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Initial experiences with Corevalve® for transcatheter aortic valve implantation in Turkey: two case reports

Transkateter aort kapak implantasyonunda Corevalve® ile Türkiye'de ilk deneyimler: İki olgu sunumu

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Transcatheter aortic valve implantation (TAVI) has become an alternative treatment modality in patients with severe aortic stenosis who are not candidates for open surgery. We performed two of the initial procedures in our center with the CoreValve® Revalving System, which has been recently introduced to the market. In this article, we report the outcomes of this procedure after a nine-month follow-up and discuss the different aspects of the two prostheses commercially available in Turkey.

Key words: Aortic stenosis; percutaneous catheter; transcatheter aortic valve implantation.

İleri aort darlığı olan ve açık cerrahi için uygun olmayan hastalarda transkateter aort kapak implantasyonu (TAKİ), alternatif bir tedavi yöntemi haline gelmiştir. Merkezimizde, pazara yakın zamanda giren CoreValve® Revalving System ile ilk uygulamalardan ikisi gerçekleştirildi. Bu yazıda, dokuz aylık takip sonrasında işlemin sonuçları sunuldu ve Türkiye'de ticari olarak kullanımda olan bu iki protezin farklı yönleri tartışıldı.

Anahtar sözcükler: Aort darlığı; perkütan kateter; transkateter aort kapak implantasyonu.

After its introduction by Dr. Cribier in 2003, transcatheter aortic valve implantation (TAVI) has become an alternative treatment modality in patients with severe aortic stenosis who are unfit for open surgery. The two prostheses available in Turkey are the Edwards-SAPIEN® (ES) (Edwards LifeSciences Corporation, Irvine, CA, USA) transcatheter heart valve and the Medtronic CoreValve® (MCV) ReValving System (Medtronic Inc, Minneapolis, MN, USA).

Following the first TAVI procedure in 2009 in Turkey with the ES prosthesis,[1] the MCV entered the market soon afterwards, and the first application was performed in the Istanbul Mehmet Akif Ersoy Hospital in 2011. We have implanted two MCV valves in patients in our center, and in this report, we will discuss the short-term results in light of the clinical available data.

CASE REPORT

Case 1– A 78-year-old male patient with dyspnea had been treated for severe chronic obstructive pulmonary disease (COPD) and pneumonia for five years until three weeks prior to being admitted to our facility. He also had severe aortic stenosis and a history of congestive heart failure. Due to severe COPD, TAVI was preferred for this patient.

A 29 mm Corevalve® aortic prosthesis was implanted via the transfemoral route. No postoperative complications were reported, and the patient was discharged on the seventh postoperative day after a one-night intensive care unit (ICU) stay.

Case 2– An 81-year-old obese female [body mass index (BMI): 41.7 kg/m^2] with a 22-year history of severe COPD was admitted to the hospital with

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increasing dyspnea, despite having received extensive diuretic therapy for the previous five weeks. Echocardiography revealed severe aortic stenosis and mild-to-moderate mitral insufficiency. After considering the comorbidities, this patient was also scheduled for TAVI.

A 26 mm CoreValve® aortic prosthesis was implanted transfemorally, but a complete atrioventricular (AV) block developed postoperatively. A previously used transvenous pacemaker was implanted temporarily, and a dual chamber rate adaptive (DDDR) permanent pacemaker was implanted on the second postoperative day. The patient had no other complications and was discharged on the fifth day. The detailed clinical findings of both patients are listed in Table 1.

The technique

For a very detailed, critical anatomical examination, echocardiography, multislice computed tomography (CT), and angiography are performed, starting from the left ventricular outflow tract (LVOT) and continuing to the femoral arteries.

Under general anesthesia in the catheterization laboratory, a transesophageal echocardiography (TEE) probe and a transvenous pacemaker lead are inserted prior to the initiation of the procedure. Following systemic heparinization, we prefer to use an open femoral arteriotomy for access. A standard balloon aortic valvuloplasty is performed during a short period of rapid ventricular pacing, followed by the transfemoral insertion of an 18 French (F) sheath. The crimped bioprosthesis is then advanced across the native aortic valve. Exact positioning of the valve is done meticulously since the valve is functional even during partial deployment (Figure 1a). The tip is released last, only after confirming the final position of the valve (Figure 1b). The arteriotomy is then surgically fixed, and dual antiplatelet therapy (aspirin and clopidogrel) is administered for six months after the procedure.

