Early Clinical Experience with Sutureless Aortic Valve Replacement for Severe Aortic Stenosis

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Background: Sutureless aortic valve replacement (SU-AVR) has been developed as an alternative surgical treatment for patients with symptomatic severe aortic stenosis (AS). The aim of this study was to evaluate the clinical outcomes of SU-AVR through an assessment of hemodynamic performance and safety. **Methods:** From December 2014 to June 2016, a total of 12 consecutive patients with severe AS underwent SU-AVR. The endpoints were overall survival and valve-related complications (paravalvular leakage, valve thrombosis, migration, endocarditis, and permanent pacemaker implantation). The mean follow-up duration was 18.1±8.6 months. **Results:** The mean age of the patients was 77.1±5.8 years and their mean Society of Thoracic Surgeons score was 9.2±17.7. The mean cardiopulmonary bypass and aortic cross-clamp times were 94.5±37.3 minutes and 54.9±12.5 minutes, respectively. Follow-up echocardiography showed good prosthesis function with low transvalvular pressure gradients (mean, 13.9±8.6 mm Hg and peak, 27.2±15.0 mm Hg) at a mean of 9.9±4.2 months. No cases of primary paravalvular leakage, valve thrombosis, migration, or endocarditis were reported. A new permanent pacemaker was implanted in 1 patient (8.3%). The 1-year overall survival rate was 83.3%±10.8%. **Conclusion:** Our initial experience with SU-AVR demonstrated excellent early clinical outcomes with good hemodynamic results. However, there was a high incidence of permanent pacemaker implantation compared to the rate for conventional AVR, which is a problem that should be solved.

Key words: 1. Aortic valve stenosis
2. Bioprosthesis
3. Heart valve prosthesis implantation

Introduction

Conventional aortic valve replacement (AVR) for patients with symptomatic severe aortic stenosis (AS) is recommended as the gold-standard treatment to alleviate symptoms and to improve survival [1-5]. The outcomes of AVR have improved over the past decades, but the incidence of mortality and morbidity after surgical management remain high among patients with older age and multiple comorbidities [6-8]. In recent years, as the number of high-risk elderly patients has increased, technological advances have led to less invasive alternative treatment modalities, including sutureless AVR (SU-AVR) and transcatheter aortic valve implantation (TAVI), which have expanded the indications for surgery to include high-

or prohibitive-risk patients [4]. SU-AVR, which involves a rapidly deploying aortic valve device, has the advantages of reducing the cardiopulmonary bypass (CPB) duration and aortic cross-clamp (ACC) time, thereby minimizing the operative risk, and enabling the straightforward implantation of an aortic biologic valve prosthesis without sutures through a minimally invasive approach [4,9,10]. Several studies have reported that these sutureless valves resulted in a lower incidence of postoperative complications, especially misplacement and paravalvular leakage, because they involve the direct removal of the calcified valve and allow accurate debridement of the diseased aortic annulus [9,11,12]. The aim of this study was to evaluate retrospectively the 1-year clinical and echocardiographic outcomes of SU-AVR through an assessment of hemodynamic performance and safety.

Methods

Between December 2014 and June 2016, a total of 12 consecutive patients with severe AS who underwent SU-AVR at Severance Cardiovascular Hospital, Yonsei University College of Medicine were reviewed. All patients were implanted with the Perceval valve system (Sorin Group Srl, Saluggia, Italy), which is a self-expanding, self-anchoring, sutureless bioprosthetic valve [13]. Patients with a congenital bicuspid aortic valve, an asymmetric aortic annulus, an annulus-to-sinotubular-junction ratio greater than 1.3, and an aortic annulus diameter less than 19 mm or greater than 27 mm were excluded from this study [12-14]. Transthoracic echocardiography (TTE) and coronary-valve computed tomography were routinely performed preoperatively to assess valvular morphology.

Preoperative and perioperative data were obtained from a review of the patients' hospital charts, and follow-up was performed when patients returned for follow-up visits or by conducting telephone interviews. The collection of follow-up data for at least 1 year was complete (100%). All patients underwent a clinical evaluation, blood tests, and TTE at each follow-up visit. The preoperative variables included in the analysis were age, sex, body surface area, hypertension, diabetes mellitus, coronary artery disease, chronic obstructive pulmonary disease, chronic kidney disease, arrhythmia, a history of a previous percutaneous coronary intervention or cardiac operation,

New York Heart Association (NYHA) functional class, Society of Thoracic Surgeons (STS) score, the logistic European System for Cardiac Operative Risk Evaluation (Euroscore), and echocardiographic indicators (left ventricular ejection fraction, aortic valve area, peak and mean systolic pressure gradient, left atrial diameter, left ventricular end systolic and diastolic dimension, left atrial volume index, left ventricular mass index, and right ventricular systolic pressure). High-risk patients were defined as those with an STS operative risk score of 8% or higher.

