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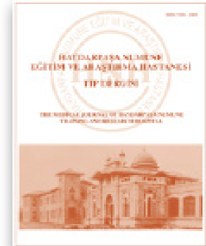

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Original Article

Percutaneous Transcatheter Aortic Valve Replacement for Critical Aortic Stenosis: Single Center Experience

Cengiz Ovalı

Department of Cardiovascular Surgery, Eskişehir Osmangazi University Faculty of Medicine, Eskişehir, Turkey

Abstract

Introduction: We aimed to assess the technical success and early period results of percutaneous transaortic valve replacement in patients with critical aortic stenosis.

Methods: Between November 2014 and June 2016, patients with severe high-risk aortic stenosis who underwent percutaneous transaortic valve replacement were included the study. All the patients received transesophageal echocardiography and cardiac tomography prior to the procedure. Edwards Saphien XT balloon expandable biologic valve was used in all patients. Valve size was selected according to measurements performed by cardiac tomography and trans-esophegal echocardiography. Patients were observed for procedural success and adverse effects during hospitalization and 30-day follow up period.

Results: Median age of 33 patients who were included in the study (18 males, 15 females) was 78.2 (with an age range from 62 to 92). Valve implantation was successfully applied in all patients. Valve size which was selected through transesophageal echocardiography was changed in only one patient with a bigger valve size following cardiac tomography. 3 patients died during the hospitalization period. No more deaths occurred during the 30-day observation period.

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

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

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

The purpose of this manuscript is to report our institutional experience related with PTVR and give information related with procedural success and adverse effects during hospitalization and 30-day follow up period.

Correspondence (İletişim): Cengiz Ovalı, M.D. Department of Cardiovascular Surgery, Eskişehir Osmangazi University Faculty of Medicine, Eskişehir, Turkey

Phone (Telefon): +90 222 239 29 79 **E-mail (E-posta):** drcengizovali@gmail.com

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Materials and Methods

Patients

Between November 2014 and June 2016, Thirty-three patients with severe high-risk aortic stenosis who underwent percutaneous transaortic valve replacement were included the study. The average age of the patients was 78.2 (18 males, 15 females) (Table 1). Before the operation, patients' TEE and cardiac tomography were provided. Edwards Saphien XT (Edwards Lifesciences, Irvine, CA) biologic valve was implanted to all patients who were agreed to have the PTVR. 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 transesophageal echocardiography evaluation of all the patients were carried out before and after PTVR operation. Aortic annulus, sinus valsalva, sinotubular production and resulting aortic diameters were measured with TEE at midsystole (Fig. 1). Transvalvular systolic and median gradients through aortic valve were measured by transthoracic echocardiography by using continuous-wave Doppler. Ejection fraction belonging to the left ventricle was measured with modified-Simpson method.

Cardiac CT analyses: Before the PTVR operation cardiac tomography was applied for detailed examination of all patients' aortic annulus, aorta and peripheral branches. Aortic annulus area and area-based annulus measurements were made from where the valves cleave into each other. Aorta and calcification load and distribution of iliac arteries, artery diameter, and detailed anatomical evaluations were made regarding the vein tortuosity.

Table 1. Clinical and demographic attributes of the patients

	n (33)	%
Age (Year)	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.

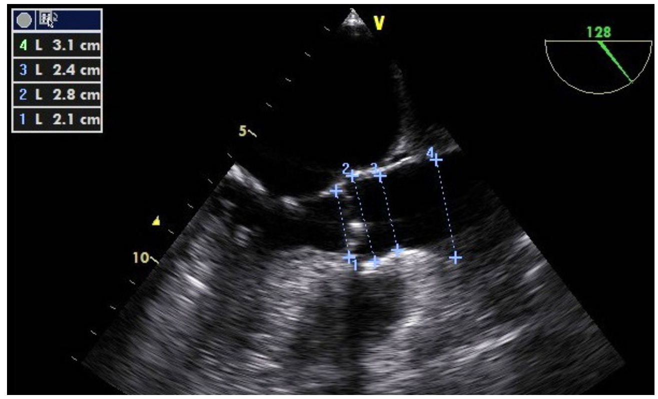

Figure 1. Measurements of midsystolic aortic annulus, sine valsalva, sinotubular product and resultant aortic diameters at transesophageal echocardiography longitudinal ax section.

