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The PARTNER 3 Bicuspid Registry for Transcatheter Aortic Valve Replacement in Low-Surgical-Risk Patients

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ABSTRACT

OBJECTIVES The study compared 1-year outcomes between transcatheter aortic valve replacement (TAVR) patients with bicuspid aortic valve (BAV) morphology and clinically similar patients having tricuspid aortic valve (TAV) morphology.

BACKGROUND There are limited prospective data on TAVR using the SAPIEN 3 device in low-surgical-risk patients with severe, symptomatic aortic stenosis and bicuspid anatomy.

METHODS Low-risk, severe aortic stenosis patients with BAV were candidates for the PARTNER 3 (Placement of Aortic Transcatheter Valves 3) (P3) bicuspid registry or the P3 bicuspid continued access protocol. Patients treated in these registries were pooled and propensity score matched to TAV patients from the P3 randomized TAVR trial. Outcomes were compared between groups. The primary endpoint was the 1-year composite rate of death, stroke, and cardiovascular rehospitalization.

RESULTS Of 320 total submitted BAV patients, 169 (53%) were treated, and most were Sievers type 1. The remaining 151 patients were excluded caused by anatomic or clinical criteria. Propensity score matching with the P3 TAVR cohort (496 patients) yielded 148 pairs. There were no differences in baseline clinical characteristics; however, BAV patients had larger annuli and they experienced longer procedure duration. There was no difference in the primary endpoint between BAV and TAV (10.9% vs 10.2%; $P = 0.80$) or in the rates of the individual components (death: 0.7% vs 1.4%; $P = 0.58$; stroke: 2.1% vs 2.0%; $P = 0.99$; cardiovascular rehospitalization: 9.6% vs 9.5%; $P = 0.96$).

CONCLUSIONS Among highly select bicuspid aortic stenosis low-surgical-risk patients without extensive raphe or subannular calcification, TAVR with the SAPIEN 3 valve demonstrated similar outcomes to a matched cohort of patients with tricuspid aortic stenosis. (J Am Coll Cardiol Intv 2022;15:523-532) © 2022 by the American College of Cardiology Foundation.

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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ABBREVIATIONS AND ACRONYMS

AVA = aortic valve area

BAV = bicuspid aortic valve

CAP = continued access protocol

KCCQ-OS = Kansas City Cardiomyopathy Questionnaire overall summary

KM = Kaplan-Meier

NYHA = New York Heart Association

P3 = PARTNER 3 trial

PVR = paravalvular regurgitation

SAVR = surgical aortic valve replacement

STS PROM = The Society of Thoracic Surgeons Predicted Risk of Mortality

TAV = tricuspid aortic valve

TAVR = transcatheter aortic valve replacement

Bicuspid aortic valve (BAV) disease is the most common congenital cardiac abnormality, affecting approximately 1% of the general population.[1] It most commonly causes aortic stenosis, accounting for up to one-half of patients requiring surgical aortic valve replacement (SAVR).[2] Transcatheter aortic valve replacement (TAVR) has been shown to be a safe and effective therapy for patients with aortic stenosis at low surgical risk.[3] However, because tricuspid aortic valve (TAV) morphology was an inclusion criterion for these trials, this foundational evidence can only be applied to TAV patients. While national registries have shown some promise for TAVR in BAV anatomy in intermediate- and high-surgical-risk patients, the data are often site reported with limited oversight of hemodynamic or clinical outcomes.[4,5] Moreover, the data in patients at low surgical risk remain very limited,[6] with no available randomized data to date comparing TAVR with SAVR in BAV anatomy. The objectives of this study were to: 1) prospectively study the 1-year safety and efficacy outcomes of TAVR with the SAPIEN 3 valve in low-surgical-risk patients with severe BAV stenosis: and 2) employ propensity score matching to compare these data to that of a clinically similar cohort of TAV patients treated in the low-risk PARTNER 3 (Placement of Aortic Transcatheter Valve 3) (P3) trial.[3] This analysis incorporated high-quality prospective data collected in a trial with independent oversight of clinical outcomes and core laboratory evaluation of baseline anatomy and echocardiographic outcomes.

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METHODS

STUDY DESIGN AND PARTICIPANTS. This analysis used patients from the P3 trial, patients from the P3 BAV registry, and those studied under the P3 bicuspid continued access protocol (CAP). Prior to enrollment, patients were screened for eligibility by a multidisciplinary heart team and national case review board. Multidetector computed tomography analyzed by the study core laboratory was used to determine anatomic eligibility for the trial. Patients with TAV morphology were considered for the randomized P3 trial, whereas those with BAV morphology were considered for the single-arm P3 BAV registry. Following completion of P3 enrollment, patients meeting study inclusion and exclusion criteria, including confirmation of BAV by the multidetector computed tomography core laboratory, could be enrolled under the P3 CAP. Oversight of the P3 CAP was provided by The Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Registry.

