Favorable Clinical Outcomes of Transcatheter Aortic Valve Implantation in Japanese Patients
— First Report From the Post-Approval K-TAVI Registry —

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Background: Very limited data exist on the outcomes of transcatheter aortic valve implantation (TAVI) since Japanese marketing approval of the first TAVI device.

Methods and Results: The Kyoto University-related hospital Transcatheter Aortic Valve Implantation (K-TAVI) registry includes prospectively collected data from 6 participating hospitals in Japan. We included 302 patients with severe aortic stenosis who underwent TAVI using the SAPIEN XT balloon-expandable valve via transfemoral (TF; n=203, 67%) or transapical (TA; n=99, 33%) approach between October 2013 and September 2015. Device success rate, based on the Valve Academic Research Consortium-2 criteria, was very high in the TF (97.0%) and TA (99.0%) groups. The 30-day mortality rates were 1.5% and 1.0% in the TF and TA groups, respectively. Major complications included stroke (transient or persistent: 2.3%), annulus rupture (1.0%), coronary intervention (1.0%), major vascular complications (1.7%), and permanent pacemaker implantation (5.4%). The procedure times of the post-proctoring period (n=210) were decreased compared with those of the proctoring period (n=89) without affecting the clinical outcomes. The survival rates at 6 and 12 months were 96.9% and 92.5% in the TF group, and 93.9% and 91.8% in the TA group, respectively.

Conclusions: The K-TAVI registry data revealed that the early outcomes of TAVI using the SAPIEN XT were favorable in real-world Japanese patients.

Key Words: Aortic valve stenosis; Japanese; Transcatheter aortic valve replacement/implantation

Original Article
Valvular Heart Disease

Transcatheter aortic valve implantation (TAVI) has become a valid option for patients with severe symptomatic aortic stenosis (AS) who are inoperable or at high-risk for conventional open surgery for aortic valve replacement (SAVR).1 However, most of the previous reports of TAVI are from Caucasian cohorts, and limited data are available on Japanese patients except for the pivotal PREVAIL-Japan study.2-4 In Japan, the SAPIEN XT balloon-expandable valve (Edwards Lifesciences, CA, USA) became commercially available in October 2013. There have been no large-scale reports of initial clinical outcomes of TAVI after marketing approval in Japan. The multicenter Kyoto University-related hospital Transcatheter Aortic Valve Implantation (K-TAVI) registry aims to...
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patients who had severe AS and underwent TAVI using the SAPIEN XT balloon-expandable valve (Edwards Lifesciences), through the transfemoral (TF; 203 patients, 67%) or transapical (TA; 99 patients, 33%) approach between October 2013 and September 2015. Although the TA and TF patients had different backgrounds and underwent different procedures, a compilation of their data was analyzed in the present study. The follow-up data were censored on October 31, 2015.

Patient Selection for TAVI

Patients with symptomatic severe AS who were deemed either inoperable or at high risk for SAVR were selected for TAVI. General criteria for severe AS included a mean gradient \( \geq 40 \text{ mmHg} \), jet velocity \( \geq 4.0 \text{ m/s} \), aortic valve area (AVA) \( \leq 0.8 \text{ cm}^2 \), or effective orifice area index \( \leq 0.5 \text{ cm}^2/\text{m}^2 \).

K-TAVI Registry

The K-TAVI registry is an ongoing prospective registry that enrolls consecutive patients undergoing TAVI at 6 participating hospitals in Japan: Kokura Memorial Hospital (Kitakyushu, Fukuoka, Japan), Kurashiki Central Hospital (Kurashiki, Okayama, Japan), Kobe City Medical Center General Hospital (Kobe, Hyogo, Japan), Kyoto University Hospital (Kyoto, Kyoto, Japan), Tenri Hospital (Tenri, Nara, Japan), and Shizuoka City Shizuoka Hospital (Shizuoka, Shizuoka, Japan). The registry complies with the Declaration of Helsinki, and the relevant review boards at all participating hospitals approved the study protocol. All patients undergoing TAVI are required to be enrolled in the national clinical database registry and written informed consent is obtained. Thus, written informed consent specific for the K-TAVI registry from each patient was waived. The current study population consisted of 302

clarify the outcomes of this newly emerging therapy in real-world clinical practice in Japan.

Methods

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The local heart team evaluated each patient’s preoperative data and selected patients for whom TAVI was deemed to be the best treatment option.