Angiographic Analyses and PTVR Operation

PTVR operation was done under a conscious sedation and local anesthesia. General anesthesia was not given to any of the patients unless it was needed. Pace maker electrode was implanted on the right ventricle through femoral artery or internal jugular. Aortic root was reached inside from 6F sheat by pigtail catheter. The big sheath which the prosthesis valve will be carried over to was placed on right or left main femoral artery. With the guidance of angiography done by pig-tail catheter which was placed on aortic root, left ventricle was reached by carrying over the aorta valve performed by a 0.035 inch thick guide wire sent through AL2 or 3 diagnostic catheter. After that, this wire replaced with a long, hard wire through pig-tail catheter. And after, to apply valvuloplasty to the area which had aortic stenosis, valvuloplasty balloon was positioned. Systolic blood pressure was dropped below <50 mmHg by rapid pacing (180-210/min) through right ventricle. At the same time, the balloon was fully expanded and aortic root angiography and valvuloplasty operations were completed in a controlled manner. After that, the valve which will be implanted was delivered under rapid pacing, with a support wire and implanted on the aortic annulus after making sure that it was on the right place for the valve. At the end, operation was evaluated regarding operation success and complications with aortic root angiography (Fig. 2).

Patients were observed for treatment success, adverse effects during hospitalization and in a 30-day period thereafter.

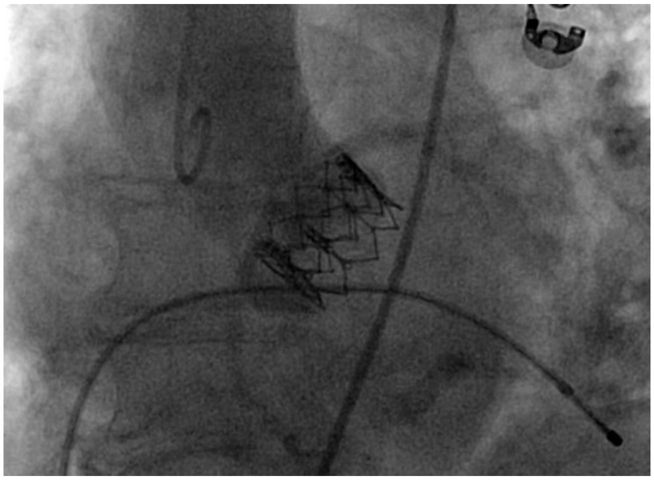

Figure 2. Aortic root angiography at the end of transaortic valve replacement operation.

Results

Median age of 33 patients who were included in the study (18 males, 15 females) was 78.2 years (with an age range from 62 to 92). PTVR operation was applied to only 2 patients under general anesthesia and all the other patients were given local anesthesia under deep conscious sedation. Valve implantation was successfully applied to all patients. Valve size which was selected via transesophageal echocardiography was changed on only one patient with a bigger valve size after evaluation of tomographic images. Cardiac arrest right after the valve implantation occurred in one patient and the patient died on operation table. This female patient had surgical bioprothesis AVR 12 years prior to procedure. There was no abnormality with this patients aortal root angiography which was acquired during resuscitation. Two of the remaining patients died during hospitalization period. In one of these patients, presence of partial annulus rupture had been observed. Other patient's blood pressure remained low and died 6 days after the operation due to cardiogenic shock. There were no more deaths at the 30th day of the polyclinic controls.

Operation success, type of anesthesia, hospitalization period and characteristics about the used valve were recorded. Results regarding the operation success were summarized on Table 2. Patients were observed during operation and hospitalization period for possible complications. Peripheral artery laceration occurred on 2 patient's main femoral artery and surgical repair was applied to these 2 patients without any additional adverse events at follow up. Critical orthopnoea occurred on a patient after 1 month. Dynamic obstruction at the level of left ventricle outflow was determined through echocardiography examination of this patient. Later, septal alcohol ablation was applied to this patient (Fig. 3). Patient's complaints dramatically got better, left ventricle outflow gradient dropped from systolic 121 mmHg to 28 mmHg. Pericardial effusion occurred in one patient possibly due to temporary pacemaker electrode perforation and pericardiocentesis was applied to that patient with uneventful course during hospitalization. Complications of patients were summarized on Table 3.

