CASE REPORT

First trans-subclavian transcatheter aortic valve replacement using Lotus valve system

Lotus kapak sistemi kullanılarak yapılan ve subklaviyan arter yoluyla uygulanan ilk transkateter aort kapak replasmanı

Serdal Baştuğ, M.D., Abdullah Nabi Aslan, M.D., Cenk Sarı, M.D., Hakan Süygün, M.D.,# Engin Bozkurt, M.D.#

Department of Cardiology, Atatürk Training and Research Hospital, Ankara, Turkey
#Department of Cardiology, Yıldırım Beyazıt University Faculty of Medicine, Ankara, Turkey

Summary– Transcatheter aortic valve implantation (TAVI), most commonly performed via retrograde femoral artery access, is a promising alternative to surgical aortic valve replacement in elderly, high-risk patients with severe aortic stenosis (AS). Approximately one-third of these patients suffer from severe iliofemoral arteriopathy, ruling out transfemoral approach. The case of a 74-year-old man with severe AS and bilateral iliofemoral arteriopathy treated with left trans-subclavian (TS) TAVI using the Lotus valve system is described in the present report.

Özet– Transkateter aort kapak implantasyonu (TAVI) ciddi aort darlığı olan yüksek riskli yaşlı hastalarda cerrahi aort kapak replasmanına karşı umut verici bir tedavi seçeneğidir. Çoğunlukla geriye doğru, femoral arter yolu ile uygulanır. Ancak, bu hastaların yaklaşık üçte birinde ciddi iliyofemoral arter hastalığı da olduğundan femoral yolla işlemi yapmak her zaman mümkün olmayabilir. Bu yazıda, ciddi aort darlığı ve iki taraflı iliyofemoral arter hastalığı olan, bu nedenle sol subklaviyan arter yoluyla Lotus kapak sistemi kullanılarak TAVI uygulanan 74 yaşında bir erkek hasta sunuldu.

Transcatheter aortic valve implantation (TAVI) is indicated for use in surgically high-risk patients with severe aortic stenosis (AS). The most common approach is femoral. However, the frequency of peripheral artery disease ranges from 19–42% in patients undergoing TAVI.[1] In response, alternative access routes have been developed, including direct aortic access and routes involving the subclavian arteries or the apex of the heart.[2] The trans-subclavian (TS) approach is currently a preferred alternative access route. While use of balloon-expandable Sapien valves (Edwards Lifesciences, Irvine, CA, USA) and the self-expandable CoreValve system (Medtronic, Dublin, Ireland) have been reported,[3,4] TS TAVI performed with the Lotus valve system (Boston Scientific Inc., Marlborough, MA, USA) is described for the first time in the present report.

Abbreviations:

AS	*Aortic stenosis*
CT	*Computed tomography*
LIMA	*Left internal mammary*
LV	*Left ventricle*
SCA	*Subclavian artery*
TAVI	*Transcatheter aortic valve implantation*
TS	*Trans-subclavian*

CASE REPORT

A 74-year-old man presented with exertional dyspnea (New York Heart Association class III) that had begun 3 months ago. He had a history of type 2 diabetes mellitus, hypertension, and hemorrhagic cerebrovascular event (8 years earlier), and had undergone coronary artery by-pass surgery (10 years earlier), and surgery for osteocarcinoma (15 years earlier). The patient was obese, with a body mass index of 32 kg/m^2, and very fragile. Coronary angiography per-formed 2 months ago had revealed patent left internal mammarian artery to left anterior descending artery, aorto-saphenous vein-obtuse marginalis-I, and aorto-saphenous vein-posterior descending artery bypass grafts. Pa-

Received: August 05, 2015 *Accepted:* December 28, 2015
Correspondence: Dr. Abdullah Nabi Aslan. 1238. Cad., Ata Apt., No: 10/35, Yukarı Öveçler, Ankara, Turkey.
Tel: +90 312 - 291 25 25 e-mail: drnabiaslan@hotmail.com

tient was referred to the clinic for TAVI evaluation following angiography. On admission, transthoracic echocardiography showed severe degenerative AS with mean gradient of 41 mmHg and aortic valve area of 0.54 cm^2. Left ventricular ejection fraction was normal (65%). The diameter of the aortic annulus was 24 mm on transthoracic and transesophageal echocardiography. Computed tomography (CT) was also used to measure aortic annulus (23x27 mm). Calculated STS score and logistic EuroSCORE were 7.6% and 21.4%, respectively. CT angiography showed significant stenosis in both iliofemoral arteries, as well as severe calcification (Figure 1). Minimal lumen diameter of the right iliac artery was 5.6 mm, while that of the left was 5.1 mm. Diameters of the left and right subclavian arteries were measured on CT angiography (Figure 2).

