

Comparison of the Outcomes between Surgical Aortic Valve Replacement and Transcatheter Aortic Valve Replacement in Patients Aged above 80

Jeong-Woo Lee, M.D., Jihoon Kim, M.D., Ph.D., Sung-Ho Jung, M.D., Ph.D.,
Cheol Hyun Chung, M.D., Ph.D., Jae Won Lee, M.D., Ph.D.

Department of Thoracic and Cardiovascular Surgery, Asan Medical Center, University of Ulsan College of Medicine

Background: Transcatheter aortic valve replacement (TAVR) has been suggested as a less invasive treatment for high-risk patients with aortic valve disease. In this study, we compared the outcomes of conventional surgical aortic valve replacement (AVR) and TAVR in elderly patients aged over 80. **Methods:** A total of 108 patients aged 80 years or older who underwent isolated AVR (n=35) or TAVR (n=73) from 2010 through 2015 at Asan Medical Center were identified. Early and late clinical outcomes, including echocardiographic findings, were evaluated in both groups. The mean follow-up duration was 766.4±528.7 days in the AVR group and 755.2±546.6 days in the TAVR group, and the average timing of the last follow-up echocardiography was at 492.6±512.5 days in the AVR group and 515.7±526.8 days in the TAVR group. **Results:** The overall early mortality was 2.8% (0 of 35, 0% in the AVR group vs. 3 of 73, 4.1% in the TAVR group). Permanent pacemaker insertion was significantly more common in the TAVR group (p=0.010). Renal failure requiring dialysis and new-onset atrial fibrillation was more frequent and the length of hospital stay was longer in the AVR group; however, this difference did not reach statistical significance. In the TAVR group, 14 patients (19.2%) were rehospitalized due to cardiac problems, and 13 patients (17.8%) had developed significant paravalvular leakage by the time of the last follow-up echocardiography. **Conclusion:** TAVR could be a good alternative to conventional surgical AVR in elderly patients. However, TAVR has several shortcomings, such as frequent significant paravalvular leakage or readmission, which should be considered in decision-making.

Key words: 1. Aortic valve, surgery
2. Heart valve disease
3. Outcomes
4. Transcatheter aortic valve replacement

Introduction

Aortic valve disease is a significant cardiovascular problem that is likely to become increasingly significant as the population ages [1,2]. In particular, aortic stenosis is an insidious disease resulting in a

high mortality rate among untreated patients [3]. Surgical replacement of the aortic valve (AVR) reduces symptoms and improves survival in patients with aortic stenosis [4,5] and, in the absence of serious coexisting conditions, the procedure is associated with a low operative mortality rate [6]. However,

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Corresponding author: Sung-Ho Jung, Department of Thoracic and Cardiovascular Surgery, Asan Medical Center, University of Ulsan College of Medicine, 88 Olympic-ro 43-gil, Songpa-gu, Seoul 05505, Korea (Tel) 82-2-3010-3580 (Fax) 82-2-3010-6966 (E-mail) csjung@amc.seoul.kr

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elderly patients with coexisting medical problems are likely to be at high risk when undergoing surgery. Recently, transcatheter aortic valve replacement (TAVR) has entered the spotlight and is now regarded as a new therapy for patients who are not candidates for surgery or who are at a high risk of complications due to surgery [7].

Several studies comparing AVR and TAVR in Korea have been conducted [8]. The present study describes the clinical outcomes and echocardiographic findings after AVR or TAVR in elderly patients aged above 80.

Methods

1) Patient population

According to Asan Medical Center database, 1,718 patients underwent AVR or TAVR between January 2010 and December 2015. Among this population, we identified 108 patients aged over 80. Of these, 35 patients underwent isolated AVR and 73 underwent TAVR. The exclusion criteria were the presence of endocarditis pathology, having undergone a previous aortic valve operation, and simultaneous operations on the aorta, coronary arteries, or other heart valves. The decision for selecting the treatment modality (AVR or TAVR) was made by a team consisting of cardiovascular surgeons and interventional cardiologists. The team considered each patient's medical history, comorbidities, and anatomical structures. In the absence of a perfect quantitative score, the risk assessment relied on the clinical judgement of the team.

