Journal of Cardiology 81 (2023) 68–75

Contents lists available at ScienceDirect

Journal of Cardiology

journal homepage: www.elsevier.com/locate/jjcc

Original Article

Long-term survival after surgical or transcatheter aortic valve replacement for low or intermediate surgical risk aortic stenosis: Comparison with general population

Shusaku Maeda (MD, PhD) [a], Koichi Toda (MD, PhD) [a,*], Kazuo Shimamura (MD, PhD) [a], Daisuke Yoshioka (MD, PhD) [a], Koichi Maeda (MD, PhD) [a], Yu Yamada (MD) [a], Masataka Igeta (PhD) [b], Yasushi Sakata (MD, PhD, FJCC) [c], Yoshiki Sawa (MD, PhD, FJCC) [a], Shigeru Miyagawa (MD, PhD) [a]

[a] Department of Cardiovascular Surgery, Osaka University Graduate School of Medicine, Suita, Osaka, Japan
[b] Department of Biostatistics, Hyogo College of Medicine, Nishinomiya, Hyogo, Japan
[c] Department of Cardiovascular Medicine, Osaka University Graduate School of Medicine, Suita, Osaka, Japan

ARTICLE INFO

Article history:
Received 22 April 2022
Received in revised form 22 July 2022
Accepted 29 July 2022
Available online 16 August 2022

Keywords:
Trans-catheter aortic valve implantation
Choice of intervention
Long-term outcome
Real-world population

ABSTRACT

Background: Long-term survival after surgery for severe aortic stenosis (AS) provides important information regarding the choice between surgical (SAVR) and transcatheter (TAVR) aortic valve replacement. This study investigated the long-term survival of AS patients with low or intermediate surgical risk who underwent SAVR or TAVR in our institution versus that of the Japanese general population.

Methods: From 2009 to 2019, 1276 consecutive patients underwent SAVR or TAVR for severe AS. Among them, we retrospectively investigated those with low ($n = 383$) or intermediate ($n = 137$) surgical risk treated with SAVR and those with low ($n = 86$) or intermediate ($n = 333$) surgical risk treated with TAVR. Their post-intervention survival was compared with that of an age- and gender-matched Japanese general population.

Results: The overall 5-year survival rate of SAVR for patients with low surgical risk (mean age, 72 ± 9 years) was not significantly different from that of the general population (90 % vs. 89 %, respectively; $p = 0.58$), whereas that of patients with intermediate surgical risk (77 ± 6 years) was significantly lower than that of the general population (77 % vs. 84 %, respectively; $p = 0.03$). After TAVR, the 5-year survival of patients with low (78 ± 8 years) or intermediate (83 ± 5 years) surgical risk was significantly lower than that of the general population (low risk, 64 % vs. 81 %, $p < 0.01$; intermediate risk, 66 % vs. 71 %, respectively, $p = 0.01$).

Conclusions: Our study demonstrated that long-term survival after SAVR for AS patients with low surgical risk was as good as that of the age- and gender-matched general population, while the long-term survival after SAVR for intermediate-risk or TAVR for low- or intermediate-risk patients was lower than that of the general population. These findings suggest that SAVR is an appropriate option for AS patients with low surgical risk and good life expectancy, especially in Japan, where the life expectancy is the longest worldwide.

Introduction

Randomized controlled trials have revealed comparable 2- to 5-year clinical results after transcatheter aortic valve replacement (TAVR) for severe aortic stenosis (AS) compared with those following surgical aortic valve replacement (SAVR); thus, TAVR is increasingly being performed for lower surgical risk patients [1–9]. According to the American College of Cardiology/American Heart Association (ACC/AHA) guidelines updated in 2020 [10], low to intermediate surgical risk patients are indicated for SAVR or transfemoral TAVR, with the choice of intervention individualized based on multiple patient-specific factors, including anatomy, comorbidities, frailty, and preference. As for the key factors in the decision-making process, the guidelines highlight a balance between life expectancy and valve durability. Because robust data for TAVR valve durability are only available for up to 5 years [11–17], SAVR (class 1) is recommended for patients with a life expectancy >20 years, SAVR (class 1) and TAVR (class 1) are recommended for those with a life expectancy of 10–20 years, and TAVR (class 1) and SAVR (class 2) are recommended for those with a life expectancy of <10 years.

* Corresponding author at: Department of Cardiovascular Surgery, Osaka University Graduate School of Medicine, 2-15 Yamadaoka, Suita, Osaka 565-0871, Japan.
E-mail address: k-toda@surg1.med.osaka-u.ac.jp (K. Toda).

https://doi.org/10.1016/j.jjcc.2022.08.003
0914-5087/

Although patient life expectancy is an essential component of the decision-making process, estimating the life expectancy of individual patients is difficult because it varies largely worldwide and is dependent on not only absolute age, but also gender, frailty, and presence of comorbidities as described in the European Society of Cardiology/European Association for Cardio-Thoracic Society (ESC/EACTS) guidelines updated in 2021 [18]. To address this issue, a comparison with an age- and gender-matched general population would be useful for estimating patient life expectancy after AS treatment. A systematic review [19] from the USA showed excellent survival after SAVR, a survival rate that was slightly lower than that of the general population, as reflected in the ACC/AHA guidelines. However, data regarding survival after SAVR or TAVR versus that of the general population in Japan, where life expectancy is the longest worldwide, are scarce [20]. This study aimed to review long-term survival of and valve performance in AS patients with low or intermediate surgical risk who underwent SAVR or TAVR and compared their survival with that of an age- and gender-matched Japanese general population.