Both of our patients were followed up for nine months. The first patient was New York Heart Association (NYHA) class II at the last visit and was only limited by his severe COPD. The second was NYHA class I. The transvalvular gradients were measured as 29/15 and 14/8 mmHg (peak/mean), respectively.

DISCUSSION

Aortic stenosis is seen in 2-7% of all adults over 65.[2] Although surgery still has good results (5-15% operative mortality in patients >70 years), especially in patients with prominent associated comorbidities, TAVI has emerged as an effective choice of treatment.

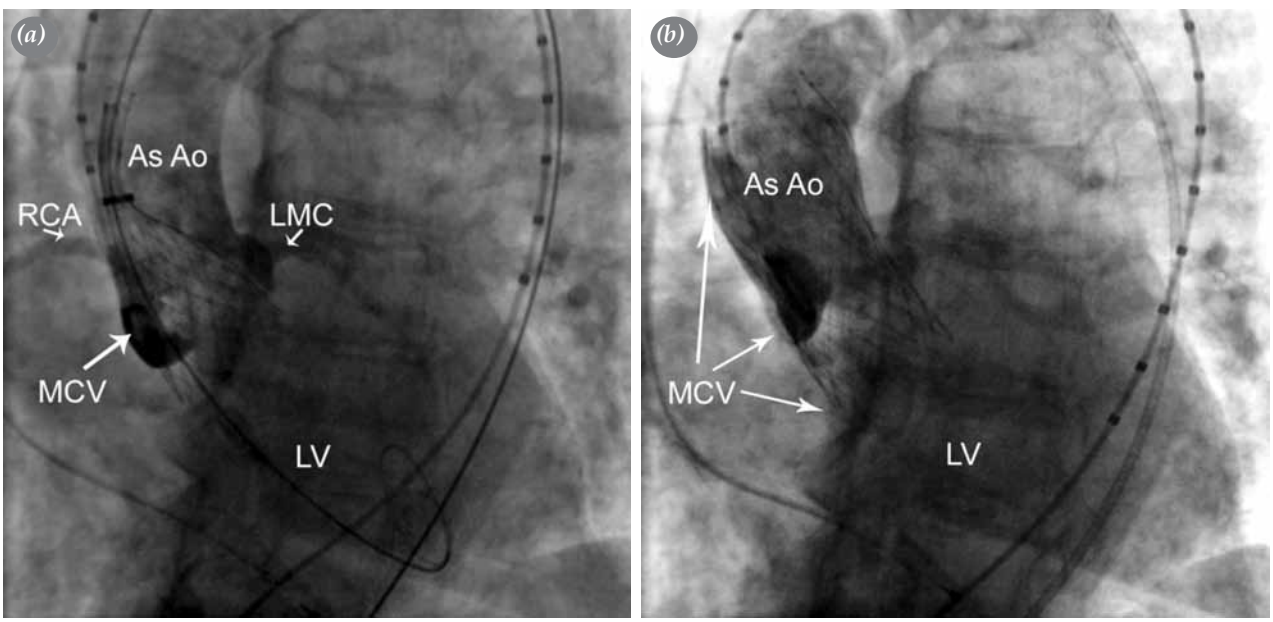

Figure 1. (a) The prosthesis is partially deployed. The lower segment is almost seated in the annulus, but the tip is released last, only after the operator is fully satisfied about the position of the valve. The valve is fully functional at this stage permitting the operator to take the time needed for perfect positioning. **(b)** Post-procedure angiography after full deployment of the prosthesis. Note the contrast within the ascending aorta showing no paravalvular leak. As Ao: Ascending aorta; RCA: Right coronary artery; MCV: Corevalve® prosthesis; LMC: Left main coronary; LV: Left ventricle.

Table 1. Preoperative and operative findings of the two cases

	Case 1	Case 2
Age (year)	78	81
Gender	Male	Female
Body mass index (kg/m^2)	31.1	41.7
Chronic obstructive pulmonary disease	Severe	Severe
Diabetes mellitus	–	–
Hypertension	+	–
Pulmonary hypertension	–	+
Peripheral arterial disease	–	–
Preoperative creatinine (mg/dl)	1.15	1.18
Coronary artery disease	–	–
Previous cardiac operation	–	–
Aortic gradient (peak/mean) (mmHg)	112/70	84/52
New York Heart Association	III	III
Ejection fraction (%)	68	75
Logistic euroSCORE (%)	4.91	15.9
Society of thoracic surgeons; score (mortality) (%)	4.0	8.1
Aortic annulus (TEE) (mm)	26.5	20.5
Sinus valsalva (TEE) (mm)	36.5	28.5
Sinotubular junction (TEE) (mm)	28.5	23.5
Ascending aorta (TEE) (mm)	38	29.5
Left ventricular outflow tract (TEE) (mm)	22	18
Vascular route	Transfemoral	Transfemoral
Prosthetic valve	29 mm corevalve	26 mm corevalve
Complication	–	Complete atrioventricular block
Intensive care unit stay (hours)	16	48
Hospital stay (days)	7	5

