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ORIGINAL ARTICLE

Experiences of Transcatheter Aortic Valve Implantation with Severe Aortic Stenosis

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Abstract

Introduction: Aortic stenosis is the most common and dangerous native valve disease and it affects 2-4% of the patients over 65 years of age. However, the surgical procedure leads the patients to undergo great risks, especially in the elderly population and in patients with concomitant disorders. In this retrospective study, we described and analyzed our experience on TAVI procedures performed in our hospital.

Methods: After the approval of the Ethics Committee to conduct this study, patients' files from June 2012 to December 2014 were reviewed retrospectively and first 100 patients' demographic data, STS, EuroSCORE, aortic valve pressure gradients, the methods of anesthesia and monitoring and postoperative complications were collected. All of the data were expressed as mean±standard deviation.

Results: Among 100 remaining patients, on whom data were collected, mean age was found as 78.6±6.7 years and 65 of the patients were female. The mean pulmonary artery pressure was 46.9±14.2 mmHg and mean pressure gradient (PG) was 48.8±10.7 mmHg, whereas the peak PG was 75.5±17.1 mmHg before the TAVI procedure; left ventricular ejection fraction before the TAVI procedure was calculated as 51.2±14.2%. Analysis of the patient charts revealed a mean value for STS as 7.8±4.7 and a mean value for EuroSCORE as 34.9±14.1%. In all patients, a probe for transesophageal echocardiography was inserted for real-time monitoring, together with a temporary pacemaker. Implanted valves were expandable CoreValve in 56%, and the Edwards Sapiens XT Valve in 43%. Following completion of the procedure, final femoral angiography was performed to verify that there were no vascular injuries. The patients were transferred coronary ICU after extubation. During postoperative period, minor complications were encountered in 11% of the patients.

Discussion and Conclusion: The findings showed that TAVI was a procedure with a low rate of complications in patients with severe aortic stenosis when the steps of the procedure had been followed meticulously, according to the results of our retrospective study. The anesthesiologist should be a key member of the staff prior, during, and following the intervention. The ongoing prospective trials and retrospective research together with the debate on indications, type of the anesthesia, location where the procedure is held will shed light on the evolvement of this relatively novel technique.

Keywords: Aortic Valve Implantation; aort stenosis; transcatheter.

Aortic stenosis (AS) is the most common and dangerous native valve disease and it affects 2-4% of the patients over 65 years of age [1]. Aortic valve replacement (AVR) via a sternotomy, using cardioplegia and cardiopulmonary bypass (CPB), is considered as the gold standard of treatment with low perioperative morbidity and mortality for patients with symptomatic AS [2]. However, the surgical procedure leads the patients to undergo great

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risks related to sternotomy or thoracotomy, CPB, cardiac arrest and general anesthesia (GA), especially in the elderly population and in patients with concomitant disorders [3]; elderly patients with AS have high mortality (4%-18%) during AVR due to the increased rate of concomitant disorders, such as severe left ventricular dysfunction, renal and respiratory disorders [4].

Severe AS is defined as either an aortic valvular area of fewer than 1 cm 2 or a mean pressure gradient of the aortic valve of greater than 40 mmHg in echocardiography [5]. At least 30% of the patients with severe symptomatic AS are not able to undergo AVR due to their advanced age and concomitant disorders [6].

Since 2002, transcatheter aortic valve implantation (TAVI) has been implemented as a less invasive alternative to AVR in high-risk patients and a new standard of care in inoperable patients [6]. Today, TAVI is considered as a safe and effective treatment for patients with severe AS with high surgical risk [7].

In this retrospectively conducted study, we described and analyzed our experience on TAVI procedures, performed in our hospital.

Materials and Methods

Following the approval of the Ethics Committee, the charts of the patients between June 2012 and December 2014 were reviewed retrospectively. Data regarding the date that the TAVI procedure was performed, age, gender, height, weight, comorbidities (diabetes mellitus, hypertension), STS, EuroSCORE, aortic valve maximal pressure gradient, pre-TAVI mean pressure gradient, pre-TAVI ejection fraction, pre-TAVI pulmonary arterial pressure, the methods of anesthesia and monitoring, the type of the prosthetic valve used for implantation, the type of femoral access and postoperative complications were collected. Body mass index (BMI) was calculated, and all of the data were expressed as mean±standard deviation.

