraction		
<50%	1/15 (7)	6/22 (27)
≥50%	31/338 (9)	31/338 (9)
Dialysis owing to renal dysfunction		
Yes	0/5	0/3
No	33/349 (10)	38/358 (11)
Atrial fibrillation or flutter		
Yes	10/69 (15)	17/65 (26)
No	23/280 (8)	21/288 (7)
Previous cerebrovascular accident		
Yes	3/23 (13)	5/30 (17)
No	30/326 (9)	33/330 (10)
Preexisting left bundle-branch block or complete heart block		
Yes	1/27 (4)	3/19 (16)
No	30/318 (10)	34/334 (10)



B Subgroup Analysis of Second Coprimary End Point through 12 Months

Subgroup	SEV	BEV
	no. of patients with an event/total no. (Kaplan–Meier % at 12 mo)	
Age		
<75 yr	9/60 (19)	32/66 (53)
≥75 yr	19/290 (8)	99/299 (39)
Sex		
Female	22/307 (8)	112/313 (42)
Male	6/43 (16)	19/52 (40)
STS-PROM		
<3%	22/181 (14)	68/192 (40)
≥3 to <5%	5/118 (5)	51/126 (47)
≥5 to <8%	1/37 (3)	10/35 (34)
≥8%	0/14	2/12 (33)
Left ventricular ejection fraction		
<50%	1/15 (10)	7/22 (46)
≥50%	27/333 (9)	123/342 (41)
Dialysis owing to renal dysfunction		
Yes	0/5	0/3
No	28/344 (10)	131/362 (42)
Atrial fibrillation or flutter		
Yes	5/67 (8)	22/67 (42)
No	23/277 (10)	104/290 (41)
Previous cerebrovascular accident		
Yes	2/23 (10)	7/30 (34)
No	26/321 (10)	123/334 (42)
Preexisting left bundle-branch block or complete heart block		
Yes	3/27 (13)	8/19 (49)
No	25/313 (9)	123/338 (42)

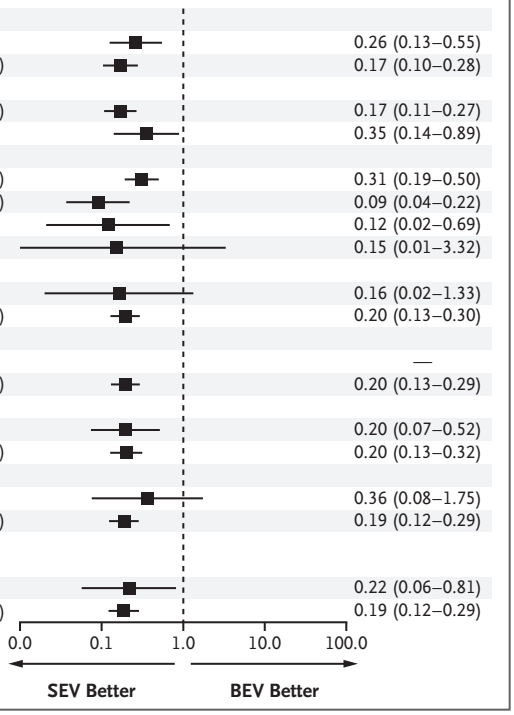


Figure 2 (facing page). Subgroup Analyses of Coprimary End Points.

Panel A shows the treatment effect of the SEV as compared with the BEV in eight prespecified clinical subgroups for the composite end point of death from any cause, disabling stroke, or rehospitalization for heart failure through 12 months, which was evaluated in the as-treated population. Panel B shows the composite end point of bioprosthetic-valve dysfunction through 12 months, which was evaluated in the population with implantation. The widths of the confidence intervals have not been adjusted for multiplicity, and the intervals may not be used in place of hypothesis testing. STS-PROM denotes Society of Thoracic Surgeons Predicted Risk of Mortality.

and subsequently updated it to include the VARC-3 definition of prosthesis–patient mismatch and aortic reintervention.[26] Nonetheless, we analyzed our data across multiple definitions of bioprosthetic-valve dysfunction, including VARC-3 criteria, and the results in all cases supported our conclusions with respect to the second coprimary end point — that is, that significantly less bioprosthetic-valve dysfunction occurred with the self-expanding valve than with balloon-expandable valve (Table S15 and Fig. S7). Finally, our results apply only to the valves studied and should not be generalized to other TAVR platforms. In addition, our results apply only to patients with a small

