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Costs Associated with Transcatheter Aortic Valve Implantation and Surgical Aortic Valve Replacement in Korea

Suk Ho Sohn, M.D.¹, Kyung Hwan Kim, M.D., Ph.D.¹, Yoonjin Kang, M.D., Ph.D.¹, Jae Woong Choi, M.D., Ph.D.¹, Seung Hyun Lee, M.D., Ph.D.², Sung Ho Shinn, M.D., Ph.D.³, Jae Suk Yoo, M.D., Ph.D.⁴, Cheong Lim, M.D., Ph.D.⁵

¹Department of Thoracic and Cardiovascular Surgery, Seoul National University Hospital, Seoul National University College of Medicine; ²Department of Thoracic and Cardiovascular Surgery, Severance Cardiovascular Hospital, Yonsei University College of Medicine, Seoul; ³Shinn Sung Ho Cardiovascular Center, Guri; ⁴Department of Thoracic and Cardiovascular Surgery, Asan Medical Center, University of Ulsan College of Medicine, Seoul; ⁵Department of Thoracic and Cardiovascular Surgery, Seoul National University Bundang Hospital, Seoul National University College of Medicine, Seongnam, Korea

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Corresponding author

Kyung Hwan Kim Tel 82-2-2072-3971 Fax 82-2-764-3664 E-mail kkh726@snu.ac.kr ORCID https://orcid.org/0000-0002-2718-8758 **Background:** This study compared the costs associated with transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR) in Korea by utilizing the National Health Insurance Service database.

Methods: Between June 2015 and May 2019, 1,468 patients underwent primary isolated transfemoral TAVI, while 2,835 patients received primary isolated SAVR with a bioprosthesis. We assessed the costs of index hospitalization and subsequent healthcare utilization, categorizing the cohort into 6 age subgroups: <70, 70–74, 75–79, 80–84, 85–89, and \geq 90 years. The median follow-up periods were 2.5 and 3.0 years in the TAVI and SAVR groups, respectively.

Results: The index hospitalization costs were 41.0 million Korean won (KRW) (interquartile range [IQR], 39.1–44.7) for the TAVI group and 24.6 million KRW (IQR, 21.3–30.2) for the SAVR group (p<0.001). The TAVI group exhibited relatively constant index hospitalization costs across different age subgroups. In contrast, the SAVR group showed increasing index hospitalization costs with advancing age. The healthcare utilization costs were 5.7 million KRW per year (IQR, 3.3–14.2) for the TAVI group and 4.0 million KRW per year (IQR, 2.2–9.0) for the SAVR group (p<0.001). Healthcare utilization costs were higher in the TAVI group than in the SAVR group for the age subgroups of <70, 70–74, and 75–79 years, and were comparable in the age subgroups of 80–84, 85–89, and \geq 90 years.

Conclusion: TAVI had much higher index hospitalization costs than SAVR. Additionally, the overall healthcare utilization costs post-discharge for TAVI were also marginally higher than those for SAVR in younger age subgroups.

Keywords: Transcatheter aortic valve implantation, Aortic valve disease, Heart valve prosthesis, Cost

Introduction

Transcatheter aortic valve implantation (TAVI) was initially introduced as an alternative to surgical aortic valve replacement (SAVR) for symptomatic patients with aortic stenosis who were at prohibitive or high surgical risk [1,2]. However, TAVI is now supplanting SAVR as the first-line treatment for severe aortic stenosis in patients with low surgical risk [3,4]. Additionally, the annual volume of TAVI procedures now surpasses that of SAVR in Western countries [5-7].

In Korea, TAVI was first included in the national health insurance coverage in 2015, with the National Health Insurance Service (NHIS) beginning to partially reimburse the costs associated with the procedure. Since then, the number of TAVI procedures has risen sharply, now exceeding 1,000 cases annually [8]. Despite the Korean government's 2015 regulation restricting TAVI to low- and intermediate-risk patients, interventional cardiologists have frequently performed it on this group, guided by emerging

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This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (http://creativecommons.org/licenses/ by-nc/4.0) which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited. evidence and updated guidelines [9,10]. Moreover, in 2022, a significant amendment to the healthcare policy on TAVI broadened the scope and depth of insurance coverage for the procedure. As a result, the economic burden on the NHIS and its impact on national finances are expected to increase significantly.

The aim of this study was to evaluate the costs associated with TAVI and SAVR during the index hospitalization and post-discharge in a real-world Korean population, utilizing the NHIS database.

Methods

The study protocol underwent review by the Institutional Review Board of Seoul National University Hospital and received approval as a minimal-risk retrospective study (approval date: 10/07/2021, approval number: H-2110-009-1259). Based on the institutional guidelines for waiving consent, individual consent was not required.

Data source and patient characteristics

The present study utilized a database from the NHIS, a government-managed single insurer that provides public health insurance to over 97% of residents in Korea [11]. This database contains demographic data such as age and sex, as well as diagnoses; it also includes information on procedures performed and medical claims per patient. Diagnoses within this database are recorded according to the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10) [11].

