High implantation technique during CoreValve replacement in a high-risk aortic stenosis patient with a sigmoid left ventricular hypertrophy and a large aortic annulus

Sigmoid sol ventrikül hipertrofisi ve geniş aort anülüsü olan yüksek riskli aort darlıklı bir hastada CoreValve yerleştirilmesi sırasında uygulanan yüksek implantasyon tekniği

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Summary– The appropriate size, accurate alignment and correct positioning of transcatheter aortic valves (TAVIs) at the point of deployment are emphasized as key factors in placement and fixation of the devices. Presence of a sigmoid left ventricular septum in the patient is one of the important limitations of TAVIs, especially with the Edwards-Sapien Valve (ESV), due to the risk of aortic embolization of the prosthesis. In cases of a pronounced sigmoid septum, transapical implantation of the ESV or the usage of a Medtronic CoreValve (MCV) is generally recommended. However, severe left ventricular hypertrophy and sigmoid septum are also risk factors for the development of conduction disturbances with the usage of MCV. The depth of implantation of MCV within the left ventricular outflow tract and larger or significantly oversized prostheses have also been reported as important predictors of permanent pacemaker (PPM) requirement after MCV implantation. Thus, recent reports indicate that there may be less need for a PPM if a high implantation technique is used to place the MCV at a short implantation depth. In this report, we present the high implantation technique under rapid pacing during transcatheter aortic MCV implantation in a surgically high-risk aortic stenosis patient with sigmoid left ventricular hypertrophy and a large aortic annulus.

Özet– Kateter yoluyla yerleştirilen aort kapaklarının uygun yerleşimi ve sabitlenmeleri için anahtar faktörler; uygun boyutta kapak seçimi, kapağın düzgün şekilde hizalanması ve doğru pozisyonda yerleştirilmesi olarak belirlenmiştir. Edwards Sapien Kapak (ESK) sistemi için en önemli kısıtlamalardan birisi, protezin aortaya embolizasyonuna yol açabilecek olan sigmoid septum varlığıdır. Özellikle belirgin şekilde sigmoid septumu olan olgularda, ESK sisteminin apikal yolla yerleştirilmesi veya Medtronic CoreValve kapak (MCK) sisteminin kullanılması önerilmektedir. Ancak ciddi sol ventrikül hipertrofisi ve sigmoid septum varlığı, MCK sisteminin kullanılması sonrası ortaya çıkabilecek kalıcı kalp pili gereksinimi için de önemli bir öngördürücüdür. Sol ventrikül çıkış yolu içerisine yerleştirilecek olan MCK sisteminin implantasyon derinliği ve büyük veya fazla geniş bir protezin yerleştirilmesi de MCK takılması sonrası kalıcı kalp pili gereksinimini öngördüren diğer faktörler olarak sıralanabilir. Yakın zamanda yayınlanan raporlar, yüksek implantasyon tekniği ile kısa implantasyon derinliğinde yerleştirilecek olan MCK sistemi sonrası kalıcı kalp pili gereksiniminin daha düşük olabileceğini işaret etmektedir. Bu yazıda, ileri aort darlığı olan, cerrahi açıdan yüksek risk taşıyan ve sigmoid sol ventrikül hipertrofisi ile birlikte geniş aort anülüsü olan hastada, kateter yoluyla aort MCK sisteminin hızlı ventrikül pacingi altında yüksek implantasyon tekniği sunuldu.

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Transcatheter aortic valve implantation (TAVI) has emerged as a life-saving therapy for patients with severe aortic valve stenosis (AS), who are considered to be surgically high-risk candidates.[1] Left ventricular hypertrophy is a common finding in these patients and a sigmoid septum is frequently observed. In the presence of a pronounced sigmoid septum, there is a paucity of data on selection of the type of current transcatheter aortic valves.[2-4] A sigmoid septum creates the potential risk of aortic embolization of the prosthesis if the Edwards-Sapien Valve (ESV) is used. On the other hand, if the Medtronic CoreValve (MCV) is preferred, the risk of conduction disturbances and the need for permanent pacemaker implantation (PPM) is higher.[5-8] Recent reports indicate that the need for a PPM may be lessened by placing the MCV at a short implantation depth.[9] However, the utility of this MCV placement technique in patients with a sigmoid septum is unknown. In this report, we present a successful high implantation of an MCV in a surgically high-risk aortic stenosis patient with a pronounced sigmoid septum and a large aortic annulus.