2) Procedures

(1) Surgical replacement of the aortic valve: Six surgeons performed the operations. The approaches used were median sternotomy (n=29), transverse sternotomy (n=3), upper sternotomy (n=2), and right anterior thoracotomy (n=1). After opening the pericardium, cardiopulmonary bypass (CPB) was established by cannulation with arterial and venous canulae. After CPB was instated, the aorta was cross-clamped and cardioplegic solution was infused. Then, an aortotomy was made and the diseased aortic valve leaflets were excised. Thereafter, a prosthetic aortic valve was suture-tied and the aortotomy was repaired. Aortic cross-clamping was then released

and the patient was weaned from CPB. Chest tubes were inserted and the wound was closed layer by layer. Finally, the patient was transferred to the intensive care unit (ICU) in an intubated state.

(2) Transcatheter aortic valve replacement: The Edwards SAPIEN prosthesis (Edwards Lifesciences, Irvine, CA, USA; n=41) and the CoreValve prosthesis (Medtronic, Minneapolis, MN, USA; n=32) were used in TAVR. The Edwards SAPIEN device consists of bovine pericardial tissue mounted in a balloon-expandable, stainless-steel stent or, more recently, a cobalt-chromium, open-cell stent (SAPIEN XT). The CoreValve prosthesis consists of porcine pericardial tissue, mounted in a self-expanding nitinol stent.

The procedure was performed in a hybrid operating room with on-site cardiac surgery on standby to prepare for emergent situations, such as aortic rupture or migration of the prosthetic valve. The procedure was performed under general anesthesia. Transesophageal echocardiography was used to ensure the size of the aortic annulus and to evaluate the valve position and function. After positioning the valve at the aortic annulus, balloon dilation was performed with rapid ventricular pacing. The patient was then transferred to the ICU.

3) Postoperative management

Patients were extubated as soon as possible after their vital signs stabilized. Then, they were transferred to the general ward in a stable condition. Postoperative echocardiography was usually performed on the third or fourth postoperative day (POD). If there were no complications, the patient was discharged.

Depending on the surgeon's preference, warfarin or aspirin was prescribed. When warfarin was used, the target prothrombin time/international normalized ratio was 2.0 for 3 months. After the discharge, whenever possible, follow-up echocardiographic evaluations were carried out 1, 3, 6, and 12 months after surgery.

4) Statistical analysis

Categorical variables, expressed in percentages or frequencies, were compared using the chi-square test or the Fisher exact test. Continuous variables, expressed as mean±standard deviation, were compared using the Student t-test. Kaplan-Meier curves were

Table 1. Baseline characteristics and hemodynamic data

Characteristic	Aortic valve replacement (n=35)	Transcatheter aortic valve replacement (n=73)	p-value
Age (yr)	82.3±3.5	83.4±2.6	0.073
Male sex	16 (45.7)	38 (52.1)	0.537
Diabetes mellitus	6 (17.1)	26 (35.6)	0.049
Hypertension	24 (68.6)	55 (75.3)	0.457
Cerebrovascular disease	4 (11.4)	6 (8.2)	0.590
Chronic obstructive pulmonary disease	6 (17.1)	15 (20.5)	0.676
Creatinine (mg/dL)	1.0±0.4	1.0±0.4	0.984
Atrial fibrillation	2 (5.7)	10 (13.7)	0.217
Body mass index (kg/m ²)	23.2±3.7	23.6±3.1	0.520
European System for Cardiac Operative Risk Evaluation II	3.3±3.4	4.7±4.3	0.108
New York Heart Association functional classification III or IV	10 (28.6)	21 (28.8)	0.983
Previous coronary artery disease	6 (17.1)	32 (43.8)	0.007
Previous percutaneous coronary intervention	1 (2.9)	22 (30.1)	0.001
Previous coronary artery bypass graft surgery	0	2 (2.7)	0.323
Previous cardiac surgery	0	3 (4.1)	0.224
Aortic valve pathology			
Stenosis	25 (71.4)	65 (89.0)	0.022
Regurgitation	3 (8.6)	0	0.011
Combined	7 (20.0)	8 (11.0)	0.204
Echocardiographic findings			
Aortic valve area (cm ²)	0.6±0.2	0.6±0.2	0.947
Mean gradient (mm Hg)	64.4±24.7	61.5±21.5	0.550
LV ejection fraction (%)	59.6±10.4	59.5±9.8	0.986
LV mass index (g/m ²)	150.6±40.5	136.6±34.1	0.078
Moderate or severe mitral regurgitation	4 (11.4)	8 (11.0)	0.942
Follow-up duration (day)	766.4±528.7	755.2±546.6	0.920

