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Clinical Outcomes Following Transcatheter Aortic Valve Replacement in Asian Population

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on behalf of the Asian TAVR Investigators

ABSTRACT

OBJECTIVES This study describes the characteristics of a real-world Asian patient population treated with transcatheter aortic valve replacement (TAVR) and evaluates their clinical outcomes.

BACKGROUND No previously reported randomized or observational studies adequately assess the safety and efficacy of TAVR in an Asian population.

METHODS The Asian TAVR registry is an international multicenter study that enrolled patients with aortic stenosis who underwent TAVR in Asian countries.

RESULTS In total, 848 patients with mean STS score of 5.2 ± 3.8% were enrolled between March 2010 and September 2014 at 11 centers in 5 countries. The Edwards Sapien or Medtronic CoreValve was implanted in 64.7% and 35.3% of patients, respectively. The procedural success rate was 97.5%. The 30-day and 1-year mortality rates were 2.5% and 10.8%, respectively. There was no difference in 1-year mortality between devices (Sapien: 9.4%; CoreValve: 12.2%; log-rank $p = 0.40$). The rates of stroke, life-threatening bleeding, major vascular complications and acute kidney injury (stage 2 to 3) were 3.8%, 6.4%, 5.0% and 3.3%, respectively. Moderate or severe paravalvular leakage was significantly more common with the CoreValve than Sapien (14.4% vs. 7.3%; $p = 0.001$). According to the multivariate model, a higher STS score, lower body mass index, New York Heart Association functional class III–IV symptoms, diabetes mellitus, prior cerebrovascular accident, low mean gradient at baseline, and moderate or severe paravalvular leakage were significantly associated with reduced survival.

CONCLUSIONS Despite anatomical features of concern, the clinical outcomes of TAVR in our Asian population were favorable in comparison with those of previously published trials and observational studies. (The Asian Transcatheter Aortic Valve Replacement Registry [Asian TAVR]; NCT02308150) (J Am Coll Cardiol Intv 2016;9:926–33)

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Transcatheter aortic valve replacement (TAVR) has revolutionized the treatment of severe aortic stenosis in elderly patients and has been performed in >100,000 patients around the world (1,2). Numerous studies of the safety and efficacy of TAVR in Western countries have been published (3–8). Given the large elderly population in Asia, a substantial number of potential candidates for TAVR is expected. However, the proportion of Asian patients in previously published randomized or observational studies is very limited. Therefore, concerns persist regarding the safety and effectiveness of this novel technology applied to Asian patients due to their anatomic features, such as a small aortic root and vascular access sites which were previously reported to cause major complications and increase mortality. Therefore, there is a potential risk that the clinical outcomes could differ from those reported by previous studies in Western countries (9–11).

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The Asian TAVR registry was an international collaboration study that evaluated the safety and effectiveness of TAVR by using balloon-expandable or self-expanding prostheses for the treatment of severe aortic stenosis in Asian populations.

METHODS

STUDY DESIGN AND PATIENT POPULATION. Starting in March 2010, all consecutive patients with severe aortic stenosis who underwent TAVR at high-volume centers in Asia were prospectively included on all-comers basis. Finally, 11 centers in Singapore, Hong Kong, Taiwan, Japan, and Korea were included in the Asian TAVR registry (NCT02308150). All patients analyzed in the present study were consecutively treated with a balloon-expandable valve (Sapien; Edwards LifeSciences, Irvine, California) or a self-expanding valve (CoreValve; Medtronic Inc., Minneapolis, Minnesota). Patients who were treated with other valves or underwent TAVR because of a degenerated bioprosthetic surgical valve (i.e., valve-in-valve) were excluded from the analysis. This study was approved by the institutional review board of each institution, and all patients provided written informed consent prior to participating.

STUDY DEVICES AND PROCEDURES. The Edwards Sapien device consists of bovine pericardial tissue mounted in a balloon-expandable, stainless steel stent or a cobalt-chromium, open-cell stent (Sapien XT valve). Three sizes are available (23, 26, and 29 mm) for aortic annulus sizes of 18 to 27 mm. The 23- and 26-mm models can be implanted using either a transfemoral approach (RetroFlex 3 delivery catheter with a 22- or 24-F introducer or Novaflex delivery catheter [both from Edwards LifeSciences] with an 18-, 19-, or 20-F introducer) or a transapical or transaortic approach (Ascendra catheter [Edwards LifeSciences] with a 24-F introducer). The 29-mm model can be implanted using a Novaflex delivery catheter or an Ascendra catheter.