The following perioperative variables were recorded: CPB and ACC time, valve size, and any concomitant cardiac procedures. Clinical outcomes were assessed in terms of all-cause mortality and postoperative valve-related complications. Valve-related events were defined as valve thrombosis, embolism, and bleeding events (formerly anticoagulant hemorrhage) according to the American Association for Thoracic Surgery guidelines for reporting morbidity and mortality after cardiac valve interventions [15].

1) Operative techniques
All operations were performed under CPB using systemic hypothermia through a median or minimal invasive upper sternotomy. A transverse aortotomy in a relatively high position, approximately 3.5 cm above the aortic annulus, was performed to accommodate the height of the prosthetic stent. After decalcification of the aortic annulus, the expandable stent was implanted in the appropriate annular position without any permanent suture. We routinely used specific sizers for the optimal valve size and 3 guiding sutures between 2 commissures to correctly insert the valve at the level of the native aortic annulus. The prosthesis was then released into the valve and dilated with a low-pressure balloon catheter for 30 seconds at a pressure of 4 atmospheres [12,13,16]. When the valve was successfully deployed, the guiding sutures were removed.

2) Statistical analysis
Statistical analyses were performed using IBM SPSS ver. 23.0 (IBM Corp., Armonk, NY, USA). All data are presented as mean±standard deviation or as frequency and percentage. Continuous variables were analyzed using the Student t-test, and categorical variables were compared using the chi-square test or

Table 1. Baseline patients' characteristics (N=12)

Variable	Value
Age (yr)	77.1±5.8 (62.0–85.0)
≥80 years older	4 (33.3)
Sex (female)	7 (58.3)
Body surface area (m^2)	1.68±0.17 (1.44–1.98)
Hypertension	10 (83.3)
Diabetes mellitus	5 (41.7)
Coronary artery disease	3 (25.0)
Chronic obstructive pulmonary disease	3 (25.0)
Chronic kidney disease	1 (8.3)
Peripheral artery disease	0
Cardiac rhythm	
Sinus rhythm	8 (66.7)
Atrial fibrillation	2 (16.7)
Pacemaker	2 (16.7)
Previous cardiac operation	3 (25.0)
NYHA class III	11 (91.7)
NYHA class IV	1 (8.3)
Society of Thoracic Surgeons score	9.2±17.7 (0.9–64.3)
Logistic Euroscore	16.2±19.2 (3.3–75.0)
Euroscore II	7.8±11.8 (1.9–42.4)

Values are presented as mean±standard deviation (range) or number (%).
NYHA, New York Heart Association; Euroscore, European System for Cardiac Operative Risk Evaluation.

Table 2. Preoperative echocardiographic data (N=12)

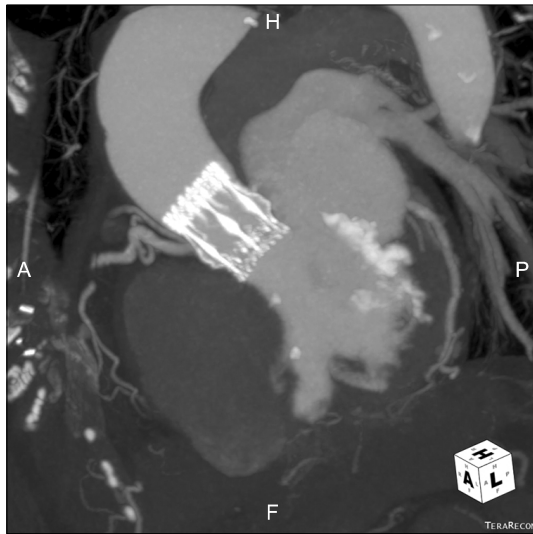| Variable	Value
Aortic valve lesion	
Stenosis	12 (100.0)
Moderate	1 (8.3)
Severe	11 (91.7)
Stenosis and regurgitation (grade ≥II)	3 (25.0)
Left ventricular ejection fraction (%)	61.4±13.9 (28–75)
E/E'$^{a)}$	22.6±7.0 (10–30)
Aortic valve area (cm^2)	0.75±0.15 (0.44–0.96)
Peak systolic pressure gradient (mm Hg)	79.8±17.8 (48–112)
Mean systolic pressure gradient (mm Hg)	47.7±9.3 (32–62)
Left atrial diameter (mm)	51.3±16.7 (37–96)
Left ventricular end systolic dimension (mm)	33.9±5.8 (26–44)
Left ventricular end diastolic dimension (mm)	50.4±4.9 (44–62)
Left atrial volume index (mL/m^2)	48.7±8.3 (38.4–67.7)
Left ventricular mass index (g/m^2)	137.3±30.0 (72.1–173.2)
Right ventricular systolic pressure (mm Hg)	38.4±14.6 (23–75)
Aortic valve annulus (mm)	23.3±1.1 (21.5–25.3)
Sinotubular junction (mm)	26.1±3.2 (21.2–31.3)
Annulus/sinotubular junction ratio	0.9±0.1 (0.8–1.1)
Height (mm)	19.2±3.4 (15.4–27.8)