Methods

Study population

From January 2010 to December 2019, 1371 patients with severe AS underwent initial SAVR or TAVR at Osaka University Hospital. Reoperation cases after SAVR or TAVR were excluded. Based on the Society of Thoracic Surgeons (STS) risk score, 469 patients (35.6 %) with an STS score <4 % were stratified into low, 470 (35.7 %) with an STS score 4–8 % into intermediate, and 378 1(28.7 %) with an STS score >8 % into high surgical risk groups [10]. In the present study, 939 patients with low or intermediate surgical risk were analyzed (Fig. 1). At our institution, the choice of intervention was made at a heart team conference based on guidelines and updated evidence [10,21,22]. During the present study period, TAVR was preferred for patients with an intermediate surgical risk and those aged >80 years. For patients with a low surgical risk and/or those aged <80 years, SAVR was the standard strategy, except for those with a limited life expectancy not reflected by the surgical

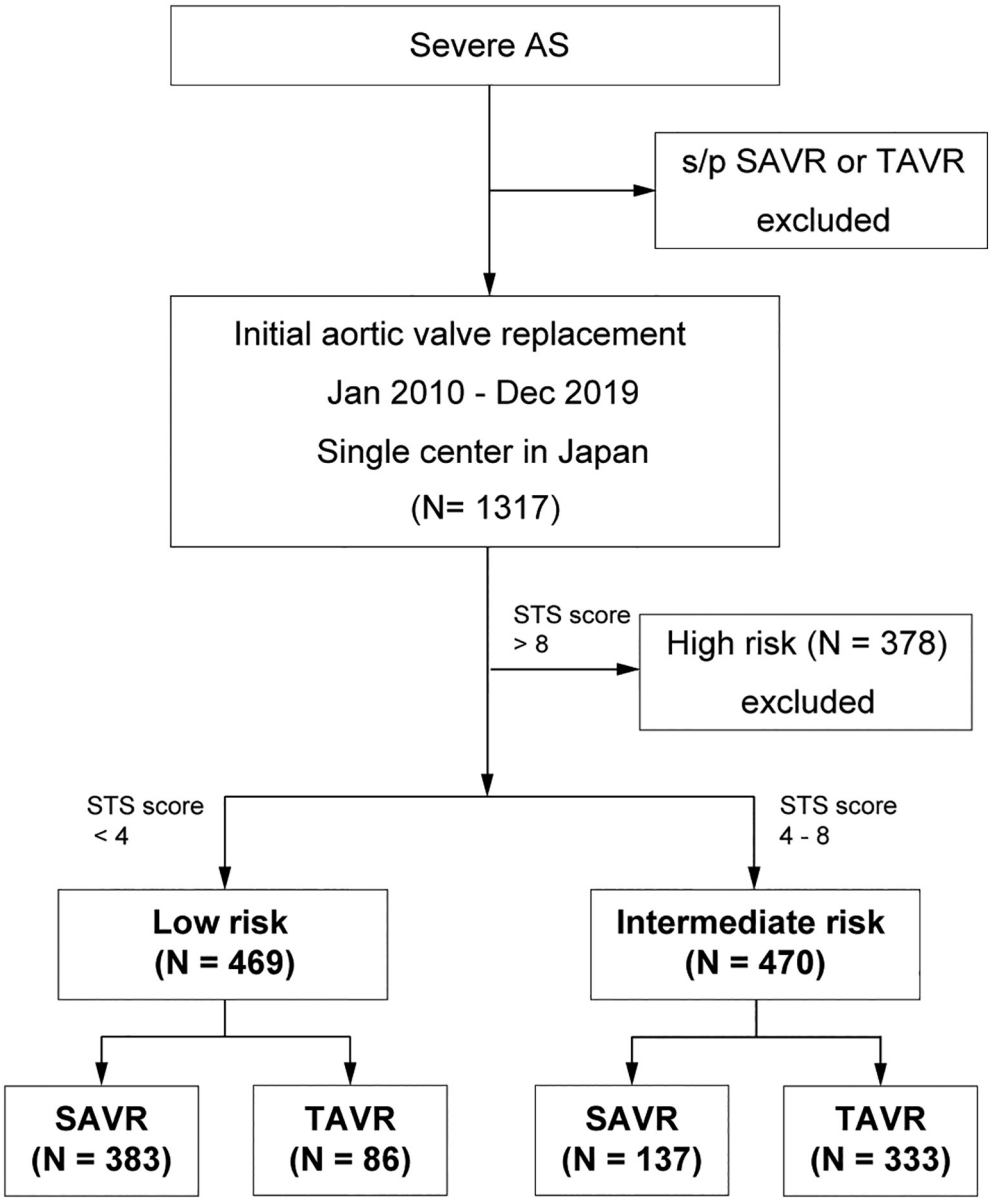


Fig. 1. Study flow chart.
AS, aortic stenosis; SAVR, surgical aortic valve replacement; STS, Society of Thoracic Surgeons; TAVR, transcatheter aortic valve replacement.

risk score, for whom TAVR was chosen. Ethical approval was obtained from the Osaka University Hospital Institutional Review Board, which waived the requirement for individual patient consent for this retrospective analysis.

Endpoints and follow-up

The primary endpoint of this study was death of any cause. Cardiovascular-related death and other clinical outcomes were defined based on the Valve Academic Research Consortium (VARC)-2 document [23]. Differently defined outcomes in the present study were as follows. Acute kidney injury was defined as stage 2 or 3 kidney injury according to the VARC definition [23]. Major bleeding was defined as bleeding requiring the transfusion of four units of packed blood cells in TAVR patients or bleeding requiring reoperation for hemostasis in SAVR patients. Since the transfusion volume required during these two procedures generally differs, major bleeding in SAVR patients was defined based on Japan Adult Cardiovascular Surgery Database criteria. Reoperation was defined as any intervention for a previously surgically treated aortic valve. Major adverse cardiovascular and cerebrovascular events (MACCE) were defined as the composite of all-cause death, reoperation for aortic valve, stroke, or myocardial infarction.

Valve performance was assessed by echocardiography. Structural valve deterioration (SVD) and paravalvular leakage (PVL) severity were defined according to the AHA recommendations [24], in which SVD stage 2S (moderate stenosis) must include an increase in mean pressure gradient of ≥10 mmHg from baseline postprocedural gradient. To match this definition, in this study, we defined postoperative severe patient-prosthesis mismatch (PPM) as a mean pressure gradient >39 mmHg and moderate PPM as 19–39 mmHg by echocardiography performed at one week postoperatively.

Follow-up, which was performed using data obtained from medical records or correspondence with referring physicians, was completed in 92 % of the SAVR patients and 94 % of the TAVR patients. In most cases, postoperative echocardiographic examinations were performed at one week postoperative and annually thereafter.