The CoreValve prosthesis consists of porcine pericardial tissue, which is mounted in a self-expanding nitinol stent. The transfemoral, trans-subclavian, or transaortic procedure was initially performed using an 18-F delivery catheter, which was later improved by an AccuTrak (Medtronic) stability layer. Four sizes are available (23, 26, 29, and 31 mm) for aortic annulus sizes of 18 to 29 mm.

Patients were selected for TAVR at the institutional level after the risk profile of each case was considered and discussed by the multidisciplinary heart team. Most centers could use only 1 type of device; at 2 centers, both devices were available. The access site was determined by the multidisciplinary heart team. All centers adopted a transfemoral approach-first policy, with criteria for performing a non-transfemoral approach based on the heart team's consideration of the size, calcification, and atheroma of the aortoiliofemoral artery. Device sizes were selected based largely on 3-dimensional (3D), multidetector computed tomography-based annular measurements. All TAVR procedures were conducted in accordance with local guidelines, using standard techniques through transfemoral, transapical, trans-subclavian, or transaortic access (12–17).

ENDPOINTS AND DEFINITIONS. All study endpoints were defined according to the Valve Academic Research Consortium-2 criteria (18). Primary outcome measures in the Asian TAVR registry were death from any cause at 1 month and at 1 year. Secondary

ABBREVIATIONS AND ACRONYMS

EuroSCORE = European System for Cardiac Operative Risk Evaluation

STS = Society of Thoracic Surgeons

TAVR = transcatheter aortic valve replacement

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outcome measures include cardiac death, stroke, bleeding events, vascular complications, acute kidney injury, and device success. Other endpoints included permanent pacemaker insertion, procedure- and device-related complications, early safety endpoints, and echocardiographic assessment of the valve and cardiac function at discharge. No core laboratory evaluations were used for echocardiography and computed tomography images, and all echocardiographic and computed tomographic data were reported by participating sites. The severity of regurgitation was qualitatively assessed and graded using transthoracic echocardiography at each institution according to established guidelines (18).

DATA COLLECTION. Data were collected using a dedicated electronic case report form that included baseline clinical, laboratory, echocardiographic, and computed tomographic data as well as procedural data and clinical follow-up data at 1, 6, 12, and 24 months. Clinical follow-up examinations were conducted by clinical visit and/or telephone interview. Referring cardiologists, general practitioners, and patients were contacted as necessary to obtain further information.

All data provided by each institution were anonymized, centrally collected, and assessed for quality. In particular, all outcome data were confirmed by source documentation, which was collected from each participating center and reviewed by an independent clinical events adjudication committee.

STATISTICAL ANALYSIS. Continuous variables are mean ± SD and were compared using Student *t* test or Mann-Whitney *U* test. Categorical variables are counts or percentages and were compared using the chi-square or Fisher exact test. Cumulative rates of death were calculated using Kaplan-Meier survival analysis, and the log-rank test was used for comparisons across the groups. Univariate Cox regression models were used to evaluate potential predictors of all-cause mortality. Statistically significant variables with a p value of <0.10 by univariate analysis were included in the multivariate model with stepwise regression. The proportional hazards assumption was confirmed by examination of log (–log[survival]) curves and by testing of partial (Shoenfeld) residuals, and no relevant violations were found. This study was conducted at multiple centers at different times. To account for differences in treatment, time, and changes in standards of care, all models (univariate and multivariate) were stratified by the participating center of origin. The estimated hazard ratio (HR) was provided by the Cox model. All tests were 2-sided. In this study, a p value of <0.05 was considered statistically significant. All statistical analyses were performed using SPSS version 21.0 software (SPSS, Inc., Chicago, Illinois).

