Transcatheter aortic valve implantation via the left axillary artery route in a patient with a permanent pacemaker: The first transaxillary artery route experience with a Meril's Myval™ transaortic valve in Turkey

Telat Keleş*, Özlem Özcan Çelebi[1], Emrah Uğuz, Kevser Balcı[1], Engin Bozkurt[2]**

Departments of *Cardiology, and **Cardiovascular Surgery, Faculty of Medicine, Ankara Yıldırım Beyazıt University, Ankara City Hospital; Ankara-*Turkey*

[1]Department of Cardiology, University of Health Sciences, Ankara City Hospital; Ankara-*Turkey*

[2]Department of Cardiology, Medicana International Ankara Hospital; Ankara-*Turkey*

Introduction

In light of because of its improved procedural and clinical success, transcatheter aortic valve implantation (TAVI) has become a significant alternative treatment option to surgery in patients with severe aortic valve stenosis. However, TAVI has its own contraindications and limitations, such as access route problems with transfemoral (TF) access being the safest and most widely used route. However, in patients in whom this route is unsuitable, axillary artery is the preferred alternative access route. Although TAVI valves are not licensed for axillary artery access, off-label use of balloon-expandable (Edwards Lifesciences, Irvine, CA, USA) and self-expandable (Evolute/CoreValve systems, Medtronic, Dublin, Ireland, as well as the Lotus valve system Boston Scientific Inc., Marlborough, MA, USA) valves have been reported.

The Meril's Myval™ transaortic valve is a new-generation transaortic balloon-expandable valve, and transaxillary TAVI with this valve has not been reported previously. Here, we report our experience with a Meril's Myval™ valve in a patient with severe aortic stenosis, peripheral artery disease, and a permanently implanted pacemaker.

Case Report

A 76-year-old man was admitted to our hospital with progressive exertional dyspnea lasting for four months. A dual-chamber permanent pacemaker was implanted two years ago for a 2:1 atrioventricular block. He also had diabetes mellitus, coronary artery disease, peripheral artery disease, hypertension, and thromboembolic cerebrovascular event. Physical examination was remarkable for a systolic ejection murmur best heard at the right upper sternal border in the second intercostal space. Transthoracic echocardiography revealed severe degenerative aortic valve stenosis with a mean gradient of 62 mm Hg and an aortic valve area of 0.5 cm^2. The left ventricular ejection fraction was 50%. A coronary angiogram showed non-stenotic coronary artery disease. The calculated STS score and logistic Euro SCORE were 8% and 22.4%, respectively. The decision of the cardiac team was to perform transaortic valve replacement.

The patient was assessed with multidetector computed tomography angiography. The diameter of the aortic annulus was 24 mm. The degree of tortuosity and calcification was evaluated and graded as previously described (1). Both the left and right iliofemoral minimal lumen diameters were below the recommended size (6 mm) in the instruction for use of the 29 mm valve. When we evaluated the upper extremity artery routes, we determined that the right axillary artery was also severely calcified and tortuous and not suitable for the procedure. However, the left axillary artery was not tortuous and was suitable for access (Fig. 1). Qualitative evaluation and measurements were performed, and the case was presented to the multidisciplinary heart team. Although the patient had a permanent pacemaker in the left subclavian region, the final decision of the cardiac team was to perform the procedure via the left axillary route.

The patient was operated upon under local anesthesia with conscious sedation. First, surgical isolation of the axillary artery was performed. Normally, the proximal third of the left axillary artery is our usual target for axillary access, but the patient had a permanent pacemaker; therefore, in this patient, we aimed to use the second segment of the axillary artery to protect the

