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# Comparison of Early Clinical Results of Transcatheter versus Surgical Aortic Valve Replacement in Symptomatic High Risk Severe Aortic Stenosis Patients

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***Background:*** Transcatheter aortic valve implantation (TAVI) has been an alternative to conventional aortic valve replacement (AVR) in old and high risk patients. The goal of this study is to compare the early outcomes of conventional AVR vs. TAVI in high risk severe AS patients. ***Methods:*** From January 2008 to July 2012, 44 high risk severe aortic stenosis patients underwent conventional AVR, and 15 patients underwent TAVI. We compared echocardiographic data, periprocedural complication, and survival. The mean follow-up duration was 14.5±10 months (AVR), and 6.8±3.5 months (TAVI), respectively. ***Results:*** AVR group was younger (78.2±2.4 years vs. 82.2±3.0 years, $p<0.001$) and had lower operative risk (Euroscore: 9.4±2.7 vs. 11.0±2.0, p=0.044) than TAVI group. There was no significant difference in early mortality (11.4% vs. 13.3%, p=0.839), and 1 year survival (87.4%±5.3% vs. 83.1%±1.1%, p=0.805). There was no significant difference in postoperative functional class. There was no significant difference in periprocedural complication except vascular complication (0% [AVR] vs. 13.3% [TAVI], p=0.014). TAVI group had more moderate and severe paravalvular leakage. ***Conclusion:*** In this study, both groups had similar periprocedural morbidity, and mortality. However, TAVI group had more greater than moderate paravalvular leakage, which can influence long-term outcome. Since more patients are treated with TAVI even in moderate risk, careful selection of the patients and appropriate guideline need to be established.

Key words: 1. Aortic valve stenosis
2. Aortic valve, surgery
3. Transcatheter aortic valve implantation

## INTRODUCTION

Symptomatic severe aortic stenosis (AS) is a progressive disease with a poor prognosis if surgical intervention is not performed [1]. Conventional surgical aortic valve replacement (AVR) through median sternotomy under cardiopulmonary bypass is the treatment of choice [2]. However, the number of high-risk elderly patients has been increasing, with the aging of the population and increase in those who do not want to have their chest opened [3]. Recently, transcatheter aortic valve implantation (TAVI) was introduced and became an attractive alternative therapy in these patients. In TAVI, a bioprosthetic valve is introduced percutaneously through a catheter, usually via the femoral artery, or less often, via the left ventricular apex (transapical approach) through thoracotomy. Furthermore, significant improvement of survival and quality

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of life after TAVI has been reported [4], and now there is a trend toward performing TAVI in healthier patients [5].

Although surgical AVR with excellent outcomes has been reported in aged and high-risk patients [6], the high risk of developing a complete AV block requiring permanent pacemaker implantation, paravalvular leakage that can negatively affect survival, and high costs are still problems associated with TAVI [7]. Therefore, we aimed to compare the early outcomes of conventional AVR and TAVI in high-risk severe AS patients.

## METHODS

Between January 2008 and July 2012, 412 cases of surgical AVR with or without a concomitant procedure were performed at Yonsei Cardiovascular Center, Yonsei University College of Medicine. Among these patients, 44 patients aged ≥75 years with one or more comorbidities were included (AVR group). Fifteen patients who underwent TAVI during the same time period were also included for comparison (TAVI group).

The patients' clinical characteristics, echocardiographic indicators, and surgical data were obtained from a review of the medical records, and follow-up was performed by reviewing hospital charts or conducting telephone interviews. Transthoracic echocardiography and coronary angiography were routinely performed preoperatively in the AVR group, and transthoracic echocardiography, transesophageal echocardiography, coronary angiography, and computed tomographic (CT) angiography were routinely performed to assess valvular morphology and vascular access in the TAVI group. TAVI was first used in 2010, and since then, the decision between TAVI and surgical AVR was made in each patient by the medical and surgical team according to the severity of the clinical symptoms, combined comorbid diseases, physical performance status, echocardiographic parameters, and vascular access.