The heart team elected to perform TAVI by TS approach due to the size, severe stenosis, and severe calcification of the iliofemoral arteries. Procedure was performed under general anesthesia. A 6-Fr pigtail catheter was advanced to the aortic root to allow for hemodynamic monitoring and landmark aortic angiography through the right femoral artery, and a temporary pacing lead was inserted into the right ventricle through the right femoral vein. The subclavian artery (SCA) was surgically isolated through a 3–5 cm incision in the deltopectoral groove. Heparin was administrated to achieve activated clotting time of 250–300 sec throughout procedure. A 7-Fr sheath was inserted into the SCA, and Amplatz Super Stiff Guidewire (Boston Scientific Inc., Marlborough, MA, USA) was advanced to the aortic root. Over this wire, a 22-Fr introducer Esheath (William Cook Europe ApS, Bjæverskov, Denmark) was inserted after consecutive predilatations of SCA. Straight, 0.038-in guidewire was inserted into the left ventricle (LV) through the introducer sheath using Amplatz left 1 catheter (Cook Medical Inc., Bloomington, IN, USA). Pressure gradient was measured and Amplatz left 1 catheter was

Figure 1. Computed tomography image showing iliofemoral arteries with severe calcification.

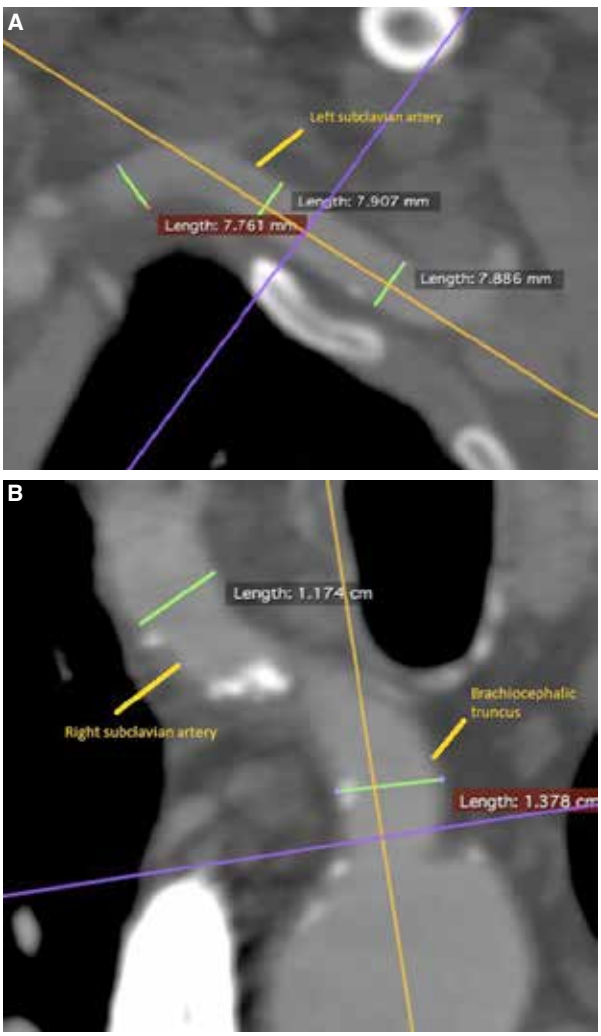

Figure 2. (A, B) Computed tomography images of left and right subclavian arteries.

exchanged with pigtail catheter. Guidewire (width: 0.035 in; length: 260 cm) with tip angled to correspond to the left ventricular apex was inserted into the LV over the pigtail catheter, and a 27-mm Lotus valve was constrained within the delivery catheter (Figure 3). After passage of the native aortic valve, the Lotus valve was unsheathed to foreshorten and expand radially. Valve performance was assessed before final release, and absence of major aortic regurgitation or left ventricular obstruction was maintained during valve implantation (Video 1*). An aortogram showed good positioning of the Lotus valve, with no aortic regurgitation (Figure 4, Video 2*). Left subclavian artery was closed surgically without complication. Postprocedural echocardiography showed well-functioning bioprosthesis with a mean gradient decreased to 10 mmHg from 41 mmHg. Patient was discharged 3 days after surgery with no cardiovascular complications.

