Transcatheter Aortic Valve Implantation: Early Experience in Korea

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Background and Objectives: Transcatheter aortic valve implantation (TAVI) was recently introduced in Korea. The present report describes the experience of early TAVI cases.

Subjects and Methods: Between March, 2010 and October, 2011, 48 patients with severe symptomatic aortic stenosis (AS) were screened at the Asan Medical Center to determine their suitability for surgical intervention. Of these, 23 were considered unsuitable and underwent TAVI. Procedural success rates, procedure-related complications, and clinical outcomes were evaluated in the TAVI patients.

Results: Transfemoral (n=20) or transapical (n=3) TAVI was performed. The mean age of patients was 75.9±5.4 years and 57% were females. The mean logistic European System for Cardiac Operative Risk Evaluation was 25.6±5.1%. Implantation was successful in 22 patients (19 transfemoral, three transapical). After successful implantation, the mean aortic valve area increased from 0.68±0.14 cm² to 1.45±0.33 cm². There were no procedure-related complications or mortality. The patients showed no paravalvular aortic regurgitation with ≥ moderate degree and remained stable without progression during follow-up. During follow-up (interquartile range, 1.1-12.9), all patients were alive without any occurrence of valve failure.

Conclusion: TAVI procedure is feasible in patients with inoperative symptomatic AS leading to hemodynamic and clinical improvement. With accumulation of experience, proper patient selection and development of device technologies, TAVI should decrease adverse events and expand the indications in the near future. (Korean Circ J 2012;42:684-691)

KEY WORDS: Aortic stenosis; Valve prosthesis.

Introduction

Aortic stenosis (AS) is the most common valvular heart disease in adults,¹⁾ and is associated with significant morbidity and mortality in advanced cases. The incidence of AS is on the rise as a result of

the aging population. Several studies have investigated the efficacy of surgical aortic valve replacement for AS, and there is now a general consensus in the field that this procedure prolongs survival.^{2,3)} However, one-third of patients with severe symptomatic AS in need of treatment are declined for surgery due to advanced age, multiple comorbidity, and a high risk of procedure-related mortality, factors which are associated with reduced life expectancy and poor quality of life.^{1,4)} The proportion of untreated patients is expected to further increase because of the aging population and improving treatment modalities in patients with chronic and advanced medical conditions.⁵⁾

With introduction of transcatheter aortic valve implantation (TAVI), those untreated patients are adapted to alternative treatment modalities. In 2002, Cribier et al.⁶⁾ performed the first TAVI, and many patients worldwide have undergone the procedure by means of two different device technologies. A recently published randomized trial for the inoperable symptomatic severe AS showed that TAVI significantly reduced the rates of death, repeat hospitalization, and car-

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diac symptoms compared with the standard procedures including balloon aortic valvuloplasty.⁷⁾ The Edward SAPIEN™ (Edwards Lifesciences LLC, Irvine, CA, USA)⁸⁾ and CoreValve ReValving® System (Medtronic LLC, Irvine, CA, USA) prosthetic heart valve obtained Conformité Européenne mark approval in August and April 2007, respectively. Both technologies are currently subjected to post-marketing surveillance studies in Europe. In 2009, Korean Food and Drug Administration authorized conduct of the first explorative studies at the Asan Medical Center in Korea. Here, we report procedural success rates and clinical outcomes for the Edwards SAPIEN™ and XT™ in the early TAVI cases in Korea.

Subjects and Methods

Study population

Between March 2010 and October 2011, 48 patients with severe symptomatic AS were screened at the Asan Medical Center to determine if they were at high risk of surgical mortality and were not proper candidates for receiving surgical operation. Patient preference alone for a percutaneous procedure was not considered adequate if surgery was an option.⁹⁾ Twenty-three patients were considered unsuitable for surgery due to the presence of multiple comorbid disorders and/or the high risk of procedure-related mortality. These patients were referred for a percutaneous procedure, and were assessed by a team of intervention cardiologists, echocardiographic cardiologists, and cardiac surgeons.

Prior to TAVI, all patients underwent transthoracic (TTE), transesophageal echocardiography (TEE), iliofemoral angiography, coronary and aortic root angiography, and computed tomographic (CT) angiography. Clinical evaluation and TTE and/or CT were obtained within 24 hours of the procedure and at 1, 6, and 12 months of follow-up.