Statistical analysis

Continuous variables are summarized as mean value with standard deviations and were compared using Welch's *t*-test. Categorical variables are summarized as frequencies with percentages. The rates of freedom from clinical events were estimated using the Kaplan-Meier product limit method. The survival distribution of an age- and gender-matched general Japanese population at the median year of operation was also estimated and then compared with the study population using the Finkelstein-Muzikansky-Schoenfeld method including a one-sample log-rank test [25,26]. For data regarding general population survival, an Excel macro file was downloaded from the Massachusetts General Hospital Biostatistics Center (http://hedwig.mgh.harvard.edu/biostatistics/node/30) and then modified using annual survival data provided by the Japanese government (https://www.mhlw.go.jp/toukei/saikin/hw/jinkou/geppo/nengai16/dl/gaikyou28.pdf). Data of age, sex, race, censorship, and follow-up duration for our cohort were entered into the Excel file, and the survival curves of an age- and gender-matched general population and result of one-sample log-rank test were obtained. All *p*-values were two-sided, and those <0.05 were considered statistically significant. Statistical analyses were performed using the JMP Pro14 and SAS software packages (SAS Institute, Cary, NC, USA).

Results

Patient characteristics

This study enrolled 939 patients with low ($n = 469$) or intermediate ($n = 470$) surgical risks (Fig. 1). Of them, SAVR was performed in 383 patients with low surgical risk (STS score, 2.2 ± 0.9) and 137 with intermediate risk (STS score, 5.5 ± 1.1); the baseline characteristics of those patients are summarized in Table 1. The mean age of the low-risk patients was lower than that of the intermediate risk patients (71.6 ± 8.7 years vs. 76.6 ± 6.2 years, respectively; $p < 0.001$). Peripheral artery disease (PAD) and hemodialysis (HD) were relatively rare comorbidities in the low-risk group and significantly more frequent in the intermediate-risk group (PAD, 3 % vs. 12 %, $p < 0.001$; HD, 2 % vs. 24 %, $p < 0.001$). Other major comorbidities, including coronary artery disease (CAD), cerebral vascular disease (CVD), diabetes mellitus (DM), and chronic kidney disease (CKD), were also more frequent in the intermediate-risk patients.

TAVR was performed in 86 patients with low surgical risk (STS score, 2.9 ± 0.8) and 333 with intermediate surgical risk (STS score, 5.9 ± 1.1); the baseline characteristics of these patients are summarized in Table 2. The mean age of the low-risk patients was lower than that of the intermediate-risk patients (77.6 ± 7.7 years vs. 83.1 ± 5.3 years). The major comorbidities were similar between the low- and intermediate-risk groups. Liver cirrhosis was more frequent in the low-risk patients (13 % vs. 3 %, $p < 0.001$), whereas CKD was less frequent (42 % vs. 67 %, $p < 0.001$). HD was a relatively rare comorbidity in the low- (0 %) and intermediate-risk (3 %) patients treated with TAVR, because TAVR was not reimbursed by the national insurance system for patients receiving HD at the time of the study.

Surgical data

The surgical data for SAVR are summarized in Table 3. Among the 520 patients treated with SAVR, 451 (86.7 %) underwent tissue valve

Table 1
Baseline characteristics of patients treated with SAVR.

Variable	Low risk ($n = 383$)	Intermediate risk ($n = 137$)	*p*-Value
Age, years	71.6 ± 8.7	76.6 ± 6.2	<0.001
Male sex, n (%)	17 (40)	48 (35)	0.0028
BMI, kg/m^2	23.3 ± 3.5	22.3 ± 3.5	0.0058
BSA, m^2	1.57 ± 0.17	1.49 ± 0.16	<0.001
STS risk score	2.2 ± 0.9	5.5 ± 1.1	<0.001
NYHA class III or IV, n (%)	62 (16)	44 (32)	<0.001
CAD, n (%)	126 (33)	64 (47)	0.0052
Three-vessel disease	27 (7)	25 (18)	<0.001
LMT disease	8 (2)	9 (7)	0.021
Previous PCI, n (%)	39 (10)	14 (10)	1
Previous CABG, n (%)	0 (0)	0 (0)	1
Previous open heart surgery, n (%)	7 (2)	7 (5)	0.061
CVD, n (%)	28 (7)	19 (14)	0.036
PAD, n (%)	12 (3)	17 (12)	<0.001
DM, n (%)	97 (25)	55 (40)	0.0015
COPD, n (%)			
Any	69 (18)	30 (22)	0.31
Moderate or severe	18 (5)	4 (3)	0.47
CKD, n (%)	180 (47)	108 (79)	<0.001
HD, n (%)	9 (2)	33 (24)	<0.001
Af, n (%)	75 (20)	34 (25)	0.22
Permanent PMI, n (%)	3 (1)	4 (3)	0.082
Clinical frailty score			
Liver cirrhosis, n (%)	1 (0)	1 (0.7)	0.46
AVA, cm^2	0.77 ± 0.21	0.75 ± 0.21	0.52
Bicuspid aortic valve	105 (27)	11 (8)	<0.001
LVEF, %	64.7 ± 12.2	61.8 ± 13.1	0.026
LVEF <30 %, n (%)	7 (2)	2 (1)	1
Moderate or severe MR, n (%)	23 (6)	20 (15)	0.0033
Moderate or severe TR, n (%)	12 (3)	16 (12)	<0.001

Mean ± standard derivation or number (%).
Af, atrial fibrillation; AVA, aortic valve area; BMI, body mass index; BSA, body surface area; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; CVD, cerebrovascular disease; DM, diabetes mellitus; HD, hemodialysis; LMT, left main trunk; LVEF, left ventricular ejection fraction; MR, mitral regurgitation; NYHA, New York Heart Association; PAD, peripheral artery disease; PCI, percutaneous coronary intervention; PMI, pacemaker implantation; SAVR, surgical aortic valve replacement; STS, Society of Thoracic Surgeons; TR, tricuspid regurgitation.

Table 2
Baseline characteristics of patients treated with TAVR.

