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Valve: Short Report

National Midterm Outcomes of Transcatheter Aortic Valve Implantation vs Surgical Aortic Valve Replacement

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ABSTRACT

BACKGROUND This study compared the early and midterm outcomes of transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR) in a real-world entire population in Korea.

METHODS During 5 years from June 2015 to May 2019, 1468 patients underwent primary isolated transfemoral TAVI and 3897 patients underwent primary isolated SAVR in Korea. Early and midterm clinical outcomes were compared between the groups, and propensity score-matched analysis was also performed to balance between the groups. Subgroup analyses were performed by dividing the overall cohort into 6 age-subgroups of <65, 65 to 69, 70 to 74, 75 to 79, 80 to 84, and ≥85 years. Follow-up was 100% complete. Median follow-up duration was 2.5 years in the TAVI group and 3.0 years in the SAVR group.

RESULTS There was no difference in periprocedural mortality between the groups in the overall cohort (3.2% in TAVI vs 3.5% in SAVR, $P = .66$), whereas SAVR demonstrated higher periprocedural mortality in the matched cohort (2.9% in TAVI vs 5.6% in SAVR, $P = .003$). Cumulative incidence of all-cause mortality was not significantly different between TAVI and SAVR in the matched cohort (hazard ratio, 0.96; 95% CI, 0.79-1.16; $P = .64$), and was also not significantly different in every matched age-subgroup. Other midterm clinical outcomes, including stroke, endocarditis, and reintervention, were comparable between the groups, whereas the cumulative incidence of permanent pacemaker implantation was significantly higher in TAVI.

CONCLUSIONS TAVI and SAVR demonstrated comparable midterm survival in the real-world entire population from 2015 to 2019 in Korea. Comparable midterm survival was also demonstrated between all age-subgroups.

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Compared with surgical aortic valve replacement (SAVR), transcatheter aortic valve implantation (TAVI) has demonstrated noninferiority across all surgical risk categories in consecutive randomized controlled trials (RCTs) and has become the standard of care for patients with severe symptomatic aortic stenosis (AS) endorsed by both American and European guidelines.[1,2] The current American guidelines[1] recommend transfemoral TAVI or SAVR in patients

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aged ≥65 years as a Class 1 recommendation, whereas the European guidelines[2] recommend receiving TAVI rather than SAVR in patients aged ≥75 years. In Korea, TAVI has been also widely performed on low-risk patients on the basis of updated international guidelines despite the government regulations prohibiting TAVI for low-risk patients.

Although RCTs have reported favorable results for TAVI, concerns remain about whether RCTs can be fully extrapolated to real-world practice with consistent results favoring TAVI.[3,4] Therefore, this study was conducted to report real-world early and midterm outcomes of TAVI and SAVR, which were performed in the late 2010s in the entire Korean population based on the national database of Korea.

IN SHORT

- Based on the database covering all the procedures in Korea, transcatheter aortic valve implantation and surgical aortic valve replacement demonstrated comparable midterm survival in the real-world entire population.
- Comparable midterm survival was also demonstrated between all age-subgroups of <65, 65 to 69, 70 to 74, 75 to 79, 80 to 84, and ≥85 years.

MATERIAL AND METHODS

DATA SOURCES AND PATIENT CHARACTERISTICS. The study protocol was reviewed by the Seoul National University Hospital Institutional Review Board and approved as a minimal risk retrospective study (approval date October 7, 2021, H-2110-009-1259), and individual consent was waived.

The data for the present study are based on the claims database of the Korean National Health Insurance Service (NHIS), which is a single insurer managed by the government and covers the entire Korean population. The NHIS provides health care insurance coverage to >97% of residents in Korea. This database comprises a complete set of medical claims and health information, including demographic data (age, sex, residential location, and level of income), procedure and diagnosis codes, and survival for inpatient and outpatient services. Diagnoses are coded on the basis of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM).

In Korea, TAVI was first introduced in 2010 and began to be covered by NHIS since June 2015. In this study, we enrolled patients from the initial 5 years of TAVI, from June 2015 to May 2019, and enrolled SAVR patients during the same period. Hospital volume comprised 4 centers performing only TAVI, 74 centers performing only SAVR, and 39 centers performing both TAVI and SAVR. Large numbers of procedures were performed in 4 or 5 high-volume centers; however, a substantial number of procedures were also performed in small-volume centers (Supplemental Figure 1).