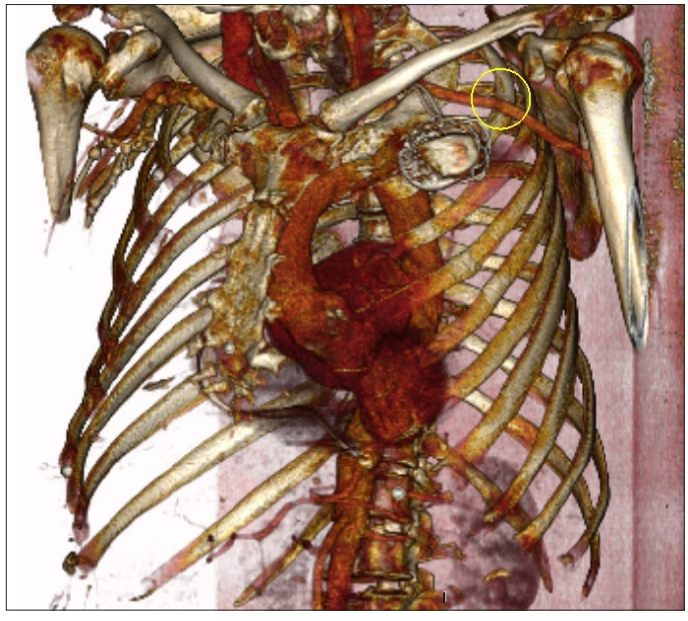

Figure 1. Three dimensional multislice computed tomography shows axillary artery suitability for transaxillary access. The circle indicates the access site

Anatol J Cardiol 2021; 25: 517-9
DOI:10.5152/AnatolJCardiol.2021.54857

generator and the leads. Surgical cut-down for the left axillary artery was performed in the deltopectoral groove (5 cm in size and 1 cm below and parallel to the clavicle from the midclavicular line to the axillary line) (Fig. 2). Once the axillary artery was isolated, a single 5-0 polypropylene purse string suture was placed on the axillary artery, and access was achieved through a 6-Fr sheath (Fig. 2).

A 7-Fr sheath was inserted into the left axillary artery, and an Amplatz left 1 catheter (AL1) (Cook Medical Inc., Bloomington, IN, USA) was advanced into the aortic root. A straight, 0.038-inch guidewire was inserted into the left ventricle (LV) through this AL-1 catheter. The AL-1 catheter was then exchanged with a pigtail catheter, and a 0.035 mm guidewire with an angled tip was inserted into the LV apex over the pigtail catheter. A 14-Fr Python™ expandable introducer sheath (Meril's Life Sciences Pvt. Ltd.) was introduced and advanced into the desired position under fluoroscopic guidance. We placed the tip of the sheath in the innominate artery for easy advancement of the system. Next, a 29 mm Meril's Myval™ bioprosthetic valve was advanced through the Python sheath. The valve was carefully positioned and deployed with rapid pacing. An aortogram showed good positioning of the valve with no aortic regurgitation (Fig. 3a, 3b). Thereafter, the introducer sheath was removed, and the axillary arteriotomy was closed with a previously placed purse string suture with good antegrade distal flow into the forearm. Post procedural echocardiography showed a well-functioning bioprosthesis with a mean gradient of 10 mm Hg. The patient was discharged two days after surgery with no cardiovascular complications.

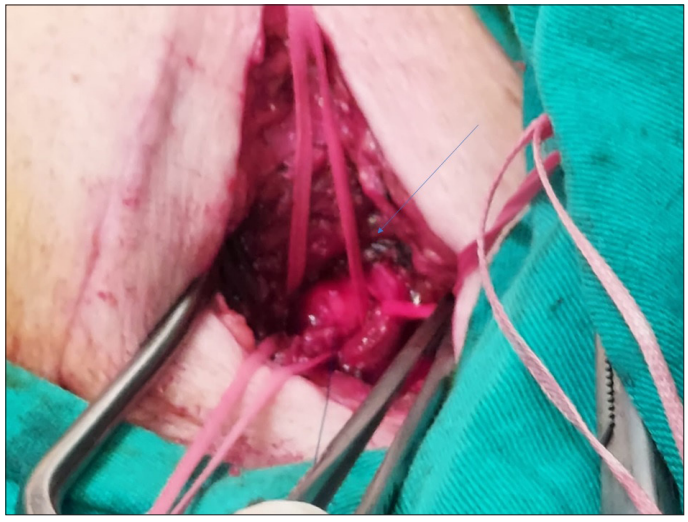

Figure 2. Surgical cut-down just above the pacemaker pocket for the transaxillary artery