Procedure

The SAPIEN XT balloon-expandable valve was used in all

Table 1. Baseline Characteristics of the Study Patients With Severe Aortic Stenosis Who Underwent TAVI

|                  | All (n=302) | TF (n=203) | TA (n=99) | P value |
|------------------|-------------|------------|-----------|---------|
| Age (years)      | 85.4±5.6    | 84.8±6.0   | 85.4±4.7  | 0.38    |
| ≥90 years        | 61 (20.2)   | 42 (20.6)  | 19 (19.1) | 0.76    |
| Male             | 103 (34.1)  | 72 (35.5)  | 31 (31.3) | 0.47    |
| STS score (%)    | 7.4±5.3     | 7.4±5.8    | 7.3±4.0   | 0.86    |
| Height (cm)      | 150±10      | 151±10     | 150±10    | 0.22    |
| Body weight (kg) | 50±11       | 52±11      | 48±12     | 0.24    |
| BMI (kg/m²)      | 22.1±3.7    | 22.2±3.6   | 21.9±3.8  | 0.39    |
| BSA (m²)         | 1.44±1.81   | 1.45±0.17  | 1.41±0.20 | 0.17    |
| Diabetes         | 81 (26.8)   | 52 (25.6)  | 29 (29.3) | 0.50    |
| Hyperlipidemia   | 168 (55.6)  | 101 (49.8) | 67 (67.7) | 0.003   |
| Hypertension     | 241 (79.8)  | 155 (76.4) | 86 (86.9) | 0.03    |
| History of stroke| 38 (12.6)   | 26 (12.8)  | 12 (12.1) | 0.84    |
| Malignancy       | 29 (9.6)    | 25 (12.3)  | 4 (4.0)   | 0.014   |
| Previous PCI     | 97 (32.1)   | 59 (29.1)  | 38 (38.4) | 0.11    |
| Previous pacemaker implantation | 18 (6.0) | 14 (6.9) | 4 (4.0) | 0.31 |
| Previous cardiac surgery | 43 (14.2) | 23 (11.3) | 20 (20.2) | 0.04 |
| Previous CABG    | 37 (12.3)   | 17 (8.4)   | 20 (20.2) | 0.004   |
| COPD (moderate-severe) | 61 (20.2) | 44 (21.7) | 17 (17.2) | 0.96 |
| NYHA class III/IV| 105 (34.8)  | 66 (32.5)  | 39 (39.4) | 0.24    |
| CRBBB            | 41 (13.6)   | 30 (14.8)  | 11 (11.1) | 0.37    |
| CLBBB            | 11 (3.6)    | 9 (4.4)    | 2 (2.0)   | 0.27    |
| Aortic valve area (cm²) | 0.62±0.17    | 0.63±0.22    | 0.61±0.13    | 0.31   |
| Aortic valve area index (cm²/m²) | 0.44±0.13    | 0.44±0.11    | 0.44±0.16    | 0.70   |
| Peak pressure gradient (mmHg) | 90.4±28.9    | 90.9±27.3    | 89.5±40.0    | 0.70   |
| Mean pressure gradient (mmHg) | 53.2±18.7    | 53.8±20.2    | 52.9±18.0    | 0.69   |
| LVEF (%)         | 61.3±10.6   | 62.2±9.9   | 59.5±11.8  | 0.04    |
| <40%             | 12 (4.0)    | 7 (3.4)    | 5 (5.0)    | 0.07    |
| Moderate-severe AR| 42 (13.9)   | 27 (13.3)  | 15 (15.1) | 0.66    |
| Annulus area (CT, mm²) | 382.3±75.3    | 384.8±79.5    | 377.6±66.9    | 0.48   |
| Access route diameter (CT, mm) | NA   | 6.7±1.0    | NA         | NA      |

Data are presented as number (%) or mean±SD. AR, aortic regurgitation; BMI, body mass index; BSA, body surface area; CABG, coronary artery bypass grafting; CLBBB, complete left bundle branch block; COPD, chronic obstructive pulmonary disease; CRBBB, complete right bundle branch block; NA, not available; PCI, percutaneous coronary intervention; STS, Society of Thoracic Surgeons; TA, transapical; TF, transfemoral; TAVI, transcatheter aortic valve implantation.
Favorable Outcomes of TAVI in Japanese Patients

Baseline and Follow-up Data Collection
Baseline data were prospectively entered into the database by the site investigators. Echocardiographic evaluation was performed by experienced cardiologists and/or technicians at each center. Clinical follow-up was conducted by regular outpatient clinic visits by the patients to the participating center. If the patients did not visit the clinic, the attending physician contacted the patient and/or family members by telephone. During follow-up, regular echocardiographic evaluation was recommended at 1, 6 and 12 months, and annually thereafter.