The first TAVI in Korea was performed in 2010 [12].

However, there was no NHIS dataset available for TAVI prior to May 2015, as it was only included in the NHIS insurance coverage starting in June 2015. In this study, we analyzed the initial 5-year period of TAVI data, from June 2015 to May 2019, following its inclusion under insurance coverage. We also enrolled patients who underwent SAVR during the same period.

Of the 1,735 patients who underwent TAVI from June 2015 to May 2019, 208 underwent additional procedures (203 coronary interventions, 3 mitral valvuloplasties, and 2 catheter ablations for arrhythmia). Six patients had unidentifiable data, and 1,521 underwent primary isolated TAVI. After excluding those who received transapical and transaortic TAVI, isolated transfemoral TAVI was performed on 1,497 patients. Following the exclusion of 29 patients with previous cardiac surgery, 1,468 patients were ultimately included in the TAVI group.

Of the 10,288 patients who underwent SAVR between June 2015 and May 2019, 4,418 underwent primary isolated SAVR. After excluding 1,303 patients who received mechanical valves, primary isolated SAVR with a bioprosthetic valve was performed on 3,115 patients. Further exclusions were made for 24 patients with previous cardiac surgery, 3 patients with prior TAVI, and 253 patients with endocarditis, leaving a total of 2,835 patients ultimately enrolled in the SAVR group (Fig. 1).

Preoperative comorbidities were assessed within 1 year prior to surgery using the diagnosis codes listed in Supplementary Table 1. The Charlson comorbidity index was determined by summing the weights assigned to 17 comorbidities, as outlined by the diagnosis codes in Supplementary Table 2 [13].

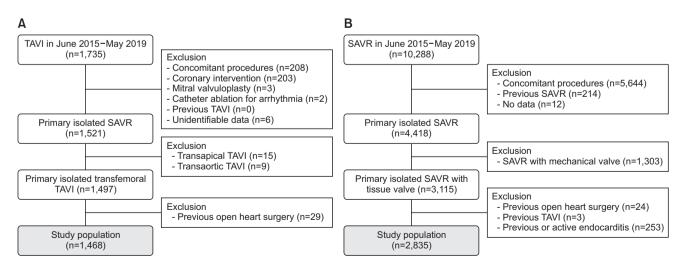


Fig. 1. (A, B) Flow diagram of patient enrollment. SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

Evaluation of early and mid-term mortality

To evaluate the impact of mortality differences between the groups on costs, we analyzed both early and mid-term mortality. Early mortality was defined as any death occurring within 30 days post-surgery or during the initial hospital admission. Mid-term mortality included any all-cause death that occurred after the surgery. Mortality status was determined by cross-referencing the discharge date of the index procedure with the date of death listed on the death certificate, as provided by Statistics Korea, a central statistical organization under the Ministry of Strategy and Finance. Additionally, the dates of mortality during follow-up were obtained from the death certificates issued by Statistics Korea.

Clinical follow-up ended on December 31, 2020, with a completeness rate of 100.0%, as mortality data were recorded in the Statistics Korea database by the government. 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.

Evaluation of costs

The total costs were categorized based on the timing of the expenses incurred, specifically into index hospitalization costs and healthcare utilization costs. Index hospitalization costs encompassed the total expenses accrued during the initial admission for TAVI or SAVR procedures. This included fees for doctors, hospitalization, prescriptions, injections, anesthesia, operations, examinations, radiologic diagnoses, medical materials, rehabilitation and physical therapy, transfusions, sonographic diagnoses, meals, and certificates. Healthcare utilization costs represented the annual costs post-discharge and consisted of 3 main components: outpatient costs, inpatient costs, and pharmacy dispensing costs (Fig. 2).

The costs were calculated based on who bore the expense; they were categorized into out-of-pocket costs, paid directly by the patient, and insurance coverage costs, paid by the NHIS. The term "out-of-pocket" referred to the copayment (i.e., the part of the healthcare service costs paid by patients to the medical service provider during a hospital visit). The copayment rate varied depending on whether the service was inpatient or outpatient, as well as the type of service and the healthcare institution's level. The out-ofpocket and insurance coverage costs were calculated using the classification tables from the National Health Insurance database. The currency unit used in the cost analysis was the Korean won (KRW).

Statistical analysis

Statistical analyses were conducted using IBM SPSS software ver. 25.0 (IBM Corp., Armonk, NY, USA) and SAS Enterprise Guide ver. 7.1 (SAS Institute Inc., Cary, NC, USA). Continuous variables are reported as either the mean±standard deviation for normally distributed data or the median with interquartile range for data that are not normally distributed. Categorical variables are expressed as the number and percentage of subjects. To compare baseline characteristics between the 2 groups, we used the chi-square test or the Fisher exact test for categorical variables and the Student t-test or the Wilcoxon rank-sum test for continuous variables.

To focus on the age criteria associated with the healthcare policy, cost analyses were conducted by dividing the patient cohort into 6 age subgroups at 5-year intervals: <70, 70–74, 75–79, 80–84, 85–89, and ≥90 years. Costs of index hospitalization and subsequent healthcare utilization were compared using a generalized linear model with a gamma distribution.