Key inclusion criteria for TAV and BAV patients were identical, including severe calcific aortic stenosis with aortic valve area (AVA) $\leq$1.0 cm^2 or AVA index $\leq$0.6 cm^2/m^2 with jet velocity $\geq$4.0 m/s or mean gradient $\geq$40 mm Hg, with symptoms either reported or elicited on exercise testing. Low surgical risk was defined by a Society of Thoracic Surgeons Predicted Risk of Mortality (STS PROM) score of <4%, or by judgment of the local heart team and national case review committee. Anatomic exclusion criteria included severe left ventricular outflow tract or raphe calcification, aortic annulus diameter <16 mm or >28 mm, and ascending aorta diameter >4 cm. Comprehensive inclusion and exclusion criteria have been previously reported.[3]

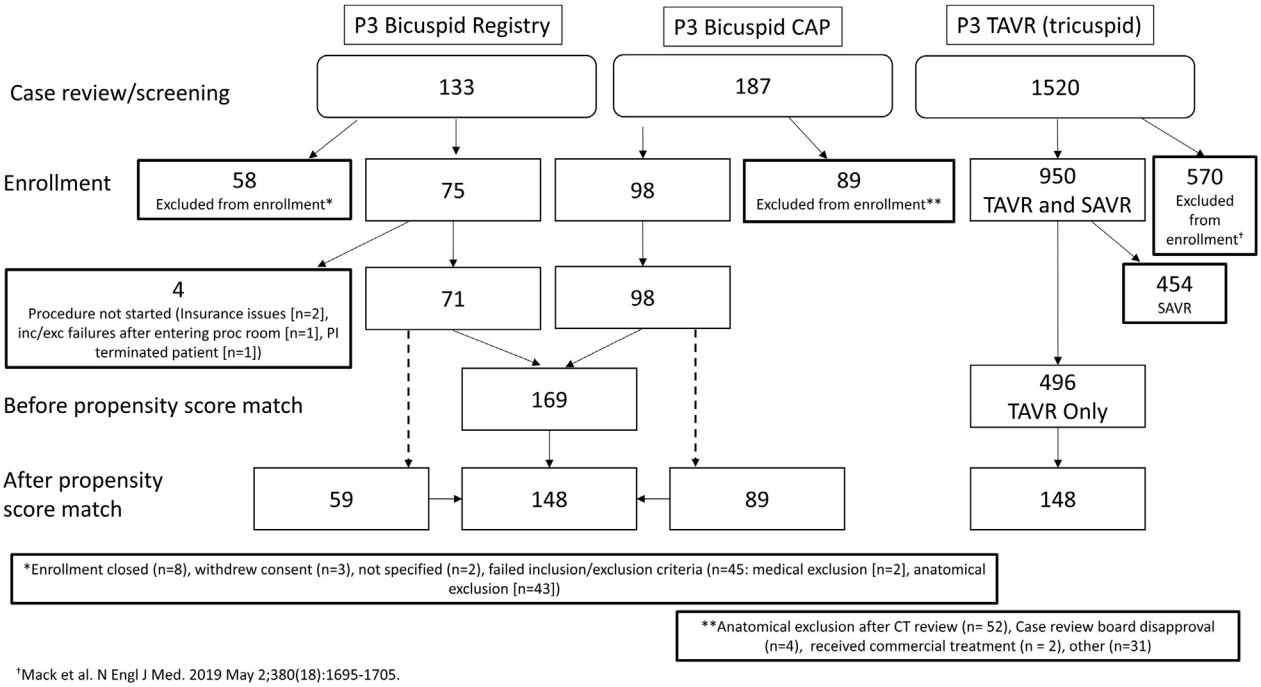
The Institutional Review Board at each participating site approved the protocols, and all patients provided written informed consent.

ENDPOINT. The primary endpoint for this analysis was the composite of all-cause mortality, all stroke, and cardiovascular rehospitalization (valve related or procedure related and including heart failure) at 1 year after valve implantation. An independent clinical events committee adjudicated the components of the primary endpoint for patients enrolled in P3 and the P3 BAV registry. Clinical data for patients studied under the P3 CAP were adjudicated by an independent medical reviewer. Secondary endpoints included need for new permanent pacemaker, symptom status classified according to the New York Heart Association (NYHA), and quality of life measured by the Kansas City Cardiomyopathy Questionnaire overall summary (KCCQ-OS) score.

ECHOCARDIOGRAPHY. Post-TAVR echocardiograms were collected to assess hemodynamic function of the implanted valve at 30 days and 1 year. A core laboratory read echo data for patients included in P3 and the P3 BAV registry. Paravalvular regurgitation (PVR) was graded as none or trace, mild, mild to moderate, moderate, moderate to severe, or severe and then reported here as none or trace, mild, and $\geq$moderate. The P3 CAP PVR data were site reported as none or trace, mild, and $\geq$moderate. Core laboratory results were not statistically compared with site-reported data.