Abbreviations:

ESV	*Edwards-Sapien Valve*
F	*French*
LVOT	*Left ventricular outflow tract*
MCV	*Medtronic CoreValve*
PPM	*Permanent pacemaker implantation*
TAVI	*Transcatheter aortic valve implantation*
TEE	*Transesophageal echocardiography*
TTE	*Transthoracic echocardiography*

CASE REPORT

A 82-year-old male patient was admitted to our clinic because of episodes of presyncope, angina on minimal effort (Canadian Cardiovascular Society, CCS, classification IV) and dyspnea on minimal activity (New York Heart Association classification, NYHA, IV). He had been hospitalized with pulmonary edema 2 months before. The patient had poor mobility and had been diagnosed with chronic obstructive lung disease and severe renal impairment with a creatinine level of 2.7 mg/dl and estimated creatinine clearance of <50 ml/min. Transthoracic echocardiography (TTE) showed left ventricular hypertrophy, a pronounced sigmoid septum with a thickness of 17 mm, a severely calcified aortic valve with a peak transvalvular gradient of 83 mmHg and a mean of 48 mmHg (calculated aortic valve area=0.66 cm^2), in association with grade 3 aortic regurgitation, severe mitral annular calcification and grade 2 mitral and grade 3 tricuspid regurgitation (Figure 1a). There was no subaortic stenosis. Diameter of the aorta was measured as 28 mm at the aortic annulus, 34 mm at the sinus of Valsalva, and 36 mm in the ascending aorta. Estimated pulmonary artery systolic pressure was calculated as 60 mmHg. The patient's calculated logistic EuroScore was 32.4%, the Society of Thoracic Surgeons score was 26.4%. He was evaluated for TAVI as recommended in discussion among our heart team here at the institution. Left heart catheterization showed normal coronary arteries, and angiography of the peripheral arteries revealed tortuosity in the right external iliac artery and normal left peripheral vasculature. Minimal diameter of both iliac and femoral arteries was measured as >6 mm. We performed a computerized tomography (CT) angiography of the aorta with low contrast because of the patient's reduced creatinine clearance. The aortic annulus was measured as 29.3 mm, but the appearance of the annulus, sinotubular junction and sinus of Valsalva width were not satisfactory for us due to the reduced amount of con-

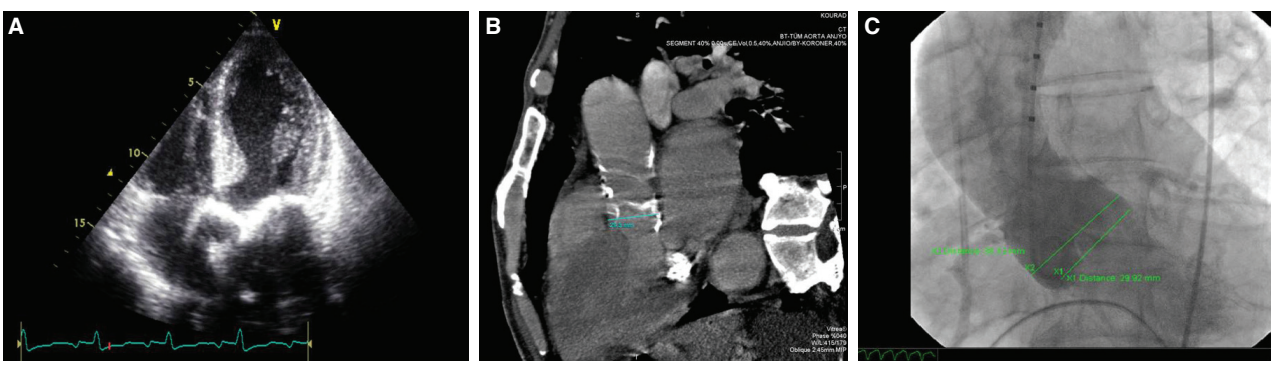


Figure 1. **(A)** Transthoracic echocardiography, sigmoid septum and severe mitral annular calcification (Four-chamber view). **(B)** CT angiography, Measurement of aortic annulus diameter. **(C)** Aortography under rapid pacing, Measurements of aortic annulus diameter and sinus Valsalva width.