Discussion

The development of TAVI is the cornerstone of the cardiovascular era. Once patients have been deemed clinically suitable for TAVI, anatomic suitability should be assessed. Attentive planning and accurate choice of proper site for vascular access play key roles in procedural success. The common femoral artery is the preferred access site in the vast majority of TAVI procedures. In the case of iliofemoral vascular disease, axillary artery access is an appealing alternative. The safety and feasibility of transaxillary artery access has been reported previously. In a recent study from our clinic, the rate of transaxillary access was 3.2%, and no major vascular complications occurred (2). In their meta-analysis, Zhan et al. (3) have reported that

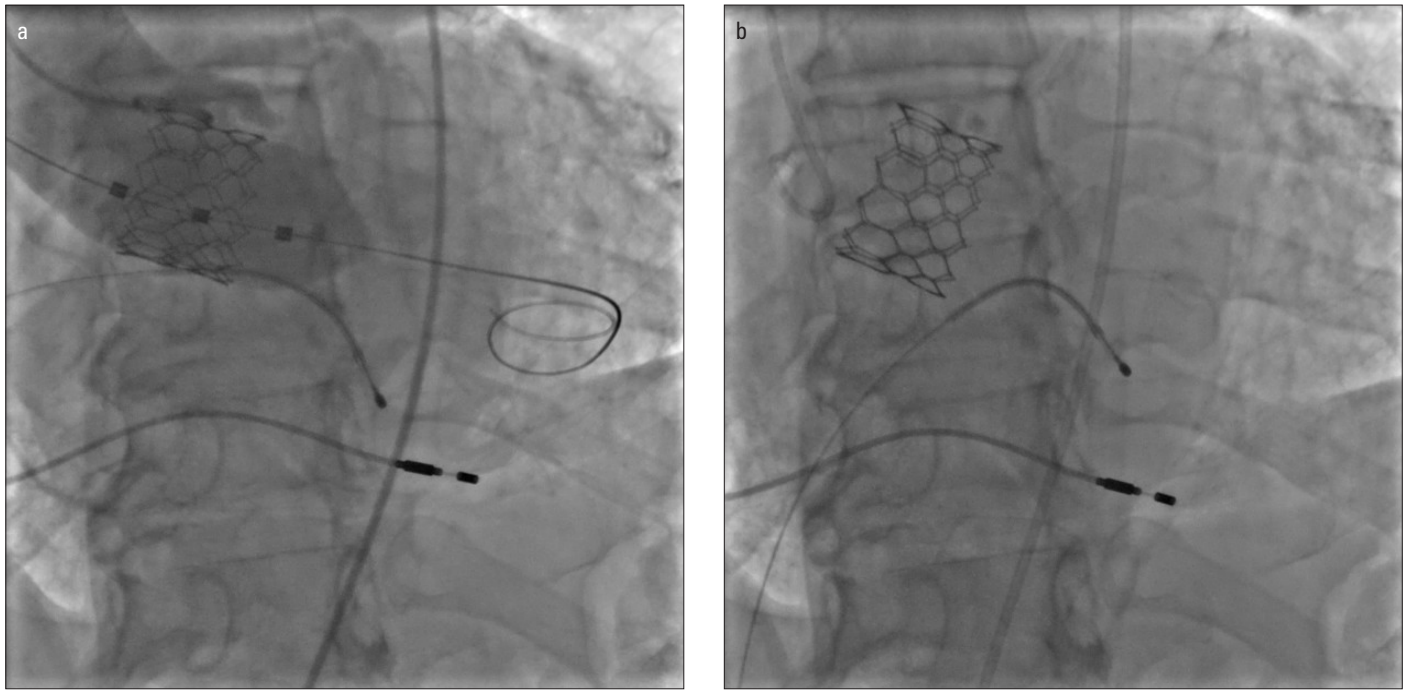

Figure 3. a) The angiographic image of 29 mm Meril's Myval™ transaortic valve during implantation; b) Final angiographic image of the Meril's Myval™ transaortic valve

despite a higher incidence of major comorbidities, transaxillary TAVI with the CoreValve was associated with overall outcomes comparable with TF-TAVR. However, an implanted pacemaker ipsilateral to the access site is a concern for the transaxillary approach. To the best of our knowledge, there has been no transaxillary TAVI reported in a patient with an ipsilateral permanently implanted pacemaker.