Values are presented as mean±standard deviation or number (%). LV, left ventricle.

formulated to illustrate patients' freedom from readmission or infective endocarditis over time. The log-rank test was used to compare the differences between the groups. All p-values < 0.05 were considered to indicate statistical significance. All analyses were performed using IBM SPSS ver. 21.0 (IBM Corp., Armonk, NY, USA).

Results

1) Baseline characteristics

The baseline demographics and clinical characteristics of all patients in both groups are summarized in Table 1. The TAVR group had significantly more patients with a history of diabetes mellitus (p=0.049) or coronary artery disease (p=0.007), and significantly more patients who had undergone percutaneous coronary interventions (p=0.001). Although the differ-

ences did not reach statistical significance, age and European System for Cardiac Operative Risk Evaluation (EuroSCORE) results were higher in the TAVR group. The mean follow-up duration was 748.7±531.8 days in the AVR group and 755.2±546.6 days in the TAVR group, and the mean timing of the last echocardiography follow-up was 481.7±509.4 days in the AVR group and 515.7±526.8 days in the TAVR group.

2) Intraoperative data

In the patients who underwent AVR, the mean CPB time was 115.8±33.7 minutes, while the mean aortic cross-clamp time was 73.6±21.4 minutes. Median sternotomies were performed in 29 patients (82.9%). In this study, the TAVR procedure was performed only by the transfemoral approach. In the AVR group, the valve sizes were 19 mm (n=6, 17.1%), 21 mm (n=20, 57.1%), 23 mm (n=8, 22.9%), and 25 mm (n=1,

2.9%). In the TAVR group, the valve sizes were 23 mm (n=17, 23.3%), 26 mm (n=27, 37.0%), 29 mm (n=24, 32.9%), and 31 mm (n=5, 6.8%) (Table 2).

Table 2. Intraoperative data

Variable	Aortic valve replacement (n=35)	Transcatheter aortic valve replacement (n=73)
Cardiopulmonary bypass time (min)	115.8±33.7	-
Aortic cross-clamp time (min)	73.6±21.4	-
Approach		
Upper sternotomy	2 (5.7)	-
Transverse sternotomy	3 (8.6)	-
Thoracotomy	1 (2.9)	-
Median sternotomy	29 (82.9)	-
Transfemoral		73 (100.0)
Valve size (mm)		
19	6 (17.1)	-
21	20 (57.1)	-
23	8 (22.9)	17 (23.3)
25	1 (2.9)	-
26	-	27 (37.0)
29	-	24 (32.9)
31	-	5 (6.8)

Values are presented as mean±standard deviation or number (%).

3) Early and late clinical outcomes

The early and late clinical outcomes of the 2 groups are shown in Table 3. Three patients (0 of 35, 0% in the AVR group versus 3 of 73, 4.1% in the TAVR group; overall 2.8%) died within 30 days after surgery. One patient had bowel ischemia followed by septic shock after the procedure. This patient died without further treatment because of advanced age and the high risk that would have been associated with further treatments. The other 2 patients contracted pneumonia after the procedure and died of sepsis owing to aggravated pneumonia.

Only permanent pacemaker (PPM) insertion was significantly more common in the TAVR group among the early clinical outcomes (1 of 36, 2.8% in the AVR group versus 16 of 73, 21.9% in the TAVR group; p=0.010). The Edwards SAPIEN device was used in 41 patients (56.2%), while the CoreValve prosthesis was used in 32 (73.8%). Among patients in whom the Edwards SAPIEN device was used, 3 (7.32%) required PPM insertion, while 13 (40.6%) of the patients who received a CoreValve required PPM insertion (p=0.01).