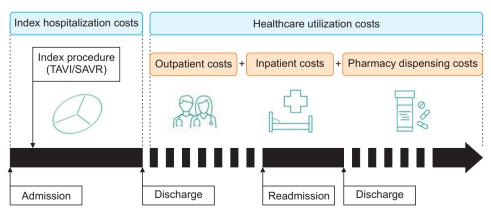


Fig. 2. Schematic diagram of the costs associated with transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR) during the index hospitalization and after discharge.

Early and mid-term mortality rates were compared between the groups to supplement the cost analysis. The risk of early mortality was assessed using multivariable logistic regression analysis. Mid-term mortality was analyzed using a Cox proportional hazard model, which accounted for the effect of covariates to adjust for baseline characteristic differences between the groups [14]. The analyses included adjustments for variables that were not balanced (standardized mean difference >0.1) between the groups. All tests were 2-tailed, and a p-value <0.05 was deemed statistically significant.

Results

Baseline characteristics

The average age of the TAVI group was higher than that of the SAVR group (80.0 ± 5.9 versus 72.6 ± 7.8 years, p< 0.001). Additionally, a greater proportion of women was observed in the TAVI group than in the SAVR group (52.5%versus 47.2%, p<0.001). The TAVI group also exhibited a higher incidence of risk factors, including diabetes mellitus, hypertension, chronic lung disease, cerebrovascular disease, renal disease, liver disease, cancer, atrial fibrillation, and coronary artery disease. As a result, the Charlson comorbidity index was higher in the TAVI group (Table 1).

Table 1. Preoperative characteristics and risk factors for the study patients

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Characteristic	TAVI (n=1,468)	SAVR (n=2,835)	SMD	p-value
Sex, female	771 (52.5)	1,337 (47.2)	0.107	< 0.001
Mean age (yr)	80.0±5.9	72.6±7.8	-1.076	< 0.001
Age group (yr)			1.129	< 0.001
<70	63 (4.3)	861 (30.4)		
70–74	157 (10.7)	749 (26.4)		
75–79	430 (29.3)	743 (26.2)		
80–84	509 (34.7)	382 (13.5)		
85–89	253 (17.2)	89 (3.1)		
≥90	56 (3.8)	11 (0.4)		
Charlson comorbidity index	4 (2–6)	3 (2–5)	-0.230	< 0.001
Risk factors				
Diabetes mellitus	735 (50.1)	1,328 (46.8)	-0.065	0.044
Hypertension	1,317 (89.7)	2,391 (84.3)	-0.161	< 0.001
Dyslipidemia	1,160 (79.0)	2,178 (76.8)	-0.053	0.102
Chronic lung disease	194 (13.2)	294 (10.4)	-0.088	0.005
Cerebrovascular disease	247 (16.8)	343 (12.1)	-0.135	< 0.001
Renal disease	203 (13.8)	270 (9.5)	-0.134	< 0.001
Liver disease	40 (2.7)	48 (1.7)	-0.070	0.023
Cancer	228 (15.5)	326 (11.5)	-0.118	< 0.001
Atrial fibrillation	250 (17.0)	267 (9.4)	-0.226	< 0.001
Coronary artery disease	503 (34.3)	806 (28.4)	-0.126	< 0.001
Peripheral vascular disease	92 (6.3)	148 (5.2)	-0.045	0.156
Diagnosis				
Aortic stenosis	1,239 (84.4)	2,034 (71.7)	-0.310	< 0.001
Aortic regurgitation	61 (4.2)	438 (15.4)	0.387	< 0.001
Aortic stenoinsufficiency	246 (16.8)	286 (10.1)	-0.197	< 0.001
Bicuspid aortic valve	36 (2.5)	187 (6.6)	0.200	< 0.001
Year of the index procedure			0.312	
2015 (from June)	83 (5.7)	304 (10.7)		
2016	237 (16.1)	642 (22.7)		
2017	376 (25.6)	739 (26.1)		
2018	486 (33.1)	807 (28.5)		
2019 (to May)	286 (19.5)	343 (12.1)		

Continuous variables are presented as the mean±standard deviation for normally distributed variables and as the median (interquartile range) for nonnormally distributed variables. Categorical variables are presented as number (%).

TAVI, transcatheter aortic valve implantation; SAVR, surgical aortic valve replacement; SMD, standardized mean difference.

However, when subgroup analyses were conducted for each age group, the differences in baseline characteristics between the groups were mostly nonsignificant, with the exception of patients aged under 70 years. In specific age subgroups, higher prevalence rates in the TAVI group were observed only for renal disease and cancer in the 70–74 years age subgroup, coronary artery disease in the 75–79 years age subgroup, dyslipidemia in the 80–84 years age subgroup, and cancer in the 85–89 years age subgroup (Supplementary Tables 3–8).