Variable	Low risk ($n = 86$)	Intermediate risk ($n = 333$)	p-Value
Age, years	77.6 ± 7.7	83.1 ± 5.3	<0.001
Male sex, n (%)	33 (38)	99 (30)	0.15
BMI, kg/m^2	23.6 ± 4.6	22.2 ± 3.4	0.0082
BSA, m^2	1.56 ± 0.20	1.43 ± 0.16	<0.001
STS risk score	2.9 ± 0.8	5.9 ± 1.1	<0.001
NYHA class III or IV, n (%)	17 (20)	87 (26)	0.26
CAD, n (%)	17 (24)	71 (27)	0.65
Three-vessel disease	4 (5)	5 (2)	0.0091
LMT disease	3 (3)	5 (2)	0.21
Previous PCI, n (%)	10 (12)	50 (15)	0.49
Previous CABG, n (%)	7 (8)	14 (4)	0.16
Previous open heart surgery, n (%)	7 (8)	28 (8)	1
CVD, n (%)	15 (17)	45 (14)	0.39
PAD, n (%)	16 (19)	55 (17)	0.63
DM, n (%)	18 (21)	93 (28)	0.22
COPD, n (%)			
Any	8 (9)	55 (17)	0.13
Moderate or severe	6 (7)	32 (10)	0.53
CKD, n (%)	36 (42)	222 (67)	<0.001
HD, n (%)	0 (0)	10 (3)	0.23
Af, n (%)	4 (5)	20 (6)	0.8
Permanent PMI, n (%)	3 (3)	12 (4)	1
Clinical frailty score	3.7 ± 1.0	4.0 ± 1.1	0.013
Liver cirrhosis, n (%)	11 (13)	10 (3)	<0.001
AVA, cm^2	0.68 ± 0.15	0.68 ± 0.17	0.68
Bicuspid aortic valve	7 (8)	21 (6)	0.63
LVEF, %	66.0 ± 11.0	64.1 ± 12.4	0.18
LVEF <30 %, n (%)	1 (1)	5 (2)	1
Moderate or severe MR, n (%)	4 (5)	27 (8)	0.36
Moderate or severe TR, n (%)	2 (2)	15 (5)	0.54

Mean ± standard derivation or number (%).
Af, atrial fibrillation; AVA, aortic valve area; BMI, body mass index; BSA, body surface area; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; CVD, cerebrovascular disease; DM, diabetes mellitus; HD, hemodialysis; LMT, left main trunk; LVEF, left ventricular ejection fraction; MR, mitral regurgitation; NYHA, New York Heart Association; PAD, peripheral artery disease; PCI, percutaneous coronary intervention; PMI, pacemaker implantation; STS, Society of Thoracic Surgeons; TAVR, transcatheter aortic valve replacement; TR, tricuspid regurgitation.

Table 3
Surgical data of patients treated with SAVR.

Variable	Low risk ($n = 383$)	Intermediate risk ($n = 137$)	p-value
Elective surgery	369 (96)	128 (93)	0.15
Urgent surgery	10 (3)	5 (4)	0.56
Emergency surgery	4 (1)	4 (3)	0.22
Valve type			
Mechanical valve	19 (5)	4 (3)	0.47
Tissue valve	335 (87)	116 (85)	0.46
Sutureless valve	29 (8)	17 (12)	0.11
Valve size			
17 or 18 mm	2 (1)	3 (2)	0.12
19 mm	115 (31)	58 (43)	0.011
21 mm	159 (42)	53 (40)	0.61
23 mm	74 (20)	18 (13)	0.12
25 mm	21 (6)	2 (1)	0.053
27 mm	4 (1)	0 (0)	0.58
Approach			
MICS	9 (2)	0 (0)	0.12
Isolated surgery	207 (54)	58 (42)	0.022
Concomitant cardiac surgery	176 (46)	79 (58)	0.022
PCI	0 (0)	0 (0)	1
CABG	95 (25)	53 (39)	0.028
MV surgery	25 (7)	20 (15)	0.0071
TV surgery	15 (4)	18 (13)	<0.001
TAA surgery	47 (12)	4 (3)	0.0012
Arrhythmia surgery	58 (15)	24 (18)	0.5
Operative time, min	307 ± 115	305 ± 105	0.85

Mean ± standard derivation or number (%).
CABG, coronary artery bypass grafting; MICS, minimally invasive cardiovascular surgery; MV, mitral valve; PCI, percutaneous coronary intervention; SAVR, surgical aortic valve replacement; TAA, thoracic aortic aneurysm; TV, tricuspid valve.

implantation and 255 (49.0 %) underwent concomitant cardiac surgery, including coronary artery bypass grafting (CABG) in 148 (28.5 %). The surgical data for TAVR cases are summarized in Table 4. Among the 419 patients treated with TAVR, 179 (42.7 %) received self-expandable valve implantation and 240 (57.3 %) received balloon-expandable valve. Regarding surgical approach, 308 patients (73.5 %) were transfemoral and 69 (16.5 %) were transapical. During the early study period, the delivery system was larger in diameter than the current device, resulting in a relatively higher frequency (14.0 %) of the transapical approach use in low-risk TAVR patients. Concomitant revascularization was performed with percutaneous coronary intervention (PCI) in 34 (8.1 %) patients and CABG in 9 (2.1 %) patients. No other concomitant cardiac surgical procedures were performed in the patients treated with TAVR.

Thirty-day mortality and early outcomes

Thirty-day mortality and early outcomes are summarized in Online Table 1 for patients treated with SAVR and in Online Table 2 for those treated with TAVR. Overall, the 30-day mortality rate after SAVR or TAVR was <1 %, which was significantly better than expected based on STS scores (all groups, $p < 0.001$). Regarding early complications in SAVR patients, mediastinitis occurred in 10 (1.9 %) patients and a pacemaker was implanted in 15 (2.9 %) patients for postoperative atrioventricular block. Moderate PPM was observed in 52 patients (10.0 %) after SAVR. Among the TAVR patients, a new pacemaker was implanted in 52 (12.4 %), while moderate PPM was found in 6 (1.4 %).

Long-term survival and late outcomes

The total follow-up time was 3286 patient-years and the mean follow-up period was 55 ± 32 months for low-risk SAVR, 43 ± 31 months for intermediate-risk SAVR, 31 ± 23 months for low-risk TAVR, and 30 ± 24 months for intermediate-risk TAVR patients.

The overall 5-year survival rate after SAVR for the low surgical risk patients was 90 %, which was not significantly different from that of

Table 4
Surgical data of patients treated with TAVR.