Surgical AVR was performed through median sternotomy, under cardiopulmonary bypass and mild hypothermia, and concomitant valvular, coronary, or aortic surgery was performed in 25 patients (Table 1). TAVI procedures were performed with AccuTrak (The CoreValve system; Medtronic, Minneapolis, MN, USA) under general anesthesia in all of the patients. The prosthetic valve was inserted in retrograde fashion through a femoral artery (n=12), a subclavian artery (n=1), or an ascending aorta (n=2) (Table 1). Immediately after deployment of the prosthetic valve, transesophageal echocardiography was performed to confirm the location and motion of the prosthetic valve, and any significant paravalvular leakage.

**Table 1.** Surgical procedures

| Variable | AVR (n=44) | TAVI (n=15) | p-value |
|---|---|---|---|
| Isolated AVR | 19 | | |
| With concomitant procedure | 25 | | |
| With CABG | 9 | | |
| With aorta surgery | 6 | | |
| With MV surgery | 4 | | |
| With TV surgery | 1 | | |
| With CABG and aorta surgery | 1 | | |
| With CABG and MV surgery | 1 | | |
| With MV surgery and aorta surgery | 2 | | |
| With MV and TV surgery | 1 | | |
| Trans-femoral | | 12 | |
| Trans-aortic | | 2 | |
| Trans-subclavian | | 1 | |
| Operation time (min) | 253±71 | 108±67 | <0.001 |
| Cardiopulmonary bypass time (min) | 126±34 | | |
| Aortic cross-clamp time (min) | 98±29 | | |

AVR, aortic valve replacement; TAVI, transcatheter aortic valve implantation; CABG, coronary artery bypass grafting; MV, mitral valve; TV, tricuspid valve.

We compared in-hospital and early clinical outcomes of surgical AVR and TAVI using medical and echocardiographic data. All-cause mortality and incidence of complications including pneumonia, neurologic deficit due to cerebrovascular accident, gastrointestinal bleeding requiring endoscopic intervention, mediastinal bleeding requiring re-operation, renal failure requiring dialysis, new onset atrial fibrillation, vascular complication, complete atrioventricular block requiring permanent pacemaker implantation, readmission due to heart failure aggravation or another cause, and pericardial effusion were analyzed.

All data are expressed as mean±standard deviation and frequency and percentage. Continuous variables were compared

**Table 2.** Patients' characteristics

| Characteristic | AVR (n=44) | TAVI (n=15) | p-value |
|---|---|---|---|
| Age (yr) | 78.2±2.417 | 82.2±3.075 | <0.001 |
| Female (%) | 23 (52.3) | 9 (60) | 0.604 |
| Body mass index (kg/m$^2$) | 23.85±3.35 | 20.98±3.35 | 0.006 |
| Diabetes mellitus | 11 (25) | 1 (6.7) | 0.128 |
| COPD or $FEV_1$ < 80 | 15 (34) | 5 (33.3) | 0.957 |
| Renal failure (eGFR < 60 mL/min) | 21 (47.7) | 8 (53.3) | 0.708 |
| Pulmonary hypertension (RVP > 55 mmHg) | 7 (15.9) | 1 (6.7) | 0.367 |
| Atrial fibrillation | 12 (27.3) | 3 (20) | 0.576 |
| Pacemaker | 3 (6.8) | 0 (0) | 0.299 |
| Cerebrovascular accident | 6 (13.6) | 1 (6.7) | 0.471 |
| Peripheral arterial occlusive disease | 4 (9.1) | 6 (40) | 0.006 |
| Coronary artery occlusive disease | 20 (45) | 11 (73) | 0.062 |
| Previous open heart surgery | 2 (4.5) | 2 (13.3) | 0.265 |
| Mitral regurgitation | 9 (20.5) | 0 (0) | 0.057 |
| Left ventricular ejection fraction (%) | 58.3±14.3 | 63.4±11.0 | 0.213 |
| Euroscore | 9.4±2.7 | 11.0±2.0 | 0.044 |
| NYHA Fc | | | |
| II | 10 (22.7) | 2 (13.3) | 0.435 |
| III or IV | 34 (77.3) | 13 (86.7) | 0.435 |
| Follow-upduration (mo) | 14.5±10 | 6.8±3.5 | <0.001 |