Early and mid-term mortality

Early mortality was higher in the SAVR group than in the TAVI group (4.0% for SAVR versus 3.2% for TAVI, p=0.009). However, mortality rates were similar between the TAVI and SAVR groups across the age subgroups of <70, 70–74, 75–79, 80–84, and 85–89 years. In contrast, for the subgroup aged \geq 90 years, early mortality was significantly higher in the SAVR group (Table 2).

In terms of mid-term mortality, the cumulative incidence of all-cause mortality was higher in the TAVI group compared to the SAVR group (p<0.001) (Supplementary Fig. 1). However, subgroup analyses for each age category showed similar outcomes between the groups, with the exception of patients younger than 70 years, where the incidence of all-cause mortality was higher in the TAVI subgroup (Supplementary Fig. 2).

Cost

Index hospitalization costs

The index hospitalization costs amounted to 41.0 million KRW (IQR, 39.1–44.7) for the TAVI group and 24.6 million KRW (IQR, 21.3–30.2) for the SAVR group (p<0.001).

Regarding these costs, the out-of-pocket expenses were 27.6 million KRW (IQR, 27.1–28.2) for the TAVI group and 1.5 million KRW (IQR, 1.2–2.3) for the SAVR group. Conversely, the insurance coverage costs were 13.4 million KRW (IQR, 11.7–16.8) for the TAVI group and 22.1 million KRW (IQR, 19.7–26.4) for the SAVR group.

In the subgroup analyses for different age categories, the TAVI group incurred higher index hospitalization costs compared to the SAVR group across all age subgroups, with the exception of those aged 90 years and above. The costs for the TAVI group remained relatively stable, varying from 40.0 to 42.2 million KRW across the different age groups. In contrast, the SAVR group showed a trend of increasing costs with age, ranging from 23.1 to 37.2 million KRW (Table 3, Fig. 3).

Healthcare utilization costs

The annual healthcare utilization costs were 5.7 million KRW (IQR, 3.3–14.2) in the TAVI group and 4.0 million KRW (IQR, 2.2–9.0) in the SAVR group. Within these costs, the out-of-pocket expenses amounted to 1.6 million KRW (IQR, 1.0–3.0) for the TAVI group and 1.0 million KRW (IQR, 0.5–1.8) for the SAVR group. The insurance coverage costs were 4.0 million KRW (IQR, 2.2–10.7) per year for the TAVI group and 2.9 million KRW (IQR, 1.5–7.1) for the SAVR group. In subgroup analyses by age, the TAVI group incurred higher costs than the SAVR group in the age subgroups of <70, 70–74, and 75–79 years. However, costs were comparable between the TAVI and SAVR groups in the age subgroups of 80–84, 85–89, and \geq 90 years (Table 4, Fig. 4A)

The annual outpatient costs were 1.4 million KRW (IQR, 0.9–2.3) for the TAVI group and 1.1 million KRW (IQR, 0.7–1.9) for the SAVR group. The TAVI group incurred slightly higher outpatient costs than the SAVR group

Table 2. Early mortality stratified by age subgroups	Table 2. Ea	ly mortality st	ratified by ac	e subgroups
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Variable	Mortality rate	e (no./total no.)	A divisted ODa) (OFO/ CI)	n value
variable	TAVI	SAVR	Adjusted OR ^{a)} (95% CI)	p-value
Overall population	3.2 (47/1,468)	4.0 (114/2,835)	0.58 (0.39–0.87)	0.009
Age subgroups (yr)				
<70	3.2 (2/60)	3.0 (26/861)	0.45 (0.09-2.36)	0.348
70–74	1.9 (3/157)	2.9 (22/749)	0.62 (0.17-2.33)	0.479
75–79	3.3 (14/430)	4.4 (33/743)	0.80 (0.39–1.63)	0.531
80–84	2.8 (14/509)	5.0 (19/382)	0.54 (0.25-1.19)	0.125
85–89	4.3 (11/253)	11.2 (10/89)	0.37 (0.12-1.11)	0.076
≥90	5.4 (3/56)	36.4 (4/11)	0.10 (0.02–0.54)	0.007

TAVI, transcatheter aortic valve implantation; SAVR, surgical aortic valve replacement; OR, odds ratio; CI, confidence interval.

^aAdjusted odds ratios were calculated using a multivariable logistic model for the variables that were not balanced (absolute standardized difference >0.1) between the groups. ORs were calculated for the TAVI group using the SAVR group as a reference.

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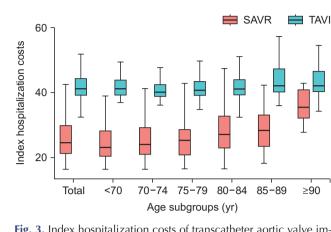


Fig. 3. Index hospitalization costs of transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR) in Korea by age subgroup. The unit of cost is 1,000,000 Korean won.

across all age subgroups (Supplementary Table 9, Fig. 4B).

The annual inpatient costs were 1.5 million KRW (IQR, 0.0–8.2) in the TAVI group and 0.9 million KRW (IQR, 0.0–4.7) in the SAVR group. In the subgroup of patients younger than 80 years, the TAVI group incurred higher outpatient costs compared to the SAVR group. Conversely, in the subgroup of patients aged 80 years and older, the SAVR group incurred higher costs (Supplementary Table 10, Fig. 4C).