Variable	Low risk ($n = 86$)	Intermediate risk ($n = 333$)	p-Value
Elective surgery	85 (99)	332 (100)	0.37
Urgent surgery	1 (1)	1 (0)	0.37
Emergency surgery	0 (0)	0 (0)	1
Valve type			
Self-expandable	42 (48.8)	137 (41.1)	0.22
Balloon-expandable	44 (51.2)	196 (58.9)	0.22
Valve size			
20 or 21 mm	3 (3)	7 (2)	0.44
23 mm	29 (34)	133 (40)	0.32
25 mm	3 (3)	6 (2)	0.40
26 mm	26 (30)	113 (34)	0.61
27 mm	0 (0)	4 (1)	0.59
29 mm	25 (29)	69 (21)	0.11
Approach			
Trans-femoral	67 (78)	241 (72)	0.34
Trans-apical	12 (14)	57 (17)	0.63
Isolated surgery	85 (99)	325 (98)	0.69
Concomitant cardiac surgery	1 (1)	8 (2)	0.69
PCI	3 (3)	31 (7)	0.12
CABG	1 (1)	8 (2)	0.69
MV surgery	0 (0)	0 (0)	1
TV surgery	0 (0)	0 (0)	1
TAA surgery	0 (0)	0 (0)	1
Arrhythmia surgery	0 (0)	0 (0)	1
Operative time, min	88 ± 33	93 ± 49	0.26

Mean ± standard derivation or number (%).
CABG, coronary artery bypass grafting; MV, mitral valve; PCI, percutaneous coronary intervention; TAA, thoracic aortic aneurysm; TAVR, transcatheter aortic valve replacement; TV, tricuspid valve.

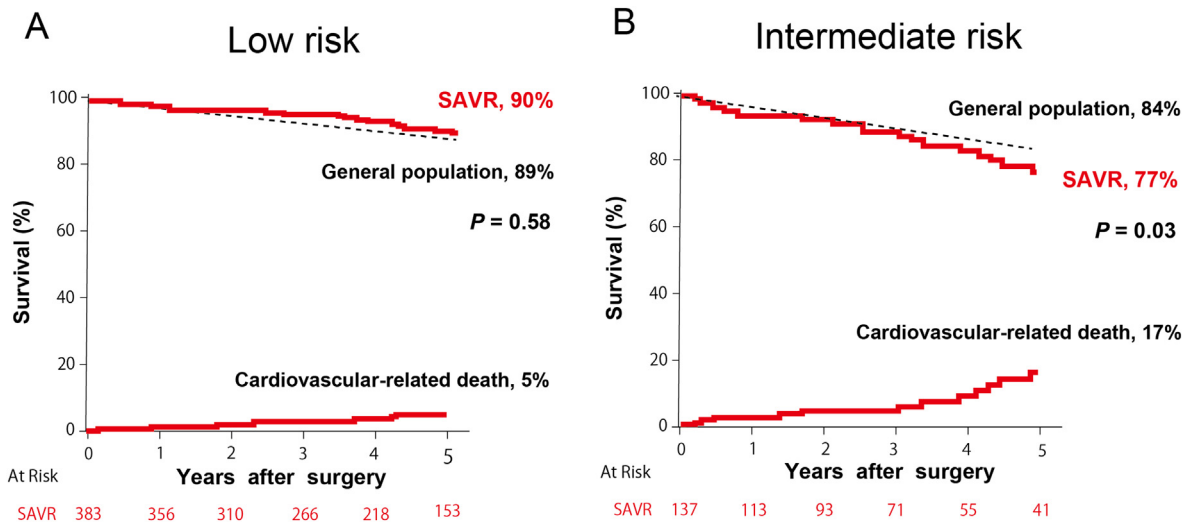


Fig. 2. Long-term survival after SAVR in patients with (A) low or (B) intermediate surgical risk.
SAVR, surgical aortic valve replacement.

the general population (89 %, $p = 0.58$) (Fig. 2A), while that for the intermediate surgical risk group was 77 %, which was significantly lower than that of the general population (84 %, $p = 0.03$) (Fig. 2B). The rate of cardiovascular-related death at 5 years was 5 % for low- and 17 % for intermediate-risk SAVR patients, showing a significant difference ($p = 0.0033$).

The overall 5-year survival rate after TAVR was 64 % in the low-risk (Fig. 3A) and 66 % in the intermediate-risk (Fig. 3B) patients, both of which were significantly lower than those of the general population (5-year survival for general population: low-risk, 81 %, $p < 0.01$; intermediate-risk, 71 %, $p = 0.01$). The 5-year rate of cardiovascular-related death was 11 % in low-risk TAVR patients and 14 % in intermediate-risk TAVR patients, showing no significant difference ($p = 0.15$). Regarding the influence of surgical approach on survival, TAVR via the transapical approach had a worse trend survival than that via the transfemoral approach (5-year survival: trans-apical approach, 58 %; trans-femoral approach, 71 %; $p = 0.15$).

The late outcomes for patients treated with SAVR and TAVR are summarized in Online Tables 3 and 4, respectively. In SAVR cases, the cardiovascular-related death rate ($p = 0.003$) and incidence of MACCE ($p = 0.03$) were significantly higher in the intermediate- versus low-risk patients, while the incidences of disabling stroke, reoperation for aortic valve, heart failure readmission, and endocarditis were not statistically different. As for TAVR cases, the cardiovascular-related death rate ($p = 0.15$) and incidences of investigated late outcomes, including MACCE ($p = 0.85$), did not differ significantly between the low- and intermediate-risk patients. Details regarding the causes of death during the follow-up period are summarized in Online Table 5.

Valve durability

The valve durability data are shown in Fig. 4. The aortic valve area (AVA) was sustained postoperatively in the SAVR and TAVR patients (Fig. 4A). The rate of freedom from severe SVD at 5 years was 99 % after SAVR and 91 % after TAVR (Fig. 4B), while that from moderate SVD at 5 years was 92 % after SAVR and 83 % after TAVR. Based on the standardized definition [24], the SVD stage in SAVR patients was 2S (moderate stenosis) in 31, 2R (moderate regurgitation) in 2, 2RS (moderate stenosis and moderate regurgitation) in 1, and 3 (severe stenosis and/or severe regurgitation) in 1 patient during a median echocardiographic follow-up of 39 months (interquartile range, 11–64 months), while that in TAVR patients was 2S in 11, 2R in 1, and 3 in 2 patients during a