Although these findings did not reach statistical significance, several complications were more common in the AVR group. Specifically, renal failure re-

Table 3. Early and late clinical outcomes

Variable	Aortic valve replacement (n=35)	Transcatheter aortic valve replacement (n=73)	p-value
30-Day mortality	0	3 (4.1)	0.224
Low cardiac output syndrome	1 (2.9)	6 (8.2)	0.289
Neurologic event ^{a)}	2 (5.7)	3 (4.1)	0.710
Major vascular complication	0	2 (2.7)	0.323
Life-threatening or disabling bleeding	2 (5.7)	3 (4.1)	0.710
Renal failure ^{b)}	6 (17.1)	5 (6.8)	0.098
New atrial fibrillation	10 (28.6)	11 (15.1)	0.097
New permanent pacemaker	1 (2.9)	16 (21.9)	0.011
Extracorporeal membrane oxygenation insertion	0	0	
Intensive care unit stay (d)	8.37±22.1	4.1±4.4	0.264
Hospital stay (d)	26.1±44.0	11.0±7.9	0.052
Readmission due to cardiac problem	2 (5.7)	14 (19.2)	0.065
Readmission due to heart failure	2 (5.7)	10 (13.7)	0.217
Reoperation	0	1 (1.4)	0.487
Infective endocarditis	0	2 (2.7)	0.323
Embolic stroke	0	1 (1.4)	0.487
Hemorrhagic stroke	0	1 (1.4)	0.487

Values are presented as number (%) or mean±standard deviation.

^{a)}In the event of hospitalization. ^{b)}Renal failure was defined by the need for dialysis for any length of time.

Variable	AVR (n=35)	TAVR (n=73)
Paravalvular leakage (immediate) ^{a)}		
No leakage	35 (100.0)	23 (31.5)
Trivial	0	14 (19.2)
Mild	0	31 (42.5)
Moderate	0	5 (6.8)
Severe	0	0
Paravalvular leakage (last follow-up) ^{b)}		
No leakage	35 (100.0)	24 (32.9)
Trivial	0	12 (16.4)
Mild	0	24 (32.9)
Moderate	0	10 (13.7)
Severe	0	3 (4.1)

Values are presented as number (%).
 AVR, aortic valve replacement; TAVR, transcatheter aortic valve replacement.

^{a)}Echocardiography was performed on postoperative day 3 or 5.
^{b)}The mean follow-up duration was 492.6±512.5 days in the AVR group and 515.7±526.8 days in the TAVR group (p=0.829).

quiring dialysis (6 of 35, 17.1% in the AVR group versus 5 of 73, 6.8% in the TAVR group; p=0.098) and new-onset atrial fibrillation (10 of 35, 28.6% in the AVR group versus 11 of 73, 15.1% in the TAVR group; p=0.097) were more frequent in the AVR group. Additionally, the hospital stay was longer in the AVR group (26.1±44.0 days in the AVR group versus 11.0±7.9 days in the TAVR group; p=0.052).

After discharge, readmissions due to cardiac problems were more common in the TAVR group, although this difference was not statistically significant (2 of 35, 5.7% in the AVR group versus 14 of 73, 19.2% in the TAVR group; p=0.065). The causes of readmission were heart failure (n=10, 71.4%), infective endocarditis (n=2, 14.3%), and arrhythmia (n=2, 14.3%). Two patients who had infective endocarditis received antibiotic treatment for 8 weeks and 12 weeks, respectively, and then improved.

A total of 12 patients (4 of 36, 11.1% in the AVR group versus 8 of 73, 11.0% in the TAVR group) also experienced moderate or severe mitral valve regurgitation (MR) before surgery. Since all patients had functional MR, the extent of MR was expected to decrease after aortic stenosis was resolved. After the operation, the extent of MR decreased in all patients with MR.