Definition of Endpoints
The primary endpoints included all-cause death, cardiovascular death, device success, early safety, and clinical efficacy at 30 days, and survival at 6 and 12 months. All these endpoints were based on the Valve Academic Research Consortium-2 (VARC-2) criteria. ECMO, extracorporeal membrane oxygenation. Other abbreviations as in Table 1.

Statistical Analysis
Categorical variables are presented as numbers and percentages, and compared with the Chi-squared test or Fisher’s exact test. Continuous variables are presented as mean and standard deviation (SD), or median and interquartile range (IQR) as appropriate. Based on their distributions, continuous variables were compared using Student’s t-test or the Wilcoxon rank sum test. Survival analysis was conducted using the Kaplan-Meier method, with patients being censored as of the last known date alive, and the differences between the TF and TA approach were assessed.

Table 2. Procedural Characteristics and Outcomes of the Study Patients With Severe Aortic Stenosis Who Underwent TAVI

| Procedural characteristics | All (n=299) | TF (n=200) | TA (n=99) | P value |
|----------------------------|------------|-----------|----------|---------|
| Procedure time (min)       | 107±47     | 102±50    | 119±38   | 0.004   |
| 20-mm valve                | 0 (0)      | 0 (0)     | 0 (0)    | NA      |
| 23-mm valve                | 193 (64.5) | 132 (66.0)| 61 (61.6)| 0.46    |
| 26-mm valve                | 96 (32.1)  | 60 (30.0) | 36 (36.4)| 0.27    |
| 29-mm valve                | 10 (3.3)   | 8 (4.0)   | 2 (2.0)  | 0.35    |
| General anesthesia         | 298 (99.7) | 199 (99.5)| 99 (100) | 0.37    |
| ECMO support               | 12 (4.0)   | 4 (2.0)   | 8 (8.1)  | 0.02    |

Procedural outcomes

| Annuus rupture | 3 (1.0) | 3 (1.7) | 0 (0.0) | 0.12 |
| Coronary intervention | 3 (1.0) | 2 (1.0) | 1 (1.0) | 0.99 |
| Stroke (total) | 7 (2.3) | 4 (2.0) | 3 (3.0) | 0.59 |
| Transient      | 2 (0.7) | 1 (0.5) | 1 (1.0) | 0.62 |
| Persistent     | 5 (1.7) | 3 (1.5) | 2 (2.0) | 0.75 |
| Life-threatening bleeding | 7 (2.3) | 5 (2.5) | 2 (2.0) | 0.79 |
| Major vascular complication | 5 (1.7) | 5 (2.5) | 0 (0.0) | 0.04 |
| Pacemaker implantation | 16 (5.4) | 14 (7.0) | 2 (2.0) | 0.051 |
| Hospital stay after TAVI (days) | 15.9±16.2 | 14.2±14.3 | 19.3±19.1 | 0.011 |
| Early safety at 30 days | 269 (90.0) | 178 (89.0) | 91 (91.9) | 0.42 |
| Clinical efficacy at 30 days | 285 (95.3) | 191 (95.5) | 94 (95.0) | 0.83 |
| 30-day mortality | 4 (1.3) | 3 (1.5) | 1 (1.0) | 0.72 |

Data are presented as number (%) or mean±SD. Procedure time was defined as the interval from the first skin incision to skin closure. Early safety, clinical efficacy, major vascular complication, and life-threatening bleeding were defined according to Valve Academic Research Consortium-2 (VARC-2) criteria. ECMO, extracorporeal membrane oxygenation. Other abbreviations as in Table 1.
using the log-rank test. All statistical analyses were conducted using JMP 10.0 software (SAS Institute Inc., NC, USA). P<0.05 was considered as statistically significant.

Results

A total of 302 patients were included in the study (TF, 203 patients, 67%; TA, 99 patients, 33%). The baseline characteristics of the patients are summarized in Table 1. The vast majority of patients were super-elderly with a mean age of 85.0±8.5 years, and approximately two-thirds of the patients were female. The mean body size was relatively small with a mean body surface area (BSA) of 1.45±0.19 (m^2). The length of hospital stay after TAVI was 14.2±14.3 (median, 11.0; IQR, 8.0–16.0) days in the TF group and 19.1±19.1 (median, 13.0; IQR, 10.0–22.0) days in the TA group (P=0.01). New permanent pacemaker implantation was required in 14 patients (7.0%) in the TF group, and in 8 patients (8.1%) in the TA group (P=0.37). The 30-day mortality rate was also