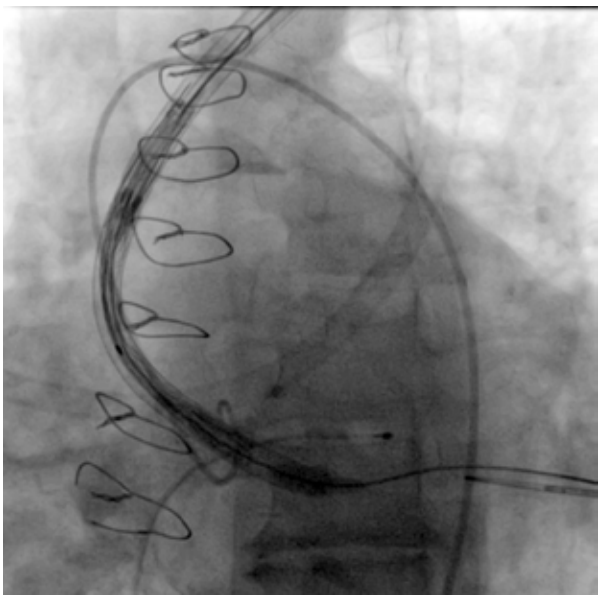

Figure 3. Lotus valve constrained within delivery catheter.

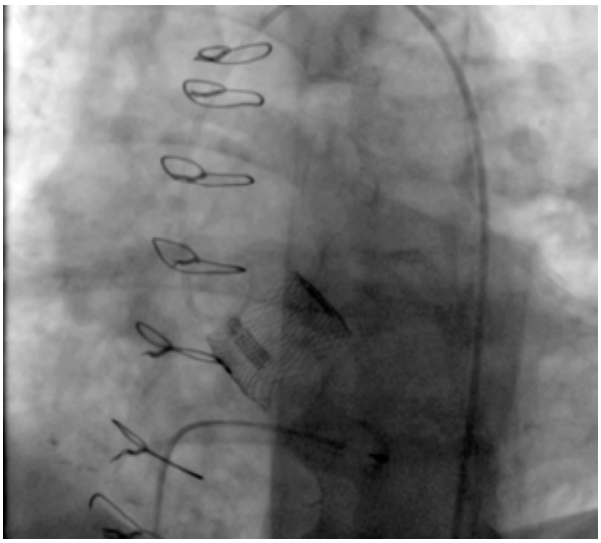

Figure 4. Successful implantation of Lotus valve.

DISCUSSION

Currently, TAVI is most commonly performed via retrograde transfemoral approach. Alternative options including anterograde transapical and retrograde TS techniques have been suggested, particularly for patients with severe iliofemoral arteriopathy or high risk of peripheral vascular complications due to severe calcification or tortuosity. TS access has been used for years with acceptable results. Recent studies have determined that the safety of TS TAVI is not inferior to that of transfemoral TAVI.[5] Petronio et al. reported 100% procedural success and 0% intraprocedural mortality rates of 54 patients who had undergone TS TAVI with CoreValve Revalving System.[6] Blumenstein et al. also reported a case of successful transcatheter aortic Edwards Sapien valve implantation through TS approach.[4] However, no experience with TS aortic Lotus valve implantation has yet been reported.

The Lotus valve system (Boston Scientific Inc., Marlborough, MA, USA) can be fully retrieved, redeployed, or repositioned. Rapid right ventricular pacing is not required during implantation, due to mechanical deployment, and the prosthesis can be resheathed and repositioned easily. It also has a C-shaped flexible delivery system, which is advantageous when performing TAVI through the left SCA on patients with horizontal aortas. While Lotus valve systems have been used in transfemoral and direct aortic TAVIs, their use in subclavian-access TAVI has never before been reported. The team took responsibility for the risks involved in implanting the prosthesis through the left SCA because this use has not been approved by the producers of the device. An approach via the left SCA and the Lotus valve system were preferred due to the C-shaped delivery system of the Lotus valve and the horizontal aorta of the patient. The contour of the aorta must be considered when selecting a valve delivery system.