Results

TAVI was performed in a total of 101 patients between June 2012 and December 2014. In one patient, no data other than age, gender and the type of valve were available and that patient was excluded from the study group. Among 100 remaining patients on whom data was collected, the diagnosis was acquired aortic stenosis in all. The mean age was found as 78.6±6.7 (range 55-91) years and the female/male ratio was 65/35. The average height was 160.5±9.5 (range 138-180) cm, and the average weight was 66.3±11.8 (range 45-86) kg. BMI was calculated to have a mean value of 25.7±4.3 (range 20-37). Regarding comorbidities, arterial hypertension was found to be diagnosed in 86% of the patients, whereas diabetes mellitus was present in 25% of the patients. The demographic and clinical characteristics, together with their comorbidities, were presented in Table 1.

Data review showed that the mean pulmonary artery pressure (PAP) was 46.9±14.2 (range 25-80) mmHg. The mean pressure gradient (PG) was 48.8±10.7 (range 28-75) mmHg, whereas the peak PG was 75.5±17.1 (range 39-120) mmHg before the TAVI procedure; left ventricular ejection fraction (LVEF) before the TAVI procedure was calculated as 51.2±14.2 (range 20-74) %. Regarding risk scoring, analysis of the patient charts revealed a mean value for STS as 7.8±4.7 (range 1.9-27.2) and a mean value for EuroSCORE (European System for Cardiac Operative Risk Evaluation) as 34.9±14.1 (range 4.6-65.7) %. The risk scorings, ejection fractions, mean/peak pressure gradients, pulmonary arterial pressures of the patients before the TAVI procedure, together with the valve type, methods for femoral access and postoperative complications were presented in Table 2. Intraoperative vasopressor use and complications presented in Figure 1 and intraoperative red blood cell (RBC) usage has shown in Figure 2.

In the chart review, it was found that a preoperative combined meeting with cardiologists and cardiothoracic surgeons, in which the indication, medical status and management of the patient would be discussed, was held before every TAVI procedure, in our hospital. The site where the TAVI procedure was performed was found to be always the Interventional Cardiology Laboratory (Coronary Angiography Room). Standard monitoring, which is recommended by American Society of Anesthesiologists (ASA) and in-

Table 1. Demographic and clinical characteristics of our patients

	n	%	Mean±SD (range)
Age (years)			78.6±6.7 (55–91)
Gender			
Female	65	65	
Male	35	35	
Height (cm)			160.5±9.5 (138–180)
Weight (kg)			66.3±11.8 (45–86)
Body mass index (kg/m^2)			25.7±4.3 (20–37)
Hypertension	86	86	
Diabetes mellitus	25	25	

Table 2. Risk scorings, pre-TAVI mean and peak pressure gradients, valve types, femoral access route and postoperative complications of the patients

	n	%	Mean±SD (range)
Pre-TAVI EF (%)			51.2±14.2 (20–74)
Pre-TAVI mean PG (mmHg)			48.8±10.7 (28–75)
Pre-TAVI peak PG (mmHg)			75.5±17.1 (39–120)
Pre-TAVI PAP (mmHg)			46.9±14.2 (25–80)
STS			7.8±4.7 (1.9–27.2)
Logistic EuroSCORE (%)			34.9±14.1 (4.6–65.7)
Valve Type			
CoreValve	56	56	
Edwards Sapiens	43	43	
Method of femoral access			
Percutaneous femoral access	28	28	
Femoral arterial cut-down	82	82	
Postoperative complication	11	11	

pre-TAVI: before transcatheter aortic valve implantation; EF: ejection fraction; PG: pressure gradient; STS: The Society of Thoracic Surgeons score; EuroSCORE: European System for Cardiac Operative Risk Evaluation.

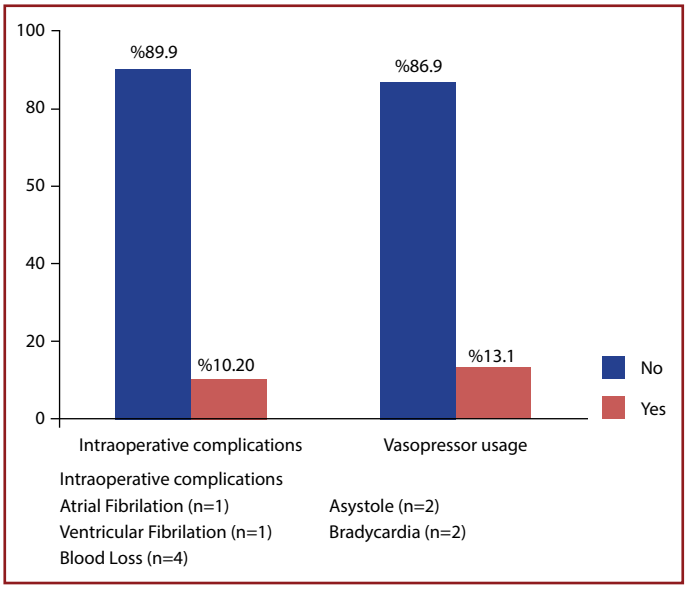

Figure 1. Intraoperative Complications and intraoperative vasopressor usage.