STATISTICAL METHODS. Patients in the P3 BAV registry and the P3 CAP were pooled to form one BAV group. To identify clinically comparable BAV and TAV

FIGURE 1 Study Workflow



This flow chart demonstrates the number of patients that were submitted for screening from each source (PARTNER 3 [Placement of Aortic Transcatheter Valve 3] [P3] bicuspid registry, P3 continued access protocol [CAP], and P3 transcatheter aortic valve replacement (TAVR) patients with tricuspid anatomy), the number that were excluded for anatomical or clinical reasons, and the remaining number treated and available for propensity score matching. Finally, the propensity-matched analysis cohorts are shown. CT = computed tomography; inc/exc = inclusion/exclusion; PI = principal investigator; proc = procedure; SAVR = surgical aortic valve replacement.

cohorts, a 1:1 propensity score–matching analysis was performed. For each cohort, a propensity score for being in the BAV group was calculated using a logistic regression model. The following baseline variables were used as covariates: age, sex, New York Heart Association (NYHA) functional class, body mass index, STS PROM score, diabetes mellitus, peripheral vascular disease, carotid disease, hypertension, renal disease, atrial fibrillation, prior cerebrovascular accident, prior percutaneous coronary intervention, aortic valve mean gradient, effective orifice area, mitral insufficiency, and KCCQ-OS score. Where necessary, missing baseline covariates were imputed using multiple imputation according to the fully conditional specification method. The matching was performed using a greedy matching algorithm with a specified caliper distance of 0.20.

Analyses of clinical outcomes, NYHA functional class, and KCCQ-OS score were performed on both the propensity score–matched and unmatched populations. Results for the composite primary endpoint and its individual components (all-cause mortality, all stroke, and cardiovascular rehospitalization) at 30 days and 1 year are presented as Kaplan-Meier (KM) rates. Additional clinical outcomes are reported as KM or incidence rates. Continuous variables are presented as mean ± SD. Baseline characteristics and echocardiographic measurements were compared using a 2-sample Student's *t*-test. The postprocedural KCCQ-OS scores were compared using analysis of covariance. Continuous variables associated with procedural outcomes are presented as median (IQR) and were compared using the Wilcoxon rank sum test. Categorical variables were compared using Fisher exact test. Time-to-event variables presented with KM estimates were compared using the log-rank test.

RESULTS

The study workflow is presented in **Figure 1**. Patients from 28 centers in the United States were included in this study (Supplemental Table 1). Of 133 patients screened for the P3 BAV registry, 62 (46.6%) were excluded, yielding 71 treated patients. Of 187 patients screened for the P3 CAP, 89 were excluded, yielding 98 treated patients. The total number of treated

TABLE 1 Anatomical Exclusions

Reason for Exclusion	P3 BAV Registry (n = 43)	P3 CAP (n = 56)
Severe raphe calcification	3 (7.0)	24 (42.0)
Ascending aorta diameter >4 cm	9 (20.9)	13 (23.0)
Severe LVOT calcification	1 (2.3)	4 (7.0)
Risk of coronary obstruction	1 (2.3)	3 (5.0)
Severe raphe calcification and severe LVOT calcification	1 (2.3)	2 (4.0)
Unsuitable annulus size	1 (2.3)	1 (2.0)
Very extreme leaflet/annular calcification in a type 2 bicuspid		1 (2.0)
Ascending aorta diameter >4 cm and severe LVOT calcification		4 (7.0)
Ascending aorta diameter >4 cm and severe raphe calcification		2 (4.0)
Ascending aorta diameter >4 cm and severe raphe calcification and severe LVOT calcification		1 (2.0)
Inadequate iliofemoral vessel characteristics		1 (2.0)
Significant abdominal or thoracic disease	1 (2.3)	
Tricuspid aortic valve	15 (34.9)	
Unsuitable annulus size and ascending aorta diameter >4 cm	1 (2.3)	
Unsuitable annulus size and risk of coronary obstruction	1 (2.3)	
Unsuitable annulus size and severe raphe calcification	1 (2.3)	
Structurally abnormal LVOT and annulus[a]	1 (2.3)	
Aortic stenosis not calcific	2 (4.7)	
Aortic stenosis not calcific and ascending aorta diameter >4 cm	1 (2.3)	
Severe raphe calcification and ascending aorta diameter >4 cm	2 (4.7)	
Small sinus of Valsalva and/or sinotubular junction	2 (4.7)	

Values are n (%). [a]Exclusion for this patient was reported by the site.

BAV = bicuspid aortic valve; CAP = continued access protocol; LVOT = left ventricular outflow tract; P3 = PARTNER 3 (Placement of Aortic Transcatheter Valves 3) trial.

bicuspid patients available for analysis was 169. Bicuspid morphology was Sievers type 1 in 145 (85.8%) patients, 23 (13.6%) patients were type 0, and 1 (0.6%) patient was type 2. The reasons for anatomical exclusion are listed in **Table 1**.

Prior to matching, the combined group of 169 BAV patients was younger, had smaller body mass index, had lower STS PROM scores, and had a larger proportion of females than the TAV group. The BAV group also had less hypertension, atrial fibrillation, diabetes, renal insufficiency, prior percutaneous coronary intervention, and diabetes, and it showed higher transvalvular gradient and lower effective orifice area at baseline (Supplemental Table 2). There was a trend to larger annuli but with less aggressive oversizing employed (BAV 4.4% [IQR: −0.7% to 11.3%] vs TAV 7.4% [IQR: 1.1% to 13.5%]; $P < 0.01$) (Supplemental Table 3). The BAV procedures were on average 9 minutes longer with longer fluoroscopy times. Conscious sedation was used in two-thirds of the procedures with no difference between BAV and TAV groups. There was only 1 conversion to SAVR (this was in the TAV group).

Outcomes of the unmatched populations are shown (Supplemental Table 4). In the BAV group, there was 100% procedure success versus 99.6% in the TAV group. There was 1 case of coronary obstruction requiring intervention in the BAV group (under the P3 CAP). There were no cases of root rupture or aortic dissection or in-hospital deaths.