TEE: Trans-esophageal echocardiography; euroSCORE: European System for Cardiac Operative Risk Evaluation.

The mid-term results involving a patient in Canada with the ES prosthesis saw a primary success rate of 93.3% along with a 30-day mortality of 10.4%, and Rodés-Cabau et al.[3] reported survival rates in the first and second years of 76% and 64%, respectively.[3] Furthermore, in the European Placement of Aortic Transcatheter Valves (PARTNER) trial, valve implantation was successful in 96.4% of the patients in the transfemoral group, and the 30-day and six-month survival rates were 91.8 and 90.2% respectively.[4]

In another report involving the placement of a the third generation 18 F CoreValve® device, the procedural success and mortality rates were 98% and 0.9%, respectively. In addition, the cumulative mortality rates were 5.4% at 30 days, 12.2% at six months, and 15.0% at one year.[5]

Both Edwards Lifesciences Corporation and Medtronic Inc. have succeeded in decreasing the profile size of the valve to 18 F. The MCV is a porcine pericardial prosthesis on a self-expanding nitinol stent, whereas the ES is a bovine pericardial prosthesis on a balloon-expandable steel stent.

The longer stent skeleton of the MCV provides a second landing zone at the level of the sino-tubular junction. This structure also helps have better parallel positioning of the prosthetic valve and the aortic annulus. Together with the self-expanding nature of the stent, the MCV aims to decrease paravalvular leakage. On the other hand, this device is associated with a higher incidence of complete AV block that requires permanent pacemaker implantation. This is attributed to the lower seating structure of the valve within the LVOT. The self-expanding MCV also makes a second balloon dilatation during another period of rapid ventricular pacing unnecessary, thus attenuating the potential for stroke.

The MCV is approved for transfemoral and trans-subclavian routes while the ES is approved for transfemoral and transapical routes. The MCV has also marketed a 31 mm valve and will soon launch a 23 mm valve in a 16 F profile.

In conclusion, despite the lack of reimbursement policies, several centers are performing TAVI procedures in Turkey. A dedicated team of clinicians

who are specifically trained for this purpose should handle the patient with maximum care and cognizance. Increased experience with the MCV together with improvements in the device technology will certainly create a potential for wider use in this country.

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REFERENCES

1. Yücel G, Paker T, Akçevin A, Sezer A, Eryilmaz A, Ozyiğit T, et al. Transcatheter aortic valve implantation: the first applications and early results in Turkey. [Article in Turkish] Turk Kardiyol Dern Ars 2010;38:258-63.
2. Vahanian A, Baumgartner H, Bax J, Butchart E, Dion R, Filippatos G, et al. Guidelines on the management of valvular heart disease: The Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology. Eur Heart J 2007;28:230-68.
3. Rodés-Cabau J, Webb JG, Cheung A, Ye J, Dumont E, Feindel CM, et al. Transcatheter aortic valve implantation for the treatment of severe symptomatic aortic stenosis in patients at very high or prohibitive surgical risk: acute and late outcomes of the multicenter Canadian experience. J Am Coll Cardiol 2010;55:1080-90. doi: 10.1016/j.jacc.2009.12.014.
4. Lefèvre T, Kappetein AP, Wolner E, Nataf P, Thomas M, Schächinger V, et al. One year follow-up of the multi-centre European PARTNER transcatheter heart valve study. Eur Heart J 2011;32:148-57. doi: 10.1093/eurheartj/ehq427.
5. Tamburino C, Capodanno D, Ramondo A, Petronio AS, Ettori F, Santoro G, et al. Incidence and predictors of early and late mortality after transcatheter aortic valve implantation in 663 patients with severe aortic stenosis. Circulation 2011;123:299-308. doi: 10.1161/CIRCULATIONAHA.110.946533.