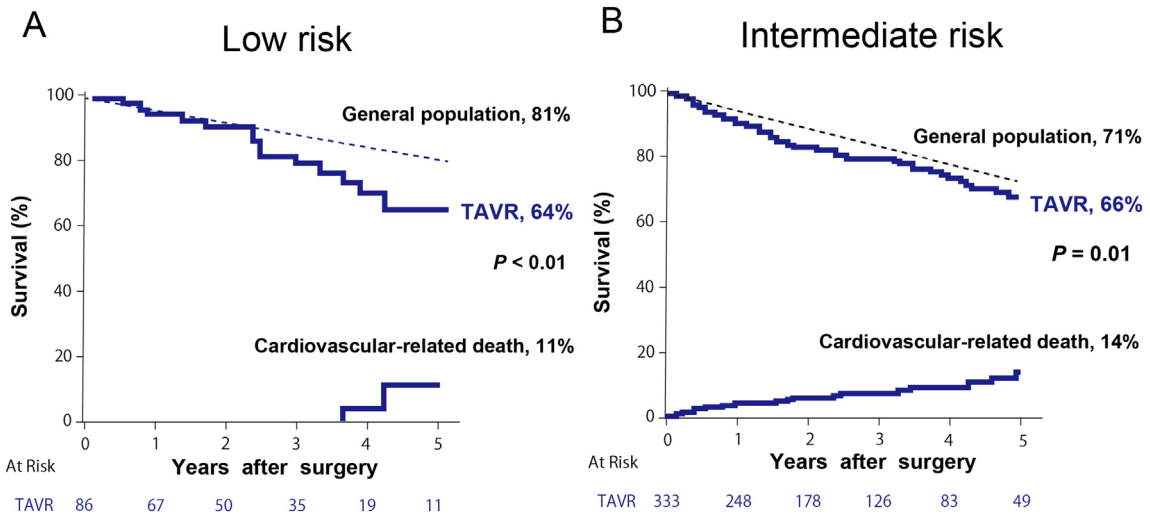
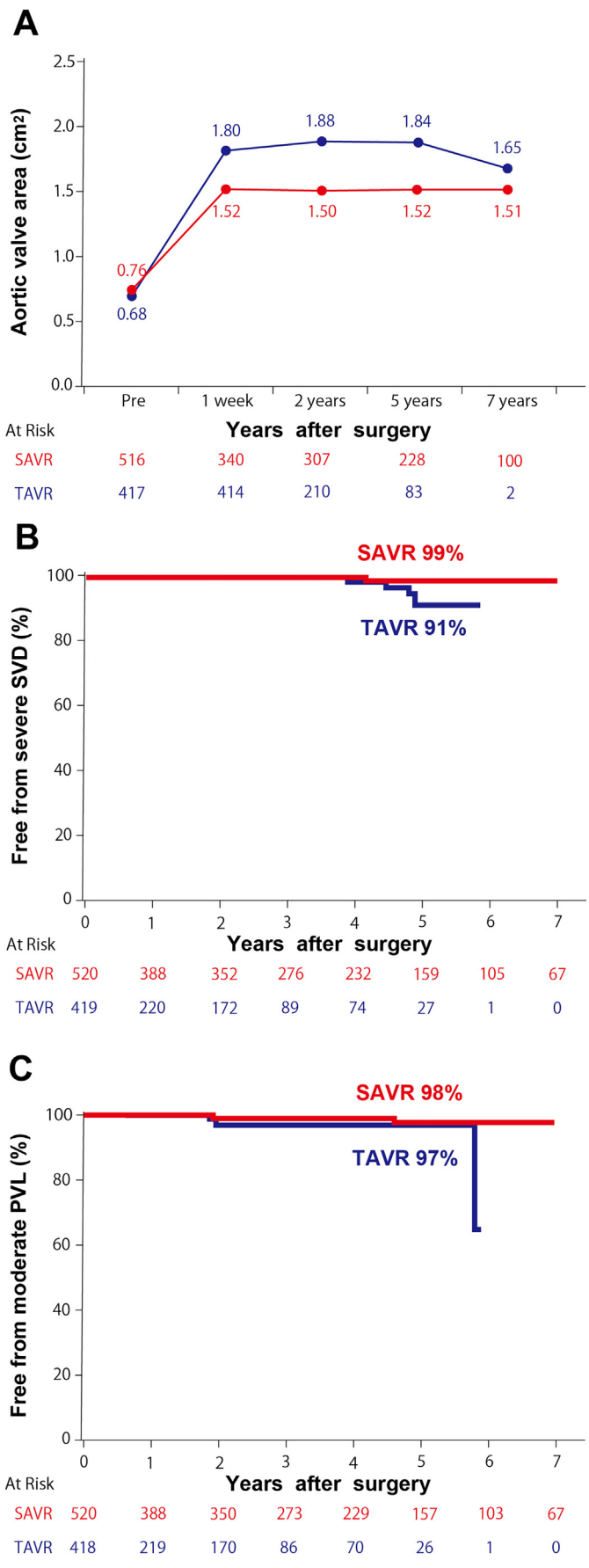


Fig. 3. Long-term survival after TAVR in patients with (A) low or (B) intermediate surgical risk.
TAVR, transcatheter aortic valve replacement.



median echocardiographic follow-up of 23 months (interquartile range, 0–24 months). The rates of freedom from severe or moderate PLV at 5 years were 98 % and 97 % after SAVR and TAVR, respectively (Fig. 4C).

Discussion

The present study examined the long-term survival and valve performance after SAVR or TAVR in AS patients with low to intermediate surgical risk. For SAVR patients with a mean age of 72 years and low surgical risk, the 5-year survival rate was 90 %, whereas that for patients with a mean age of 77 years and intermediate surgical risk was 77 %. As for TAVR, the 5-year survival rate for patients with a mean age of 78 years and low surgical risk was 64 %, while that for patients with a mean age of 83 years and intermediate surgical risk was 66 %. Compared with an age- and gender-matched Japanese general population, survival after SAVR in patients with low surgical risk was not statistically different, while those rates after SAVR in intermediate-risk patients or after TAVR in low- and intermediate-risk patients were lower than those in the general population. Valve performance was satisfactory for up to 5 years for both SAVR and TAVR cases, although longer follow-up data after TAVR were limited.