TABLE 1 Baseline Patient Characteristics

	All Patients (N = 848)	Sapien (n = 549)	CoreValve (n = 299)	p Value
Age, yrs	81.8 ± 6.6	82.7 ± 6.5	80.1 ± 6.5	<0.001
Females	452 (53.3)	319 (58.1)	133 (44.5)	<0.001
Height, cm	153.7 ± 9.6	151.9 ± 9.5	157.0 ± 8.8	<0.001
Weight, kg	54.5 ± 11.2	52.8 ± 11.4	57.5 ± 10.3	<0.001
Body mass index, kg/m^2	23.0 ± 3.8	22.8 ± 3.9	23.4 ± 3.6	0.03
NYHA functional class III or IV	534 (63.0)	328 (59.7)	206 (68.9)	0.008
Logistic EuroSCORE, %	16.5 ± 12.0	16.4 ± 11.2	16.6 ± 13.2	0.86
STS score, %	5.2 ± 3.8	5.4 ± 3.8	5.0 ± 3.8	0.13
Diabetes mellitus	255 (30.1)	165 (30.1)	90 (30.1)	0.99
Renal insufficiency*	321 (37.9)	177 (32.2)	144 (48.2)	<0.001
Hypertension	645 (76.1)	432 (78.7)	213 (71.2)	0.015
Coronary artery disease	379 (44.7)	223 (40.6)	156 (52.2)	0.001
Peripheral vascular disease	131 (15.4)	89 (16.2)	42 (14.0)	0.41
Prior cerebrovascular accident	89 (10.5)	50 (9.1)	39 (13.0)	0.07
Chronic lung disease	99 (11.7)	67 (12.2)	32 (10.7)	0.52
Prior PCI	276 (32.5)	173 (31.5)	103 (34.4)	0.38
Prior cardiac surgery	82 (9.7)	60 (10.9)	22 (7.4)	0.09
Bicuspid aortic valve	49 (5.8)	8 (1.5)	41 (13.7)	<0.001
Echocardiographic findings				
Mean gradient, mm Hg	51.4 ± 18.7	50.8 ± 18.6	52.6 ± 18.9	0.17
Aortic valve area, cm^2	0.6 ± 0.2	0.6 ± 0.2	0.6 ± 0.2	0.48
LVEF, %	59.2 ± 12.3	59.9 ± 11.9	58.0 ± 12.8	0.029
Mitral regurgitation ≥ moderate	118 (13.9)	52 (9.5)	66 (22.1)	<0.001
Pulmonary hypertension†	108 (12.7)	33 (6.0)	75 (25.1)	<0.001

Values are mean ± SD or n (%). *Renal insufficiency indicates creatinine clearance <60 ml/min/1.73 m^2. †Pulmonary hypertension indicates pulmonary artery pressure ≥60 mm Hg.

EuroSCORE = European System for Cardiac Operative Risk Evaluation; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; STS = Society of Thoracic Surgeons.

RESULTS

BASELINE CHARACTERISTICS. In total, 873 patients were treated with TAVR across 11 participating centers between March 2010 and September 2014. Eighteen patients treated with other valves and 7 patients who underwent aortic valve-in-valve TAVR were excluded from analysis. A final cohort of 848 patients was analyzed in the present study. Baseline demographics of the study patients are outlined in Table 1. The mean patient age was 81.8 ± 6.6 years, 53.3% were female, and mean body mass index was 23.0 ± 3.8 kg/m^2. Mean Logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) and Society of Thoracic Surgeons (STS) scores for predicting risk of mortality were 16.5 ± 12.0 and 5.2 ± 3.8, respectively.

The Sapien prosthesis valve was used in 549 patients (64.7%), and the CoreValve in 299 patients (35.3%). Generally, patients treated with Sapien were

older, more likely to be female, have a smaller body mass index, and were more likely to demonstrate hypertension. On the other hand, patients who received the CoreValve were more likely to have New York Heart Association functional class III to IV symptoms, renal insufficiency, coronary artery disease, a low ejection fraction, mitral regurgitation classified as greater than moderate, and pulmonary hypertension. There were no significant differences with respect to Logistic EuroSCORE and STS scores between these groups. Of note, 49 patients (5.8%) with bicuspid aortic valves were treated with TAVR (Sapien: 1.5%; CoreValve: 13.7%; $p < 0.001$).