The present patient had also undergone left internal mammary (LIMA) coronary artery bypass graft-

ing with the revascularization of the left anterior descending artery, which has the potential to present challenges during TS TAVI. It has been reported that patent LIMA graft renders subclavian approach impossible, as the insertion of an almost occlusive 22-Fr sheath may hinder blood flow to the LIMA graft, resulting in myocardial ischemia. However, successful implantations have also been reported.[3] To prevent such a complication, diameter of the SCA should be larger (>6 mm) than usual and free of atherosclerotic disease, as was that of the present patient. To minimize time of myocardial ischemia, 22-Fr E-sheath distal was withdrawn to the origin of the LIMA graft just after valve deployment. Rather than inserting the E-sheath before advancing into the LV, as is done in cases of transfemoral TAVI, Amplatz Super Stiff wire was advanced into the LV, and the E-sheath was inserted into the SCA for added support. This technique is especially important for a safe and successful procedure, and should be taken into consideration when performing TS TAVI. For cases such as the present, with severe septal bulging and mild calcification in the root of the aortic valve, the Lotus valve system offers better prevention of complications including valve embolization and severe aortic regurgitation.

Right SCA was not used for access in the present case due to the oblique position of the aorta (45°), as determined by CT. The right SCA had 2 sharp angles, at the origin and at the horizontal aorta, rendering TAVI by this route impossible. Bioprostheses such as Sapien 3 can be implanted with smaller systems of delivery via transfemoral access, but these were not used due to refunding problems.

The Lotus valve system can be implanted via SCA in patients undergoing TAVI. However, technique is crucial for a successful and safe procedure. Therefore, TS TAVI must be performed only by experienced interventional cardiologists after comprehensive evaluation of access site using multimodal imaging techniques.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

Conflict-of-interest issues regarding the authorship or article: None declared.

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

REFERENCES

1. Moat NE, Ludman P, de Belder MA, Bridgewater B, Cunningham AD, Young CP, et al. Long-term outcomes after transcatheter aortic valve implantation in high-risk patients with severe aortic stenosis: the U.K. TAVI (United Kingdom Transcatheter Aortic Valve Implantation) Registry. J Am Coll Cardiol 2011;58:2130–8. Crossref
2. Muensterer A, Mazzitelli D, Ruge H, Wagner A, Hettich I, Piazza N, et al. Safety and efficacy of the subclavian access route for TAVI in cases of missing transfemoral access. Clin Res Cardiol 2013;102:627–36. Crossref
3. Bruschi G, Fratto P, De Marco F, Oreglia J, Colombo P, Botta L, et al. The trans-subclavian retrograde approach for transcatheter aortic valve replacement: single-center experience. J Thorac Cardiovasc Surg 2010;140:911–5. Crossref
4. Blumenstein J, Van Linden A, Kempfert J, Kim WK, Liebetrau C, Hamm C, et al. Retrograde, transsubclavian implantation of a SAPIEN XT™ aortic valve prosthesis with the Edwards NovaFlex+™ system. Clin Res Cardiol 2012;101:773–5.
5. Witkowski A, Dąbrowski M, Chmielak Z, Demkow M, Stępińska J, Juraszyński Z, et al. Transcatheter aortic valve implantation using transfemoral/transsubclavian or transapical approach: 30-day follow-up of the initial 30 patients. Kardiol Pol 2011;69:105–14.
6. Petronio AS, De Carlo M, Bedogni F, Marzocchi A, Klugmann S, Maisano F, et al. Safety and efficacy of the subclavian approach for transcatheter aortic valve implantation with the CoreValve revalving system. Circ Cardiovasc Interv 2010;3:359–66. Crossref

Keywords: Aortic stenosis; Lotus valve system; transcatheter aortic valve implantation; transsubclavian approach.

Anahtar sözcükler: Aort darlığı; Lotus kapak sistemi; transkateter aort kapak implantasyonu; transsubklaviyan yaklaşım.