The combined BAV group had 169 patients eligible for propensity score matching against 496 eligible TAV patients in P3 (**Figure 1**). Matching yielded 148 pairs with no significant difference in baseline clinical characteristics or transvalvular gradients; however, the larger annular area in BAV patients remained significant, as did the lesser degree of valvular oversizing (**Tables 2 and 3**). The median follow-up time was 374.5 days (IQR: 366.5-391.0 days) in the BAV group and 380.5 days (IQR: 370.5-496.0 days) in the TAV group. At 30 days, there were no significant differences in death (0% vs 0%), stroke (1.4% vs 1.4%), rehospitalization (5.4% vs 4.1%), or their composite (6.8% vs 4.7%) between BAV and TAV groups. Similarly, at 1 year, rates of death (0.7% vs 1.4%), stroke (2.1% vs 2.0%), rehospitalization (9.6% vs 9.5%), and the composite primary endpoint (10.9% vs 10.2%) were not different between groups (**Table 4, Central Illustration**). The frequency of permanent pacemaker implantation at 30 days was similar (6.1% vs 6.8%). The NYHA functional class and KCCQ-OS scores were also similar between the BAV and TAV groups at both time points (**Figure 2**).

Echocardiographic findings are shown for unmatched patients from P3 TAV, P3 BAV registry, and P3 CAP (**Figure 3**). At 30 days, moderate or greater PVR was seen in 0.8% of P3 TAV patients, 1.4% of P3 BAV registry patients, and 2.3% of the P3 CAP patients; mean aortic valve gradient was 12.8 ± 0.2 mm Hg in P3 TAV, 14.0 ± 0.6 mm Hg in the P3 BAV registry, and 12.5 ± 0.53 mm Hg in the P3 CAP (**Figure 3**). The findings were similar at 1 year.

DISCUSSION

This prospective evaluation of contemporary balloon-expandable TAVR in BAV aortic stenosis, in patients at low surgical risk, showed rates of death, stroke, rehospitalization, and new pacemaker implantation that were similar to those in a propensity-matched

TABLE 2 Baseline Characteristics for Matched Subjects

	Bicuspid (n = 148)	Tricuspid (n = 148)	*P* Value
Age, y	71.0 (68.0-75.0) (148)	72.0 (68.0-75.0) (148)	0.76
Male	86/148 (58.1)	89/148 (60.1)	0.81
Body mass index, kg/m^2	28.0 (25.2-30.8) (148)	27.6 (25.1-31.3) (148)	0.98
Hypertension	109/146 (74.7)	112/148 (75.7)	0.89
Prior stroke	4/148 (2.7)	6/148 (4.1)	0.75
Carotid disease	12/124 (9.7)	14/146 (9.6)	>0.99
History of atrial fibrillation	7/148 (4.7)	2/148 (1.4)	0.17
Diabetes mellitus	26/147 (17.7)	27/148 (18.2)	>0.99
Renal insufficiency	8/148 (5.4)	9/148 (6.1)	>0.99
Peripheral vascular disease	4/148 (2.7)	5/147 (3.4)	0.75
Prior PCI	16/148 (10.8)	17/147 (11.6)	0.86
NYHA functional class III/IV	44/148 (29.7)	39/148 (26.4)	0.60
Mitral regurgitation ≥moderate	4/113 (3.5)	4/146 (2.7)	0.73
Tricuspid regurgitation ≥moderate	3/143 (2.1)	1/144 (0.7)	0.37
Mean gradient, mm Hg	49.0 (42.0-58.0) (147)	50.1 (40.2-60.6) (145)	0.57
AV area, cm^2	0.7 (0.6-0.8) (140)	0.7 (0.6-0.8) (136)	0.57
KCCQ-OS score	72.7 (55.5-83.6) (148)	72.9 (53.9-85.9) (147)	0.54
STS PROM score, %	1.4 (1.0-1.9) (148)	1.5 (1.2-1.8) (148)	0.67

Values median (IQR) (n) or n/n (%). The *t* test was used to compare continuous variables and Fisher exact test was used for categorical ones.

AV = aortic valve; KCCQ-OS = Kansas City Cardiomyopathy Questionnaire overall summary; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; STS PROM = The Society of Thoracic Surgeons Predicted Risk of Mortality.

TABLE 3 Procedural Outcomes in Matched Subjects

	Bicuspid (n = 148)	Tricuspid (n = 148)	*P* Value
Procedure duration, min	64.0 (46.0 to 89.5)	50.0 (36.0 to 65.0)	<0.01
Fluoroscopy time, min	13.3 (10.0 to 19.8)	12.0 (9.0 to 16.0)	<0.01
Annulus area, mm^2	486.0 (406.2 to 541.6) (147)	457.1 (390.3 to 516.3) (144)	0.01
Valve size			0.42
20 mm	2/148 (1.4)	5/148 (3.4)	
23 mm	47/148 (31.8)	56/148 (37.8)	
26 mm	68/148 (45.9)	61/148 (41.2)	
29 mm	31/148 (20.9)	26/148 (17.6)	
Valve size grouped			0.19
20 or 23 mm	49/148 (33.1)	61/148 (41.2)	
26 or 29 mm	99/148 (66.9)	87/148 (58.8)	
Annular oversizing, %	4.4 (-0.5 to 11.6) (147)	7.6 (1.1 to 13.8) (144)	0.02
Type of anesthesia used			0.54
General	45/148 (30.4)	55/148 (37.2)	
Conscious sedation	102/148 (68.9)	92/148 (62.2)	
Conscious sedation to general	1/148 (0.7)	1/148 (0.7)	
Procedure aborted	0/148 (0.0)	0/148 (0.0)	NA
Conversion to SAVR	0/148 (0.0)	1/148 (0.7)	>0.99
Procedure success	148/148 (100.0)	147/148 (99.3)	>0.99

