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ORIGINAL ARTICLE

Percutaneous Aortic Valve Replacement for Critical Aortic Stenosis: A Single-Center Experience

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Abstract

Introduction: This study aimed to assess the procedural success and early term outcomes of percutaneous aortic valve replacement in patients with critical aortic stenosis.

Methods: This study included patients with severe high-risk aortic stenosis who underwent transcatheter aortic valve replacement between November 2014 and June 2016. All patients underwent transesophageal echocardiography and cardiac tomography prior to the procedure. The Edwards Sapien XT balloon-expandable transcatheter aortic valve was used in all patients. The valve size was selected according to measurements obtained from cardiac tomography and transesophageal echocardiography. Patients were evaluated for procedural success and adverse effects during hospitalization and a 30-day follow-up period.

Results: This study included a total of 33 patients (18 males, 15 females) with a median age of 78.2 (range: 62–92) years. Valve implantation was successfully performed in all patients. The valve size, which was selected according to transesophageal echocardiography, was increased in only one patient following cardiac tomography. Three patients died during the hospitalization period. No further deaths occurred during the 30-day observation period.

Discussion and Conclusion: Percutaneous transaortic valve replacement treatment for patients with high-risk aortic stenosis is an efficient and reliable treatment modality. Transesophageal echocardiography is a complementary and irreplaceable element for cardiac tomography when determining the valve size and operation strategy.

Keywords: Aortic stenosis; transesophageal echocardiography; transaortic valve replacement.

Critical aortic stenosis (AS) is a serious health problem that reduces life expectancy and quality and is generally observed in the elderly [1, 2]. Transvalvular systolic gradient at an aortic valve level of >64 mmHg and average gradient of >40 mmHg at echocardiography is defined as critical AS. Aortic valve replacement is an indispensable treatment for patients with symptomatic (orthopnoea, angina pectoris, and syncope) AS [3, 4]. Percutaneous transcatheter aortic valve replacement (TAVR) is a treatment that should be especially applied to older patients with AS and additional diseases at high risk during operation. For TAVR, the valve size for implantation is determined by transesophageal echocardiography (TEE) or cardiac tomography [5].

The purpose of the present study is to report our institutional experience related with PTVR and provide information related to the procedural success and adverse effects during hospitalization and a 30-day follow-up period.

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Materials and Methods

Patients

This study included 33 patients (18 males, 15 females) with severe high-risk aortic stenosis who underwent TAVR between November 2014 and June 2016. The average age of the patients was 78.2 years (Table 1). Before the operation, the patients underwent TEE and cardiac tomography. The Edwards Sapien XT (Edwards Lifesciences, Irvine, CA, USA) transcatheter aortic valve was implanted in all patients who agreed to undergo TAVR. TEE and computerized tomography (CT) was used as the main measurement method for determining the valve size.

Before beginning the study, approval was obtained from the ethics committee of Eskişehir Osmangazi University Faculty of Medicine.

Echocardiography Analyses

Transthoracic and TEE evaluations of all the patients were conducted before and after TAVR. The aortic annulus, sinus of Valsalva, sinotubular production, and resulting aortic diameters were measured with TEE at the mid-systole (Fig. 1). The transvalvular systolic and median gradients in the aortic valve were measured by transthoracic echocardiography using continuous-wave Doppler. The ejection fraction in the left ventricle was measured according to the modified-Simpson method.

Cardiac CT Analyses

Before TAVR, cardiac tomography was performed in all patients for the detailed examination the aortic annulus, aorta, and peripheral branches. The area of the aortic annulus and area-based annulus measurements were made at the site where the valves cleave into each other. Diameters of aorta and iliac arteries, their tortuosity in addition to load and distribution of calcification loads in these arteries were evaluated.

Table 1. Clinical and demographic attributes of the patients

	n (33)	%
Age (years)	78.2 ± 6.6	
Gender		
Male	18	54
Female	15	46
HT	23	69.7
DM	12	36.4
Smoking	15	46
COPD	12	36.4
CAD	10	30
Rhythm		
Sinus	27	81.8
AF	6	18.2

AF: Atrial Fibrillation; CAD: Coronary Artery Disease; COPD: Chronic Obstructive Pulmonary Disease; DM: Diabetes Mellitus; HT: Hypertension.