The annual pharmacy dispensing costs were 1.7 million KRW (IQR, 1.1–2.3) in the TAVI group and 1.2 million KRW (IQR, 0.7–1.7) in the SAVR group. The TAVI group consistently showed slightly higher pharmacy dispensing costs than the SAVR group across all age subgroups (Supplementary Table 11, Fig. 4D).

Discussion

The present study demonstrated 2 main findings. First, the index hospitalization costs, which were defined as the total costs incurred during the index hospitalization to perform TAVI or SAVR, were much higher for TAVI than for SAVR. Second, the healthcare utilization costs, which were defined as the maintenance costs per year during the follow-up after discharge, were also slightly higher in the TAVI group than in the SAVR group.

In 2010, the first TAVI in Korea was classified as a "nonbenefit" item by the national health insurance system, meaning it was not covered by insurance, and patients were responsible for the full cost [12]. This made the procedure very expensive. However, in 2015, the NHIS reclassified TAVI as a "selective healthcare benefit" item. Consequently, the government established a fixed price for the

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Mariable	No. of patients	oatients	Tot	fotal cost (A+B)		Out-o	Out-of-pocket (A)		Insuran	Insurance coverage (B)	
Vallable	TAVI	TAVI SAVR	TAVI	SAVR	p-value	TAVI	SAVR p-value	p-value	TAVI	SAVR	p-value
Overall population	1,468	2,835	Dverall population 1,468 2,835 41.0 (39.1–44.7) 24.6 (21.3–30.2) <0.001 27.6 (27.1–28.2) 1.5 (1.2–2.3) <0.001 13.4 (11.7–16.8) 22.1 (19.7–26.4) <0.001	24.6 (21.3–30.2)	<0.001	27.6 (27.1–28.2)	1.5 (1.2–2.3)	<0.001	13.4 (11.7–16.8)	22.1 (19.7–26.4)	<0.001
Age subgroups (yr)											
<70	63	63 861		41.1 (39.2-47.2) 23.1 (20.3-28.3) <0.001	<0.001	27.9 (27.3–28.5)	1.4 (1.1–1.9)	<0.001	27.9 (27.3–28.5) 1.4 (1.1–1.9) <0.001 13.1 (11.6–18.8) 21.0 (19.0–24.5) <0.001	21.0 (19.0-24.5)	<0.001
70–74	157	749	40.0 (38.6-42.5)	24.0 (21.0–29.4) <0.001	<0.001	27.5 (27.1–28.1) 1.4 (1.1–2.0) <0.001	1.4 (1.1-2.0)	<0.001	12.3 (11.3–15.0) 21.8 (19.6–25.4) <0.001	21.8 (19.6–25.4)	<0.001
75-79	430	743	40.6 (38.9-43.4)	25.6 (21.8–31.0) <0.001	<0.001	27.6 (27.0–28.1) 1.5 (1.2–2.7) <0.001	1.5 (1.2–2.7)	<0.001	13.1 (11.5–15.8) 22.7 (20.2–26.9) <0.001	22.7 (20.2–26.9)	<0.001
80-84	509	382	41.0 (39.1-44.0)	27.2 (22.9–33.4) <0.001	<0.001	27.6 (27.1–28.2) 1.7 (1.3–6.7) <0.001	1.7 (1.3-6.7)	<0.001	13.4 (11.6–16.5) 24.1 (20.8–28.9) <0.001	24.1 (20.8-28.9)	<0.001
85–89	253	89	42.2 (40.1-47.3)	28.4 (23.6–35.2) <0.001	<0.001	27.8 (27.2–28.4) 1.6 (1.3–5.2) <0.001	1.6 (1.3–5.2)	<0.001	14.6 (12.3-19.1) 24.3 (21.7-31.3) <0.001	24.3 (21.7-31.3)	<0.001
≥90	56	11	42.0 (39.9-47.3)	37.2 (32.1-42.9)	0.423	37.2 (32.1-42.9) 0.423 27.6 (27.1-28.5) 8.3 (1.9-9.3) <0.001 14.4 (12.3-20.1) 32.1 (25.9-40.5) <0.001	8.3 (1.9–9.3)	<0.001	14.4 (12.3–20.1)	32.1 (25.9-40.5)	<0.001
Values are presented as number of patients or medians (interquartile range) unless otherwise stated. The unit of cost is 1,000,000 Korean won. TAVI, transcatheter aortic valve implantation; SAVR, surgical aortic valve replacement.	as number rtic valve	^r of patien implantat	ts or medians (interquion; SAVR, surgical a	quartile range) unless othe aortic valve replacement.	otherwise ent.	stated. The unit of cc	st is 1,000,000	Korean woi	ć		