Among the 1735 patients who underwent TAVI from June 2015 to May 2019, 1468 patients who underwent primary isolated transfemoral TAVI for AS with no previous cardiac operations were included in the TAVI group. Among the 10,288 patients who underwent SAVR from June 2015 to May 2019, primary isolated SAVR for AS was performed in 4418 patients. After patients with previous cardiac surgery, previous TAVI, and endocarditis were excluded, 3897 patients were included in the SAVR group (Supplemental Figure 2).

Preoperative comorbidities were evaluated using ICD-10-CM diagnosis codes within 1 year before surgery (Supplemental Table 1).

EVALUATION OF EARLY AND MIDTERM CLINICAL OUTCOMES. Evaluation of clinical outcomes is detailed in the Supplemental Materials. Data regarding all-cause mortality were obtained from death certificates from Statistics Korea, a central organization for statistics under the Ministry of Strategy and Finance.

Clinical follow-up was closed on December 31, 2020. The completeness of follow-up was 100.0% because the government recorded every death in the Statistics Korea database. The median follow-up duration was 2.5 years (interquartile range [IQR], 1.8-3.5 years) for the TAVI group and 3.0 years (IQR, 2.1-4.1 years) for the SAVR group.

STATISTICAL ANALYSIS. Statistical analyses were performed using propensity score-matched analysis to adjust differences in preoperative characteristics. Also, to focus on the age criteria in the selection between TAVI and SAVR, subgroup analyses were performed by dividing the cohort into 6 age-subgroups of <65, 65 to 69, 70 to 74, 75 to 79, 80 to 84, and ≥85 years. Detailed methods regarding statistical analysis are provided in Supplemental Materials.

RESULTS

BASELINE CHARACTERISTICS. In the overall population, the TAVI group was older and had more comorbidities than the SAVR group. However, after matching, the differences were adjusted with a

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TABLE 1 Preoperative Characteristics

Variable	Overall Population TAVI (n = 1468)	Overall Population SAVR (n = 3897)	Overall Population SMD	Matched Population TAVI (n = 1017)	Matched Population SAVR (n = 1017)	Matched Population SMD
Female sex	771 (52.5)	1670 (42.9)	0.195	518 (50.9)	496 (48.8)	0.043
Age, mean (SD), y	80.0 (5.9)	68.2 (11.2)	−1.320	78.2 (5.2)	78.2 (5.3)	−0.017
Age-subgroups			1.464			<0.001
<65 years	25 (1.7)	1226 (31.55)		19 (1.9)	19 (1.9)	
65-69 years	38 (2.6)	637 (16.4)		33 (3.2)	33 (3.2)	
70-74 years	157 (10.7)	791 (20.3)		150 (14.8)	150 (14.8)	
75-79 years	430 (29.3)	754 (19.4)		401 (39.4)	401 (39.4)	
80-84 years	509 (34.7)	386 (9.9)		319 (31.4)	319 (31.4)	
≥85 years	309 (21.5)	103 (2.6)		95 (9.3)	95 (9.3)	
Risk factors						
Diabetes mellitus	735 (50.1)	1725 (44.3)	−0.116	509 (50.1)	488 (48.0)	−0.041
Hypertension	1317 (89.7)	3132 (80.4)	−0.264	909 (89.4)	886 (87.1)	−0.070
Dyslipidemia	1160 (79.0)	2885 (74.0)	−0.118	805 (79.2)	797 (78.4)	−0.019
Chronic lung disease	194 (13.2)	347 (8.9)	−0.138	122 (12.0)	142 (14.0)	−0.059
Cerebrovascular disease	247 (16.8)	407 (10.4)	−0.187	156 (15.3)	176 (17.3)	0.053
Dialysis	70 (4.8)	153 (3.9)	−0.041	39 (3.8)	42 (4.1)	0.015
Liver disease	40 (2.7)	64 (1.6)	−0.074	15 (1.5)	22 (2.2)	0.052
Cancer	228 (15.5)	403 (10.3)	−0.155	149 (14.7)	155 (15.2)	0.017
Atrial fibrillation	250 (17.0)	340 (8.7)	−0.250	139 (13.7)	163 (16.0)	0.066
Coronary artery disease	503 (34.3)	1068 (27.4)	−0.149	355 (34.9)	354 (34.8)	−0.002
Peripheral vascular disease	92 (6.3)	178 (4.6)	−0.075	59 (5.8)	72 (7.1)	0.052
Cardiomyopathy	68 (4.6)	157 (4.0)	−0.030	43 (4.2)	52 (5.1)	0.042