trast (Figure 1b) because of patient's reduced renal function. Thus, we decided to confirm diameters of the aorta at different levels by using transesophageal echocardiography (TEE) at the time of implantation.

Written informed consent form was taken from the patient. The procedure was done under general anesthesia and mechanical ventilation. We could not insert the TEE probe into the patient, and in order not to do oro-pharyngeal injury, we decided to take measurements by doing an aortic angiography under rapid pacing to minimize contrast administration. A 5 French (F) pigtail was inserted into the left common femoral artery (CFA) with a 6F sheath and a transvenous pacemaker was inserted via a 6 F sheath placed in the left femoral vein. The aortic angiography was done under rapid pacing with 20 ml contrast in an antero-posterior caudal 10 degrees projection (Suppl. Video*). To identify the virtual annulus, the pigtail catheter was seated in the nadir of the non-coronary cusp. The aortic annulus was measured as over 29 mm and sinus of Valsalva as 36 mm (Figure 1c). Due to the presence of a pronounced sigmoid septum and a large aortic annulus, we decided to implant a MCV into the patient instead of an ESV. Although the annulus was measured as 29 mm, we did not choose a 31 mm MCV, as there is a greater risk of downward slippage with a 31 mm MCV than with a 29 mm MCV in a patient with severely calcific aortic valve and a large aortic annulus since the two valves have important structural differences. This would be very problematic in this case with the patient having a sigmoid septum. We decided therefore to make a high implantation of a 29 mm MCV by putting the bioprosthesis with the inflow part of the MCV just at the level of the aortic annulus, defined by the nadir of the non-coronary cusp in the angiographic projection with the three coronary cusps aligned on a single plane.

Balloon dilation of the stenotic aortic valve was successfully performed with a 20x40 mm balloon (Zmed, NuMED Inc., Hopkinton, NY, USA) under rapid pacing. After aortic balloon valvuloplasty, a high implantation of the MCV was successfully done under rapid pacing in order to prevent valve dislodgement with marked improvement of the trans-valvular gradients, patent coronary ostia and minimal paravalvular regurgitation (Figure 2a-f, Suppl. Video*). After the pro-