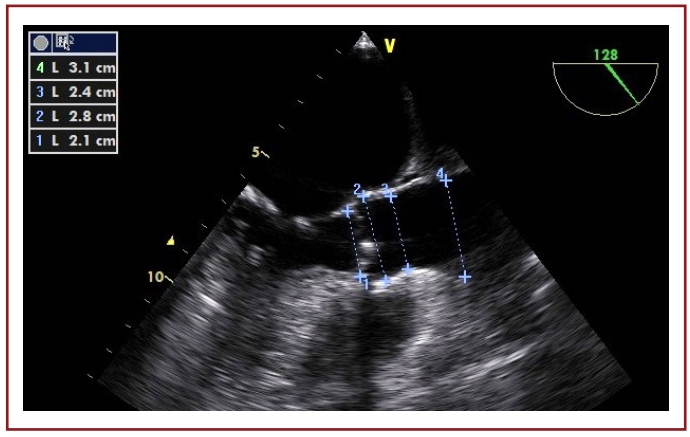

Figure 1. Measurements of the aortic annulus, sinus of Valsalva, sinotubular product, and resultant aortic diameters at the mid-systole using transesophageal echocardiography from a longitudinal axis section.

Angiographic Analyses and TAVR

TAVR was performed under a conscious sedation and local anesthesia. General anesthesia was not administered to any patient unless required. A pacemaker electrode was implanted in the right ventricle through the femoral artery or the internal jugular vein. The aortic root was accessed with a 6F sheath using a pigtail catheter. A larger sheath (22-24F) was placed on the right or left femoral artery to allow passage of prosthesis valve. With the guidance of angiography using a pigtail catheter, which was placed on the aortic root, the left ventricle was accessed by carrying over the aorta valve using a 0.035-inch thick guide wire sent through a AL2 or 3 diagnostic catheter. Subsequently, this wire was replaced with a long, hard wire through the pigtail catheter, and then a valvuloplasty balloon was positioned to perform valvuloplasty at the area of the AS. The systolic blood pressure decreased to <50 mmHg by rapid pacing (180–210/min) in the right ventricle. At the same time, the balloon was fully expanded, and aortic root angiography and valvuloplasty were completed in a controlled manner. Subsequently, the valve, which will be implanted, was delivered under rapid pacing, with a support wire and implanted on the aortic annulus after ensuring that the valve was on the right place. Lastly, the operation was evaluated for operation success and complications associated with aortic root angiography (Fig. 2). Patients were evaluated for treatment success and adverse effects during hospitalization and the 30-day follow-up period.

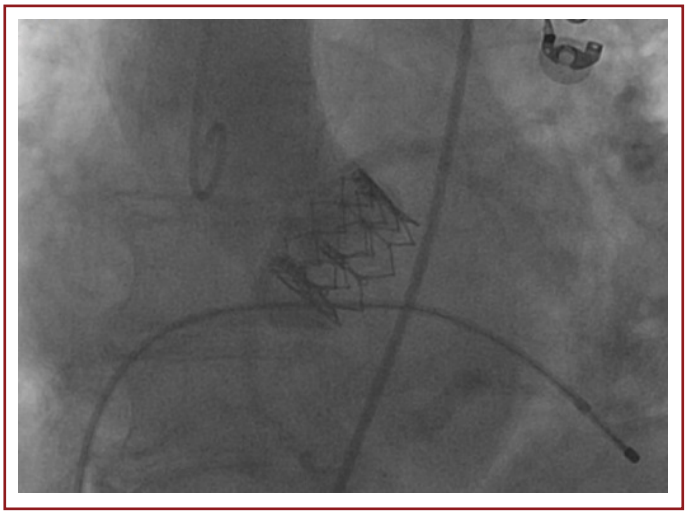

Figure 2. Aortic root angiography at the end of transaortic valve replacement.

