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Redo transcatheter aortic valve implantation: Our single-center experience and mid-term outcomes

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ABSTRACT

Objectives: In this study, we present our mid-term outcomes on redo transcatheter aortic valve implantation (TAVI).

Patients and methods: Between June 2012 and May 2019, a total of eight TAVI-in-TAVI patients (2 males, 6 females; mean age: 73.8±3.9 years; range, 66 to 79 year) were retrospectively analyzed. All patients were evaluated for comorbidity, characteristics of the first TAVI valve, indications for redo-TAVI, transthoracic echocardiographic parameters, mortality, pacemaker requirement, and valve function during follow-up.

Results: Five (62.5%) of the patients required a redo-TAVI procedure due to severe aortic regurgitation, while three (37.5%) required a redo-TAVI procedure due to degeneration of the first TAVI valve. The first TAVI valves of the patients were two Portico™, four CoreValve™ and two Edwards SAPIEN™. In redo-TAVI procedures of the patients, four CoreValve™, two Portico™, and two MyVal™ valves were used. The median time after the first procedure was 62 months. One patient had hypertensive pulmonary edema during the procedure and was intubated, and in-hospital mortality occurred due to infectious causes during intensive care follow-up. There was no in-hospital mortality and no need for pacemaker in other patients. There was no mortality at a median follow-up of 31 months after redo-TAVI procedures.

Conclusion: Redo-TAVI procedure is a feasible intervention and can be successfully done in selected patients requiring reintervention due to valve degeneration or severe aortic regurgitation.

Keywords: Aortic stenosis, redo, transcatheter aortic valve implantation.

Transcatheter aortic valve implantation (TAVI) is a well-established and widely used procedure for the treatment of severe aortic stenosis.[1] Although initially limited to high-risk patients, TAVI has demonstrated its efficacy in low-risk patients in recent years.[2-6]

With the widespread use of TAVI in Türkiye and the increase in valve durability, the number of patients undergoing TAVI has increased. Therefore, there has been a certain increase in the number of patients who need TAVI-in-TAVI (redo-TAVI). Our clinic is among the first facilities in our country to complete TAVI procedures.[7]

In the present study, we aimed to evaluate mid-term outcomes on redo-TAVI procedures.

PATIENTS AND METHODS

This single-center, descriptive, retrospective study was conducted at Dokuz Eylül University, Faculty of Medicine, Department of Cardiology between June 1st, 2012 and May 31st, 2019. A total of 441 patients with symptomatic severe aortic

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stenosis who were admitted to our hospital were deemed eligible for TAVI. Of these patients, eight (2 males, 6 females; mean age: 73.8±3.9 years; range, 66 to 79 year) who were TAVI-in-TAVI cases were included in the study. A written informed consent was obtained from each patient. The study protocol was approved by the Dokuz Eylül University Non-Invasive Ethics Committee (date: 03/01/2024, no: 2024/01-22). The study was conducted in accordance with the principles of the Declaration of Helsinki.

All patients were analyzed for comorbidity, characteristics of the first TAVI valve, indications for redo-TAVI, transthoracic echocardiographic parameters, mortality, pacemaker requirement, and valve function during follow-up.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). The normal distribution of variables was evaluated with the Kolmogorov-Smirnov test, and the homogeneity of variance was evaluated with the Levene test. Continuous variables were presented in mean ± standard deviation, while categorical variables were presented in number and frequency.

RESULTS

Of eight patients included in the study, two (25%) had coronary artery disease and three (37.5%) had chronic renal failure. Demographic, clinical, and laboratory data of the patients are given in Table 1.

Five (62.5%) of the patients required a redo-TAVI procedure due to severe aortic regurgitation and three (37.5%) of the patients required a redo-TAVI procedure due to degeneration of the first TAVI valve. The first TAVI valves of the patients were two Portico™ valves (St. Jude Medical, Minneapolis, MN, USA), four CoreValves™ (Medtronic Inc., Minneapolis, MN, USA), and two Edwards SAPIEN™ (Edwards Lifesciences Inc., Irvine, CA, USA). One patient had two valves in the first procedure due to pop-out-related valve-in-valve (Figure 1). Aortic gradients, aortic regurgitation, and time passed after the first procedure before the redo-TAVI procedure are given in Table 2. In the TAVI-in-TAVI procedures of the patients, four CoreValve™ (Medtronic Inc., Minneapolis, MN, USA), two Portico™ valves (St. Jude Medical, Minneapolis, MN, USA) and two MyVal™ (Meril Life Sciences Pvt. Ltd., India) were used (Table 2). The median time after the first procedure was 62 (range, 19 to 89) months.