Table 4. Healthcare utilization costs after discharge in patients who underwent TAVI or SAVR	ization costs ¿	after discharg	e in patients who und	erwent TAVI or SAVF	~				
1/2	No. of patients	oatients	To	Total cost (A+B)		Out-of-p	Out-of-pocket (A)	Insurance coverage (B)	overage (B)
variable	TAVI	SAVR	TAVI	SAVR	p-value	TAVI	SAVR	TAVI	SAVR
Overall population	1,421	2,721	5.7 (3.3-14.2)	4.0 (2.2–9.0)	<0.001	1.6 (1.0–3.0)	1.0 (0.5–1.8)	4.0 (2.2–10.7)	2.9 (1.5-7.1)
Age subgroups									
<70	61	835	11.7 (4.1–38.1)	3.1 (1.7–7.1)	<0.001	1.8 (0.7-3.6)	0.8 (0.4–1.4)	8.8 (3.0-33.9)	2.2 (1.2-5.4)
70–74	154	727	5.3 (3.3–17.5)	4.2 (2.3–8.7)	<0.001	1.6 (1.0–2.9)	1.0 (0.5–1.7)	3.8 (2.1–13.6)	3.0 (1.6-7.0)
75-79	416	710	5.2 (3.3-12.3)	4.4 (2.5–9.9)	<0.001	1.5 (1.0–2.5)	1.0 (0.6-2.0)	3.9 (2.2–9.1)	3.2 (1.8–7.8)
80-84	495	363	5.5 (3.3-11.1)	4.7 (2.8–11.2)	0.955	1.6 (1.0–2.9)	1.1 (0.6–2.2)	3.9 (2.2–8.7)	3.5 (1.9–9.2)
85-89	242	79	6.4 (3.5-15.3)	6.2 (3.9–18.8)	0.629	1.7 (1.0–3.5)	1.3 (0.6–2.3)	4.6 (2.3–12.9)	4.8 (2.7–14.4)
≥90	53	7	5.6 (3.3-20.4)	3.7 (2.6–19.3)	0.958	1.7 (1.0–5.0)	1.2 (0.7-4.5)	4.4 (2.0–15.2)	2.5 (1.8–14.8)
Values are presented as number of patients or medians (interquartile range) unless otherwise stated. The unit of cost is 1,000,000 KRW. TAVI, transcatheter aortic valve implantation; SAVR, surgical aortic valve replacement.	number of pat c valve implar	tients or medi. Itation; SAVR,	ans (interquartile range surgical aortic valve re	.) unless otherwise st. eplacement.	ated. The unit o	of cost is 1,000,000	KRW.		

materials and procedures involved in TAVI, and the NHIS began to cover 20% of these costs. This change significantly reduced the financial burden on patients and led to a marked increase in the number of TAVI procedures performed.

In 2022, the Ministry of Health and Welfare of the Korean government announced an expansion of the reimbursement indications and an increase in the proportion of costs covered by the NHIS. The NHIS now reimburses 95% of the costs for patients who meet at least 1 of the following 3 criteria: (1) a Society of Thoracic Surgeons (STS) score greater than 8%, (2) age 80 years or older, or (3) classified as "inoperable" by consensus of 2 cardiac surgeons within a multidisciplinary TAVI team. Patients who do not meet any of these criteria receive NHIS coverage of only 20% of the costs if they are low-risk (STS score less than 4%) or 50% if they are intermediate-risk (STS score between 4% and 8%). Following this amendment in 2022, there was a significant increase in both the proportion of costs borne by the NHIS per patient and the total number of patients undergoing TAVI. Given these developments, it is necessary to assess the costs associated with TAVI and SAVR to guide future directions of TAVI insurance policy in Korea.

Several international studies have reported the superior cost-effectiveness of TAVI compared to SAVR. A recent study highlighted significant cost savings with the latest generation TAVI device over a 10-year period for patients with intermediate surgical risks [15]. For patients with low surgical risk and severe aortic stenosis, multiple studies from various countries have consistently suggested that TAVI is a cost-effective option [16-19]. These cost savings are primarily attributed to lower long-term management costs, which include expenses related to postsurgical rehabilitation, atrial fibrillation, and disabling stroke [18]. However, these studies have inherent limitations as they rely on efficacy inputs from The Placement of Aortic Transcatheter Valves (PARTNER) 3 trial and base their cost-effectiveness models on this trial. The conclusions drawn from these studies cannot be generalized to the entire aortic stenosis population, particularly those with bicuspid valves or other high-risk anatomical features such as annular calcification and unfavorable coronary anatomy. This is because the PARTNER 3 trial excluded patients who were at a high risk of postinterventional complications [4]. Additionally, these cost-effectiveness models are limited by assumptions made with the "best fit" data or a scarcity of data, extrapolations beyond the existing data range, and potential underestimations or overestimations due to differences in healthcare systems [18].