Although the guidelines [10,18] note that a balance between patient life expectancy and valve durability is essential when choosing SAVR or TAVR, patient selection for TAVR is difficult because long-term outcomes following TAVR have rarely been reported in Japan, where life expectancy is the longest worldwide [27]. The present study revealed a 90 % 5-year survival rate after SAVR for low surgical risk patients, similar to that for the general Japanese population. According to government reports, the mean life expectancy in Japan for 70- and 75-year-old men is 16 and 13 years, respectively, while that for 70- and 75-year-old women is 20 and 16 years, respectively. Such a life expectancy is expected following SAVR for low surgical risk AS patients aged 70–75 years, which is important information for physicians when determining the mode of intervention. Whereas fifteen-year SAVR valve durability has been established, data beyond 5 years for TAVR valve durability are limited [11–17,19]. Taken together, SAVR for Japanese patients aged 70–75 years with low surgical risk, whose life expectancy following surgery is approximately 15 years, seems reasonable, while TAVR for AS patients with low surgical risk requires careful determination. Therefore, we propose SAVR rather than TAVR for Japanese patients with severe AS and a low surgical risk who are <80 years of age. Notably, excellent survival after SAVR in the present low surgical risk patients was achieved even in patients with serious complications, including CAD (33 %), CKD (47 %), and DM (25 %).

In the present study, the survival after SAVR for AS patients with intermediate surgical risk was 77 %, lower than that in an age- and gender-matched general population. Cardiovascular-related comorbidities such as CAD, CKD, CVD, DM, PAD, and HD, were more frequent in intermediate-risk than low-risk patients, resulting in a higher rate of cardiovascular-related deaths during the long-term follow-up period. The impact of HD and PAD on survival is reportedly significant [28–30]. Despite a statistically worse prognosis than that of the general population, the 5-year survival after SAVR for intermediate surgical risk AS patients in the present study seems better than that reported in Western countries [1,2,4].

Five-year survival after TAVR for our low to intermediate surgical risk AS patients was approximately 65 %, significantly lower than that of the age- and gender-matched general population. There were fewer cardiovascular-related deaths after TAVR than after SAVR, with most incidents from non-cardiovascular causes, such as infection, cancer, and senile decay (Online Table 5). As for intermediate surgical risk patients,

Fig. 4. Valve durability data. (A) Aortic valve area. (B) Rate of freedom from severe SVD. (C) Rate of freedom from moderate PVL.
PVL, paravalvular leakage; SVD, structural valve deterioration; SAVR, surgical aortic valve replacement; TAVR, transcatheter aortic valve replacement.

TAVR was preferred for those aged >80 years during our study and the 5-year survival rate of intermediate surgical risk patients treated with TAVR was 66 %, significantly lower but only 5 % lower than that of the general population. The excellent long-term survival after TAVR as well as SAVR in the Japanese population suggests that the introduction of TAVR contributed to improved survival of patients with severe AS. As for low surgical risk cases, SAVR was the standard strategy, while TAVR was chosen for those with a limited life expectancy not reflected by the surgical risk score during our study. As a result, TAVR patients with low surgical risk had a significantly lower survival rate than those in the general population in our study. Our results in this Japanese population should be carefully interpreted for patients with low surgical risk, although long-term outcomes after SAVR or TAVR in randomized controlled trials would have a considerable impact.

In the present study, the rates of freedom from severe SVD or moderate PVL were >90 % at 5 years after SAVR or TAVR. The findings regarding valve performance in the present SAVR cases demonstrated long-term results similar to those of previous reports [19]. However, data regarding very long-term SAVR valve durability for patients in Japan remain insufficient from the viewpoint of excellent survival after SAVR. As for valve performance in TAVR cases, that within 5 years was satisfactory, while that beyond 5 years remains uncertain because of the limited number of patients who survived for that period as well as findings noted in previous reports from Western countries [11–17]. A statistical comparison of valve durability between SAVR and TAVR valves might be difficult in our study because the patients' backgrounds and follow-up periods differed widely. Although severe or moderate SVD seemed to occur more frequently in TAVR patients, further investigations are needed to confirm the difference in long-term valve durability between these procedures.

Limitations

The present study has some limitations. First, it used a retrospective design and analyzed patients treated at a single center over 10 years. A multicenter study covering a longer period is required to confirm these findings. Second, the comparison of clinical outcomes between patients who underwent SAVR and TAVR was difficult in our study because of the largely different patient backgrounds. Although the results of randomized controlled trials and guidelines should emphasize the importance of choice of surgical mode, no randomized controlled trials have examined the treatment of severe AS in Japan. Our study showed satisfactory long-term survival after SAVR and TAVR by comparing with a general population, which were obviously better than those reported in Western countries [1,2,4], suggesting that TAVR should be carefully chosen in Japan compared to the recommendations of Western countries. Third, along with better devices and further development of technical skills for TAVR, valve durability may improve in the near future. However, recent progress in SAVR methods, such as a minimally invasive approach or use of sutureless valves, may also lead to better outcomes after SAVR. Finally, in the present study, there was no record of frailty scores for the SAVR patients; thus, it was impossible to show these data. Most patients who underwent SAVR in the present study were not frail, equivalent to a clinical frailty scale of 1 or 2; however, the availability of these objective data would be important in future investigations.

Conclusions

Our study demonstrated that long-term survival after SAVR for AS patients with low surgical risk was comparable to that of an age- and gender-matched general population, while long-term survival after SAVR for intermediate-risk patients or survival after TAVR was lower than that of the general population. These findings suggest that SAVR is an appropriate option for AS patients with low surgical risk and good life expectancy, especially in Japan, where the average life expectancy is the highest worldwide.

Funding

None.

Declaration of competing interest

None to declare.

Acknowledgments

All of the authors had joint responsibility for the decision to submit the manuscript for publication.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jjcc.2022.08.003.