Values are presented as mean±standard deviation or number (%).
AVR, aortic valve replacement; TAVI, transcatheter aortic valve implantation; COPD, chronic obstructive pulmonary disease; $FEV_1$, forced expiratory volume in 1 second; eGFR, estimated glomerular filtration rate; RVP, right ventricular pressure; NYHA Fc, New York Heart Association functional classification.

using the t-test, and categorical variables were compared using the chi-square test or Fisher's exact test. Survival was evaluated with the Kaplan-Meier method, and the log-rank test was used to compare the groups. All statistical analyses were performed using SPSS ver. 17.0 (SPSS Inc., Chicago, IL, USA).

## RESULTS

### 1) Patient characteristics

The patient characteristics of the AVR group and TAVI group are summarized in Table 2. The AVR group was younger (mean age: 78.2±2.4 years [range, 76 to 87 years] vs. 82.2±3.0 years [range, 75 to 85 years], p<0.001), and had lower operative risks (Euroscore: 9.4±2.7 vs. 11.0±2.0, p=0.044). The TAVI group had a lower body mass index (23.85±3.35 kg/m$^2$ vs. 20.98±3.35 kg/m$^2$, p=0.006) and had more peripheral vascular disease (4 [9.1%] vs. 6 [40%], p=0.006).

### 2) Operative data

Nineteen patients in the AVR group underwent isolated AVR, and 25 patients underwent AVR with a concomitant valvular, coronary, or aortic procedure. Coronary artery bypass grafting (CABG) was most frequently performed concomitantly with AVR. The operation time was significantly longer in the AVR group (Table 1).

### 3) Clinical outcomes

The clinical outcomes are summarized in Table 3. The AVR group had significantly longer intensive care unit (ICU: 6.09±7.97 days vs. 3.20±1.74 days, p=0.030) and hospital stays than the TAVI group (15.36±13.59 days vs. 7.13±3.18 days, p≤0.001). There was no significant difference in hospital mortality or one-year survival between the two groups (87.4%±5.3% [AVR group] vs. 83.1%±1.1% [TAVI group], p=0.805) (Fig. 1). The causes of death were postoperative bleeding (n=1), gastrointestinal bleeding (n=1), sepsis (n=2),

**Table 3.** Clinical outcome

| Variable | AVR (n=44) | TAVI (n=15) | p-value |
|---|---|---|---|
| Intensive care unit stay (day) | 6.09±7.97 | 3.20±1.74 | 0.030 |
| Hospital stay (day) | 15.36±13.59 | 7.13±3.18 | <0.001 |
| Complications | | | |
| Pneumonia | 4 (9.1) | 2 (13.3) | 0.639 |
| Stroke | 3 (6.8) | 0 (0) | 0.299 |
| Gastrointestinal bleeding | 6 (13.6) | 2 (13.3) | 0.976 |
| Renal failure requiring dialysis | 3 (6.8) | 1 (6.7) | 0.984 |
| New onset atrial fibrillation | 6 (13.6) | 0 (0) | 0.131 |
| Mediastinal bleeding | 2 (4.5) | 1 (6.7) | 0.747 |
| Vascular complication | 0 (0) | 2 (13.3) | 0.014 |
| Pacemaker insertion | 2 (4.5) | 1 (6.7) | 0.747 |
| Readmission for heart failure aggravation | 4 (9.1) | 1 (6.7) | 0.771 |
| Readmission for other causes | 3 (6.8) | 1 (6.7) | 0.984 |
| Pericardial effusion | 0 (0) | 1 (6.7) | 0.084 |
| Postoperative NYHA Fc | | | |
| I | 30 (68.2) | 6 (40.0) | 0.053 |
| II | 8 (18.2) | 6 (40.0) | 0.086 |
| III, IV | 0 (0) | 1 (6.7) | 0.084 |
| Mortality | 5 (11.4) | 2 (13.3) | 0.839 |
| 30-day | 2 (4.5) | 0 (0) | 0.401 |
| During follow-up | 3 (6.8) | 2 (13.3) | 0.434 |

Values are presented as mean±standard deviation or number (%).
AVR, aortic valve replacement; TAVI, transcatheter aortic valve implantation; NYHA Fc, New York Heart Association functional classification.