Table 3. Procedural Outcomes During and After the Proctoring Period for the Study Group of Patients With Severe Aortic Stenosis Who Underwent TAVI

|                                | During the proctoring period (n=89) | After the proctoring period (n=210) | P value |
|--------------------------------|----------------------------------|-----------------------------------|---------|
| Procedure time (min)           | 134.8±50.4                       | 96.4±40.0                        | <0.0001 |
| Hospital stay after TAVI (days)| 18.3±21.7                        | 14.9±13.2                        | 0.09    |
| Early safety at 30 days (%)    | 93.3                             | 89.5                             | 0.30    |
| Clinical efficacy at 30 days   | 94.5                             | 96.7                             | 0.37    |
| 30-day mortality (%)           | 3.40                             | 0.5                              | 0.06    |

TAVI, transcatheter aortic valve implantation.
very low in both groups (TF: 3 patients (1.5%); TA: 1 patient (1.0%)). The causes of death were interstitial pneumonia, tuberculosis, and cardiogenic shock in the TF group, and pneumonia in the TA group. Early safety rates were high in both the TF group (89.5%) and the TA group (93.0%). Clinical efficacy rates were 96.0% and 96.0% in the TF and TA groups, respectively (Table 3).

The mean follow-up period was $10.3 \pm 6.3$ (median, 9.5; IQR, 4.7–15.0) months in the TF group and $9.2 \pm 6.2$ (median, 7.5; IQR, 4.3–12.7) months in the TA group, with all patients completing the 30-day follow-up. The respective survival rates at 6 and 12 months were 96.9% and 92.5% in the TF group, and 93.9% and 91.8% in the TA group (log-rank $P=0.47$, Figure 2). The causes of death after 30 days are listed in Figure 2, and most were considered unrelated to the TAVI procedure. Echocardiographically, the aortic valve area increased significantly after TAVI from $0.62 \pm 0.17 \text{cm}^2$ to $1.62 \pm 0.37 \text{cm}^2$, while the mean pressure gradient decreased significantly from $53.2 \pm 18.7 \text{mmHg}$ to $10.9 \pm 4.4 \text{mmHg}$. These improvements were maintained at 1 year. Moderate to severe paravalvular regurgitation was rarely observed at 6 or 12 months in the TF (1.2% and 0.0%) and TA (5.4% and 0.0%) group.

We also conducted a subgroup analysis to evaluate the relationship between the STS score and the clinical outcomes. We divided the entire cohort into the high (STS score >8%; Group H) and low-intermediate (STS score ≤8%; Group LI) groups and then compared the primary endpoints. The early safety and clinical efficacy rates were significantly higher in Group LI (Table 4), as was the survival rate (Figure 3).

**Discussion**

The present study analyzed the early outcomes of TAVI based on K-TAVI registry data, and demonstrated that early outcomes of TAVI had favorable results shortly after marketing approval of the SAPIEN XT valve in Japan.

In the past decade, TAVI has become a therapeutic alternative to surgery for the treatment of severe AS in high-risk surgical patients in many European countries. In Japan, reimbursement of TAVI was approved in October 2013. However, only limited data on TAVI are currently available, and its efficacy and safety in Japanese patients have not yet been sufficiently investigated. Smaller body size is the main characteristic difference between Japanese and European patients. A smaller body size translates to a smaller aortic annulus size and smaller vascular access, which can be a premise for a higher risk of annulus rupture, or access site vascular injury. However, the K-TAVI registry data indicated that both major vascular injury and annulus rupture are very rare in Japanese patients. Other than body size, advanced age and predominance of female sex are the common characteristics of Japanese TAVI patients (Table 3).

Our results revealed that the early outcomes of TAVI in real-world Japanese patients were more favorable than the previous European or US data suggested (Table 5). Most previous studies reported more favorable results for the TF approach than for the TA approach. However, there were no differences between approaches in the K-TAVI registry, which is explained by the excellent results of the TA approach. The early and 1-year results of the K-TAVI registry are favorable for both the TF and TA approach. Device improvements and pre-procedural screening sys-

| Table 4. Procedural Outcomes in the Low-Intermediate Risk and High-Risk Groups of the Study Patients According to STS Score |
|-------------------------------------------------|-------------------------------------------------|----------------|
| Procedure time (min) | Low-intermediate risk group (n=200) | High-risk group (n=99) | P value |
| Procedure time (min) | 105.2±39.6 | 113.2±58.4 | 0.16 |
| Hospital stay after TAVI (days) | 14.0±13.1 | 19.7±20.7 | 0.004 |
| Early safety at 30 days (%) | 94.5 | 92.3 | 0.0497 |
| Clinical efficacy at 30 days (%) | 97.5 | 91.9 | 0.04 |
| 30-day mortality (%) | 0.5 | 3.0 | 0.08 |