Devices

The devices used in the present study were the Edwards SAPIEN™ (n=10) and SAPIEN XT™ (n=13, Edwards Lifesciences Inc., Irvine, CA, USA). Both consist of a trileaflet bovine pericardial valve and a balloon-expandable, stainless-steel support frame (Fig. 1). Valves are supplied sterile in glutaraldehyde and required onsite preparation. A mechanical crimping device was used to attach the prosthesis onto a specially constructed valvuloplasty balloon catheter. For the transfemoral approach, the occlusive fabric skirt had to be mounted distally on the balloon catheter. The opposite orientation would be required for a transapical approach.

The diameter of the aortic annulus was measured from the parasternal long-axis view of TTE or TEE, immediately below the insertion point of the valve leaflets (Fig. 2A). Measurements were also done

Fig. 1. Edwards prosthetic valve. An equine pericardial valve is seen within a stainless steel frame. A fabric skirt covers the bottom third of the steel. Edwards SAPIEN (A) and SAPIEN XT (B) valves.

from the sagittal (similar to parasternal long-axis view of TTE or TEE), coronal, and double-oblique views of CT (Fig. 2B, C and D). The size was finally decided based on the both imaging modalities. A 23-mm valve was considered appropriate for an annulus diameter of 18 to 22 mm, and a 26-mm valve was considered appropriate for an annulus diameter of 21 to 25 mm.

Procedure

Detailed descriptions of the transfemoral and transapical procedures are provided elsewhere.¹⁰⁾¹¹⁾ The procedure was performed in a catheterization laboratory under operating-room-like sterile conditions. Patients were premedicated with clopidogrel and aspirin, and received prophylactic antibiotics immediately prior to the procedure.

For the 23-mm prosthetic valve, femoral arterial sheaths (Edwards Lifesciences Inc) with an internal diameter of 22F (RetroFlex) or 18F (NovaFlex) were used. For the 26-mm prosthetic valve, femoral artery sheaths with an internal diameter of 24F (RetroFlex) or 19F (NovaFlex) were used. The minimum required iliofemoral arterial diameter was 6 mm for an 18F sheath, 7 mm for a 19F sheath, 8 mm for a 22F sheath, and 9 mm for a 24F sheath. However, the presence of short segments of noncalcified focal stenosis was not considered as exclusions. In the initial transfemoral procedures (n=4), closure of the surgical access site was performed by a vascular surgeon. In later patients (n=16), percutaneous closure was performed (Proglide, Abbott Vascular, Chicago, IL, USA). A deflectable guiding catheter (Edwards Lifesciences Inc.) was used to facilitate passage of the prosthesis through the arterial system and the aortic valve (Fig. 3A and B). For the transapical approach, we used the dedicated guiding catheter, Ascendra-1 (26 or 33F) or 2 (22 or 24F) delivery system (Edwards Lifesciences Inc) (Fig. 3C).

After the procedure, the patients received clopidogrel for 6 months and aspirin indefinitely.

Training and proctoring

Our teams underwent didactic, simulated training at a specialized training center, and after visited the New York Presbyterian Hospital,

Fig. 2. Annulus size measurement using echocardiography (A) and computed tomography (B, C and D). Coronal view (B); sagittal view (similar to parasternal long-axis view of echocardiography, C); double oblique view at the annulus level (D).

Fig. 3. Delivery systems used in transfemoral (A and B) and transapical approach (C). A: the deflection catheter (RetroFlex-3) facilitates delivery of the prosthetic valve to the native valve. B: NovaFlex delivery system. C: ascendra transapical delivery system.

which is a center with extensive experience of TAVI. Proctors (John Webb, Alain Cribier, Augusto Pichard, and Jian Ye) were present during the pre-procedural evaluation and implantation of the first nine cases performed at the Asan Medical Center (transfemoral, $n=8$; transapical, $n=1$). For the 11 subsequent transfemoral cases, implant-

ation was performed without proctor instruction.

Statistical analysis

Results were given in a standard fashion throughout the manuscript. Continuous variables were expressed as mean $\pm$ SD or as median when appropriate, and categorical variables were expressed as proportions.

Results

Baseline characteristics

Baseline characteristics are shown in Table 1 and 2. The mean age of the patients was 75.9 ± 5.4 years and 57% (13/23) were females. The mean logistic European System for Cardiac Operative Risk Evaluation was $25.6\pm 5.1\%$ (Table 1).