Categorical data are presented as n (%) and continuous data as mean (SD), as indicated. SAVR, surgical aortic valve replacement; SMD, standardized mean difference; TAVI, transcatheter aortic valve implantation.

standardized mean difference of <0.1 (Table 1). In the 6 age-subgroups, the differences in baseline characteristics were also largely reduced after matching (Supplemental Tables 2-7).

EARLY CLINICAL OUTCOMES. In the entire population, periprocedural mortality was comparable between the groups (3.2% in TAVI vs 3.5% in SAVR, $P = .66$). However, it was higher in the SAVR group in the matched population (2.9% in TAVI vs 5.6% in SAVR, $P = .66$). The SAVR group had a higher occurrence of acute kidney injury requiring renal replacement therapy (2.4% in TAVI vs 6.1% in SAVR, $P < .001$), whereas the TAVI group had a higher pacemaker implantation rate (8.0% in TAVI vs 2.4% in SAVR, $P < .001$) (Table 2).

MIDTERM CLINICAL OUTCOMES.

All-Cause Mortality. In the matched population, the cumulative incidence of all-cause mortality was not significantly different between TAVI and SAVR (hazard ratio [HR], 0.96; 95% CI, 0.79-1.16; $P = .64$) (Figure 1). When subgroup analyses were performed for each age-subgroup, the cumulative incidences of all-cause mortality were also not significantly different between the groups (Figure 2).

TABLE 2 Early Clinical Outcomes

Variable	Overall Population TAVI	Overall Population SAVR	Overall Population OR[a] (95% CI)	Overall Population *P*	Matched Population TAVI	Matched Population SAVR	Matched Population OR[a] (95% CI)	Matched Population *P*
Periprocedural mortality	3.2 (47/1468)	3.5 (135/3897)	0.93 (0.66-1.30)	.66	2.9 (29/1017)	5.6 (57/1017)	0.51 (0.32-0.80)	.003
Postoperative complications								
Stroke	3.8 (46/1197)	2.3 (81/3483)	1.69 (1.17-2.43)	.005	3.9 (33/844)	3.3 (28/851)	1.16 (0.71-1.88)	.56
AKI requiring RRT	2.9 (40/1379)	3.8 (142/3719)	0.76 (0.53-1.08)	.13	2.4 (23/964)	6.1 (59/965)	0.38 (0.24-0.62)	<.001
Pacemaker implantation	7.1 (103/1446)	1.9 (73/3869)	3.98 (2.93-5.40)	<.001	8.0 (80/1001)	2.4 (24/1006)	3.53 (2.25-5.55)	<.001

[a]The ORs of the SAVR group were used as reference values. Data are presented as percentage (n/N). AKI, acute kidney injury; OR, odds ratio; RRT, renal replacement therapy; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

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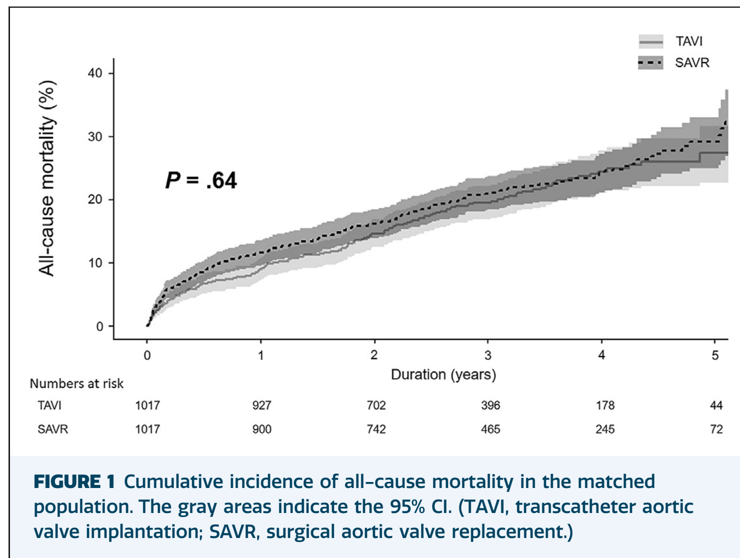

FIGURE 1 Cumulative incidence of all-cause mortality in the matched population. The gray areas indicate the 95% CI. (TAVI, transcatheter aortic valve implantation; SAVR, surgical aortic valve replacement.)