Results

This study included a total of 33 patients (18 males, 15 females) with a median age of 78.2 (range: 62–92) years. TAVR was performed for only two patients under general anesthesia, and the remaining patients were administered local anesthesia under deep conscious sedation. Valve implantation was successfully performed for all patients. The valve size, which was selected according to TEE, was increased in only one patient after evaluating the tomographic images. Cardiac arrest immediately after valve implantation occurred in one patient, who had died on the operation table. This female patient had surgical aortic valve replacement (bioprothes) 12 years prior to the procedure. There was no abnormality with this patient's aortal root angiography, which was acquired during resuscitation. Two of the remaining patients died during the hospitalization period. In one of these patients, the presence of partial annulus rupture was observed. In the other patient, the blood pressure remained low, and the patient died 6 days postoperatively due to cardiogenic shock. There were no further deaths at the 30th after the surgery.

The operation success, type of anesthesia, hospitalization period, and characteristics of the used valve were recorded. The results regarding the operation success are summarized in Table 2. Patients were evaluated during the operation and hospitalization period for possible complications. Peripheral artery laceration occurred in the main femoral artery in two patients, and surgical repair was performed without any additional adverse events at follow-up. Critical orthopnoea occurred in one patient after 1 month. In this patient, dynamic obstruction at the level of left ventricle outflow was determined via echocardiography. Later, septal alcohol ablation was performed for this patient (Fig. 3). The patient's complaints markedly recuperated, and the left ventricle outflow gradient decreased from systolic 121 mmHg to 28 mmHg. Pericardial effusion occurred in one patient possibly due to temporary pacemaker electrode perforation, and pericardiocentesis was performed for this patient who had an uneventful course during hospitalization. The complications of the patients are summarized in Table 3.

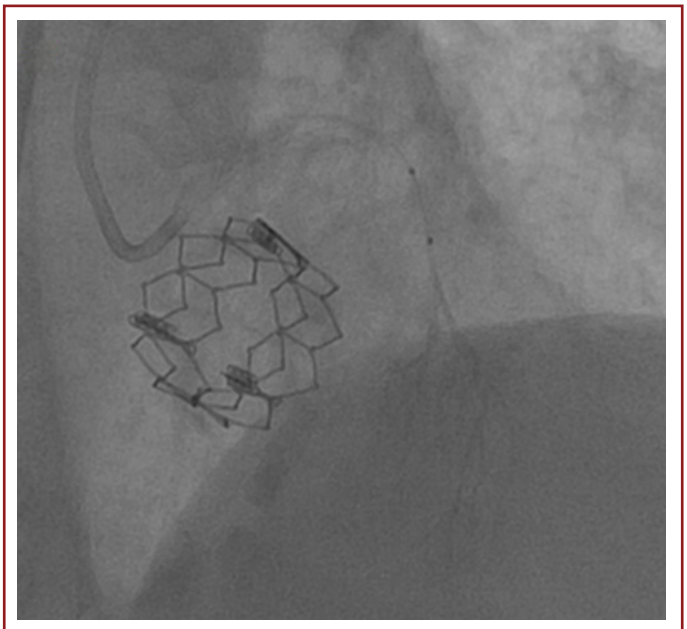

Figure 3. Septal alcohol ablation for the patient who developed dynamic left ventricle outflow tract obstruction.

Table 2. Intervention-related results

	n	%
Death		
In-hospital	3	9
After hospitalization (30 days)	0	0
Anulus rupture	2	6
Cardiogenic shock	1	3
Pericardial effusion	2	6
Vascular complication	1	3
AV Block	2	6
Hematoma	0	0
Major bleeding	0	0
Infection	0	0
Stroke	0	0
Transient Ischemic Attack	0	0
Permanent pacemaker	0	0

AV Block: Atrioventricular Block.

Table 3. Attributes of complications observed in patients

	n (33)	%	Mean±SD
Hospitalization period (days)			3.6 ±2.1
Cover number			
23	12	36.5	
26	10	30	
29	11	33.5	
Aortic annulus diameter (mm)			
TEE	33	24.5 ± 3.1	
CT	27	27.2 ± 4.4	
Interference path			
Transfemoral	31	94	
Transsubclavian	2	6	
Transapical	0	0	
Type of anesthesia			
General	2	6	
Local	31	94	

CT: Computed Tomography; TEE: Transe sophageal Echocardiography.