Procedural and clinical outcomes

Procedural outcomes are shown in Table 3. Procedures were per-

Table 1. Baseline clinical characteristics

Variable	N=23
Age (years)	75.9±5.4
Female gender (%)	13 (56.5)
Diabetes (%)	9 (39.1)
Hypertension (%)	23 (100)
Syncope (%)	3 (13.0)
Past and current smoker (%)	10 (43.5)
Previous stroke (%)	17 (73.9)
Peripheral vascular disease (%)	22 (95.7)
Coronary artery disease (%)	16 (69.6)
Previous myocardial infarction (%)	5 (21.7)
Previous coronary angioplasty (%)	10 (43.5)
Previous CABG (%)	1 (4.4)
Previous major operation (%)	12 (52.7)
Previous congestive heart failure (%)	5 (21.7)
Chronic lung disease (%)	20 (87.0)
Chronic kidney disease (%)	3 (13.0)
Chronic liver disease (%)	2 (8.7)
Previous malignancy (%)	3 (13.0)
Porcelain aorta (%)	4 (17.4)
Mobile aortic atheroma (%)	5 (21.7)
Chest deformity (%)	2 (8.7)
Chest radiation	0
Atrial fibrillation (%)	7 (30.4)
Logistic EuroSCORE (%)	25.6±5.1
NYHA class	3 (2-4)

The values are presented with mean mean±SD, median (interquartile range) and number (percentage). CABG: coronary artery bypass graft, EuroSCORE: European System for Cardiac Operative Risk Evaluation, NYHA: New York Heart Association

Table 2. Baseline iliofemoral artery evaluation and access route

Variable	Angiogram (n=23)	CT angiogram (n=23)
Aorto-iliac bifurcation (%)		
Severe calcification	2 (8.7)	11 (47.8)
Severe tortuosity	9 (39.1)	12 (52.2)
Iliac artery		
Minimum diameter (mm)	11.4±1.4	10.2±2.1
Severe calcification (%)	4 (17.4)	14 (60.9)
Severe tortuosity (%)	10 (43.5)	12 (52.2)
Femoral artery		
Minimum diameter (mm)	8.6±1.3	8.2±1.6
Severe calcification (%)	2 (8.7)	6 (26.1)
Severe tortuosity (%)	7 (30.4)	10 (43.5)

The values are presented with median (interquartile range) and number (percentage). CT: computed tomography

Table 3. Procedural parameters and outcomes

Variable	N=23
Successful valvuloplasty	23 (100)
Successful valve implantation	22 (95.7)
Implanted valve size (mm)	
23 (%)	13 (59.1)
26 (%)	9 (40.9)
Access Route in transfemoral approach (n=20)	
Right femoral access (%)	18 (90.0)
Left femoral access (%)	2 (10.0)
Surgical closure (%)	4 (20.0)
Percutaneous puncture (%)	16 (80.0)
Transfemoral approach (%)	20 (87.0)
Transapical approach (%)	3 (13.0)
Conversion to open aortic valve replacement (%)	3 (13.0)
AR>grade 2	0
Paravalvular leak>moderate	0
Valve embolization (%)	3 (13.0)
Valve-in-valve implantation (%)	1 (4.4)
Coronary obstruction	0
Vascular complications in transfemoral approach (n=20)	
Iliac perforation (%)	1 (5.0)
Aortic dissection	0
Renal impairment	0
Permanent pacemaker	0
Left ventricular perforation	0
Cardiac tamponade	0
Neurologic events	0
Transient ischemic attack	0
Stroke	0
Procedure-related death	0
Myocardial infarction	0

AR: aortic regurgitation

formed with general anesthesia. Transfemoral or transapical placement of the introducer sheath was successful in all patients selected for the procedure on the basis of screening femoral angiography and CT angiography. The transfemoral approach was used on twenty patients and the transapical approach on 3 patients. We successfully implanted prosthetic aortic valves in 22 of 23 patients (95.7%). Prosthesis deployment was unsuccessful in 1 patient. In this unsuccessful case (this was one of the earlier cases when the proctor was present), we initially tried to use a retrograde approach through the aorta to the left ventricle, however it was hard to cross the wire through the stenotic valve. We then decided to use an antegrade approach using transseptal puncture to the aortic valve. However, the delivery balloon was asymmetrically inflated in the aorta side

Fig. 4. Prosthetic valve was asymmetrically inflated in the aorta side first and spilled out to the left ventricle side (A, B and C). Successful removal of the prosthesis using the small size balloon from the left ventricle (D and E).