Values are presented as number (%) or mean±standard deviation (range).
$^{a)}$Ratio of early diastolic transmitral velocity to early diastolic tissue velocity.

the Fisher exact test. The long-term survival curve was evaluated using the Kaplan-Meier method. All p-values less than 0.05 were considered to indicate statistical significance, and rates are expressed with 95% confidence limits.

Results

1) Patient characteristics and preoperative echocardiographic data

The mean age of the patients was 77.1±5.8 years (range, 62.0 to 85.0 years) and 33.3% were at least 80 years old. The study population consisted of 7 women (58.3%) and 5 men (41.7%). The preoperative characteristics of the patients and their cardiovascular comorbidities are summarized in Table 1. Eleven patients (91.7%) were classified as NYHA functional class III, and 1 (8.3%) was classified as NYHA functional class IV. The mean STS score was 9.2±17.7, the logistic Euroscore was 16.2±19.2, and the Euroscore II was 7.8±11.8. In 3 patients (25.0%), previous cardiac surgery was performed be-

fore the SU-AVR procedure, such as coronary artery bypass grafting or mitral valve replacement. As shown in Table 2, the preoperative left ventricular ejection fraction was 61.4%±13.9% (range, 28% to 75%) and the peak and mean systolic pressure gradients were 79.8±17.8 mm Hg and 47.7±9.3 mm Hg, respectively.

2) Perioperative data

The sutureless valve was successfully implanted in all patients (Fig. 1). One patient required a second attempt due to size mismatching. The valves were sized medium (n=5, 41.7%), large (n=4, 33.3%), and extra-large (n=3, 25.0%). Eleven patients underwent isolated AVR, and concomitant coronary artery bypass grafting was performed in 1 patient with 3-vessel disease. Minimally invasive surgery (upper ster-

Fig. 1. Computed tomography scan performed 1 month post-operatively, showing a well-functioning Perceval S sutureless bioprosthesis. A, anterior; P, posterior; H, head; F, foot.
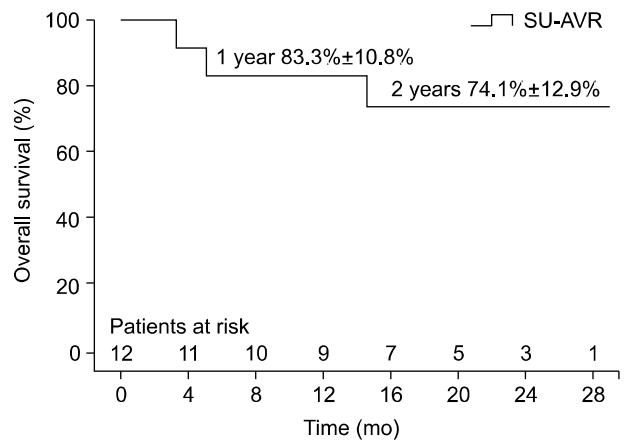

Fig. 2. Kaplan-Meier curve showing the overall survival rate in patients who were implanted with a sutureless valve (SU-AVR). SU-AVR, sutureless aortic valve replacement.

Table 3. Perioperative data

Variable	Value
Surgical approach	
Median sternotomy	6 (50.0)
Minimal invasive approach	6 (50.0)
Valve size	
S (21 mm)	0
M (23 mm)	5 (41.7)
L (25 mm)	4 (33.3)
XL (27 mm)	3 (25.0)
Cardiopulmonary bypass time (min)	94.5±37.3 (55.0–183.0)
Aortic cross clamp time (min)	54.9±12.5 (39.0–87.0)
Concomitant cardiac surgery	
Coronary artery bypass grafting	1 (8.3)

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

Table 4. Clinical outcomes

Variable	Value
Reoperation for bleeding	0
Newly required dialysis	0
Delayed ventilation	1 (8.3)
Early stroke	0
Gastrointestinal bleeding	0
Arrhythmia/pacemaker implantation	2 (16.7)/1 (8.3)
Hospital stay (day)	16.8±14.8 (7–59)
Postoperative New York Heart Association class	
I	5 (41.7)
II	7 (58.3)
In hospital mortality	0
Late mortality	3 (25.0)
Valve thrombosis	0
Endocarditis	0
Valve migration	0
Paravalvular leak	0

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

notomy) was performed in 6 patients (50.0%). Three patients underwent redo surgery. The mean CPB and ACC times were 94.5±37.3 minutes and 54.9±12.5 minutes, respectively (Table 3).