After TAVR, 1 patient needed a reoperation. This patient was an 88-year-old male who had severe de-

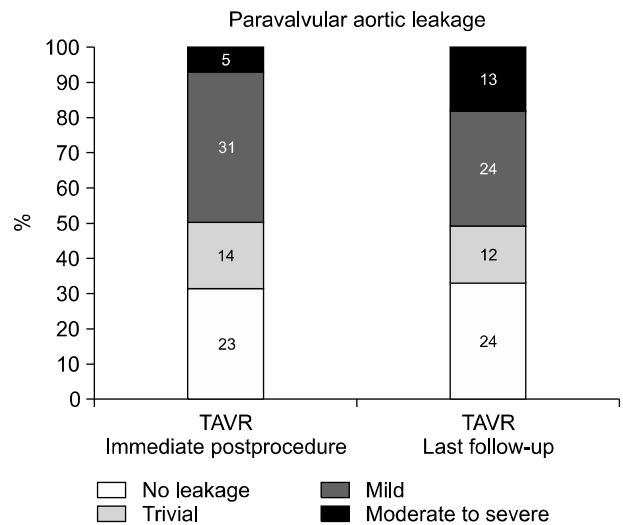


Fig. 1. Changes in the degree of paravalvular aortic leakage (p=0.153). TAVR, transcatheter aortic valve replacement.

generative aortic stenosis with mild to moderate paravalvular aortic regurgitation (PAR), and severe left ventricle (LV) dysfunction (33%) with moderate to severe functional MR and a high LV filling pressure. He underwent implantation of a 29-mm CoreValve. On the post-procedural echocardiography performed 2 days after TAVR, moderate to severe paravalvular leakage and mild valvular AR, persistent severe LV dysfunction, and moderate functional MR were observed. The patient complained of persistent dyspnea during the entire ICU stay. On the seventh day after TAVR, follow-up echocardiography was performed and a malposition of the CoreValve with a hemodynamically significant AR was identified. After discussion among the cardiovascular surgery team, urgent AVR and mitral valvuloplasty were performed. In the operative findings, the CoreValve had migrated, so it was extracted and easily separated from the adjacent aortic wall. The patient was extubated on POD 1, transferred to the general ward on POD 10, and discharged without further complications on POD 20. On follow-up echocardiography 45 months after surgery, mild paravalvular leakage was reported; at present, the patient is doing well and has no symptoms.

4) Echocardiographic findings

Significant paravalvular leakage (p<0.001) appeared both on immediately postoperative echocardiog-

Table 5. Echocardiographic changes after AVR and TAVR

Variable	AVR			TAVR		
	Pre	Post	p-value	Pre	Post	p-value
Mean pressure gradient (mm Hg)	65.1±25.3	18.1±8.7	<0.001	61.5±21.5	12.7±6.8	<0.001
LV ejection fraction (%)	59.6±10.3	62.7±7.1	0.054	59.5±9.8	59.4±9.1	0.905
LV mass index (g/m ²)	147.6±40.6	100.4±30.6	<0.001	136.6±34.1	113.0±30.5	<0.001

Values are presented as mean±standard deviation.

AVR, aortic valve replacement; TAVR, transcatheter aortic valve replacement; LV, left ventricle.