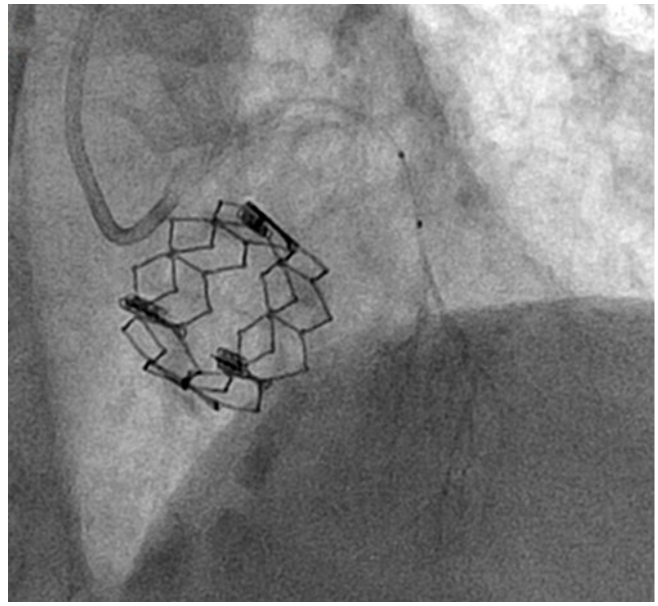

Figure 3. Septal alcohol ablation operation to the patient who developed dynamic left ventricle outflow tract obstruction.

Hemodynamical success of the operation was evaluated

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 on patients

	n (33)	%	mean±std
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: Computerize Tomography; TEE: Trans Esophageal Echocardiography.

Table 4. Pre- and post operation hemodynamic and clinic success criterions belonging to the patients

	Preop	Postop	p
Aortic gradient (mmHg)	80.3±18.5	15.4±4.5	<0.01
Maximum			
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.

with invasive transaortic gradient measurement at catheterization laboratory and non-invasive echocardiography, before and after PTVR. Clinical success was evaluated according to the improvement in New York Heart Association (NYHA) classification which was evaluated one month before and after the operation. Hemodynamic and clinical success criteria were summarized at the Table 4.

Discussion

First institutional PTVR results of the patients with critical AS were discussed in our study. PTVR operation was applied with 91% success rate to 33 patients. Although 3 of the patients died during the hospitalization period, no more deaths occurred during follow up period.

PTVR operation is a treatment method developed as an alternative to surgery for patients with high surgical risk. Especially patients at high perioperative death risk and patients who may experience technical difficulties in surgery due to adherences from previous mediastinal surgeries are priority applicants for the PTVR [6]. Randomized research on this high risk patient group shows that PTVR is a good alternative to surgery. Operation morality at PTVR branch was considered low compared to surgery during the pioneer study of this field, PARTNER-1 (6.5% vs 3.4%, p=0.07). But cerebral event development was higher at the PTVR branch (%2.4 opposed to %5.5, p=0.04) [7]. Morality similarity between PTVR and surgery was observed during another randomized study [8]. Patients in our study population were also the patients at surgical high risk or patients in prohibitive risk group. Our patient group's morality ratio was slightly higher compared to the literature. Relating to this issue, Webb et al.[9] categorized their PTVR experiences as first and second term; where they found the first term's operational success as 89% and 30 days morality ratio as 14% while the second term's operational success was 99% and morality ratio was 8%. Our patients were our first cases and our results were similar to Webb et al.'s first term results.

Cardiac tomography and TEE were performed on all patients before the operation. TEE was used as the main measurement method for determining the valve size. Correlation between TEE and cardiac tomography was also examined. Chosen valve was applied to 32 out of 33 patients and it was decided to change one patient's valve size to a bigger one after cardiac tomography evaluation. In a related study, tomography measured the annulus diameter bigger than the normal size in 72.2 % of the patients while TEE measured tomography diameter smaller than the normal size in 51.1% of the patients. When the two methods combined, the ratio of mismeasuring the annulus diameter dropped to 0% and ratio of mismeasuring the annulus diameter to 4.4% [10]. Aortic annulus diameter measured at midsystole by providing a good visual with TEE from 120-degree longitudinal ax incision is adequate and efficient for determining aortic annulus diameter valve size. Also better results can be obtained by getting and interpreting results regarding aortic annulus from deep gastric and short axis incisions [11]. Switching to a bigger valve size is optional depending on whether the aorta shown at the control aortography during the balloon valvuloplasty before PTVR is blocked by the balloon and whether there is aortic insufficiency oozing. we do not have a chance to fix the valve if it is decided to proceed with a size bigger for the valve to be implemented; but thanks to valvuloplasty, we can switch from a bigger valve to a smaller one. In fact, tomography is better than PTVR in terms of being able to show both iliofemoral and calcification load around the aortic annulus much better [12]. Our results are compatible with the foregoing article. We think that combining cardiac tomography with TEE to determine the valve size can be more accurate rather than determining with cardiac tomography alone.