References

[1] Leon MB, Smith CR, Mack MJ, Makkar RR, Svensson LG, Kodali SK, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. N Engl J Med 2016;374:1609–20.
[2] Reardon MJ, Van Mieghem NM, Popma JJ, Kleiman NS, Søndergaard L, Mumtaz M, et al. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. N Engl J Med 2017;376:1321–31.
[3] Thyregod HG, Steinbrüchel DA, Ihlemann N, Nissen H, Kjeldsen BJ, Petursson P, et al. Transcatheter versus surgical aortic valve replacement in patients with severe aortic valve stenosis: 1-year results from the all-comers NOTION randomized clinical trial. J Am Coll Cardiol 2015;65:2184–94.
[4] Siemieniuk RA, Agoritsas T, Manja V, Devji T, Chang Y, Bala MM, et al. Transcatheter versus surgical aortic valve replacement in patients with severe aortic stenosis at low and intermediate risk: systematic review and meta-analysis. BMJ 2016;354:i5130.
[5] Popma JJ, Deeb GM, Yakubov SJ, Mumtaz M, Gada H, O'Hair D, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. N Engl J Med 2019;380:1706–15.
[6] Mack MJ, Leon MB, Thourani VH, Makkar R, Kodali SK, Russo M, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. N Engl J Med 2019;380:1695–705.
[7] Siontis GCM, Overtchouk P, Cahill TJ, Modine T, Prendergast B, Praz F, et al. Transcatheter aortic valve implantation vs. Surgical aortic valve replacement for treatment of symptomatic severe aortic stenosis: an updated meta-analysis. Eur Heart J 2019;40:3143–53.
[8] Barbanti M, Tamburino C, D'Errigo P, Biancari F, Ranucci M, Rosato S, et al. Five-year outcomes of transfemoral transcatheter aortic valve replacement or surgical aortic valve replacement in a real world population. Circ Cardiovasc Interv 2019;12:e007825.
[9] Tarantini G, Lefèvre T, Terkelsen CJ, Frerker C, Ohlmann P, Mojoli M, et al. One-year outcomes of a european transcatheter aortic valve implantation cohort according to surgical risk. Circ Cardiovasc Interv 2019;12:e006724.
[10] Otto CM, Nishimura RA, Bonow RO, Carabello BA, Erwin 3rd JP, Gentile F, et al. 2020 ACC/AHA guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association joint committee on clinical practice guidelines. Circulation 2021;143:e72-227.
[11] Foroutan F, Guyatt GH, Otto CM, Siemieniuk RA, Schandelmaier S, Agoritsas T, et al. Structural valve deterioration after transcatheter aortic valve implantation. Heart 2017;103:1899–905.
[12] Barbanti M, Costa G, Zappulla P, Todaro D, Picci A, Rapisarda G, et al. Incidence of long-term structural valve dysfunction and bioprosthetic valve failure after transcatheter aortic valve replacement. J Am Heart Assoc 2018;7:e008440.
[13] Didier R, Eltchaninoff H, Donzeau-Gouge P, Chevreul K, Fajadet J, Leprince P, et al. Five-year clinical outcome and valve durability after transcatheter aortic valve replacement in high-risk patients. Circulation 2018;138:2597–607.
[14] Panico RA, Giannini C, De Carlo M, Angelillis M, Spontoni P, Pieroni A, et al. Long-term results and durability of the CoreValve transcatheter aortic bioprosthesis: outcomes beyond five years. EuroIntervention 2019;14:1639–47.
[15] Søndergaard L, Ihlemann N, Capodanno D, Jørgensen TH, Nissen H, Kjeldsen BJ, et al. Durability of transcatheter and surgical bioprosthetic aortic valves in patients at lower surgical risk. J Am Coll Cardiol 2019;73:546–53.
[16] Durand E, Sokoloff A, Urena-Alcazar M, Chevalier B, Chassaing S, Didier R, et al. Assessment of long-term structural deterioration of transcatheter aortic bioprosthetic valves using the new European definition. Circ Cardiovasc Interv 2019;12:e007597.
[17] Blackman DJ, Saraf S, MacCarthy PA, Myat A, Anderson SG, Malkin CJ, et al. Long-term durability of transcatheter aortic valve prostheses. J Am Coll Cardiol 2019;73:537–45.
[18] Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S, Bauersachs J, et al. ESC/EACTS guidelines for the management of valvular heart disease. Eur Heart J 2021;2021:ehab395.

[19] Foroutan F, Guyatt GH, O'Brien K, Bain E, Stein M, Bhagra S, et al. Prognosis after surgical replacement with a bioprosthetic aortic valve in patients with severe symptomatic aortic stenosis: systematic review of observational studies. BMJ 2016;354:i5065.
[20] Mathers CD, Sadana R, Salomon JA, Murray CJ, Lopez AD. Healthy life expectancy in 191 countries, 1999. Lancet 2001;357:1685–91.
[21] Nishimura RA, Otto CM, Bonow RO, Carabello BA, Erwin 3rd JP, Fleisher LA, et al. 2017 AHA/ACC focused update of the 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association task force on clinical practice guidelines. Circulation 2017;135:e1159–95.
[22] Nishimura RA, Otto CM, Bonow RO, Carabello BA, Erwin 3rd JP, Guyton RA, et al. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: executive summary: a report of the American College of Cardiology/American Heart Association task force on practice guidelines. Circulation 2014;129:2440–92.
[23] Garcia-Garcia HM, McFadden EP, Farb A, Mehran R, Stone GW, Spertus J, et al. Standardized end point definitions for coronary intervention trials: the academic research consortium-2 consensus document. Circulation 2018;137:2635–50.
[24] Dvir D, Bourguignon T, Otto CM, Hahn RT, Rosenhek R, Webb JG, et al. Standardized definition of structural valve degeneration for surgical and transcatheter bioprosthetic aortic valves. Circulation 2018;137:388–99.
[25] Finkelstein DM, Muzikansky A, Schoenfeld DA. Comparing survival of a sample to that of a standard population. J Natl Cancer Inst 2003;95:1434–9.
[26] Maeda S, Taniguchi K, Toda K, Funatsu T, Kondoh H, Yokota T, et al. Outcomes after aortic valve replacement for asymptomatic severe aortic regurgitation and normal ejection fraction. Semin Thorac Cardiovasc Surg 2019;31:763–70.
[27] Takeji Y, Taniguchi T, Morimoto T, Saito N, Ando K, Shirai S, et al. Transcatheter aortic valve implantation vs. Surgical aortic valve replacement for severe aortic stenosis in real-world clinical practice. Circ J 2020;84:806–14.
[28] Bhise V, Kanade P, Shantha GP, Balan P, Nguyen TC, Loyalka P, et al. Transcatheter and surgical aortic valve replacement in patients with end-stage renal disease. J Am Coll Cardiol 2017;69:1875–6.
[29] Szerlip M, Zajarias A, Vemalapalli S, Brennan M, Dai D, Maniar H, et al. Transcatheter aortic valve replacement in patients with end-stage renal disease. J Am Coll Cardiol 2019;73:2806–15.
[30] Färber G, Bleiziffer S, Doenst T, Bon D, Böning A, Weiler H, et al. Transcatheter or surgical aortic valve implantation in chronic dialysis patients: a German aortic valve registry analysis. Clin Res Cardiol 2020;110:357–67.