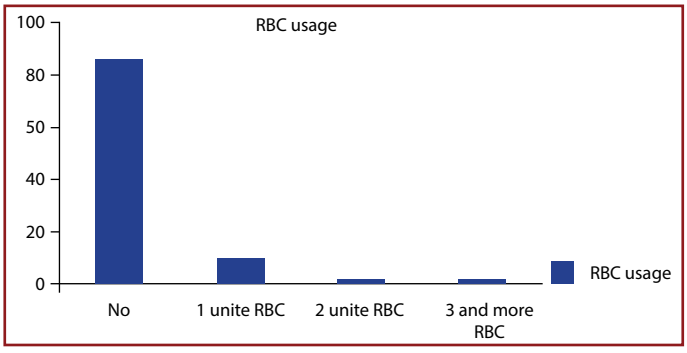

Figure 2. Intraoperative Red Blood Cell (RBC) usage.

cluded heart rate, blood pressure, SaO_2, end-tidal CO_2, and ECG was determined to be initiated together with insertion of a urinary catheter for measurement of the urinary output, insertion of a centrally- extended peripheral catheter for measurement of central venous pressure before the induction of anesthesia. In all patients, general anesthesia (GA) was found to be the preferred method. Following the induction of GA with thiopental (4-7 mg/kg) and fentanyl (1-2 mcg/kg), endotracheal intubation was performed. Maintenance of anesthesia was provided by sevoflurane 2%+ air 50%+ O_2 50%.

In all patients, a probe for transesophageal echocardiography was inserted for real-time monitoring of the TAVI procedure, together with a temporary pacemaker, following induction of anesthesia. Our retrospective analysis revealed that femoral angiography and aortic angiography were performed to assess the status of the vessels and coronary arteries. Transesophageal echocardiography (TEE) was performed for the reassessment of cardiac anatomy/function together with valvular parameters and continued throughout the procedure. The balloon aortic valvuloplasty (BAV) using fluoroscopy was found as the next step of the procedure. Then, the TAVI procedure was completed by insertion of the prosthetic valve with the proper size. The expandable CoreValve (Medtronic Inc., Minneapolis, MN, USA) was implanted in 56 (56%) of the patients, and the Edwards Sapiens XT Valve (Edwards Life Sciences, Irvine, CA, USA) was implanted in 43 (43%) of the patients. For both steps, femoral arteries were found to be used. The access through the femoral artery was achieved percutaneously in 28 (28%) of the patients, whereas the cut-down procedure performed by the Cardiovascular Surgery Team was used in the rest of the patients. Rapid ventricular pacing was used during the steps of BAV and prosthetic valve insertion in all patients. Norepinephrine was used when required.

Our chart review revealed that, following completion of the procedure, final femoral angiography was performed to verify that there were no vascular injuries. Then, the patients were extubated and transferred to the Coronary Intensive Care Unit. No sedation was used. The temporary pacemaker was removed as soon as it was confirmed to be unnecessary. The patients were transferred from the Coronary Intensive Care Unit on the 3rd or 4th post-interventional day. During the postoperative period, complications were encountered in 11 (11%) patients.

Discussion

Since the first percutaneous antegrade transseptal implantation of the aortic valve prosthesis in 2002 by Cribier et al. [8], TAVI has increasingly become a useful option, initially for the patients with relative contraindications for open surgery, and then, as an alternative to elective open surgery. However, it is not a complication-free procedure, and the technique and the used materials and equipment are still evolving.

Today, it is an intriguing but a robust procedure for the anesthesiologists. An extensive evaluation should be performed by the anesthesiologist before the TAVI procedure. Preferably, a preoperative meeting with contributions of anesthesiologists, cardiologists and cardiovascular surgeons is a preferable step for better assessment of the patient. In our hospital, our policy has been to discuss in detail the indications, comorbidities, risk scoring and perioperative anesthetic/interventional planning for each TAVI candidate in a preoperative meeting with cardiologists and cardiovascular surgeons.

During this evaluation process, the anesthesiologist should concentrate on factors predicting the stability of the procedure, such as LVEF, PAP and mean and peak PG, together with concomitant disorders such as diabetes mellitus and arterial hypertension.

