For decades, surgical aortic valve replacement (SAVR) has been the only option to improve the clinical outcomes of patients with symptomatic severe aortic stenosis (AS).

However, transcatheter aortic valve implantation (TAVI) has emerged as an effective alternative to SAVR. The Placement of Aortic Transcatheter Valves (PARTNER) trial demonstrated better clinical outcomes.

Background: There are no data comparing transcatheter aortic valve implantation (TAVI) with surgical aortic valve replacement (SAVR) outcomes in real clinical practice in Japan.

Methods and Results: We combined 2 independent registries, the K-TAVI Registry (a 6-center prospective registry of consecutive patients who underwent TAVI) and the CURRENT AS Registry (a large, 27-center registry of 3,815 consecutive patients with severe aortic stenosis [AS]). In the K-TAVI Registry, 338 patients underwent TAVI with SAPIEN XT balloon-expandable valves from October 2013 to January 2016, whereas in the CURRENT AS Registry 237 patients with severe AS underwent SAVR from January 2003 to December 2011. Propensity score matching was conducted, with final cohort comprising 306 patients. The cumulative 2-year incidence of all-cause death and heart failure (HF) hospitalization did not differ significantly between the TAVI and SAVR groups (13.7% vs. 12.4% [P=0.81] and 7.9% vs 3.9% [P=0.13], respectively). After adjusting for residual confounders, there were no significant differences between the TAVI and SAVR groups in the risk for all-cause death (hazard ratio [HR] 0.74; 95% confidence interval [CI] 0.35–1.58; P=0.43) or HF hospitalization (HR 1.27; 95% CI 0.40–4.59; P=0.69).

Conclusions: These findings from 2 independent Japanese registries suggest that the 2-year risk of all-cause mortality and HF does not differ significantly between TAVI and SAVR groups in real-world practice in Japan.

Key Words: Aortic stenosis; Surgical aortic valve replacement; Transcatheter aortic valve implantation

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after TAVI compared with conventional conservative management for inoperable patients with comorbidities.7-10 Furthermore, several randomized trials have demonstrated that, compared with SAVR, TAVI in severe AS patients with high or intermediate surgical risk was associated with comparable clinical outcomes.11-20 More recently, TAVI was demonstrated to be non-inferior or even superior to SAVR in randomized clinical trials enrolling low-risk patients with severe AS.21,22 Furthermore, in real clinical practice, several observational studies have suggested comparable early and mid-term clinical outcomes of TAVI relative to SAVR.23-29 However, there no previous study has compared TAVI with SAVR in Japanese patients. Hence, we sought to compare 2-year clinical outcomes of patients who underwent TAVI and those who underwent SAVR using propensity score (PS)-matched analysis using Japanese large-scale real-world data.

Methods

Subjects
In this study we combined 2 independent registries in Japan, namely the Kyoto University-related hospital Transcatheter Aortic Valve Implantation (K-TAVI) and Contemporary outcomes after sURgery and medical tREatmeNT in patients with severe Aortic Stenosis (CURRENT AS) registries, to compare the clinical outcomes of TAVI with SAVR in patients with severe AS. Previously, we reported results of the comparison between TAVI and conservative management from the same combined database.20 The K-TAVI Registry is a 6-center prospective registry that has enrolled consecutive patients with severe AS who have undergone TAVI since October 2013. The selection of patients and the procedures of the K-TAVI Registry are detailed elsewhere.31 In the present study, we enrolled 449 patients from the K-TAVI Registry who had undergone TAVI with SAPIEN XT balloon-expandable valves (Edwards Lifesciences, Irvine, CA, USA) between October 2013 and June 2016. The age distribution of patients was quite different between the SAVR and TAVI groups; thus, in the present study, we excluded 111 patients aged <80 or >90 years because age overlap in the TAVI and SAVR patients was mostly seen in the age 80-90 years range (Supplementary Figure 1). Finally, we retrieved records for 338 TAVI patients aged 80-90 years for the TAVI group in the present study (Figure 1).