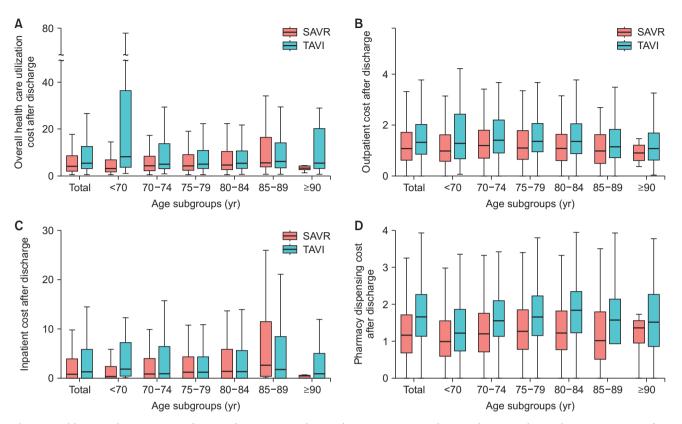


Fig. 4. Healthcare utilization costs of transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR) after discharge in Korea by age subgroup. (A) Overall healthcare utilization costs after discharge, (B) outpatient costs after discharge, (C) inpatient costs after discharge, and (D) pharmacy dispensing costs after discharge. The unit of cost is 1,000,000 Korean won.

Another study evaluated the costs associated with TAVI and SAVR using real-world data, adjusted for STS risk and key sociodemographic factors. It found that both the cost of the initial procedure and the total costs up to 30 days post-procedure were lower for TAVI than for SAVR, achieving a cost savings of 13% during the 30-day follow-up period [20]. However, the generalizability of this study is limited due to significant differences in the index hospitalization costs compared to other countries and its nature as a single-center study with a brief follow-up period. Additionally, the study did not account for community-incurred costs, such as visits to general practitioners, prescription medications, or other nonsubsidized health services costs.

In contrast to previous international cost-effectiveness studies, our research was grounded in the actual costs incurred by all patients across various institutions in Korea. The findings revealed that both the procedural and index admission costs—collectively referred to as the initial costs—were significantly higher for TAVI than for SAVR. Additionally, the healthcare utilization costs, or maintenance costs, were marginally higher for TAVI than for SAVR. Typically, the higher initial cost of a procedure could be justified if its subsequent maintenance costs are lower than those of an alternative procedure. However, our study indicated that TAVI not only demands greater expenditure initially but also incurs higher costs during both short-term and follow-up management.

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In terms of clinical outcomes, there is no doubt that the outcomes of TAVI will continue to improve and that the demand for TAVI will increase in the coming years. The 2020 American College of Cardiology/American Heart Association guidelines recommend TAVI for severe aortic stenosis, taking into account only the patient's age, life expectancy, and suitability for transfemoral TAVI, regardless of the risk score [9]. The most recent 2021 European guidelines recommend TAVI for all patients aged 75 years and older, irrespective of their surgical risk [10]. The indications for TAVI are likely to expand further in the near future, and the long-term outcomes are also expected to be satisfactory. From a societal perspective, TAVI may offer additional benefits over SAVR that have not yet been fully recognized, such as a quicker return to normal activities, which could reduce the need for caregivers.

However, further cost reductions of TAVI will be limit-

ed, even though TAVI has become more efficient due to operator learning, procedural modifications, advances in postprocedural care, and a consequent reduction in the average length of hospital stays [21]. The primary obstacle to lowering TAVI costs is the high price of the TAVI valve itself, which costs approximately 30,000,000 KRW and represents about 75% of the total index hospitalization cost. In contrast, SAVR is significantly less expensive than TAVI. This is because the government-set cost for SAVR is relatively low compared to that in Western countries. The procedure cost for SAVR, including the prosthetic valve, is approximately 17,000,000 KRW, with national health insurance covering up to 95% of the index hospitalization cost.

The reasons behind the higher post-discharge costs for TAVI compared to SAVR remain unclear. One hypothesis is that patients undergoing TAVI may experience more complications such as paravalvular leakage, heart failure, and the need for pacemaker implantation. As a result, cardiologists may prescribe more medications than cardiac surgeons typically do. Furthermore, despite similar ages and comparable risk factors between the groups within the same age subgroups, TAVI patients may have additional undisclosed comorbidities not captured in the database. These could include conditions like porcelain aorta, postchest radiation status, severe aortic annulus calcifications, or diminished left ventricular function.

In Korea's healthcare system, careful policy-making is essential to ensure both outstanding clinical results and the equitable distribution of resources for patients with severe aortic stenosis. Given the costs associated with TAVI and SAVR, healthcare policies should guide low-risk patients, who are likely to recover well from SAVR, towards this option due to its proven long-term benefits and lower costs. Additionally, for patients under 70 years old with a high likelihood of having a bicuspid aortic valve, healthcare policies should strongly discourage the use of TAVI, not only because of its cost but also due to its less optimal clinical outcomes [22,23]. TAVI in patients with a bicuspid aortic valve is known to carry a higher risk of device malposition and underexpansion, which can compromise the success of the procedure [24]. Furthermore, long-term durability data for TAVI in patients with bicuspid valves remain inadequate [25], and a previous study indicated a time-varying risk that favors SAVR over TAVI for these patients at later timepoints [26].