Advanced age, elevated BMI, present comorbidities, and presence of severe aortic stenosis are all high risks for AVR, suggesting to be considered within the indications for TAVI. One of the major criteria defining severe aortic stenosis is the mean pressure gradient of the aortic valve being greater than 40 mmHg in echocardiography [5]. The mean age of our TAVI patients was 78.6, which was the border between middle-old and very-old age groups. Mean BMI of our patient group was 25.7, which showed that the majority of the group had overweight characteristics. Regarding comorbidities, 86% of the group had arterial hypertension, and 25% had diabetes mellitus, which both increased the risk for AVR. The mean pressure gradient of our patients was 48.8, and it revealed that severe aortic stenosis was present in the majority of our patients.

The best individual risk assessment can be made using a combination of objective quantitative models named EuroSCORE "European System for Cardiac Operative Risk Evaluation (EuroSCORE)" and STS "The Society of Thoracic Surgeons (STS)"[9]. When logistic EuroSCORE value is ≥20% and/or STS value is ≥10%, it is suggested to be above the high-risk threshold value and the European Society recommends TAVI [10]. The mean logistic EuroSCORE value of our patients was 34.9 and consistent with the recommendations of European Society, TAVI was performed. However, the mean STS value of our patients was 7.8 and the group did not have the indication in terms of STS scoring. This may be due to the reported inconsistency between EuroSCORE and STS Scorings, both of which were not constituted for TAVI, but for determination of high-risk cardiac patients, in general; they do not take into account the risk factors specific to TAVI, such as porcelain aorta or frailty [6].

Regarding the anesthetic methods which are usable for TAVI procedure through the transfemoral route, two methods are valid today: GA with endotracheal intubation or local anesthesia with conscious sedation. Both methods have their own benefits, such as availability of TEE during GA or prevention of hemodynamic instability during conscious sedation [6]. Our preference was GA with endotracheal intubation as the anesthetic method in all of our patients since TEE was used during the procedure. Our results with GA were acceptable in our 57 patients and we encountered no anesthesia-associated complication in any of them.

Since a stable balloon position is required during BAV and a stable device position is required during valve deployment, rapid ventricular pacing (RVP) has been considered as an indispensable step for both BAV and deployment of the prosthetic valve [6], to accomplish them reliably and successfully. RVP has been suggested to be used with rates of 160-220 beats per minute. We also used RVP in all of our cases with the same purpose and the recommended rates.

The depression of cardiac output and the impairment of hemodynamic status have been reported as major complications of RVP, especially in the presence of concomitant disorders in patients with AS [5, 11]. Vasopressor or inotropic support, intra-aortic balloon pump, or even cardiopulmonary bypass are management options for handling such major complications. Some authors have reported using a bolus dose of norepinephrine before RVP for avoiding these complications [5]. Some others have suggested administration of a bolus dose of etilefrine when mean arterial pressure could not be maintained above 65 mmHg by volume management alone, when more than four boluses were necessary, their preference was the continuous infusion of norepinephrine [3]. We did not prefer using norep-

inephrine in a routine manner and administered it when required during the procedure.

Imaging techniques, such as high-resolution fluoroscopy, contrast angiography and TEE, have been considered as essential components for successful management in terms of TAVI. Among these, TEE was considered to have the utmost importance as a baseline investigation and also throughout the procedure by Billings et al. [12], which was the reason for them to suggest that GA was mandatory. However, they also interpreted that the TEE probe might have had some interference with fluoroscopy and needed to be withdrawn. Today, there is an ongoing debate on the absolute necessity of TEE. While some authors claim that TEE under GA is mandatory, some other authors claim that if meticulous preoperative high-resolution imaging is performed and diagnosis of AS is confirmed together with the size of the valve, TEE performed just before the procedure may be unnecessary and time spending [1]. We performed TEE throughout the procedure in all of our patients for its benefits, such as assistance in selection, of a correctly-sized prosthesis or early diagnosis and management of complications [13].

In conclusion, we found that TAVI was a procedure with a low rate of complications in patients with severe aortic stenosis when the steps of the procedure had been followed meticulously, according to the results of our retrospective study. The anesthesiologist should be a key member of the staff prior, during, and following the intervention. The ongoing prospective trials and retrospective research, together with the debate on indications, type of the anesthesia, the location where the procedure is held, variations in technique and equipment, etc., will serve to shed light on the evolvement of this relatively novel technique.

Ethics Committee Approval: The Ethics Committee of Dokuz Eylul University provided the ethics committee approval for this study (2016/01-12).

Peer-review: Externally peer-reviewed.

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