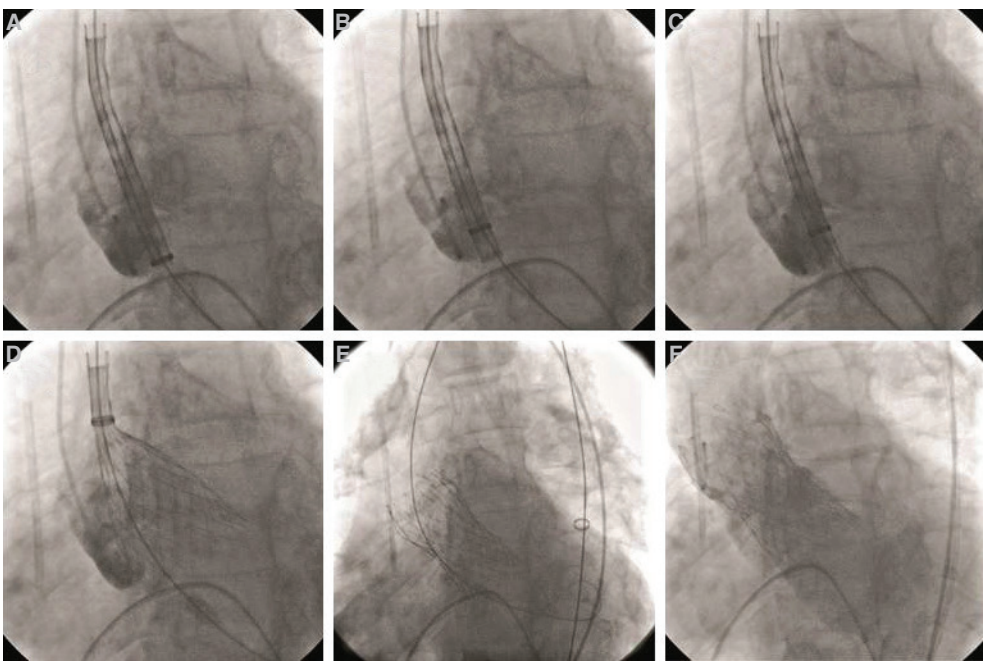
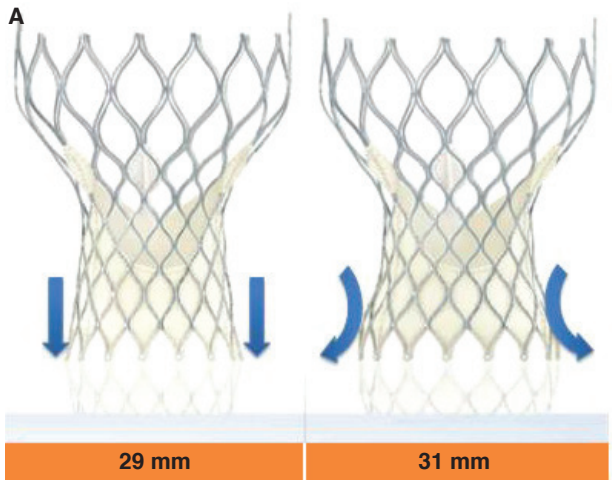


Figure 2. **(A)** First phase of high implantation of the MCV, pigtail is in the nadir of the non-coronary sinus, the inflow portion of the bioprosthesis is located just at the level of the aortic annulus. **(B)** Second phase of high implantation of the MCV, separation of the radiopaque marker of the protective sheath from the cone of the delivery catheter. **(C)** Third phase of high implantation of the MCV. **(D)** Parachute phase (Frame reaches opposite side of the aortic root). **(E)** Complete retrieval of the system. **(F)** Final aortography (Patent coronary ostia, minimal paravalvular regurgitation).



	29 mm	31 mm
Height	53 mm	52 mm
Outflow	43 mm	43 mm
Waist	24 mm	24 mm
Inflow	29 mm	31 mm
Accommodates annulus of	23 mm to 27 mm	26 mm to 29 mm