In addition, considering the aging population and the increasing number of patients with aortic stenosis who require aortic valve intervention, the NHIS covering up to 95% of the total cost will undoubtedly impose a significant financial burden. To ensure the sustainability of the national healthcare insurance system, the reimbursement policy for TAVI needs to be stricter and more restrictive. It is essential to engage in public discussions and reach a social consensus on various issues, including the appropriate percentages for copayments and insurance coverage, limitations on performing TAVI in patients with very short life expectancies, and regulations on performing TAVI in extremely frail patients who are unlikely to benefit from the procedure.

It is widely understood that healthcare policy, especially in terms of costs, significantly impacts real-world practice. It is crucial to develop a nuanced policy that considers the costs of procedures, long-term management, and overall budgets comprehensively. This approach will prevent the wastage of national healthcare resources and ensure that patients receive the necessary treatments.

Limitations

Several limitations of the current study must be recognized. First, the study relied on the NHIS database, which only includes diagnosis codes with ICD-10 classifications, and did not allow for the collection of STS scores. Second, the retrospective analysis involved nonrandomized groups with varying baseline characteristics. Although subgroup analyses by age partially adjusted for these differences, they may still have impacted the findings. The higher healthcare utilization costs observed in the TAVI group may not be solely due to the costs associated with the aortic valve prosthesis. The increased prevalence of comorbidities among TAVI patients suggests a broader need for medical care beyond treating aortic valve disease. Third, this study did not include a long-term cost evaluation. In a long-term follow-up, factors such as the durability of transcatheter and surgical valves, and the potential need for subsequent interventions like TAVI after TAVI, SAVR after TAVI, and TAVI after SAVR, could significantly influence the conclusions of this type of cost analysis. Fourth, the study did not conduct a cost-effectiveness evaluation that included quality of life. From another perspective, a higher cost might be justified if it results in significant improvements in quality of life and secondary socioeconomic benefits, such as an early return to work. Fifth, the out-ofpocket costs reported in this study may differ significantly from those encountered in everyday practice due to several factors. These include non-benefit items not captured in the database, varying costs across different hospitals, and individual patient copayment rates.

Conclusions

The index hospitalization costs for TAVI were much higher than those for SAVR, and the overall healthcare utilization costs of TAVI after discharge were also slightly higher than those for SAVR. Based on the results of this study, the cost of the index procedures during the index admission and after discharge should be considered when establishing a national health insurance policy regarding procedures for aortic valve diseases.

Article information

ORCID

Suk Ho Sohn: https://orcid.org/0000-0001-7391-3415 Kyung Hwan Kim: https://orcid.org/0000-0002-2718-8758 Yoonjin Kang: https://orcid.org/0000-0002-2528-173X Jae Woong Choi: https://orcid.org/0000-0002-0921-756X Seung Hyun Lee: https://orcid.org/0000-0002-0311-6565 Sung Ho Shinn: https://orcid.org/0000-0001-9539-7941 Jae Suk Yoo: https://orcid.org/0000-0002-7008-054X Cheong Lim: https://orcid.org/0000-0003-0913-7014

Author contributions

Conceptualization: SH Sohn, KHK, YK, SHL, SH Shinn, CL. Data curation: SH Sohn, YK. Formal analysis: SH Sohn. Methodology: SH Sohn, KHK, JWC, SHL, SH Shinn, JSY, CL. Visualization: SH Sohn. Writing-original draft: SH Sohn. Writing-review & editing: KHK, JWC, SHL, SH Shinn, JSY, CL. Final approval of the manuscript: SH Sohn, KHK, JWC, SHL, SH Shinn, JSY, CL.

Conflict of interest

Jae Woong Choi serves as an Editorial Board member of the *Journal of Chest Surgery* but has no role in the decision to publish this article. Except for that, no potential conflict of interest relevant to this article was reported.

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Supplementary materials

Supplementary materials can be found via https://doi. org/10.5090/jcs.24.048. Supplementary Table 1. Diagnosis codes used for the evaluation of preoperative comorbidities. Supplementary Table 2. Medical conditions, disease codes, and weighted values for the calculation of the Charlson comorbidity index. Supplementary Table 3. Preoperative characteristics and risk factors for the subgroup aged under 70 years. Supplementary Table 4. Preoperative characteristics and risk factors for the subgroup aged from 70 to 74 years. Supplementary Table 5. Preoperative characteristics and risk factors for the subgroup aged from 75 to 79 years. Supplementary Table 6. Preoperative characteristics and risk factors for the subgroup aged from 80 to 84 years. Supplementary Table 7. Preoperative characteristics and risk factors for the subgroup aged from 85 to 89 years. Supplementary Table 8. Preoperative characteristics and risk factors for the subgroup aged 90 years or more. Supplementary Table 9. Outpatient costs after discharge for TAVI and SAVR. Supplementary Table 10. Inpatient costs after discharge for TAVI and SAVR. Supplementary Table 11. Pharmacy dispensing costs after discharge for TAVI and SAVR. Supplementary Fig. 1. The cumulative incidence of all-cause mortality between the transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR) groups in the entire population. Supplementary Fig. 2. The cumulative incidence of all-cause mortality between transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR) in the age subgroups of (A) <70, (B) 70-74, (C) 75-79, (D) 80-84, (E) 85–89, and (F) ≥90 years.

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