COMPUTED TOMOGRAPHY AND PROCEDURAL DATA. Computed tomographic findings showed a mean annulus diameter of 23.0 ± 2.1 mm, a mean annulus area of 405.0 ± 75.1 mm^2, and a mean perimeter of 72.8 ± 6.6 mm (Online Table 1). The height of the coronary artery ostium was 16.6 ± 2.8 mm on the right side and 12.8 ± 2.6 mm on the left side. The minimal diameters of the iliofemoral artery were 6.5 ± 1.3 mm on the right side and 6.3 ± 1.5 mm on the left side. Patients treated with the CoreValve demonstrated larger annulus dimensions and iliofemoral artery diameters. Transfemoral access was more commonly used in the CoreValve group (80.3% vs. 97.0%, respectively; $p < 0.001$). The size most commonly used was 23 mm in the Sapien group and 26 mm in the CoreValve group.

PROCEDURAL AND CLINICAL OUTCOMES. Procedural and clinical outcomes are presented in Table 2. Procedural success rate was 97.5%. Conversion to open heart surgery and coronary obstruction occurred in 1.8% and 1.3% of patients, respectively. The Sapien group demonstrated a strong trend toward increased incidence of aortic injury, although this was not statistically significant (1.3% vs. 0.0%, respectively; $p = 0.056$), and the CoreValve group demonstrated a significantly higher requirement for a second valve implantation (0.7% vs. 11.4%, respectively; $p < 0.001$) or a new permanent pacemaker (4.0% vs. 19.4%, respectively; $p < 0.001$). Moderate or severe paravalvular leakage occurred more frequently in the CoreValve group than in the Sapien group (14.4% vs. 7.3%, respectively; $p = 0.001$). Accordingly, the device success rate was significantly higher in the Sapien group (91.1% vs. 75.3%, respectively; $p < 0.001$).

The rates of any stroke, life-threatening or major bleeding, major vascular complications, and acute kidney injury (stages 2-3) were 3.8%, 10.8%, 5.0%, and 3.3%, respectively. There were no differences between the devices in terms of major complications, except for a higher rate of vascular complications in the Sapien group (11.7% vs. 6.0%, respectively; $p = 0.008$).