The CURRENT AS Registry is a multicenter, retrospective registry that enrolled consecutive patients with severe AS from 27 centers (20 centers with onsite surgical facilities) across Japan just before the introduction of TAVI in Japan between January 2003 and December 2011. All 6 centers that participated in the K-TAVI Registry also participated in the CURRENT AS Registry. In the present study we defined severe AS as peak aortic jet velocity (Vmax) >4.0 m/s, mean aortic pressure gradient (PG) >40 mmHg, or aortic valve area (AVA) <1.0 cm². The design and results of the CURRENT AS Registry are detailed elsewhere.32 Of 3,815 patients enrolled in the CURRENT AS registry, aortic valve replacement (AVR) strategy was initially selected in 1,197 patients. To create an SAVR population comparable to the TAVI population selected for this study, we excluded 34 patients who did not undergo SAVR, 131 patients on hemodialysis (HD) for whom TAVI has not been yet approved in Japan, and 139 asymptomatic patients with Vmax <5 m/s and left ventricular ejection fraction (LVEF) ≥50%, who are not considered candidates for SAVR or TAVI based on current guidelines. Furthermore, we excluded 656 patients aged <80 or >90 years. Finally, we retrieved data for 237 patients for the SAVR group in the present study (Figure 1).

Follow-up started on the day of TAVI or SAVR. Follow-up was censored at 2 years in both groups considering the minimal follow-up interval in the K-TAVI Registry. We obtained clinical follow-up data from the medical records, by mail, and/or through telephone interviews with patients, families, or referring physicians.

The study protocols of both registries were approved by the relevant institutional review boards at all participating hospitals, and the studies were conducted in accordance with the Declaration of Helsinki. The requirement to obtain written informed consent specifically for the K-TAVI Registry was waived because patients undergoing TAVI had provided written informed consent for the compulsory national clinical database registry; the requirement for written informed consent in the CURRENT AS Registry was also waived because of the retrospective design of the study.
Outcomes

Valve implantation for TAVI was regarded as successful if the procedure was completed without valve delivery failure, second valve implantation, annulus rupture, or conversion to open heart surgery. Other procedural endpoints of TAVI were defined based on the Valve Academic Research Consortium (VARC)-2 classification. Device success was defined as the absence of procedural mortality and correct positioning of a single prosthetic heart valve into the proper anatomical location and intended performance of the prosthetic heart valve (no prosthesis patient mismatch and mean aortic valve gradient <20 mmHg or peak velocity <3 m/s, and no moderate or severe prosthetic valve regurgitation). The primary outcome measures in this study were defined as all-cause death and heart failure (HF) hospitalizations at 2 years. Secondary outcome measures included aortic valve-related death, aortic valve procedure death, cardiovascular death, sudden death, non-cardiovascular death, myocardial infarction, stroke, infectious endocarditis, and a composite of aortic valve-related deaths or HF hospitalization. Aortic valve-related death included aortic valve procedure death, sudden death, and death due to HF possibly related to the aortic valve. HF hospitalization was defined as hospitalization due to worsening HF requiring intravenous drug therapy. Definitions of other clinical events are described in Supplementary Appendix 3. Clinical events were adjudicated by the clinical event committee (Supplementary Appendix) in the CURRENT AS Registry, whereas site-reported events were not adjudicated in the K-TAVI Registry.

Statistical Analysis

Continuous variables are presented as mean±SD or as median (IQR) and were compared using Student’s t-test or the Wilcoxon rank-sum test based on their distribution. Categorical variables are presented as n (%) and were
compared using chi-squared test.

In the comparison between TAVI and SAVR, PS matching was used as the main analysis. Once data were collected for 338 TAVI patients from the K-TAVI Registry and 237 SAVR patients from the CURRENT AS Registry, a multivariable logistic regression model was used to develop PS for the selection of TAVI with 12 variables relevant to the selection of AVR used in our previous study30 (Table 1). The c-statistic was 0.75 and the coefficients of the independent variables are presented in Supplementary Table 1. For each patient, these variables were multiplied by coefficients in the model to estimate the PS for each patient (Supplementary Figure 2). Patients were excluded without counterparts with the corresponding PS and, finally, constructed a PS-matched cohort of 306 patients (TAVI group, 153 patients; SAVR group, 153 patients). Cumulative incidences were estimated using Kaplan-Meier curves, and difference were evaluated with the log-rank test.

We constructed multivariable Cox proportional hazard models adjusted for 2 variables (age and Society of Thoracic Surgeons [STS]-predicted risk of mortality [PROM]), because these factors are strongly correlated with the indications for TAVI or SAVR, and are thus not balanced after PS matching. Hazard ratios (HRs) and their 95% confidence intervals (CIs) were determined to assess the risk of the TAVI compared with SAVR group for each outcome measure. As sensitivity analyses, multivariable Cox proportional hazards models were constructed incorporating 18 clinically relevant risk-adjusting variables (Table 1) among the entire cohort of 575 patients (TAVI group, 338 patients; SAVR group, 237 patients). In all analyses, 2-sided P<0.05 was considered significant. In the present study, all analyses were performed using JMP 14.0.0 or SAS 9.4 software (SAS Institute, Cary, NC, USA).