Stroke, Endocarditis, Reintervention, and Permanent Pacemaker Implantation. In the matched population, the midterm clinical outcomes were not significantly different for stroke (HR, 0.9; 95% CI, 0.65-1.23; $P = .50$), endocarditis (HR, 0.95; 95% CI, 0.60-1.53; $P = .84$), and reintervention (HR, 0.77; 95% CI, 40.37-1.61; $P = .49$). However, the cumulative incidence of permanent pacemaker implantation was significantly higher in the TAVI group (HR, 2.88; 95% CI, 2.02-4.10; $P < .001$) (Supplemental Figure 3).

COMMENT

Although the pivotal RCTs demonstrated TAVI to be the preferred treatment for AS regardless of the risks, several concerns about remaining biases in those RCTs exist: (1) a substantial proportion of patients were excluded after randomization and deviated from the assigned treatment, (2) the progressive increase in loss to follow-up was biased toward a consistent pattern favoring TAVI, (3) and an imbalance in concomitant procedures between the TAVI group and the SAVR group was present in almost all the RCTs.[5] Thus, the results of those RCTs should be extrapolated carefully to real-world outcomes because RCTs do not necessarily represent real-world settings.

Observational studies may better reflect routine clinical practice and real-world outcomes because they generally have less restrictive inclusion criteria and enroll so-called all-comers. Several observational studies have demonstrated results that contradict those of the RCTs. A previous study revealed that SAVR was associated with lower mortality and lower major adverse cardiac events at 5 years in low- and intermediate-risk patients.[6] Another study showed that early mortality was comparable between TAVI and SAVR (3.32% vs 3.03%, $P = .801$) and that the survival curves began to diverge at 2 years in favor of SAVR, which was associated with a 30% reduction in mortality.[7] A real-world study in low-risk patients demonstrated that compared with SAVR, TAVI yielded similar short-term outcomes and inferior 5-year survival.[8] In a study of 18,010 patients from a national registry, TAVI with early-generation prostheses was associated with higher 5-year mortality than SAVR.[9]

The present study demonstrated comparable midterm survival between TAVI and SAVR in every subcohort and even in the subcohort of patients aged ≥75 years. According to our subanalyses, operative mortality in age ≥80 years was higher, although it failed to prove statistical significance, in SAVR group than in the TAVI group, as expected. However, if they survived the early post-SAVR period, the midterm survival of the SAVR population was comparable to the TAVI population. We think this finding could be valid because SAVR has a proven durability and is relatively free from the issue of paravalvular leakage in the midterm. Also, the risk of SAVR in octogenarians might be overestimated in the past literature, and we think it might be safely performed if we carefully select the patients.

LIMITATIONS. Limitations of this study include being a retrospective observational study with small sample size, lack of novelty mirroring previous studies, and relatively short follow-up duration. Another limitation is the intrinsic inaccuracy of a registration database based on the ICD-10-CM diagnosis codes. For example, "coronary artery disease" in preoperative characteristics is speculated to be subclinical diseases that do not require concomitant coronary revascularization procedures. Also, the outcomes of TAVI should be cautiously interpreted considering the suboptimal outcomes by early experience because it began to be covered by national health insurance from 2015 in Korea and showed a sharp increase in volume since then.

CONCLUSION. TAVI and SAVR demonstrated comparable midterm survival in the entire real-world population in Korea from 2015 to 2019.