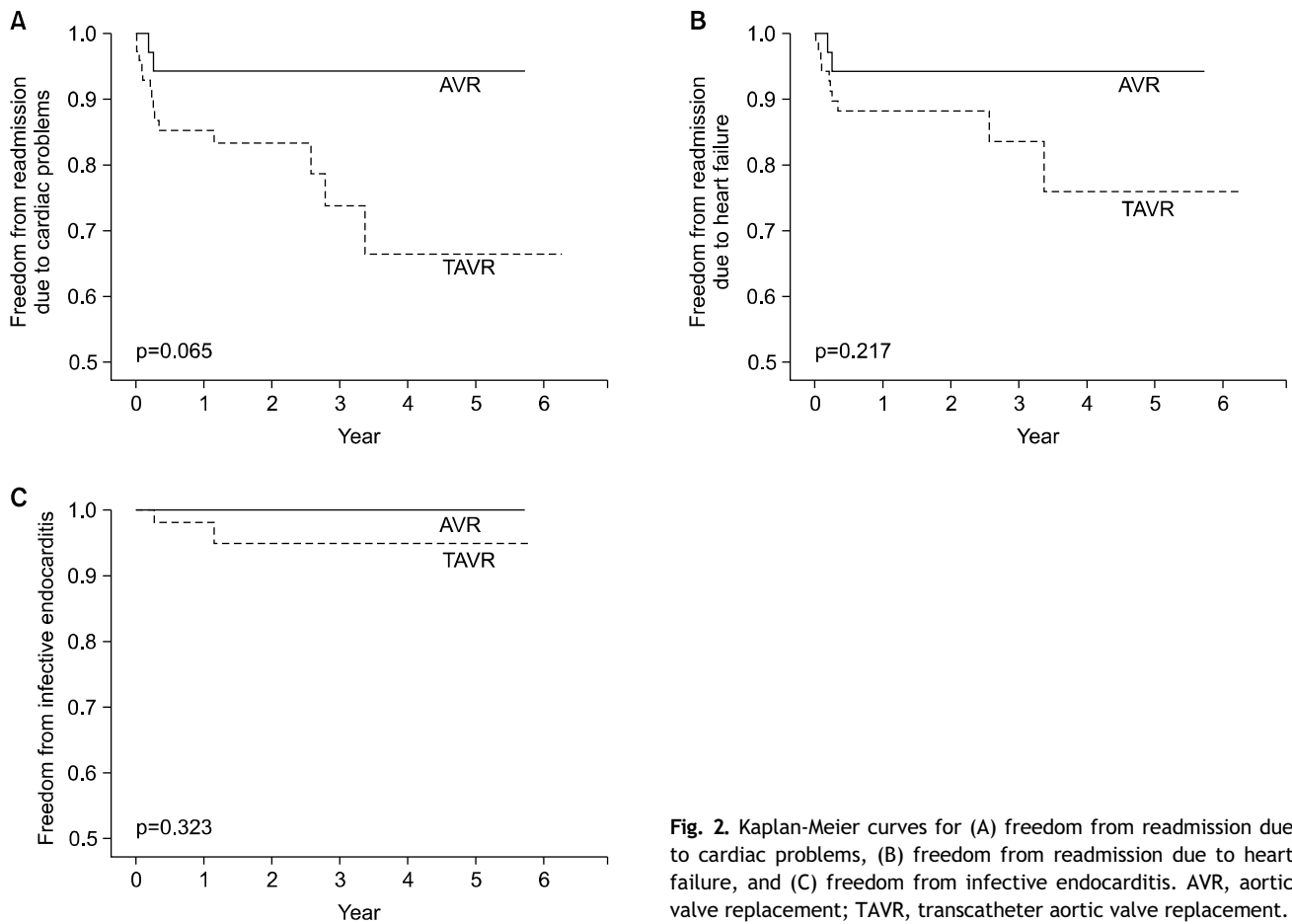


Fig. 2. Kaplan-Meier curves for (A) freedom from readmission due to cardiac problems, (B) freedom from readmission due to heart failure, and (C) freedom from infective endocarditis. AVR, aortic valve replacement; TAVR, transcatheter aortic valve replacement.

raphy and the last follow-up echocardiography in the TAVR group (Table 4). The degree of paravalvular leakage in the follow-up echocardiography was aggravated in comparison with the immediate post-operative echocardiography; however, the difference was not statistically significant (Fig. 1). The mean pressure gradient and LV mass index decreased significantly in both groups after surgery, but the change in the left ventricular ejection fraction was not significant (Table 5).

Freedom from other late complications after the aortic valve procedure is shown in Fig. 2. Although statistically insignificant, TAVR was associated with more readmissions due to cardiac problems, and the other late complications were more frequent.

Discussion

Aortic valve disease, especially aortic stenosis, is associated with high mortality after the appearance

of cardiac symptoms [3]. Previously, AVR was considered as the only definitive therapy [4]. However, more recent observational studies have identified various subgroups of patients who are at an increased risk of operative complications or death [6].

These surgical risks can be assessed using various methods. Operative mortality can be estimated using a scoring system that incorporates a combination of risk factors, such as the Society of Thoracic Surgeons' risk estimate or the EuroSCORE. Frailty, major organ system compromise, and procedure-specific impediments are also factors considered in risk assessment [3]. In our institution, the EuroSCORE II was used for risk assessment and, based on these factors, decisions for selecting the treatment modality (AVR versus TAVR) were made in cooperation with the heart team.