Table 4. Clinical outcomes including procedural outcomes

Variable	N=23
Follow up	2 (1.1-12.9) months
All cause death	0
Cardiovascular death	0
Procedure-related death	0
Myocardial infarction	0
Endocarditis	0
Hospital readmission	1
Neurologic events	0
Transient ischemic attack	0
Stroke	0

The values are presented with median (interquartile range) and number (percentage)

only and the prosthetic valve spilled out to the left ventricle (Fig. 4). We were able to pull out the prosthesis using the small size balloon from the left ventricle. We finally decided to refer to operation.

No intraprocedural deaths or strokes occurred. During the follow-up (interquartile range, 1.1-12.9), no deaths, strokes, or major cardiovascular complications occurred (Table 4).

Procedural complications

Prosthesis embolization occurred in 3 cases (Table 3). The first event occurred in the first patient immediately after deflation of the deployment balloon. Potential contributor to embolization was

early termination of rapid pacing while the deployment balloon remained inflated, which carried the prosthesis with it. After the placement of the prosthesis in the descending aorta, the patient received additional 23-mm diameter prosthesis (valve-in-valve), and she remained well. No further cases of embolization secondary to early termination of rapid pacing occurred. In the second case, the patient had heavy eccentric calcium in the left coronary cusp. Although the stent remained below the coronary ostia, it did not expand well in its upper portion (Fig. 5). Initial post-procedure TEE and angiography indicated successful implantation. However, migration of the prosthesis to the ventricular side was detected during a TTE routine follow-up 3 days later. In the third case, embolization occurred as a result of valve position. The patient had heavy eccentric calcium in the noncoronary cusp, which prevented total coverage of the cusp by the prosthesis (Fig. 6).

An iliac arterial complication occurred in one patient (Table 3). In the first patient, a 22F sheath was advanced with considerable difficulty through a very heavily calcified and tortuous common iliac artery. During surgical removal of the sheath 2 hours later, perforation of the common iliac artery occurred. Surgical removal of the sheath 2 hours later was associated with perforation of the common iliac artery. The ruptured artery was blocked via ballooning, and the patient underwent uneventful femoral to femoral artery bypass surgery. In the 18 subsequent patients, the NovaFlex system (18 or 19F) was used, and no further major femoral or transapical ac-

Fig. 5. Asymmetric expansion of the prosthetic valve led to embolization of the prosthesis after the procedure: fluoroscopic view (A) and computed tomography (B).

Fig. 6. An embolized case; computed tomography showed heavy calcific leaflets in the noncoronary cusp (A: coronal view, B: basal portion of valve, C: top of valve); aortic root angiography showed incomplete coverage of the noncoronary cusp due to heavy calcium (white arrow head, D).

Table 5. Echocardiographic characteristics

Variable	Baseline (n=23)	Postprocedure (n=23)	Follow-up of 9 months (n=17)
Left ventricular ejection fraction (%)	59.5±8.8	64.4±7.0	63.0±3.8
Aortic valve area (cm ²)	0.68±0.14	1.45±0.33	1.35±0.4
Aortic annulus diameter (mm)	21.4±2.0	NA	NA
Mean transaortic valve gradient (mm Hg)	59.4±22.4	16.6±5.7	15.6±7.1
Peak transaortic valve gradient (mm Hg)	98.7±34.5	30.5±9.5	29.1±11.9
Moderate to severe AR	0	0	0
Aortic paravalvular leak	NA	Trivial (trivial-mild)	Trivial (trivial-mild)*
Moderate to severe MR	0	0	0
Moderate to severe pulmonary HTN	0	0	0

The values are presented with median (interquartile range) and number (percentage). *Three cases of trivial paravalvular leak were disappeared. AR: aortic regurgitation, NA: not available, MR: mitral regurgitation, HTN: hypertension

cess site complications or hematomas occurred.

No stroke, renal insufficiency, coronary artery obstruction, or conduction abnormality occurred in the cohort (Table 3).