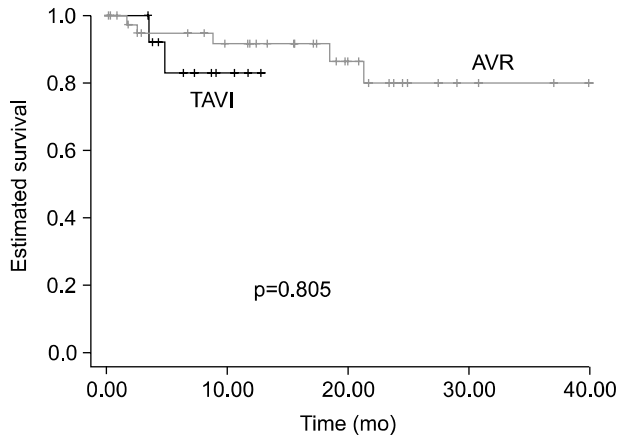


**Fig. 1.** Comparison of Kaplan-Meier estimated survival. AVR, aortic valve replacement; TAVI, transcatheter aortic valve implantation.

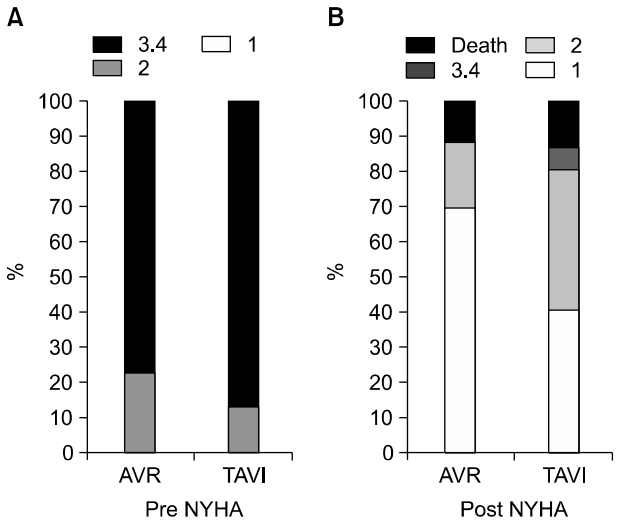


**Fig. 2.** Comparison of (A) preoperative and (B) postoperative New York Heart Association (NYHA) functional classification.

and pneumonia (n=1) in the AVR group, and pneumonia (n=1) and sepsis (n=1) in the TAVI group. The AVR group had greater improvement in the New York Heart Association functional class (NYHA Fc). However, this difference did not reach statistical significance (NYHA Fc I: 76.9% vs. 56.3%, p=0.037) (Fig. 2). There was no significant difference in periprocedural complications between the two groups except vascular complications (0% [AVR group] vs. 13.3% [TAVI

**Table 4.** Echocardiographic data

| Variable | Preoperative | 1st follow-up echocardiography | Last follow-up echocardiography |
|---|---|---|---|
| Time after operation | | | |
| AVR (n=39) | | 6.8±2.9 days | 9.6±7.9 months |
| TAVI (n=13) | | 0.1±0.3 days | 4.4±2.7 months |
| Left ventricular ejection fraction (%) | | | |
| AVR (n=39) | 60.1±12.7 | 64.0±7.8 | 63.2±11.7 |
| TAVI (n=13) | 61.5±10.5 | 57.7±13.0 | 63.8±10.2 |
| p-valve | 0.721 | 0.113 | 0.875 |
| Paravalvular leak (≥moderate) | | | |
| AVR (n=39) | | 0 (0) | 0 (0) |
| TAVI (n=13) | | 3 (23.1) | 4 (30.8) |
| p-valve | | 0.002 | <0.001 |

Values are presented as mean±standard deviation or number (%). Mortality cases were excluded.
AVR, aortic valve replacement; TAVI, transcatheter aortic valve implantation.

group], p=0.014). The causes of readmission other than heart failure aggravation were general weakness (n=2) and aggravation of renal failure (n=1) in the AVR group, and pressure sore management (n=2) in the TAVI group.