Table 1. Baseline Patient Characteristics

| Clinical characteristics | TAVI group (n=338) | SAVR group (n=237) | P-value | TAVI group (n=153) | SAVR group (n=153) | P-value |
|--------------------------|-------------------|-------------------|---------|-------------------|-------------------|---------|
| Age† (years)            | 86±2.9            | 83±2.6            | <0.0001 | 86±2.8            | 83±2.6            | <0.0001 |
| Men†,‡                   | 115 (34)          | 80 (34)           | 0.95    | 47 (31)           | 44 (29)           | 0.71    |
| BMI (kg/m²)             | 22.0±3.5          | 22.2±3.6          | 0.53    | 22.2±3.5          | 22.4±3.7          | 0.55    |
| BMI <22.0 kg/m²†,‡       | 173 (51)          | 118 (50)          | 0.74    | 73 (48)           | 73 (48)           | 1.00    |
| BSA (m²)                | 1.42±0.2          | 1.43±0.2          | 0.41    | 1.41±0.2          | 1.43±0.2          | 0.25    |
| Hypertension†           | 267 (79)          | 168 (71)          | 0.03    | 114 (75)          | 109 (71)          | 0.52    |
| Smoking†                | 58 (17)           | 46 (19)           | 0.49    | 26 (17)           | 29 (19)           | 0.66    |
| Dyslipidemia            | 171 (51)          | 87 (37)           | 0.0009  | 76 (50)           | 58 (38)           | 0.04    |
| Diabetes mellitus       | 97 (29)           | 45 (19)           | 0.007   | 42 (28)           | 33 (22)           | 0.23    |
| On insulin therapy†     | 9 (2.7)           | 11 (4.6)          | 0.20    | 4 (2.6)           | 6 (3.9)           | 0.52    |
| Prior MI†               | 14 (4.1)          | 13 (5.5)          | 0.46    | 6 (3.9)           | 9 (5.9)           | 0.43    |
| Prior PCI               | 92 (27)           | 16 (6.8)          | <0.0001 | 37 (24)           | 11 (7.2)          | <0.0001 |
| Prior CABG              | 33 (9.8)          | 2 (0.8)           | <0.0001 | 2 (1.3)           | 2 (1.3)           | 1.00    |
| Prior heart surgery‡    | 61 (18)           | 3 (1.3)           | <0.0001 | 3 (2.0)           | 3 (2.0)           | 1.00    |
| Prior symptomatic stroke†,‡ | 47 (14)   | 24 (10)          | 0.17    | 12 (7.8)          | 16 (10)           | 0.43    |
| Atrial fibrillation or flutter† | 41 (12) | 42 (17)        | 0.06    | 16 (10)           | 23 (15)           | 0.23    |
| Aortic or peripheral vascular disease† | 59 (17) | 36 (15)     | 0.47    | 21 (14)           | 24 (16)           | 0.63    |
| Serum creatinine† (mg/dL) | 0.9 (0.7–1.2)  | 0.9 (0.7–1.1)   | 0.05    | 0.9 (0.7–1.2)     | 0.9 (0.7–1.1)     | 0.05    |
| Serum creatinine >2 mg/dL‡ | 7 (2.1)            | 3 (1.3)          | 0.46    | 3 (2.0)           | 3 (2.0)           | 1.00    |
| Anemia†,‡               | 255 (76)          | 174 (73)          | 0.54    | 121 (80)          | 115 (75)          | 0.35    |
| Malignancy†,‡           | 28 (8.3)          | 30 (13)           | 0.09    | 17 (11)           | 15 (9.8)          | 0.71    |
| Immunosuppressive therapy‡ | 15 (4.4)          | 5 (2.1)          | 0.12    | 4 (2.6)           | 5 (3.3)           | 0.73    |
| Chronic lung disease    | 104 (31)          | 31 (13)           | <0.0001 | 34 (22)           | 19 (12)           | 0.02    |
| Chronic lung disease moderate or severe†,‡ | 37 (11) | 2 (0.8)      | <0.0001 | 2 (1.3)           | 2 (1.3)           | 1.00    |
| Coronary artery disease† | 143 (42)          | 88 (37)          | 0.21    | 56 (37)           | 54 (35)           | 0.81    |
| STS score (PROM; %)     | 6.3 (4.6–8.7)     | 4.7 (3.4–6.4)    | <0.0001 | 6.2 (4.6–9.3)     | 4.7 (3.4–6.3)     | <0.0001 |