Values median (IQR) (n) or n/n (%). The Wilcoxon rank sum test was used to compare groups for procedure time and fluoroscopy time. The *t* test was used for comparison of groups for annular area. Fisher's exact test was used to compare groups with categorical variables.

NA = not applicable; SAVR = surgical aortic valve replacement.

cohort of patients with TAV aortic stenosis. Moreover, important echocardiographic outcomes such as paravalvular regurgitation and transvalvular gradients were also similar in the populations studied.

CASE SELECTION AND ANATOMICAL RISK OF TAVR IN BAV AORTIC STENOSIS. Unlike TAV, BAV anatomy is highly heterogeneous. Patients exhibit variable degrees of valve calcification as well as raphe calcification, when a raphe is present. Hence, one must be careful not to extrapolate the findings observed in this study to the entire BAV low-surgical-risk population.

A new imaging-based anatomical framework for BAV risk assessment has been recently proposed, in which patients with a combination of severe valvular and severe raphe calcification were identified at highest risk for adverse outcomes including root injury and paravalvular regurgitation.[2] Based on these data of Yoon et al,[2] the presence of this combination, which they observed in a quarter of patients undergoing TAVR, may be regarded as high anatomical, or "high estimated TAVR risk," with the presence of either severe valve or severe raphe

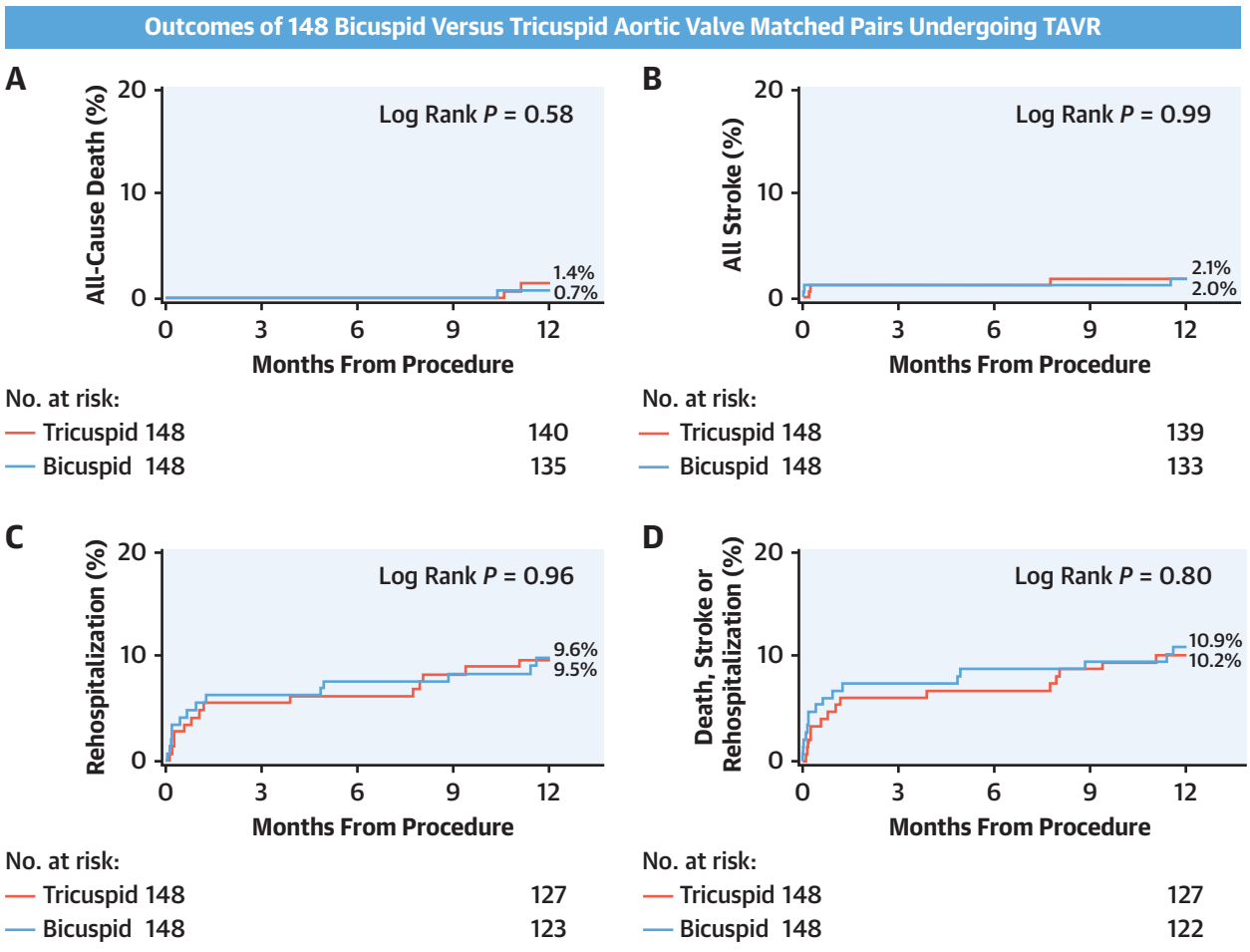
TABLE 4 Clinical Outcomes in Matched Subjects