Echocardiographic outcomes from the survivors are summarized in Table 4. The TAVI group had more moderate and severe paravalvular leakage at the first and last follow-up echocardiography. A complete AV block requiring pacemaker implantation developed in 3 patients (2 patients in the AVR group, and 1 patient in the TAVI group) without a significant difference between the two groups.

## DISCUSSION

The prognosis in patients with symptomatic severe AS is poor if treated medically [1,8,9]. After symptom onset, the 1-year mortality rate in patients with severe AS and without surgical AVR is around 30%, and surgical AVR is the treatment of choice for patients with symptomatic severe AS [1,9]. However, the risk of surgical mortality increases significantly with age and other comorbid conditions [10-12]. Therefore, the TAVI procedure is becoming an alternative therapeutic option in elderly patients with high risks, and with proven safety and efficacy, more patients aged over 80 years who would have been candidates for surgical AVR are now undergoing TAVI [3,13-15].

The Placement of Aortic Transcatheter Valves (PARTNER) trial is a randomized trial to evaluate TAVI in humans. In PARTNER trial B, 358 patients who were considered inoperable were randomly assigned to TAVI or standard therapy. TAVI significantly reduced mortality from all causes and cardiac symptoms. However, major stroke and vascular complications were more common in TAVI [4].

In PARTNER trial A, the results of isolated AVR and TAVI were compared in high-risk patients. Six hundred and ninety-nine patients were randomly assigned to AVR or TAVI. There was no significant difference in mortality (1-year mortality rate: 26.8% vs. 24.2%). Major bleeding and new-onset atrial fibrillation were more common in the AVR group. In addition, vascular complications and major stoke were more common in the TAVI group. There was no significant difference in NYHA Fc at 1 year. More than moderate AR due to paravalvular leakage was more common in the TAVI group [16].

In this study, the TAVI group had a similar 1-year survival to the AVR group despite the fact that TAVI was performed in older and higher risk patients. In addition, the TAVI group had a shorter operative time, and ICU and hospital stay durations. However, the AVR group had greater improvement in NYHA functional class. This may be related to 1) more favorable echocardiographic results (less paravalvular leakage) and 2) correction of other valvular pathology and coronary

artery occlusive disease by concomitant CABG and other valvular surgery.

Previous publications have reported that the 30-day mortality rate after TAVI ranges from 3.2% to 15.2% [4,13-16]. In this study, the early mortality in the TAVI group was 0.0%, and the rate of complete heart block was also lower than in previous reports. These low rates of mortality and complications may have been achieved due to meticulous preoperative evaluation and careful patient selection by a team approach (cardiologist, at least two surgeons, anesthesiologist, coordinator, and surgical nursing staff). Therefore, the TAVI procedure should be performed by skillful surgeons following meticulous patient selection and pre-procedural planning, along with post-procedural care in strict compliance with recommendations from TAVI experts and accumulated data.

Chiappini et al. [17] reported excellent early and late outcomes of AVR in octogenarians in 2004 (1-year survival: 86.5% and 5-year survival: 69.4%). Subramanian et al. [18] also reported excellent outcomes of AVR in TAVI candidates (1-year survival: 87.5% and 3-year survival: 72.7%). In this study, the mean age of the patients was 80 years, and the early and mid-term follow-up results were satisfactory. The causes for TAVI denial in these patients were 1) large annulus, 2) acceptable risk profile for AVR, 3) the need for an urgent operation, and 4) concomitant pathology that required a concomitant procedure.

The main limitation of this study was the small sample size and short follow-up duration. Because only one and a half years have passed since TAVI was first performed, a longer duration of follow-up with a larger population of randomized patients is required for more accurate comparison of the two treatment modalities.

In conclusion, TAVI is a good alternative treatment modality in inoperable or high-risk patients. However, the TAVI group had more frequent paravalvular leakage at a moderate level or higher, which can influence long-term outcomes. AVR can be performed in old and high risk patients with good results and an acceptable level of risk. Since more and more patients are treated with TAVI even at moderate risk, careful selection of the patients and an appropriate guideline need to be established.

## CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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