Table 1 continued the next page.
Results

Patient Characteristics
In the entire cohort, even after excluding patients aged <80 and >90 years, patients in the TAVI group were older than those in the SAVR group (Table 1). Compared with patients in the SAVR group, patients in the TAVI group more often had hypertension, dyslipidemia, diabetes mellitus, prior percutaneous coronary intervention (PCI), prior coronary artery bypass grafting (CABG), prior heart surgery, chronic lung disease, and a higher STS score. Regarding the etiology of AS, degenerative AS was more often noted in the TAVI than SAVR group. Regarding echocardiographic data, Vmax, peak aortic PG, and LVEF were greater in the SAVR than TAVI group, and any combined valvular disease was more common in patients in the SAVR than TAVI group (Table 1). In the PS-matched cohort, the clinical characteristics were still not balanced for age, STS score, dyslipidemia, prior PCI, and chronic lung disease.

Procedural Characteristics and Outcomes of TAVI and SAVR
In the PS-matched cohort of the TAVI group, the transfemoral approach was used in only 62.1% of patients, and 98.7% of TAVI procedures were performed under general anesthesia. Selected valve sizes for TAVI were predominantly 23 or 26 mm, substantially smaller than those used for TAVI. Anemia was defined as serum hemoglobin <12 g/dL for women or <13 g/dL for men. AR, aortic regurgitation; AS, aortic stenosis; AVA, aortic valve area; BMI, body mass index; BSA, body surface area; CABG, coronary artery bypass grafting; IVST, interventricular septum thickness; LVDd, left ventricular end-diastolic diameter; LVDs, left ventricular end-systolic diameter; LVEF, left ventricular ejection fraction; MI, myocardial infarction; MR, mitral regurgitation; MS, mitral stenosis; PCI, percutaneous coronary intervention; PG, pressure gradient; PROM, predicted risk of mortality; PWT, posterior wall thickness; SAVR, surgical aortic valve replacement; STS, Society of Thoracic Surgeons; TR, tricuspid regurgitation; Vmax, peak aortic jet velocity.
**Clinical Outcomes in the PS-Matched Cohort**

The cumulative 30-day incidence of all-cause death was comparable between the 2 groups (1.3% in both the TAVI and SAVR groups; log-rank P=0.99). The cumulative 30-day incidence of stroke tended to be lower in the TAVI than SAVR group (1.3% vs. 3.9%, respectively; log-rank P=0.15; Table 2; Supplementary Table 4).

The cumulative 2-year incidence of all-cause death was not significantly different between the TAVI and SAVR groups (13.7% and 12.4%, respectively; log-rank P=0.81; Figure 2A; Table 2). Cardiovascular death tended to be higher in the SAVR group, whereas non-cardiovascular death tended to be higher in the TAVI group (Table 2; Supplementary Figures 3A, 4D). The cumulative 2-year incidence of HF hospitalization tended to be higher in the TAVI group, but the difference between the 2 groups was not significant (7.9% vs. 3.9%, respectively; log-rank P=0.13; Table 2; Figure 2B). The cumulative 2-year incidence of secondary outcome measures, such as aortic valve-related death, myocardial infarction, stroke, and a composite of aortic valve-related death or HF hospitalization, did not differ significantly between the 2 groups (Table 2; Supplementary Figures 3–5).

After adjusting for the residual confounders, there were no differences remaining in the risks for all-cause death and HF hospitalization between the 2 groups (HR 0.74 [95% CI 0.35–1.58; P=0.43] and HR 1.27 [95% CI 0.40–4.59; P=0.69], respectively; Table 2).

After excluding patients with a transapical approach, the cumulative 2-year incidence of all-cause death and HF hospitalization did not differ significantly between the TAVI and SAVR groups (12.1% and 13.4%, respectively, for all-cause death [log-rank P=0.76; 3.3% and 2.4%, respectively, for HF hospitalization [log-rank P=0.69]; Supplementary Table 5).

**Sensitivity Analysis**

After adjustment for confounders, the result for all-cause death was consistent with that in the PS-matched cohort (adjusted HR 1.40, 95% CI 0.81–2.48, P=0.23; Supplementary Figure 6A; Supplementary Table 6). Conversely, there was a significant excess risk for HF hospitalization in the TAVI compared with SAVR group (adjusted HR 2.66, 95% CI 1.14–6.82, P=0.02; Supplementary Figure 6B; Supplementary Table 6). The excess risk of the TAVI group relative to the SAVR group for non-cardiovascular death was also significant (adjusted HR 2.61, 95% CI 1.12–6.56, P=0.03; Supplementary Table 6). There were no excess risks of the TAVI group relative to the SAVR group for other secondary outcome measures, consistent with the results of analyses in the PS-matched cohort (Supplementary Figures 7–9; Supplementary Table 6).