	Time Point	Bicuspid (n = 148)	Tricuspid (n = 148)	*P* Value
Death, stroke, or rehospitalization	30 d	10 (6.8)	7 (4.7)	0.44
	1 y	16 (10.9)	15 (10.2)	0.80
Death	30 d	0 (0.0)	0 (0.0)	NA
	1 y	1 (0.7)	2 (1.4)	0.58
Rehospitalization	30 d	8 (5.4)	6 (4.1)	0.58
	1 y	14 (9.6)	14 (9.5)	0.96
Stroke	30 d	2 (1.4)	2 (1.4)	0.99
	1 y	3 (2.1)	3 (2.0)	0.99
New permanent pacemaker	30 d	9 (6.1)	10 (6.8)	0.81
	1 y	10 (6.8)	11 (7.4)	0.82

Values are n (%). The *P* values were determined from the log-rank test.

NA = not applicable.

CENTRAL ILLUSTRATION **Time-to Event Curves for Propensity-Matched Tricuspid and Bicuspid Patients Through 1 Year**



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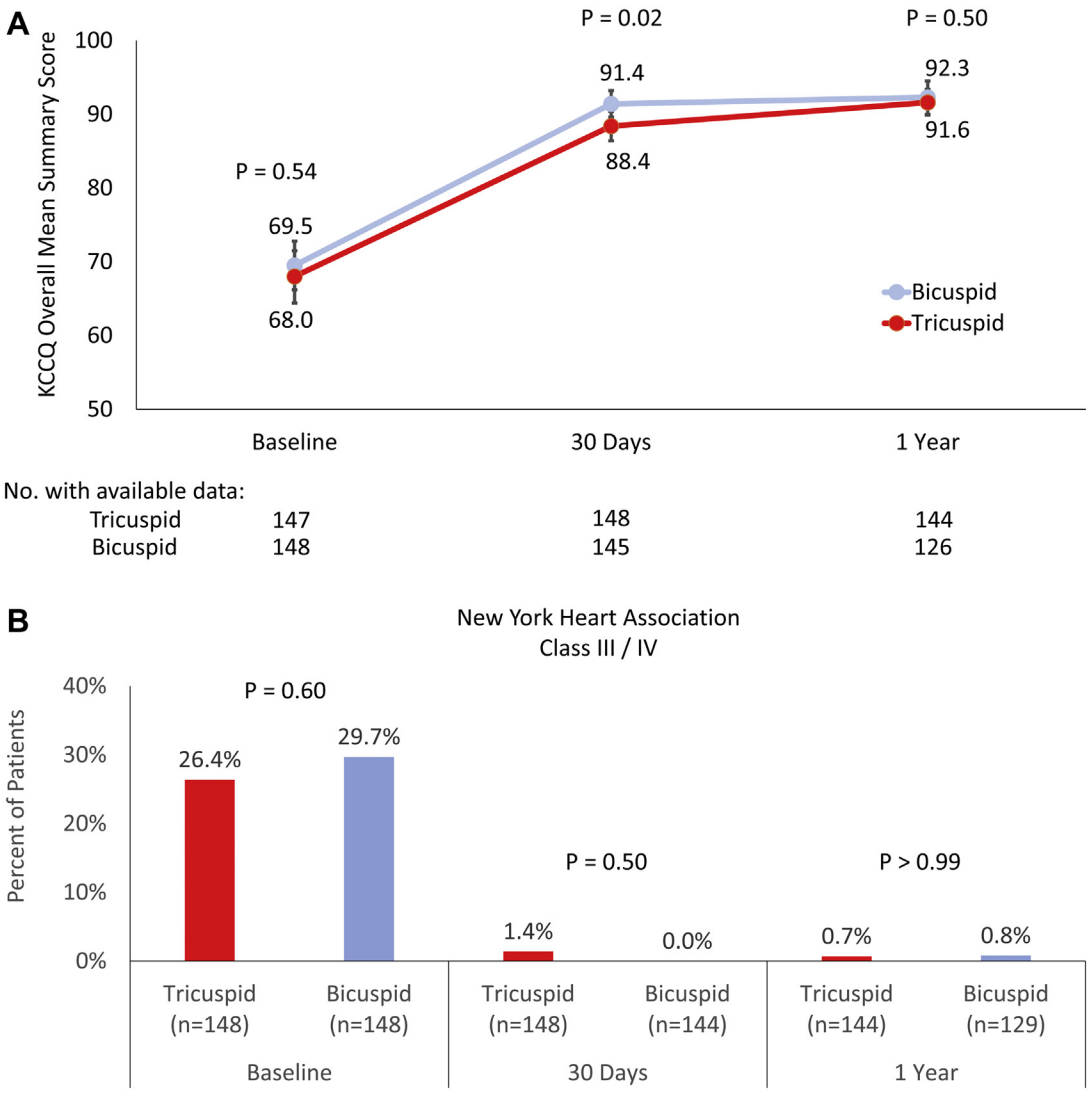
Kaplan-Meier rates are shown for **(A)** death, **(B)** stroke, **(C)** cardiovascular rehospitalization, and **(D)** the composite primary endpoint (death, stroke, or rehospitalization [Rehosp]) through 1 year in propensity score–matched bicuspid and tricuspid groups. The *P* values were determined from the log-rank test. There were no significant differences between groups for any outcome. TAVR = transcatheter aortic valve replacement.