3) Clinical outcomes

The mean follow-up duration was 18.1±8.6 months (range, 3.3 to 28.9 months). The overall survival rate at 1 year was 83.3%±10.8%. The Kaplan-Meier risk curve for overall survival is shown in Fig. 2. There was no case of 30-day in-hospital mortality. Three

patients (25.0%) in the population died during the follow-up period. The causes of death were cerebral hemorrhage (n=1), fungal sepsis (n=1), and gastrointestinal bleeding due to the rupture of esophageal varices (n=1). An 81-year-old woman who had worked at a sanatorium as a physician died at 3.3 months postoperatively due to septic shock with cultured *Candida albicans*, and another 81-year-old woman with an uncontrolled international normalized ratio died during follow-up due to anti-

Table 5. Hemodynamic data from postoperative to latest follow-up

Variable	Pre	Post	p-value (pre vs. post)	Latest	p-value (pre vs. latest)	⊿ Mean (pre-last)
Left ventricular ejection fraction (%)	61.4±13.9	56.9±5.8	0.168	57.6±11.8	0.058	−3.8±6.3
E/E'[a)]	22.6±7.4	26.0±8.6	0.248	26.6±9.1	0.189	5.4±10.4
Aortic valve area (cm^2)	0.77±0.15					
Peak systolic pressure gradient (mm Hg)	79.8±17.8	30.2±9.0	<0.001	27.2±15.0	<0.001	−52.6±24.4
Mean systolic pressure gradient (mm Hg)	47.7±9.3	16.7±5.1	<0.001	13.9±8.6	<0.001	−33.8±12.8
Left atrial diameter (mm)	51.3±16.7	45.9±7.2	0.139	47.2±6.7	0.300	−4.2±13.3
Left ventricular end systolic dimension (mm)	33.9±5.8	34.9±4.4	0.491	34.0±5.8	0.948	0.1±4.3
Left ventricular end diastolic dimension (mm)	50.4±4.9	47.3±4.9	0.040	47.8±5.7	0.145	−2.6±5.7
Left atrial volume index (mL/m^2)	48.7±8.3	47.8±12.5	0.651	51.0±22.6	0.628	2.3±16.1
Left ventricular mass index (g/m^2)	137.3±30.0	120.7±29.4	0.057	104.2±39.8	0.006	−33.2±34.2
Right ventricular systolic pressure (mm Hg)	38.4±14.6	40.9±14.1	0.520	37.1±13.0	0.677	−1.3±9.8

Values are presented as mean±standard deviation.
Pre, preoperative; Post, postoperative.
[a)]Ratio of early diastolic transmitral velocity to early diastolic tissue velocity.

coagulation-related hemorrhage.

No cases of postoperative paravalvular leakage, valve thrombosis, migration, or endocarditis were reported (Table 4). Arrhythmia occurred in 2 cases (16.7%). A new permanent pacemaker was implanted in 1 patient as a result of postoperative third-degree atrioventricular block. No patients underwent reoperation due to bioprosthesis valve dysfunction. The NYHA functional class improved by at least 1 level in all patients (class I, 41.7% and class II, 58.3% at the 1-year follow-up).

The echocardiographic outcomes of the survivors at 6–12 months postoperatively are summarized in Table 5. The mean echocardiographic follow-up duration was 9.9±4.2 months (range, 2.5 to 14.2 months). All valves functioned well. The final peak systolic pressure gradient was 27.2±15.0 mm Hg, and the mean gradient was 13.9±8.6 mm Hg. In terms of hemodynamic outcomes, the changes in the peak systolic pressure gradient, mean systolic pressure gradient, and the left ventricular mass index showed significant improvement: −52.6±24.4 mm Hg (p<0.001), −33.8±12.8 mm Hg (p<0.001), and −33.2±34.2 g/m^2 (p=0.006), respectively.

Discussion

This study evaluated early clinical outcomes in patients who underwent SU-AVR for symptomatic severe AS. In this initial experience, there were no prosthesis-related complications such as paravalvular leakage, valve thrombosis, reoperation, or endocarditis. All patients showed an improved NYHA functional class to grade II or less (grade I, 41.7% and grade II, 58.3%).