**Discussion**

The main finding of the present study was that the 2-year risk of all-cause mortality and HF hospitalization did not differ significantly between the TAVI and SAVR groups in real-world practice in Japan.

Some randomized clinical trials have demonstrated that TAVI has comparable clinical results with SAVR, and that TAVI could be an alternative to SAVR for patients with AS who are at intermediate to high surgical risk. Therefore, current guidelines stipulate that TAVI is a reasonable alternative to SAVR for patients with AS who are at intermediate to high surgical risk. To date, several matched studies using real-world data have compared TAVI with SAVR in terms of early (≤30 days) and mid-term (≤1 year) clinical outcomes. A meta-analysis of these studies reported that TAVI exhibited comparable early and mid-term clinical outcomes compared with SAVR. However, studies from real clinical practice reporting long-term
clinical outcomes comparing TAVI with conventional SAVR have been limited, with only single-center, small studies. A retrospective multicenter study comparing TAVI with SAVR suggested that overall survival was lower in the SAVR compared with TAVI group after 2 years.

Real-world data to compare TAVI and SAVR in Japan is scarce. Evaluating clinical incidence and comparing clinical outcomes from real-world data are important to expand the indication for TAVI in Japan, and this study is the first to compare TAVI and SAVR from real-world clinical registries in Japan. In this study, the 2-year clinical outcome for all-cause mortality was similar between the TAVI and SAVR groups, consistent with previous randomized clinical trials. The mean value of the STS score (PROM) was 6.2% in the TAVI group, indicating that the present TAVI population represented not only patients at high surgical risk or a contraindication for SAVR, but also patients with intermediate or even low risk in real-world clinical practice. This situation made it possible to compare TAVI with SAVR using PS matching in real-world practice. However, even after PS matching, differences in age between the 2 groups remained significant, because the age difference between these 2 strategies in this era was evident in the real world. To address this difference, we first selected only patients aged <80 or >90 years, and then used age as a risk-adjusting variable for further adjustment after PS matching.

In the PS-matched cohort, there was no significant difference in the risk for HF hospitalization between the TAVI and SAVR groups, although the adjusted risk for HF hospitalization was significantly higher after TAVI than SAVR. Given the comparable risk for rehospitalization between the TAVI and SAVR groups in randomized trials, the slight excess risk of TAVI relative to SAVR for HF hospitalization in the present study may be related to residual confounding rather than to differences in the performance of TAVI and SAVR valves.

Regarding perioperative outcomes, the incidence of aortic valve-related death or aortic valve procedure death was 1.3% in both the TAVI and SAVR groups, demonstrating the clinical safety of both procedures in Japan. Furthermore, the 30-day incidence of stroke tended to be lower in the TAVI than SAVR group. The lower incidence of stroke in this study is supported by the Japanese National TAVI Registry assessing that the 30-day incidence of stroke (0.9%).

The results of the present study suggesting similar 2-year clinical outcomes between TAVI and SAVR are remarkable considering that the TAVI population in the present study reflected very early Japanese experience using an old generation TAVI device (SAPIEN XT), and that 30% of patients underwent TAVI with the transapical approach, which is quite high compared with current TAVI practice. Therefore, with the adoption of a predominantly transfemoral approach and improved devices, together with improved operator expertise, contemporary TAVI may have already achieved superior outcomes compared with SAVR, which has been demonstrated in the PARTNER 3 trial.

The present study has several limitations. First, we combined 2 different registries and developed a PS for the choice of TAVI in the dataset derived from 2 different registries, which is not a formal way of developing PS. Thus, the presence of unmeasured confounding variables cannot be eliminated. However, in the clinical database of
SAVR and TAVI after introduction of TAVI, the patient characteristics are completely different between the SAVR and TAVI groups. Therefore, it is not possible for us to compare the outcomes between TAVI and SAVR. This is why we selected SAVR patients from the CURRENT AS Registry, which enrolled SAVR patients before the introduction of TAVI. Second, some perioperative adverse events were not collected in the SAVR group of the CURRENT AS Registry (e.g., AKI and pacemaker implantation). Third, TAVI was selected for patients who are at high surgical risk or in whom SAVR is contraindicated in Japan. Thus, it was difficult to construct a fully matched cohort between the 2 registries. Finally, this study did not have adequate statistical power because of the low incidence of events in both groups.

Conclusions
The results of this study from 2 independent registries in Japan suggest that the 2-year risk of all-cause mortality and HF hospitalization does not differ significantly differently between the TAVI and SAVR groups in real-world practice in Japan.

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None.

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Supplementary Files

Please find supplementary file(s):
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