In the AVR group of the present study, the early surgical mortality was 0%. Regarding early clinical outcomes, neurologic events occurred in 5.7% of patients, renal failure in 17.1%, atrial fibrillation in 28.6%, and PPM insertion in 2.9%. The ICU stay was 8.37 ± 22.1 days and the hospital stay was 26.1 ± 44.0 days. Yamane et al. [9] reported the results of aortic valve surgery between 1997 and 2010 in 308 patients aged 70 years or older. In that study, the operative mortality rate was 4.4% in patients aged 80–92 years who underwent isolated AVR ($n=3$ of 68). Furthermore, Vasques et al. [10] reviewed the literature and performed a meta-analysis of the data on octogenarians and nonagenarians who underwent isolated AVR. The pooled proportion of immediate postoperative mortality was 6.7%, and the corresponding proportion for postoperative stroke was 2.4%, 2.6% for postoperative dialysis, 4.7% for implantation of a pacemaker, and the mean length of stay in the ICU was 3.5 days, while the mean length of in-hospital stays was 13.3 days. Comparing these results to those found for AVR in the present study, it appears that our operative outcomes were acceptable.

In the TAVR group of the present study, the early mortality rate was 4.1% and the PPM insertion rate was 21.9%. After discharge, the repeat hospitalization rate was 19.2% and significant paravalvular leakage appeared in 17.8% of patients. Although intended not only for patients over 80 years of age, the Placement of Aortic Transcatheter Valves (PARTNER) trial, a

randomized trial to evaluate TAVR in humans, was recently performed in high-risk and intermediate-risk patients [7,11,12]. This trial used only the SAPIEN prosthesis, and SAPIEN XT in PARTNER 2. Early mortality was 3.4% in PARTNER A, 5.0% in PARTNER B, and 6.1% in PARTNER 2. The PPM implantation rates were 3.8%, 3.4%, and 8.5%, respectively. The repeat hospitalization rate was 18.2%, 22.3%, and 19.6% in PARTNER A, PARTNER B, and PARTNER 2, respectively, and the significant paravalvular leakage rate was 6.8% in PARTNER A, and 10.5% in PARTNER B at 1 year after TAVR.

Gilard et al. [13] reported the results of a prospective multicenter study of the French national transcatheter aortic-valve implantation registry, FRANCE 2. In this registry, both the Edwards SAPIEN/SAPIEN XT and CoreValve valves were used. In that study, early mortality was 9.7%, grade 2 paravalvular leakage was found in 301 of 1,915 patients (15.7%), and grade 3 paravalvular leakage was found in 15 of 1,915 patients (0.8%) on the 30th day. The frequency of PPM implantation was different between the 2 groups: 11.5% in the SAPIEN group and 24.2% in the CoreValve group. Compared to the results of other studies, our study showed a low early mortality rate, which might be due to the presence of few relatively high-risk patients in our sample. In our study, the PPM insertion rate was relatively high, which could have been the result of using CoreValve.

Yu et al. [8] reported a comparison of TAVR and AVR in 44 high-risk severe aortic stenosis patients. The TAVR group had more frequent instances of greater than moderate paravalvular leakage, which can influence long-term outcomes. In the present study, the incidence of repeat hospitalization and significant paravalvular leakage were also higher after TAVR. In the 2-year follow-up of the patients in the PARTNER trial, paravalvular leakage was more common after TAVR and was associated with an increased late mortality rate [14].

Based on the results of the present study, we were not able to conclude whether TAVR is superior to AVR (or vice versa) in patients aged over 80. To establish the best treatment plan between TAVR and AVR, a decision should be made based on discussions within a multidisciplinary heart team.

Unlike AVR, which has decades of history, TAVR is a new technology and it is still being developed and

improved. Therefore, interpreting the results of the early era of TAVR requires a cautious approach.

This is a retrospective study with a small sample size, especially in the AVR group, as this study represents a single-center experience. Due to the characteristics of elderly patients, regular follow-up could not be thoroughly performed; this is a limitation of the present study.

TAVR could a good alternative to conventional surgical AVR in elderly patients. However, TAVR has several shortcomings, such as frequent significant paravalvular leakage and readmission, and these factors should be considered in decision-making.

Conflict of interest

No potential conflicts of interest relevant to this article are reported.

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