calcium indicating "intermediate estimated TAVR risk." Indeed, the presence of subvalvular (also known as left ventricular outflow tract) calcium may also be considered an indicator of "high estimated TAVR risk" for patients with both BAV and TAV. Such patients with severe left ventricular outflow tract calcium or severe raphe calcium were, per protocol, excluded from the present study. Although most anatomical exclusions were for tricuspid anatomy in P3 BAV registry, severe raphe calcification accounted for 42% of anatomical exclusions from the P3 BAV CAP (Table 1). Thus, the favorable outcomes of the present study must be placed in this context of a large cohort of BAV patients excluded based on these anatomical criteria. This is a testament to appropriate case selection for the study but raises a caveat on the extrapolation of its findings to the entire BAV population.

In contrast to surgical risk, which is clearly quantifiable by clinical parameters in the STS PROM score, quantification of TAVR risk is predominantly anatomically driven and remains an important concept for future research; in the absence of such clarity, undoubtedly when evaluating low-surgical-

FIGURE 2 **Health and Symptom Status Through 1 Year**

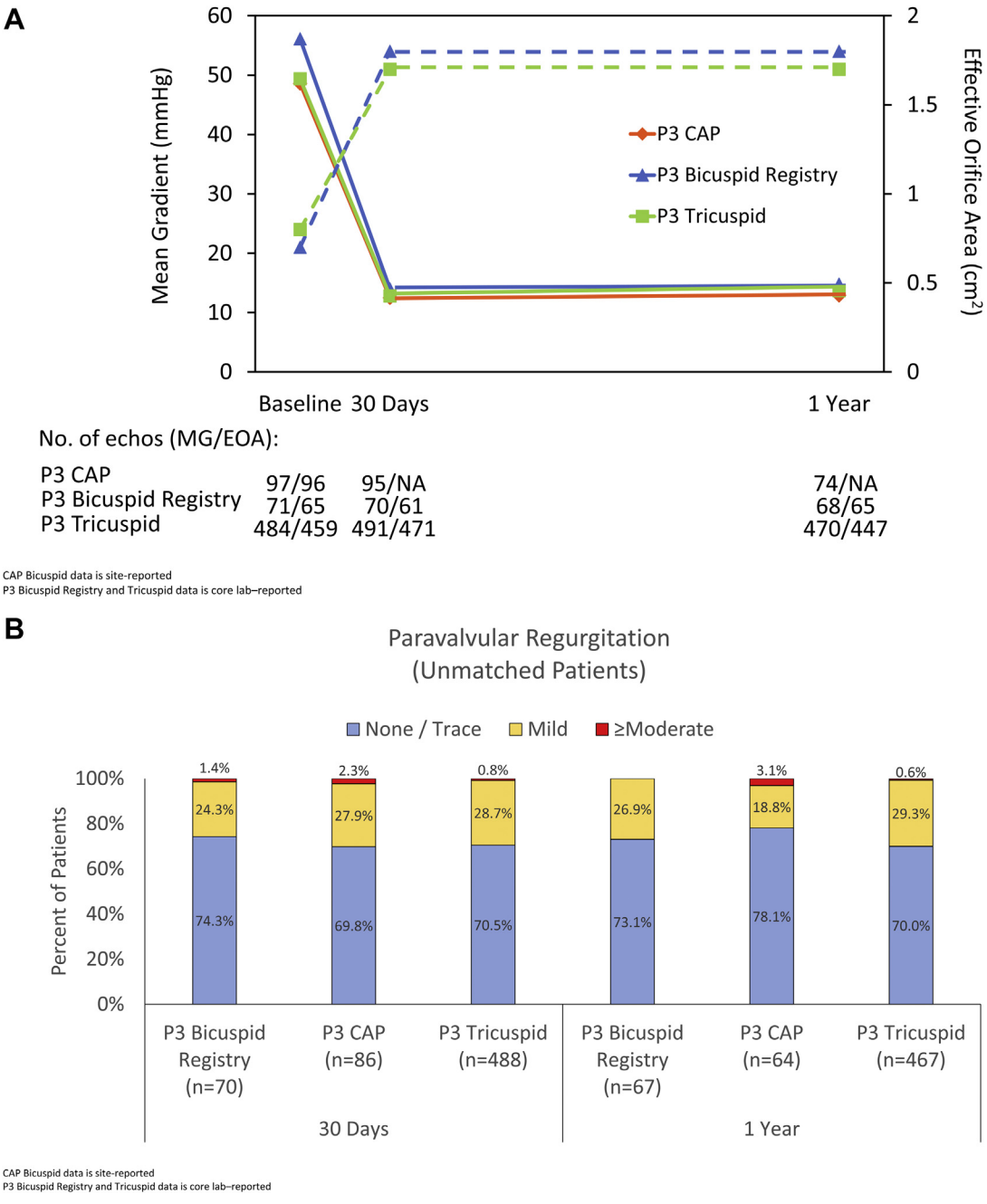


(A) The overall summary score for the Kansas City Cardiomyopathy Questionnaire (KCCQ) at baseline, 30 days, and 1 year is shown. The scale ranges from 0 to 100, with an increasing number indicating better health. Group means at each time point were compared using analysis of covariance. Bicuspid patients had a significantly better quality of life relative to tricuspid patients at 30 days, but this difference disappeared at 1 year. Both groups had a clinically meaningful improvement relative to baseline. **Error bars** represent 95% CIs. **(B)** The percentage of patients in New York Heart Association functional class III or IV at baseline, 30 days, and 1 year is presented. The *P* values were calculated from Fisher exact test. Almost no patients remained with New York Heart Association functional class III or IV symptoms following treatment.

risk BAV patients, the heart team should carefully consider the putative, currently qualitative, "estimated TAVR risk" and appropriately direct patients with elevated estimated TAVR risk to SAVR. There is considerable scope in the future for greater precision in this anatomical-based selection, including a potential application of artificial intelligence and computer-derived predictive algorithms.[7,8]

OTHER ANATOMICAL CONSIDERATIONS IN THE BAV POPULATION. Even in the absence of a raphe, patterns of calcification exist that could significantly impact device expansion. For instance, calcification may be extremely asymmetric and can also be circumferential or near circumferential, regardless of Sievers subtype. Such patterns may also present elevated "estimated TAVR risk."

FIGURE 3 Hemodynamics Through 1 Year



The available echocardiography data are presented for the bicuspid and tricuspid patients without propensity score matching. Data for patients in the P3 CAP were provided by the sites, whereas data from P3 TAVR and the P3 bicuspid registry were analyzed by a core laboratory. No statistical comparisons were performed between groups. **(A)** The line chart representation of mean gradient (MG) **(solid lines)** and effective orifice area (EOA) **(dotted lines)** at baseline, 30 days, and 1 year demonstrates that treatment relieved flow obstruction across the aortic valve in bicuspid and tricuspid patients. **(B)** This stacked bar chart shows that most patients had no paravalvular regurgitation at 30 days and 1 year. NA = not applicable; other abbreviations as in Figure 1.