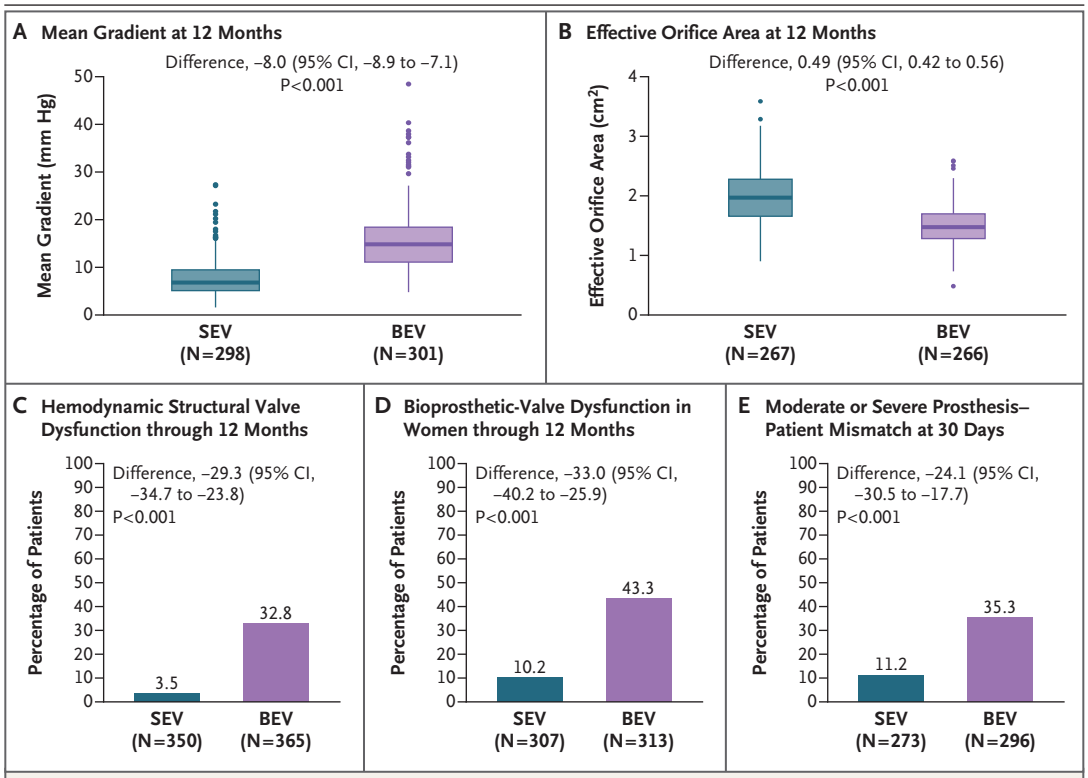


Figure 3. Secondary End Points.

The results of analyses of secondary end points with multiple imputation to account for missing data are shown. Results for continuous variables are shown as box plots for the mean gradient at 12 months (Panel A) and the effective orifice area at 12 months (Panel B). The horizontal line within the box represents the median, the box ends represent the first and third quartiles, and the whiskers represent the minimum and maximum (excluding outliers). Data outliers are shown as individual data points. In Panels A and B, the differences, 95% confidence intervals, and associated P values are based on multiple imputation analysis; the box plots represent the observed data. Bar graphs are shown for outcomes based on multiple imputation for hemodynamic structural valve dysfunction, defined as a mean gradient of 20 mm Hg or greater, through 12 months (Panel C), bioprosthetic-valve dysfunction in women through 12 months (Panel D), and moderate or severe prosthesis–patient mismatch at 30 days (Panel E) (all P<0.001). Findings are based on the echocardiography core laboratory assessment.

aortic annulus and not to all patients undergoing TAVR with these valves.

Among patients with severe aortic stenosis and small aortic annuli who were undergoing TAVR, clinical outcomes after implantation of a self-expanding supraannular valve were noninferior to those with a balloon-expandable valve, and the self-expanding valve was superior to the balloon-expandable valve with respect to bioprosthetic-valve dysfunction through 12 months.

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A data sharing statement provided by the authors is available with the full text of this article at NEJM.org.

APPENDIX

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