TABLE 2 Procedural and Clinical Outcomes

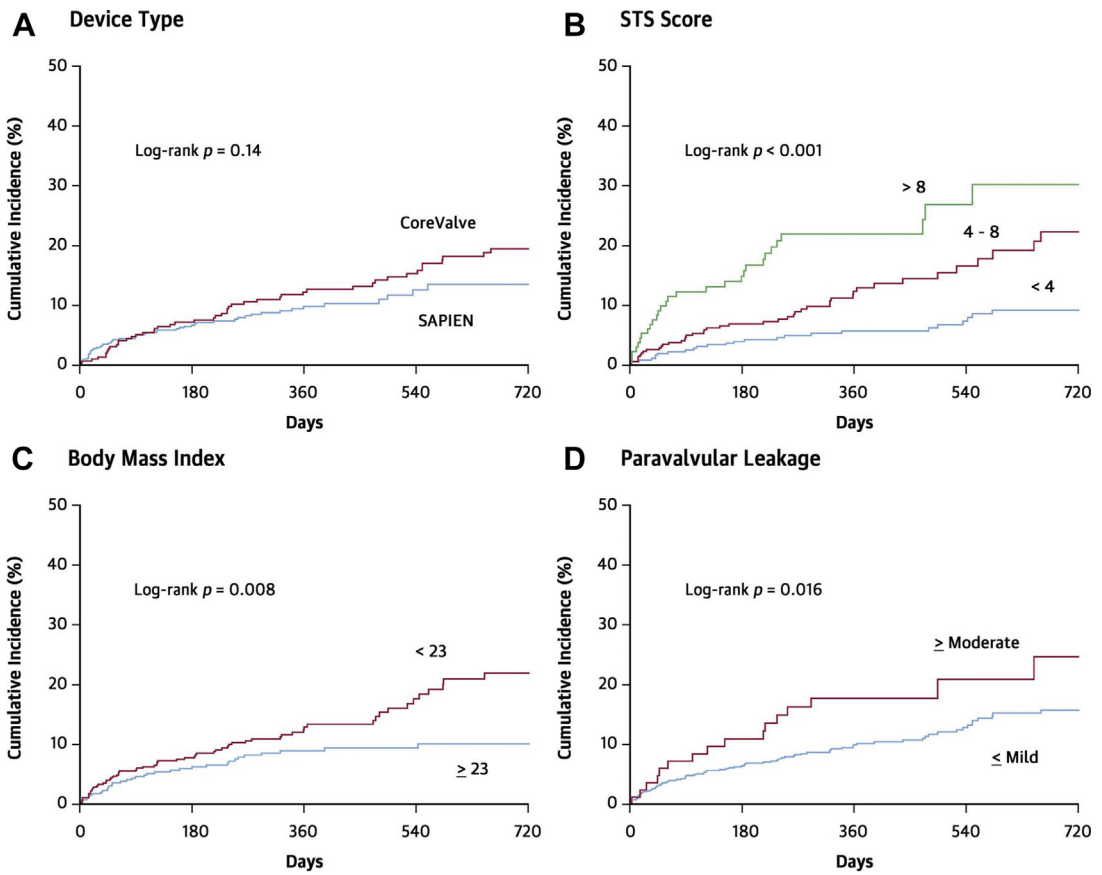
Outcome	All Patients (N = 848)	Sapien (n = 549)	CoreValve (n = 299)	p Value
Procedural outcomes				
Procedural success	827 (97.5)	534 (97.3)	293 (98.0)	0.52
Conversion to open heart surgery	15 (1.8)	10 (1.8)	5 (1.7)	0.88
Coronary obstruction	11 (1.3)	8 (1.5)	3 (1.0)	0.76
Aortic injury	7 (0.8)	7 (1.3)	0 (0.0)	0.056
Aortic root rupture	4 (0.5)	4 (0.9)	0 (0.0)	0.30
Aortic dissection	3 (0.4)	3 (0.7)	0 (0.0)	0.56
Implantation of two valves	38 (4.5)	4 (0.7)	34 (11.4)	<0.001
Permanent pacemaker implantation	80 (9.5)	22 (4.0)	58 (19.4)	<0.001
Paravalvular leak ≥ moderate	83 (9.8)	40 (7.3)	43 (14.4)	0.001
Device success	725 (85.5)	500 (91.1)	225 (75.3)	<0.001
Clinical outcomes				
Stroke	32 (3.8)	24 (4.4)	8 (2.7)	0.22
Disabling	19 (2.2)	14 (2.6)	5 (1.7)	0.56
Nondisabling	13 (1.5)	10 (1.8)	3 (1.0)	0.41
Bleeding	92 (10.8)	59 (10.7)	33 (11.0)	0.90
Life-threatening	54 (6.4)	37 (6.7)	17 (5.7)	0.55
Major	38 (4.5)	22 (4.0)	16 (5.4)	0.37
Vascular complications	82 (9.7)	64 (11.7)	18 (6.0)	0.008
Major	42 (5.0)	33 (6.0)	9 (3.0)	0.054
Minor	40 (4.7)	31 (5.6)	9 (3.0)	0.08
Acute kidney injury (stage 2 or 3)	28 (3.3)	14 (2.6)	14 (4.7)	0.10
Early safety endpoints at 30 days	124 (14.6)	85 (15.5)	39 (13.0)	0.34
Death				
At 30 days				
From any cause	21 (2.5)	17 (3.1)	4 (1.3)	0.12
From cardiovascular cause	14 (1.7)	10 (1.8)	4 (1.3)	0.78
At 1 year				
From any cause	81 (10.8)	47 (9.4)	34 (12.2)	0.40
From cardiovascular cause	35 (4.6)	20 (4.3)	15 (5.4)	0.48
At 2 years				
From any cause	99 (16.7)	52 (13.5)	47 (19.5)	0.20
From cardiovascular cause	44 (8.0)	22 (6.2)	22 (9.6)	0.25

Values are mean ± SD or n (%).

Rates of death from any cause at 30 days and at 1 and 2 years were 2.5%, 10.8%, and 16.7%, respectively (Online Figure 1). There were no differences in mortality between device subjects (HR: 1.33; 95% confidence interval [CI]: 0.91 to 1.95; $p = 0.14$) (Figure 1A). Mortality differed significantly among patients with low, intermediate, and high surgical risk according to STS score (<4, 4-8, or >8; HR of STS 4-8 vs. STS <4: 2.20; 95% CI: 1.39 to 3.47; $p < 0.001$; and HR of STS >8 vs. STS <4: 4.18; 95% CI: 2.52 to 6.93; $p < 0.001$) (Figure 1B). Furthermore, low body mass index and moderate or severe paravalvular leakage were significantly associated with increased mortality (Figures 1C and 1D).