Prosthetic valve function and follow-up measurements

Valve function was assessed by echocardiography immediately after implantation, and again 24 hours and 9 months later. In all patients, valve function remained essentially unchanged (Table 5). Paravalvular aortic regurgitation was generally mild. Although paravalvular leak was common, most cases were trivial or mild. No late valve failure occurred. At the 9-month follow-up assessment (which involved 17/23 patients, 74%), the improvements in the aortic valve area and the mean gradient were maintained, and the degree of paravalvular leak was unchanged (Table 5).

Discussion

The present report describes an experience of 23 TAVI cases in Korea. Twenty valves were implanted transfemorally and three transapically. Successful prosthesis implantation was achieved in 22 patients. In the cases that failed, difficulties were encountered in the passage of the wire through the stenotic valve and in the positioning of the prosthesis, in which open replacement was performed. Prosthesis embolization and a major vascular complication occurred in three cases and one case, respectively. However, no death, stroke, renal insufficiency, coronary artery obstruction, or conduction abnormality occurred in the cohort, and all complications occurred in patients who underwent the procedure during the early period of the study cases.

Although surgical aortic valve replacement is a standard therapy for severe symptomatic AS,^{23,12} many patients are considered unsuitable for surgery due to excessive risk, advanced age, high risk of procedure-related mortality, and multiple comorbidity.¹⁴ Prog-

nosis following medical treatment is poor, and although balloon aortic valvuloplasty provides both a temporary improvement in valvular function and symptom relief, it is associated with a high rate of procedure-related complications and mortality.¹³ For this reason, TAVI is a good alternative for patients who refuse conventional surgery and have a high risk of mortality.^{7,8,14}

A recent randomized trial for inoperable symptomatic severe AS showed that at 1 year, TAVI was associated with a significant reduction in mortality rate {30.7% vs. 50.7%; hazard ratio with TAVI, 0.55; 95% confidence interval (CI), 0.40-0.74; $p<0.001$ }, repeat hospitalization, and cardiac symptoms compared to standard treatments such as balloon aortic valvuloplasty.⁷ In a randomized trial for patients with a high risk of mortality, TAVI and open heart surgery were associated with similar rates of survival at both 1 month (3.4% vs. 6.5%, $p=0.07$) and 1 year (24.2% vs. 26.8%, $p=0.44$; a reduction of 2.6 percentage points in TAVI; upper limit of 95% CI, 3.0 percentage points; predefined margin, 7.5 percentage points; $P_{\text{noninferiority}}=0.001$).¹⁴ However, the rate of stroke was significantly higher for TAVI than for open heart surgery at 1 month (5.5% vs. 2.4%, $p=0.04$) and 1 year (8.3% vs. 4.3%, $p=0.04$). Major vascular complications were also significantly higher in TAVI at 1 month (11.0% vs. 3.2%, $p<0.001$). In contrast, the surgery group showed a significantly higher incidence of major bleeding (9.3% vs. 19.5%, $p<0.001$) and new-onset of atrial fibrillation (8.6% vs. 16.0%, $p=0.006$) at 1 month.¹⁴

Previous studies reported that successful TAVI involves a learning curve, and that outcomes improve with experience and device development.^{15,16} Although our experience was limited in terms of its duration and the number of cases, prosthesis implantation was successful in 22 patients (96%) with one failed case and all complications occurred in patients who underwent the procedure during the early period of study.

Important factors in successful TAVI include adequate patient se-

lection, correct sizing,¹⁷⁻¹⁹⁾ positioning, 20 coaxial alignment, timely reduction of cardiac output, operator techniques,¹⁵⁾¹⁶⁾ and organized team approach.²⁰⁾ In the present cohort, the team approach ensured reduction, early detection, and treatment of complications. Our initial experience was mainly derived by the early version of prosthesis and delivery systems and caused a major vascular complication. However, we were able to reduce the complications and increase the success rate after the introduction of new smaller, atraumatic, more advanced delivery system (NovaFlex) and prosthesis (Edwards SA-PIEN XT™ valve).

In conclusion, TAVI is a new technology that is of potential benefit to patients with severe symptomatic AS, particularly for those who are inoperable or at high surgical risk. With advancements in device technology, procedure related complications will decrease and prosthesis durability will improve. This will allow an expansion of the indications for TAVI. Although our initial experiences are promising, application of this procedure should be limited to patients who are poor candidates for surgical valve replacement.

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