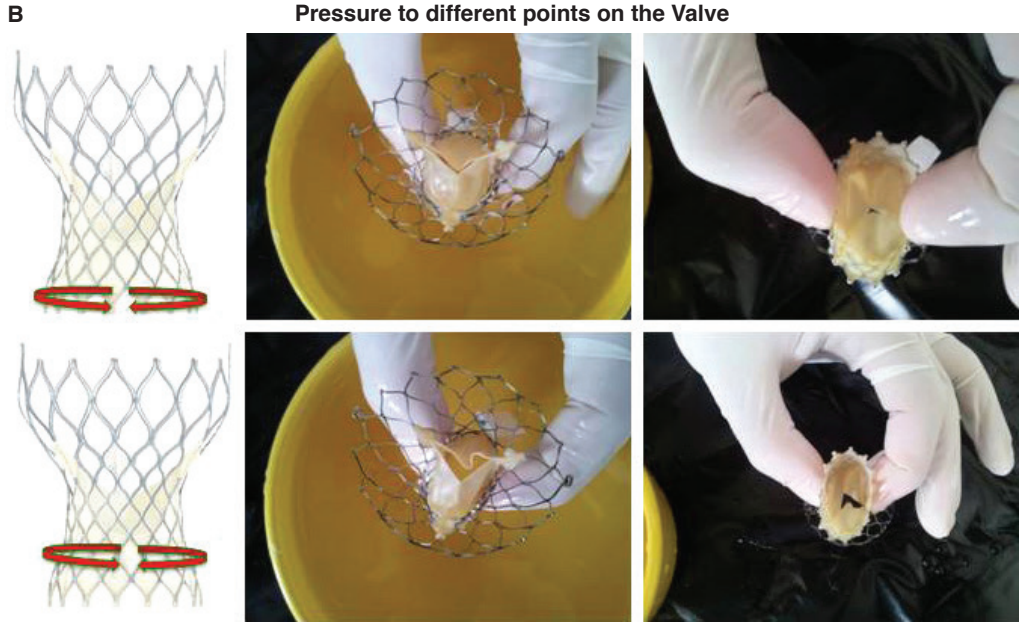


Figure 3. **(A)** Design differences between the 31 mm and the 29 mm MCV, shape of the 31 mm MCV from inflow to waist is more conical than that of the 29 mm MCV. **(B)** Schematic illustration of the risk of leaflet deformation during deep implantation of MCV.

cedure, the patient was observed in an intensive care unit for 72 hours with continuous ECG monitoring and temporary pacemaker back-up. No conduction abnormalities were observed. Post-procedural TTE demonstrated a well-functioning MCV with a mean systolic pressure gradient of 10 mmHg and peak systolic pressure gradient of 20 mmHg. Right ventricular systolic pressure decreased from 60 to 15 mmHg, accompanied by mild paravalvular aortic regurgitation. The patient's symptoms subsequently improved from NYHA class IV to class I, and he was discharged twelve days after the procedure in a well clinical status.

DISCUSSION

Presence of a sigmoid septum is an important limitation of TAVI. Because accurate positioning of the percutaneous aortic valves, in particular the ESV, may be hampered by the small diameter of the left ventricular outflow tract (LVOT). This situation creates a potential risk for embolization of the ESV. Thus, transapical implantation of the ESV or the use of an MCV is generally recommended in these patients.[2-4] However, sigmoid septum is also a risk factor for the development of significant conduction disturbances and

the need for a PPM with the use of an MCV.[5,6] Recent reports indicate that PPM rates may be lowered by placing the MCV at a small implantation depth.[9] Nevertheless, no study has especially focused on the utility of the high implantation technique of an MCV in preventing development of new conduction disturbances and the need for a PPM among patients with a sigmoid septum.

In our case, the patient had a pronounced sigmoid septum and a large aortic annulus measured as 29 mm, which is also the upper limit for ESV use. For these reasons, we preferred to use an MCV in the patient. Although a 31 mm MCV is recommended for 26-29 mm annuli, we chose a 29 mm valve in our patient because we know that there are some important structural differences between 29 mm and 31 mm valves. First, although both valves have the same waist diameters (24 mm), the shape of the 31 mm MCV from inflow to waist is more conical than a 29 mm MCV (Figure 3a). Thus, a 31 mm valve has a greater tendency than a 29 mm valve to slide down into the LVOT. This would be very problematic in our case since the patient had a pronounced sigmoid septum. Secondly, the highest radial force is at the inflow part of an MCV, and if the valve is placed deeper into the LVOT, the annulus will squeeze the valve and this situation may induce more deformation in the valve leaflets (Figure 3b). This phenomenon may also be more prominent in a 31 mm MCV. Accordingly, we decided to make a high implantation of a 29 mm MCV using the İnce technique, and putting the inflow part of the MCV just at the level of the aortic annulus. With this technique, high implantation can be achieved with only 70 cc of contrast under rapid pacing after undersized balloon-valvuloplasty. It was also more difficult to implant a 31 mm MCV in high position in the present case because a 31 mm MCV usually tends to slide deep into the left ventricle despite rapid pacing.