Before redo-TAVI, computed tomography (CT) was repeated both to evaluate the initial valve structure and to select a new valve. All patients underwent

Tablo 1
Comorbidities and laboratory values of the redo-TAVI patients

Variables	n	%	Mean±SD
Age			73.8±3.9
Sex			
Male	2	25	
Coronary artery disease	2	25	
Diabetes mellitus	3	37.5	
Hypertension	8	100	
Chronic kidney disease	3	37.5	
Creatinin			1.30±0.57
Sodium			138.33±4.22
Potassium			4.22±0.25
Albumin			2.85±0.39
White blood cells			9.42±1.29
Hemoglobin			10.33±1.20

TAVI: Transcatheter aortic valve implantation; SD: Standard deviation.

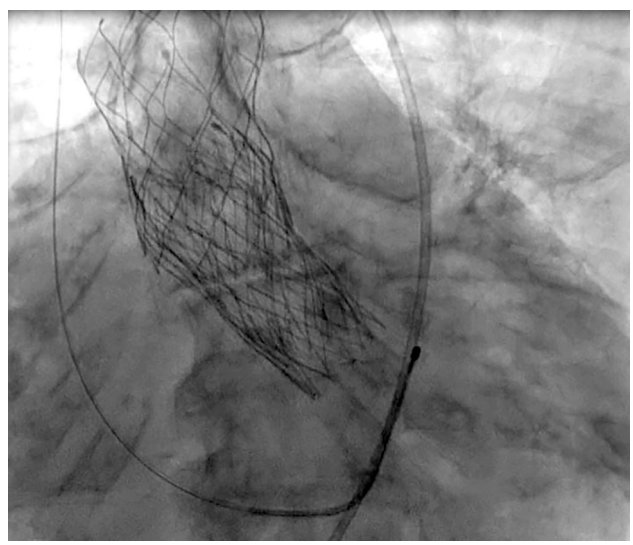

Figure 1. Post redo-TAVI aortography image for patient 1.
TAVI: Transcatheter aortic valve implantation.

Table 2
TAVI valves and echocardiographic characteristics of patients

Patients	First TAVI valve	LVEF (%)	Aortic gradient	Aortic regurgitation	Passed time after first TAVI (month)	Second TAVI valve
1	29 mm Portico + 27 mm Portico	60	70/39	Moderate	46	26 mm Corevalve
2	29 mm Edwards	35	25/11	Severe	60	27 mm Portico
3	29 mm Corevalve evolute-R	50	38/20	Severe	32	29 mm Portico
4	29 mm Edwards	20	88/53	Moderate	72	29 mm Corevalve
5	29 mm Portico	40	36/18	Severe	89	29 mm Corevalve
6	29 mm Corevalve evolute-R	50	29/11	Severe	19	34 mm Corevalve
7	29 mm Corevalve evolute-R	22	7/3	Severe	59	26 mm Meril Myval
8	29 mm Corevalve evolute-R	55	71/49	Mild	121	26 mm Meril Myval

TAVI: Transcatheter aortic valve implantation; LVEF: Left ventricular ejection fraction.

the procedure through the femoral artery. One patient had hypertensive pulmonary edema during the procedure and was intubated and in-hospital mortality occurred due to infectious causes during intensive care follow-up (Patient No. 2). There was no in-hospital mortality and pacemaker requirement in other patients. In seven patients, post-procedural echocardiographic valve evaluation revealed a median aortic gradient of 17/8 mmHg and no more than mild aortic regurgitation. Coronary artery occlusion was not seen in any case. There was no mortality at a median follow-up of 31 months after TAVI-in-TAVI procedures.

DISCUSSION

Transcatheter aortic valve implantation is an increasingly widespread method in the treatment of severe aortic stenosis.[8] However, the primary uncertainty regarding the long-term follow-up of TAVI is its durability. Advancements in TAVI valve design and deployment methods may enhance long-term durability.[9] With the increase in long-term durability, we expect an increase in redo-TAVI procedures in the near future.