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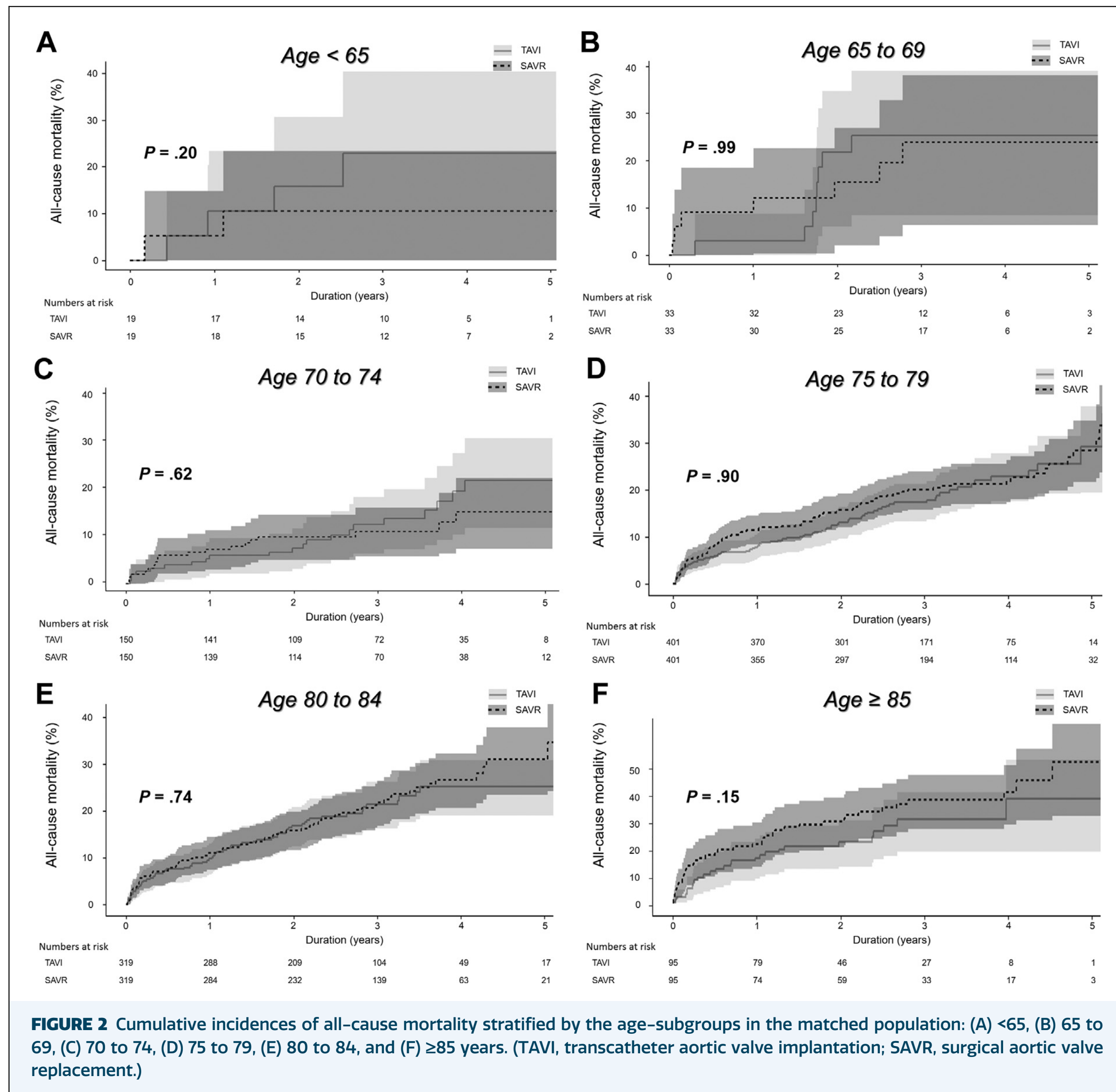

FIGURE 2 Cumulative incidences of all-cause mortality stratified by the age-subgroups in the matched population: (A) <65, (B) 65 to 69, (C) 70 to 74, (D) 75 to 79, (E) 80 to 84, and (F) ≥85 years. (TAVI, transcatheter aortic valve implantation; SAVR, surgical aortic valve replacement.)

Comparable midterm survival was also demonstrated between all age-subgroups.

The Supplemental Material can be viewed in the online version of this article [https://doi.org/10.1016/j.atssr.2025.05.008] on https://www.annalsthoracicsurgeryshortrep.org.

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DISCLOSURES

The authors have no conflicts of interest to disclose.

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