When there is an ipsilateral implanted pacemaker, it is important to isolate the axillary artery from the second part. It is also important to use fluoroscopy guidance to prevent damage to the leads. Percutaneous closure should be performed for axillary artery access. However, for safety reasons, we preferred surgical cut-down for cannulating the left axillary artery.

Self-expandable valve systems have been mainly used for transaxillary access. Only a few balloon-expandable valves have been used in the past. It has been reported that SAPIEN XT™ and SAPIEN 3 are safe and feasible for transaxillary access in TAVI (4, 5). The Myval valve system is a new generation balloon expanding aortic valve system, and the first use of this valve was reported recently by Arslan et al. (6). Their report regarding this valve system was positive. To date, there has been no reported use of the Myval valve system for transaxillary access worldwide. The main problem with the use of a balloon-expandable valve is the alignment of the prosthesis with the balloon catheter. This step is performed in the descending aorta during TF-TAVI as the descending aorta allows for an anatomically straight setting. However, in the case of the transaxillary approach, loading should be performed onto the ascending aorta, which may result in alignment problems. Myval balloon-expandable valve technology serves a solution for this problem. The Myval valve is directly crimped on a stent balloon delivery system, and there is no need to load the valve onto the balloon. In addition, the design of the handle allows feasible movement of the delivery system. The Myval valve system combines both open and closed cells. This unique design creates a fluoroscopic "dark and light" band pattern and helps accurate valve positioning and orthotopic deployment.

Conclusion

Therefore, TAVI through an axillary approach with the Myval valve system is safe and feasible and is preferred as a second option when the TF approach is suboptimal. It is a relatively simple technique; and in our experience, we were able to implant the prostheses successfully without any major procedural complications.

Informed consent: Informed consent was obtained from the patient.

References

1. Eltchaninoff H, Kerkeni M, Zajarias A, Tron C, Godin M, Sanchez Giron C, et al. Aorto-iliac angiography as a screening tool in selecting patients for transfemoral aortic valve implantation with the Edwards SAPIEN bioprosthesis. EuroIntervention 2009; 5: 438-42. [Crossref]
2. Duran Karaduman B, Ayhan H, Keleş T, Bozkurt E. Evaluation of procedural and clinical outcomes of transcatheter aortic valve implantation: A single-center experience. Anatol J Cardiol 2020; 23: 288-96. [Crossref]
3. Zhan Y, Saadat S, Soin A, Kawabori M, Chen FY. A meta-analysis comparing transaxillary and transfemoral transcatheter aortic valve replacement. J Thorac Dis 2019; 11: 5140-51. [Crossref]
4. Ciuca C, Tarantini G, Latib A, Gasparetto V, Savini C, Di Eusanio M, et al. Trans-subclavian versus transapical access for transcatheter aortic valve implantation: A multicenter study. Catheter Cardiovasc Interv 2016; 87: 332-8. [Crossref]
5. Koifman E, Magalhaes M, Kiramijyan S, Escarcega RO, Didier R, Torguson R, et al. Impact of transfemoral versus transapical access on mortality among patients with severe aortic stenosis undergoing transcatheter aortic valve replacement. Cardiovasc Revasc Med 2016; 17: 318-21. [Crossref]
6. Arslan U, Erdoğan G, Uçar M, Yenerçağ M. First experiences with the balloon-expandable Myval® transcatheter aortic valve from Turkey. Anatol J Cardiol 2020; 24: 361-3. [Crossref]

Address for Correspondence: Dr. Özlem Özcan Çelebi,
Sağlık Bilimleri Üniversitesi, Ankara Şehir Hastanesi, Kardiyoloji Kliniği, Ankara-*Türkiye*
Phone: +90 505 312 14 85
E-mail: drozlemoz79@yahoo.com

DOI:10.5152/AnatolJCardiol.2021.54857