The Valve Academic Research Consortium-3 identifies four primary mechanisms which contribute to the dysfunction of bioprosthetic valves for TAVI: *(i)* endocarditis; *(ii)* structural valve deterioration (SVD); *(iii)* valve thrombosis; and *(iv)* non-SVD.[10]

The recommendation for redo-TAVI versus surgical aortic valve replacement (SAVR) in patients with SVD and non-SVD depends on multiple criteria. Recent data from the United States indicate that the 30-day mortality rate for redo-TAVR is lower than that of SAVR.[11,12]

In their study, Şentürk et al.[7] showed that the number of true SVD was low in patients who underwent TAVI, confirming that the durability of TAVI valves was high. In our study, the indications for redo-TAVI were mainly due to paravalvular leak rather than SVD. In patients with paravalvular leak compared to those with SVD, the need for redo-TAVI has occurred earlier. This also highlights the necessity for the first TAVI procedure to be optimal for durability.

While preparing for a redo-TAVR procedure, it is essential to take into careful consideration the structure of the dysfunctional first TAVI valves. These TAVI valves differ in terms of the form and size of the metal stent frame, as well as the location of the leaflets inside the frame.[13]

Inserting a new TAVI valve into a defective TAVI valve leads the leaflets of the first valve

to remain in the open position. This basically transforms a portion of the initial valve into an enclosed cylindrical conduit. The vertical dimension of the enclosed cylinder is usually known as the neoskirt height. The neoskirt height is strongly influenced by the particular stent frame type and the precise positioning of the leaflets. The height of a neoskirt has a direct influence on the likelihood of possible coronary blockage.[14-17] Several parameters, including as TAVI valves design, implant depth, and TAVI valve choice for redo-TAVR, increase the possibility of coronary blockage. Performing cardiac CT is a standard procedure to assess the risk of coronary occlusion while managing a failing bioprosthetic valve with TAVI.

Currently, there is insufficient evidence to inform TAVI valve selection for redo-TAVR. The choice of TAVI valve device for redo-TAVR depends on the characteristics and location of the first TAVI valve, the underlying reason of failure, and its surrounding anatomical structure.[18-20]

There is a limited number of empirical evidence available on the practice of redo-TAVI in real-life scenarios. TAVI accounted for 0.46% of the 133,250 TAVI operations in the Medicare database from 2012 to 2017. In addition, it included 0.33% of the 63,876 procedures in the redo-TAVI worldwide registry, which are the two largest published series. In selected patients, redo-TAVI is usually safe and successful, with minimal procedural complications and significant relief in symptoms. Survival rates at 30 days are similar to those reported in other valve-in-valve transcatheter aortic valve replacements (TAVRs) performed in patients with intermediate-to-high surgical risk. The mortality rate ranges from 2.9 to 6.0%, the stroke rate ranges from 1.4 to 1.8%, and the pacemaker rate ranges from 4.2 to 9.6%.[13] However, the survival rate at one year is lower, ranging from 13.5 to 22%.[13] This could be due to the higher risk of mortality in this particular population, which affects the overall outcomes.[11-14,19]

Although TAVI can be performed in degeneration of surgical aortic valves, initial TAVI preserves the patient's surgical chances and provides the opportunity to perform percutaneous procedures in the future.[21] Younger patients undergoing open SAVR may be encouraged to start using bioprostheses more, instead of mechanical valves in the near future, given the availability of this effective technique for replacing a malfunctioning surgical bioprosthesis. It is well-known that the mortality of redo surgery is high compared to redo-TAVI.[22,23]

The main limitation to this study is that it has a single-center and retrospective design with a relatively small sample size. Of note, although different surgeons performed the first and second TAVI procedures, all were experienced in TAVI.

In conclusion, with the widespread use of TAVI procedures and increased valve durability, patients are followed for longer periods of time currently. Some patients require reintervention due to valve degeneration or severe aortic regurgitation. Redo-TAVI can be performed in these patients. Redo-TAVI procedure is feasible and successful. However, further large-scale, long-term, prospective studies are required to further assess its effectiveness and safety.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Idea, critical review: K.D.; Design, writing the article: A.A.B.; Control/supervision: H.D., D.K.; Data collection: S.K., O.Ç., H.O.; Analysis and/or interpretation: O.Ç., H.O.; Literature review: H.D., A.A.B.

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