On multivariate analysis, we found that the factors that had significant associations with mortality

FIGURE 1 Time-To-Event Curves for Death From Any Cause by Subgroup



Cumulative incidence curves for all-cause mortality are shown separately according to **(A)** device type, **(B)** STS score (<4, 4 to 8, or >8), **(C)** body mass index, and **(D)** paravalvular leakage. Event rates were calculated using Kaplan-Meier methods and were compared using the log-rank test. STS = Society of Thoracic Surgeons.

included a high STS score, low body mass index, New York Heart Association functional classes III to IV symptoms, diabetes mellitus, prior cerebrovascular accident, low mean gradient at baseline, and moderate or severe paravalvular leakage (Table 3).

DISCUSSION

This is the first large-scale study to evaluate the safety, efficacy, and clinical outcomes of Asian patients who underwent TAVR by using Sapien and CoreValve prostheses. The main findings included acceptable clinical outcomes of TAVR in Asian patients despite anatomical features of concern and Sapien and CoreValve demonstrated similar mortality rates, although different device-specific complications were observed. The present study also evaluated Asian patient characteristics, including small stature. Body mass indexes, annulus dimensions, and iliofemoral arteries are smaller in Asian patients than in Western patients. All these anatomical features raise concerns about an increased risk of major

TABLE 3 Multivariate Predictors of Death From Any Cause

Predictor	Multivariate Analysis Hazard Ratio (95% CI)	p Value
Body mass index, m^2/kg	0.92 (0.87–0.97)	0.003
NYHA functional class III or IV	2.25 (1.38–3.67)	0.001
STS score	1.07 (1.04–1.09)	<0.001
Diabetes mellitus	1.56 (1.05–2.32)	0.03
Prior cerebrovascular accident	1.87 (1.15–3.02)	0.011
Mean gradient at baseline, per increase of 10 mm Hg	0.86 (0.77–0.96)	0.009
Paravalvular leak ≥ moderate	2.41 (1.42–4.09)	0.001

CI = confidence interval; other abbreviations as in Table 1.

complications and poorer long-term outcomes. There have been no comparable studies that adequately assessed the clinical outcomes of TAVR, using the Sapien and CoreValve devices.

Among the 848 patients in our present study cohort who underwent TAVR, the Sapien device was used in 549 cases (64.7%) and the CoreValve device in the remaining 299 patients (35.3%). Transfemoral access was used in 441 patients (80.3%) who received Sapien and in 290 patients (97.0%) who received CoreValve. Most patients received the smallest prosthesis (23 mm for Sapien or 23 to 26 mm for CoreValve). Due to the 3D assessment of the annulus dimensions, using computed tomography, the selected optimal device size was most likely correct. TAVR was carried out successfully in most patients, demonstrating a technical success rate of 97.5%. The incidences of emergent open surgery and aortic injury in the present study series were comparable to those previously reported (19,20). The incidence of coronary obstruction was 1.3% in our current cohort. This relatively higher rate might have been associated with anatomical features such as a small annulus and lower left coronary height in Asian patients, and the importance of careful screening thus needs to be highlighted (21,22). The incidences of moderate and severe paravalvular leakage after Sapien and CoreValve implantation (7.3% and 14.4%, respectively) were comparable to the 9.1% and 16.0% rates reported in a previously published meta-analysis (23). Similarly, the rate of new permanent pacemaker insertion in our present patients was comparable to previously reported rates (20). However, the observed higher rate of second CoreValve implantation might have been associated with early experience and may require further investigation. Due to more frequent paravalvular leakage and the need for second valve implantation, device success rate was significantly lower in CoreValve group (75.3% vs. 91.1%, respectively; $p < 0.001$). Interestingly, the prevalence of bicuspid aortic valve in Asian population was reported to be 5.8% and would increase to 10.8% with exclusion of Japanese centers in which bicuspid aortic valve was ruled out for the indication of TAVR. This rate, which was numerically higher than those reported from Europe and North America (1.3% to 4.7%), and its associated outcomes, should be evaluated in further studies (24–27).