The hemodynamical success of the operation was evaluated with invasive transaortic gradient measurement at a catheterization laboratory and non-invasive echocardiography before and after TAVR. The clinical success was evaluated according to the improvement in New York Heart Association (NYHA) classification scores, which were evaluated 1 month preoperatively and postoperatively. The hemodynamic and clinical success criteria are summarized in Table 4.

Discussion

The outcomes of TAVR performed at a single institution for patients with critical AS are discussed in our study. TAVR was performed with a 91% success rate in 33 patients. Although three patients died during the hospitalization period, no further deaths occurred during the follow-up period.

TAVR is a treatment modality developed as an alternative to surgery for patients with high surgical risk. In particular, patients at a high risk of perioperative death and patients who may experience technical difficulties during surgery due to adherences from previous mediastinal surgeries are priority candidates for TAVR [6]. Randomized research on this high-risk patient group shows that TAVR is a good alternative to surgery. According to the pioneer study of this field, PARTNER-1, the operation mortality for the TAVR branch was lower than that for the surgery branch (6.5% vs 3.4%, p=0.07). However, the development of a cerebral event was higher in the TAVR branch than in the surgery branch (2.4% vs 5.5%, p=0.04) [7]. Another randomized study reported a similarity in the mortality between TAVR

Table 4. Pre- and post operative hemodynamic and clinic success criteria of patients

	Preoperative	Postoperative	p
Aortic gradient (mmHg) Maximum	80.3±18.5	15.4±4.5	<0.01
Medium	51.5±14.6	9.16±2.7	<0.01
Aortic valve area	0.7±0.1	1.65±0.15	<0.01
EF	47.9 ± 15.7	50.8±14.2	<0.01
Severe AI (n)	3	0	0.4
FC	3.2±0.3	2.1±0.5	<0.01

AI: Aortic Insufficiency; EF: Ejection Fraction; FC: Functional Capacity.

and surgery [8]. The patients in our study population were also at a high surgical risk or belonged to a prohibitive risk group. The mortality ratio for our patient cohort was slightly higher than that reported in the literature. Relating to this issue, Webb et al. categorized their TAVR experiences as first and second term; they found the first term's operational success as 89% and the 30-day mortality ratio as 14%, whereas the second term's operational success was 99% and the mortality ratio was 8% [9]. The patients in the present study were our first cases, and our results were similar to the first term results reported by Webb et al.

Cardiac tomography and TEE were performed for all patients before the operation. TEE was used as the main measurement method for determining the valve size. A correlation between TEE and cardiac tomography was also examined. The chosen valve was implanted in 32 out of 33 patients, and after cardiac tomography evaluation, the valve size in one patient was increased. In a related study, the annulus diameter measured by tomography was larger than the normal size in 72.2% of the patients, whereas TEE measurements were smaller than the normal size in 51.1% of the patients. When the two methods were combined, while the ratio of mismeasuring the annulus diameter smaller than normal decreased to 0%, mismeasuring it larger than normal was reduced to 4.4% [10]. The aortic annulus diameter size measured at the mid-systole using a good visual with TEE from a 120-degree longitudinal axis incision is adequate and efficient for determining the valve size. In addition, better results can be established regarding aortic annulus through interpreting combined measurements obtained from deep gastric and short axis sections [11].

Switching to a bigger valve size is optional depending on whether the aorta shown at the control aortography during the balloon valvuloplasty before TAVR is blocked by the balloon and whether there is aortic insufficiency. If the operation is decided with a valve size bigger than that of

the valve to be implemented, there may be no chance of fixing the valve; however, thanks to valvuloplasty, the valve can be switched from a bigger size to a smaller one. In fact, tomography is better than TAVR in terms of being able to show both iliofemoral and calcification loads around the aortic annulus [12]. Our results are compatible with the foregoing article. We believe that the valve size can be determined more accurately using a combination of cardiac tomography and TEE rather than cardiac tomography alone.