We also examined the complications developed in our patients. PTVR-related complications were reduced as a result of increased operator experience and technical developments [13]. PTVR-related complications couldn't be reduced to the desired level because of the abundance of patients' co-morbid factors and the aggressive nature of the operation. 3 of our patients passed away because of acute complications. Two of them were related to annulus rupture. Annulus rupture is not rare and most of the time is unforeseen, therefore it is the most lethal PTVR-related complication. The most important risk factors for the annulus rupture are; annulus and sinotubular intersection size being small, intense calcification load, using the balloon expandable valve and application of aggressive pre/post dilatation. When the annulus rupture occurs, pericardiocentesis and autotransfusion must be performed and the patient must be taken to surgery for repair [14]. In one of our patients who developed annulus rupture, upper left coronary sinus was observed to be underdeveloped compared to the non-coronary sinus and there was intense calcification load around the aortic annulus. This patient was implanted a valve with a predilatation of approximately 29 mm. When the patient's blood pressure dropped 20 minutes after valve implantation, TTE was applied with the suspicion of acute complication. Pericardiocentesis and autotransfusion was started to be applied after observing pericardial effusion. As the patient's hemodynamic results were not improved, the patient was immediately taken to surgery. Even though the rupture was mended with annulus repairing, the patient died. Other patient who developed annulus rupture was an 85 year old woman. This patient was implanted a 23 mm valve. Annulus rupture right after the valve implantation was seen on control aortography. The patient developed sudden cardiac arrest and did not respond to resuscitation. Self-expandable valves should be preferred rather than balloon expandable valve for patients at high annulus rupture risk [14]. But according to our pre-operation evaluation, our patients did not represent high risk for annulus rupture. It should be acknowledged that PTVR is not a perfect treatment method which has completed its evolution.

Another important PTVR related complication is arterial injuries regarding the entry point. Especially iliac artery rupture can cause abundant bleeding to the retroperitoneal area which can have lethal consequences. The most important issue which must be paid attention to prevent this complication is making sure that arterial way which will be the entry point has enough width. Calcification intensity and distribution also increase the likelihood of arterial injuries. To prevent this complication, gradual pre-dilatation must be applied and sufficient support wire must be used. On the other hand, if it is thought that rupture/laceration risk is high, another support wire can be placed on the entry vein through groin or arm before implanting the sheath. In case of iliofemoral rupture developing during the operation, graft stent can be moved through this wire with haste and a lethal complication can be averted. In one of our patients, longitudinal injuries occurred at the main femoral entry point [15]. This patient's treatment was also surgical because he was operated with surgical cut-down method. There were no arterial alimentation complications during the observation.

In our study, an 84 year old female patient developed serious orthopnea 1 month after the PTVR operation (according to NYHA class 4). When the patient's echocardiography was taken, 121 mmHg peak systolic gradient was measured on the left ventricle outflow. TEE was applied to the patient who had been hospitalized. Patient's valve functions were normal, anterior mitral folium's movement towards front (SAM) was observed during systolic, the left ventricle septum (17 mm) and posterior wall (15 mm) were highly hypertrophic. It was thought that the obstacle on the left ventricle outflow tract developed due to hypertrophic cardiomyopathy physiology. Fluid replacement and beta-blocker treatment started for the patient. But there were no developments on patient's clinical charts. After patient's coronary angiography was observed, septal alcohol ablation was applied to the 1st septal coroner artery. After the septal alcohol ablation, patient dramatically improved. At the end of the first month, the patient's functional capacity was reduced to NYHA class 2 and left ventricle outflow tract (LVOT) peak systolic gradient was reduced to 28 mmHg at her echocardiography. LVOT obstruction after PTVR operation is a newly defined phenomenon. This complication occurs because of hypertrophic cardiomyopathy (HCMP) and critical AS co-existing or HCMP turning into a more serious obstruction because of the decline in post-PTVR after load. Septal alcohol ablation is the treatment which must be opted for patients with suitable coroner anatomy if clinical improvement cannot be achieved with conservative precautions such as intravenous fluid replacement and beta-blockers. When LVOT occurs post-PTVR, aside from the development of valve thrombosis and valve dysfunction, this new phenomenon must also be considered [16].

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

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Conflict of Interest: None declared.

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