TAVI, transcatheter aortic valve implantation.
tems using multidetector computed tomography have been identified as the important contributing factors to these favorable outcomes. Another explanation is the employment of proctoring and pre-screening systems in Japan, in which all TAVI candidates are reviewed by experienced proctors in the initial 25 cases, and all procedures are done under the supervision of an experienced proctor for the initial 8 cases for both TF and TA approaches. When comparing the procedural outcomes during the prostctoring period and the post-proctoring period, the procedure time became shorter without affecting clinical outcomes. The proctoring and pre-screening system is a unique training system in Japan, and the K-TAVI registry indicates that it is currently functioning well. Another possible reason for the favorable clinical outcomes in the present study might be related to somewhat lower STS scores in the K-TAVI registry as compared with the France 2 registry and the PARTNER Cohort A (Table 5).

Study Limitations
Several important limitations exist in the present study. First, the sample size of the K-TAVI registry is relatively small (only 302 patients) when compared with other registries. Second, the follow-up duration was also short. The K-TAVI registry is ongoing, but the current analysis only included the data for the first 2 years after the approval of TAVI in Japan. Thus, approximately half of the patients did not reach the 1-year follow-up point in the current analysis. More research is necessary to reveal the true efficacy of TAVI in Japanese patients. Third, the SAPIEN XT is no longer used in the majority of TAVI institutions since the SAPIEN 3 and other new-generation TAVI devices with better crossing profile have been approved and TA-TAVI is becoming rare. However, the SAPIEN XT, either with the TF or TA approach, was the most widely used and most extensively studied first-generation TAVI device. Thus, clinical outcomes of the SAPIEN XT can be a reliable benchmark for the new-generation TAVI devices.

Conclusions
Analysis of the K-TAVI registry data revealed that the early outcomes of TAVI using the SAPIEN XT were favorable in real-world Japanese patients using the TF or TA approach.

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None.

Disclosures
S.S., Y.A. and T.G. are physician proctors for Edwards Lifesciences. The other authors report no conflicts of interest.

Table 5. Summary of Results in Previous Reports of Using the SAPIEN Valve in TAVI vs. the Present Study

| Study and TAVI approach          | No. of patients | Age (years) | STS score | Female (%) | 30-day mortality (%) | 1-year mortality (%) |
|---------------------------------|----------------|-------------|-----------|------------|----------------------|----------------------|
| SOURCE Registry-TF18            | 463            | 81.7±6.7    | NA        | 55.1       | 6.3                  | 19.9                 |
| SOURCE Registry-TA18            | 575            | 80.7±7.0    | NA        | 55.8       | 10.3                 | 27.9                 |
| GARY Registry-TF13,14           | 2,695          | 81.1±6.2    | NA        | 58.8       | 5.6                  | 20.7                 |
| GARY Registry-TA13,14           | 1,181          | 80.3±6.1    | NA        | 49.8       | 9.0                  | 28.0                 |
| UK Registry-TF11                | 599            | 81.9±7.1    | NA        | 48.1       | 5.5                  | 18.5                 |
| UK Registry-TA11               | 271            | 82.3±6.6    | NA        | 46.5       | 10.7                 | 27.7                 |
| France 2 Registry-TF3           | 2,361          | 83.0±7.2    | 14.5±11.9 | 52.6       | 8.5                  | 21.7                 |
| France 2 Registry-TA9          | 567            | 81.5±7.4    | 15.1±13.8 | 41.4       | 13.9                 | 32.3                 |
| PARTNER Cohort A-TF and TA10   | 348            | 83.6±6.8    | 11.8±3.3  | 42.2       | 3.4                  | 24.2                 |
| PREVAIL-Japan-TF               | 37             | 83.2±6.5    | 7.8±3.2   | 64.9       | 5.6                  | *5.6 (6-month)        |
| PREVAIL-Japan-TA               | 27             | 85.9±5.3    | 10.6±5.3  | 66.7       | 11.5                 | *19.2 (6-month)       |
| K-TAVI-TF                      | 203            | 84.8±6.0    | 7.4±5.8   | 64.5       | 1.5                  | 7.5                  |
| K-TAVI-TA                      | 99             | 85.4±4.7    | 7.3±4.0   | 68.7       | 1.0                  | 8.2                  |

*The 1-year mortality rate of the PREVAIL-Japan study is not available. TAVI, transcatheter aortic valve implantation.
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Supplementary Files
Supplementary File 1
Figure S1. Three cases of coronary intervention after TAVI.
Figure S2. Three cases of annulus rupture after TAVI.
Please find supplementary file(s): http://dx.doi.org/10.1253/circj.CJ-16-0546