Recently, TAVI and SU-AVR were developed to minimize the adverse effects in previously inoperable high-risk patients [3,10-12,17]. At our institution, we have used sutureless valves as an alternative treatment option to reduce the surgical risk and to facilitate minimally invasive procedures in aged and high-risk patients with comorbidities. Indications for SU-AVR in our early series were patients with significant comorbidities who were at least 75 years of age, or patients with a significant surgical risk in whom concomitant procedures requiring a long CPB time were planned.

Previous studies have reported that an increased risk for mortality was associated with the duration of CPB and ACC, and that these factors were independent predictors of survival [3-5]. A potential advantage of SU-AVR in comparison to conventional AVR is the reduced CPB and ACC time, due to the rapid sutureless deployment [9,10,17]. In the European multicenter Cavalier trial, the mean ACC and CPB times were 32.4 and 53.4 minutes, respectively, in isolated AVR through a full sternotomy [12]. The ACC and CPB times in our study were longer because 3 patients had previously undergone coronary artery bypass surgery or mitral valve replacement and in 1 patient, AVR was performed with concomitant coronary artery bypass grafting. Yu et al. [18] previously

published a study analyzing the early outcomes of conventional AVR compared with TAVI in severe AS patients. The duration of CPB and ACC in patients aged 75 years or more in the AVR group was 126±34 minutes and 98±29 minutes, respectively; these results were inferior to those obtained with SU-AVR, although the study lacked statistical power.

During the follow-up period, the incidence of para-valvular leakage and valve-related complications in terms of valve thrombosis, reoperation, and endocarditis was low (0%). These findings are in accordance with the results of Santarpino et al. [3]. They reported that the paravalvular regurgitation rate was higher in the TAVI group than in the SU-AVR group (13.5% versus 0%, p=0.027) [3]. The PARTNER trial also demonstrated that TAVI resulted in much more frequent paravalvular leakage [11,19]. The primary reason for this may be related to the technique of decalcifying the native aortic valve. To avoid paravalvular leakage as much as possible, calcium at the annulus, including severely fibrotic tissue, should be removed completely.

Although we did not observe moderate to severe paravalvular leakage or valvular regurgitation in our patients, there were 3 deaths among our 12 cases. Two cases were very high-risk patients preoperatively. One patient was an 81-year-old physician who had served in a sanatorium and was in cardiogenic shock with severe left ventricular failure at admission. On the third postoperative day, fungal pneumonia developed, but was well-treated at discharge. The other was a 62-year-old physician with severe esophageal varices associated with liver cirrhosis. Thus, our mortality rate may have reflected the risk factor profile in terms of comorbidities and elderly patients.

The sutureless valve demonstrated excellent hemodynamic performance, with a significant reduction of the pressure gradient (p<0.001) and regression in left ventricular mass (p=0.006) in our echocardiographic data. Flameng et al. [9] reported similar results, finding that the hemodynamics at the final follow-up indicated good function, with low transvalvular pressure gradients (mean, 12 mm Hg and peak, 23 mm Hg). These stable hemodynamic results may support the efficacy and safety of the sutureless valve in high-risk populations.

The most important benefit of the sutureless valve is thought to be its long-term durability after implantation. According to the animal study conducted by Kiefer et al. [20], the structural changes in the leaflets that were caused by crimping may have clinical significance regarding long-term durability. A sutureless valve does not require crimping for implantation; instead, it only requires folding for it to be introduced, in contrast to the crimping required for TAVI. Therefore, in some patients with intermediate or high surgical risk, for whom long-term survival is expected, SU-AVR may be a good alternative to TAVI or conventional AVR.

The major limitations of this study include its retrospective nature, lack of a control group, and the inclusion of a small number of patients with short-term follow-up. Since the sample size was small, it is possible that certain factors associated with postoperative complications or overall survival could have been overlooked due to a lack of statistical power. Because SU-AVR was first performed in Korea in December 2014, the mid- and long-term outcomes of SU-AVR in Korea are not yet available. A larger study of randomized patients with a longer follow-up duration is required for a more accurate comparison of the treatment modalities for severe AS in elderly patients and in those with comorbidities.

In conclusion, although SU-AVR did not show an advantage over TAVI or conventional AVR in terms of overall survival, the early clinical and hemodynamic results appeared to be excellent in high-risk patients with comorbidities. Therefore, it seems that SU-AVR may be an alternative to TAVI in some patients with a high surgical risk profile for whom long-term survival is expected.

Conflict of interest

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

Acknowledgments

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