We also examined the complications developed in our patients. TAVR-related complications were reduced as a result of increased operator experience and technical developments [13]. However, TAVR-related complications could not be reduced to the desired level, owing to the abundance of comorbid factors in our patient cohort and the aggressive nature of the operation. Three patients died due to acute complications. Two of them were related to annulus rupture. Annulus rupture is not rare and is usually unforeseen; therefore, it is the most lethal TAVR-related complication. The most important risk factors for annulus rupture are as follows: small annulus and sinotubular intersection size, intense calcification load, use of the balloon-expandable valve, and application of aggressive pre/post dilatation. When annulus rupture occurs, pericardiocentesis and autotransfusion must be performed, and the patient must undergo surgery for repair [14]. In one of our patients who developed annulus rupture, upper left coronary sinus was observed to be underdeveloped in comparison to the non-coronary sinus, and there was intense calcification load around the aortic annulus. A valve with a predilatation of approximately 29 mm was implanted in this patient. When the patient's blood pressure decreased 20 min after valve implantation, an acute complication was suspected, and TTE was applied. Pericardiocentesis and autotransfusion were initiated after observing pericardial effusion. As the patient's hemodynamic results had not improved, the patient immediately underwent surgery. Although the rupture was mended with annulus repairing, the patient died. The other patient who developed annulus rupture was an 85-year-old woman. A 23-mm valve was implanted in this patient. Annulus rupture immediately after the valve implantation was observed on control aortography. The patient developed sudden cardiac arrest and did not respond to resuscitation. Self-expandable valves are more preferred than balloon-expandable valve for patients at a high risk of annulus rupture [14]. However, according to our preoperative evaluation, our patients were not at a high risk of annulus rupture. TAVR Another important TAVR-related complication is arterial injury at the entry point. In particular, iliac artery rupture can cause abundant bleeding in the retroperitoneal area, which can result in lethal consequences. The most important factor to prevent occurring of these complications is to assure that the arterial entry site is large enough. Calcification intensity and distribution also increase the likelihood of arterial injuries. To prevent this complication, gradual predilatation of artery must be applied and the wire should provide sufficient support. On the other hand, if it is thought that the risk of rupture/laceration is high, another support wire can be placed on the entry vein through the groin or the arm before implanting the sheath. In case of iliofemoral rupture developed during the operation, the graft stent can be rapidly moved through this wire, and a lethal complication can be averted. In one of our patients, longitudinal injuries occurred at the main femoral entry point [15]. Surgical treatment was provided for this patient because he was operated with a surgical cut-down method. There were no arterial alimentation complications during the observation period.

In our study, an 84-year-old female patient developed serious orthopnea 1 month after TAVR (according to NYHA class 4). When the patient's echocardiography was taken, a peak systolic gradient of 121 mmHg was obtained for the left ventricle outflow. TEE was performed for the patient who had been hospitalized. This patient's valve functions were normal, anterior movement of the anterior cusp of the mitral valve was observed during the systole and the left ventricle septum (17 mm) and posterior wall (15 mm) were highly hypertrophic. It was thought that the obstacle in the left ventricle outflow tract developed due to hypertrophic cardiomyopathy physiology Fluid replacement and beta-blocker treatment were initiated for the patient. However, there were no developments according to the patient's clinical charts. After the patient's coronary angiography was observed, septal alcohol ablation was performed for the first septal coronary artery. After septal alcohol ablation, the patient's conditions dramatically improved. At the end of the first month, the patient's functional capacity was reduced to NYHA class 2, and the peak systolic gradient in the left ventricle outflow tract (LVOT) was reduced to 28 mmHg on echocardiography. LVOT obstruction after TAVR is a newly defined phenomenon. This complication occurs because of hypertrophic cardiomyopathy (HCMP) and critical AS coexisting or HCMP progressing into a more serious obstruction because of the decline in post-TAVR after load. Septal alcohol ablation must be opted for patients with suitable coronary anatomy if clinical improvement cannot be achieved with conservative treatment precautions such as intravenous fluid replacement and beta-blockers. When

LVOT obstruction occurs after TAVR, aside from the development of valve thrombosis and valve dysfunction, this new phenomenon must also be considered [16].

TAVR is the most efficient and safest treatment modality for patients at high-risk surgical AS. TEE is a complementary and irreplaceable element for cardiac tomography when determining the valve size and operation strategy.

Ethics Committee Approval: Before beginning the study, approval was obtained from the Ethics Committee of Eskişehir Osmangazi University Faculty of Medicine (04.01.2017 - 80558721/6-11).

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

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