Tchetche et al. reported that in implants higher than 4 mm there may be a tendency for the MCV to generate an upward movement of the prosthesis during the last phase of deployment.[9,10] This phenomenon also seems to be amplified by the presence of a septal bulge that pushes the inflow frame of the valve towards the ascending aorta. Thus, one aortic embolization of the MCV occurred in the study of Tchetche et al., and they inserted a second valve into their patient.[9] Nevertheless, the authors concluded that with increased experience in the use of an MCV catheter, this late upward movement can be anticipated and minimized by applying a gentle push on the catheter shaft and pull on the intra-ventricular stiff wire prior to final detachment of the MCV.[9] One alternative method to prevent MCV dislocation is to implant the bioprosthesis under rapid pacing.[10] We also inserted the MCV under rapid pacing and used the manipulation described by Tchetche et al. during the last phase of deployment in our patient and no aortic embolization occurred. We believe that the high implantation technique of an MCV under rapid pacing is very useful, especially in patients with a pronounced sigmoid septum and narrow LVOT. However, further studies with large number of patients are required to validate the efficacy and safety of this technique and its effect on long term outcomes in patients with a sigmoid septum and narrow LVOT.

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****Supplementary video file associated with this article can be found in the online version of the journal.***

REFERENCES

1. Leon MB, Smith CR, Mack M, Miller DC, Moses JW, Svensson LG, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med 2010;363:1597-607. CrossRef
2. Al-Lamee R, Godino C, Colombo A. Transcatheter aortic valve implantation: current principles of patient and technique selection and future perspectives. Circ Cardiovasc Interv 2011;4:387-95. CrossRef
3. Tops LF, Wood DA, Delgado V, Schuijf JD, Mayo JR, Pasupati S, et al. Noninvasive evaluation of the aortic root with multislice computed tomography implications for transcatheter aortic valve replacement. JACC Cardiovasc Imaging 2008;1:321-30. CrossRef
4. Vahanian A, Alfieri O, Al-Attar N, Antunes M, Bax J, Cormier B, et al. Transcatheter valve implantation for patients with aortic stenosis: a position statement from the European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Inter-

ventions (EAPCI). Eur Heart J 2008;29:1463-70. CrossRef
5. Jilaihawi H, Chin D, Vasa-Nicotera M, Jeilan M, Spyt T, Ng GA, et al. Predictors for permanent pacemaker requirement after transcatheter aortic valve implantation with the CoreValve bioprosthesis. Am Heart J 2009;157:860-6. CrossRef
6. Baan J Jr, Yong ZY, Koch KT, Henriques JP, Bouma BJ, Vis MM, et al. Factors associated with cardiac conduction disorders and permanent pacemaker implantation after percutaneous aortic valve implantation with the CoreValve prosthesis. Am Heart J 2010;159:497-503. CrossRef
7. Muñoz-García AJ, Hernández-García JM, Jiménez-Navarro MF, Alonso-Briales JH, Domínguez-Franco AJ, Fernández-Pastor J, et al. Factors predicting and having an impact on the need for a permanent pacemaker after CoreValve prosthesis implantation using the new Accutrak delivery catheter system. JACC Cardiovasc Interv 2012;5:533-9. CrossRef
8. Bleiziffer S, Ruge H, Hörer J, Hutter A, Geisbüsch S, Brockmann G, et al. Predictors for new-onset complete heart block after transcatheter aortic valve implantation. JACC Cardiovasc Interv 2010;3:524-30. CrossRef
9. Tchetche D, Modine T, Farah B, Vahdat O, Sudre A, Koussa M, et al. Update on the need for a permanent pacemaker after transcatheter aortic valve implantation using the CoreValve® Accutrak™ system. EuroIntervention 2012;8:556-62. CrossRef
10. Kahlert P, Eggebrecht H, Erbel R. CoreValve dislocation: breaking the wave of enthusiasm? Circ Cardiovasc Interv 2010;3:523-5. CrossRef

Key words: Aortic valve/surgery; cardiac catheterization; CoreValve; transcatheter aortic valve implantation; pacemaker, artificial.

Anahtar sözcükler: Aort kapağı/cerrahi; kalp kateterizasyonu; CoreValve; transkateter aort kapak implantasyonu; pacemaker, yapay.