The presence of aortopathy is important in the low-surgical-risk BAV population, as it presents a disease state whose only current effective therapy is open surgery. The presented study erred on the side of caution in excluding patients with an ascending aorta diameter over 40 mm. Limited data exist on progression of aortopathy following TAVR, and such data are crucial for decision making in the low-surgical-risk population. Moreover, aortopathy may also be associated with a friable or thin aortic vessel wall, which poses the theoretical risk of aortic injury with device manipulation, although this may be mitigated by the "no contact" feature of the steerable system employed.

DURABILITY OF TAVR IN BAV. The data available in BAV thus far have focused on early TAVR outcomes. Although such outcomes in the aforementioned "low estimated TAVR risk" BAV anatomy may be favorable, the presence of asymmetric calcification may result in device frame distortion. Even with favorable immediate hemodynamics, such distortion could impact durability. For balloon-expandable TAVR in TAV, device frame distortion is extremely rare, and the majority of deployments are circular; hence, durability studies for TAVR in TAV cannot be extrapolated to BAV and require separate careful follow-up.

STUDY LIMITATIONS. The P3 BAV registry has planned a 10-year follow-up; however, follow-up only goes through 1 year under the P3 CAP. Therefore, only 1-year outcomes in the combined bicuspid group may be studied. Long-term assessment of structural valve deterioration in bicuspid patients is needed. As with all registries, our results apply to the enrolled aortic stenosis population who met inclusion and exclusion criteria. Our findings may not be generalizable to all bicuspid morphologies.

CONCLUSIONS

Among highly select low-surgical-risk patients with BAV aortic stenosis with no severe raphe calcification or aorta dilation, TAVR with the SAPIEN 3 valve demonstrated similar and favorable clinical and echocardiographic outcomes to a matched cohort of TAV aortic stenosis. These findings are reassuring but care should be made not to extrapolate them to potentially elevated TAVR risk BAV anatomies, given that severe raphe calcification was a notable exclusion from the study.

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PERSPECTIVES

WHAT IS KNOWN? TAVR is a safe and effective therapy in select high-risk aortic stenosis patients with BAV morphology.

WHAT IS NEW? Among highly select low-surgical-risk patients with BAV aortic stenosis with no severe raphe calcification or aorta dilation, TAVR with the SAPIEN 3 valve can produce early clinical and echocardiographic outcomes that are similar to those achieved in patients with TAV morphology.

WHAT IS NEXT? Long-term assessment of structural valve deterioration in low-risk bicuspid patients is needed.

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KEY WORDS aortic stenosis, bicuspid, TAVR, transcatheter aortic valve replacement

APPENDIX For supplemental tables, please see the online version of this paper.