The incidence of stroke, bleeding, vascular complications, and acute kidney injury was favorable in our present patients in comparison to those reported previously (20). Dedicated assessments of the access sites using multimodal imaging might outweigh the potential risks of bleeding and vascular complications in Asian patients with small iliofemoral arteries. Rates of vascular complications in the Sapien group tended to be higher than those in the CoreValve group, most likely due to the different device profiles and iliofemoral artery sizes in each group. In terms of device comparison, complications such as aortic injury and vascular complications that can develop immediately after surgery tended to be more common in patients with Sapien implants, whereas complications such as paravalvular leakage and new permanent pacemaker implantation, which could affect long-term outcomes, were more common in patients who underwent CoreValve implantation.

The 30-day mortality was 2.5% in our present study. The 30-day mortality has decreased from 10% to approximately 3% in recent studies. In 2011 to 2012, the FRANCE 2 (French Aortic National CoreValve and Edwards) registry reported a 30-day mortality rate of 9.7%, and the U.K. TAVI (United Kingdom Transcatheter Aortic Valve Implantation) registry reported a 30-day mortality rate of 7.1% (5,7). Several years later, the GARY (German Aortic Valve Registry) and ADVANCE (CoreValve Advance International) study reported in-hospital and 30-day mortality rates of 5.2% and 4.5%, respectively (28,29). More recently, the OBSERVANT (Observational Study of Effectiveness of SAVR-TAVI Procedures for Severe Aortic Stenosis Treatment) and NOTION (Nordic Aortic Valve Intervention) trial reported 30-day mortality rates of 3.2% and 2.1%, respectively (30,31). The trend toward decreases in 30-day mortality might be due to the combination of optimized patient selection, advanced device technology, and fewer baseline comorbidities.

The 1-year mortality rate in our present study was 10.8%, which is one of the lowest observed in a real-world setting. Early mortality tended to be higher in the Sapien group than in the CoreValve group, as expected from the higher frequency of complications following Sapien implantation that affect the acute phase. However, this difference diminished during the follow-up period, probably due to more frequent paravalvular leakage with CoreValve and other baseline comorbidities. Our multivariate analysis affirmed the importance of coexisting comorbidities, as the STS score was found to be a significant predictor of mortality. In addition, low body mass index was significantly associated with reduced survival. This finding is in line with results of the PARTNER trial (3). Furthermore, moderate or severe paravalvular leakage was associated with increased mortality. Given the optimized 3D assessment of the annulus

dimensions, the incidence of paravalvular leakage warrants further advancements in implantation technique and device design.

STUDY LIMITATIONS. First, this was a nonrandomized and observational study, and thus, the results should be carefully interpreted. In particular, significant differences in baseline characteristics, including age, sex, and comorbidities, might have affected clinical outcomes between the groups. Therefore, direct comparisons of the clinical outcomes between the Sapien and CoreValve devices require further investigation. Second, mean STS score of 5.2% and mean EuroSCORE results of 17.3% found in our analysis are consistent with an intermediate-risk population, rather than a purely high-risk population. This occurred despite the fact that standard inclusion and exclusion criteria were applied and that the heart team agreed that each patient was at increased surgical risk. The reasons for this discrepancy, thus, remain unclear. The shortcomings of the STS score and EuroSCORE mechanisms may have also played a role in this outcome because they do not incorporate a number of important patient comorbidities such as frailty, hostile mediastinum, or porcelain aorta, all of which are critical to determining the patient's overall risk. Nevertheless, we acknowledge that a lower risk profile might have contributed to our favorable clinical outcomes. Finally, the lack of a core laboratory to centrally assess the echocardiographic findings could have led to an under- or overestimation of the paravalvular leakage grades. Also, there were no follow-up echocardiographic assessments in this study, which should be included in further studies.

CONCLUSIONS

Despite anatomic features of concern, the clinical outcomes of TAVR in Asian patients are comparable with those of previously published trials and observational studies from Western countries.

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PERSPECTIVES

WHAT IS KNOWN? Although numerous studies have demonstrated the safety and efficacy of TAVR in Western countries, very limited data exist for clinical outcomes of TAVR in Asian populations.

WHAT IS NEW? Despite concerns regarding the safety and effectiveness of TAVR in Asian patients with anatomic features, clinical outcomes of TAVR using balloon-expandable or self-expanding prostheses in Asian populations were comparable with previous published trials and observational studies from Western countries.

WHAT IS NEXT? Additional studies are needed to evaluate the safety and efficacy of TAVR in Asian populations during long-term follow-up.

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APPENDIX For a supplemental table and figure, please see the online version of this article.