Proximal embolization of Edwards SAPIEN prosthesis in transcatheter aortic valve implantation

Transkateter aort kapak yerleştirme sırasında Edwards SAPIEN protezin geriye doğru embolizasyonu

İsa Öner Yüksel, M.D., Erkan Köklü, M.D., Şakir Arslan, M.D., Göksel Çağırcı, M.D., Selçuk Küçükseymen, M.D.

Department of Cardiology, Antalya Training and Research Hospital, Antalya, Turkey

Summary-- Transcatheter aortic valve implantation (TAVI) is considered an alternative therapy in high-risk patients with severe aortic stenosis (AS). However, this minimally invasive procedure carries potential complications, such as valve embolization at time of TAVI. We present a case of balloon-expandable aortic valve embolization which was managed nonsurgically. Valve embolization was managed conservatively, as the patient refused open heart surgery for definitive treatment. The patient was transferred to the intensive care unit in stable hemodynamic condition and discharged 1 week following the procedure.

CASE REPORT

A 72-year-old man diagnosed with symptomatic severe AS was referred for TAVI. The patient had a history of hypertension, coronary artery disease, and severe chronic obstructive pulmonary disease. He was immobile due to orthopedic reasons. On admission, electrocardiogram showed atrial fibrillation, with a ventricular rate of 85/min. Transthoracic and color Doppler echocardiographic scans revealed a mean aortic gradient of 42 mmHg, an aortic valve area of 0.90 cm², and ejection fraction of 60%. Two-dimensional transesophageal echocardiography (2D TEE) revealed severe AS, and aortic annulus was measured as 25 mm. Preoperative logistic EuroSCORE was 21, and Society of Thoracic Surgeons score was 8. The patient was considered to be too high risk for surgical aortic valve replacement and was referred for TAVI by transfemoral approach.

Abbreviations:
2D Two-dimensional
AS Aortic stenosis
CT Computed tomography
LVOT Left ventricular outflow tract
TAVI Transcatheter aortic valve implantation
TEE Transesophageal echocardiography
TTE Transthoracic echocardiography

Received: May 24, 2015  Accepted: August 04, 2015
Correspondence: Dr. Isa Öner Yüksel. Kültür Mahallesi, 3805 Sokak, Durukent Sitesi, H Blok, No: 22, Kepez, Antalya, Turkey.
Tel: +90 242 - 291 25 25 (4849 - 4340)  e-mail: drisayuksel2@hotmail.com
© 2016 Turkish Society of Cardiology
The process was performed under deep anesthesia and transthoracic echocardiography (TTE) guidance. TAVI was performed through the right femoral artery using a 26-mm Edwards SAPIEN XT valve (Edwards Lifesciences, Irvine, CA, USA). Following pre-dilation with a 23x40 mm balloon inflated under rapid pacing (180 bpm, TA <50 mmHg), the Edwards SAPIEN XT valve was implanted in the appropriate co-planar angle valve position (Video 1*). Following the valve implantation, an arch angiography was carried out, at which point it was observed in the fluoroscopy that the Edwards SAPIEN XT valve was sliding under the aortic annulus (Figure 1, Video 2*). TTE revealed that the prosthesis valve was seen in the left ventricular outflow tract (LVOT), mean gradient was 14 mmHg, and mild paravalvular aortic regurgitation was observed. The embolized valve was not intervened because of taken back extra stiff wire in the ventricle and throughout the system. The prosthetic aortic valve was stable, and no hemodynamic disturbances occurred. The patient and his relatives were informed regarding this complication, and the necessity of urgent operation was discussed. However, though informed of the possible risks, the patient and his relatives refused the operation. The patient was transferred to the s care unit in stable hemodynamic condition.

In the intensive care unit, hemodynamics were stable. It was not observed to create obstruction because one end of the embolized valve was free, while the other end was holding to LVOT and opened formation in obtained TTE and TEE images (Figure 2a, b). One month after discharge, mild paravalvular aortic regurgitation was observed, and there was no valve gradient in TTE and TEE control images (Figure 3, Video 3*). He was started on coumadin due to prosthetic valve embolization and atrial fibrillation. At 6-month follow-up, the patient had no valve-related symptoms.

**DISCUSSION**

TAVI is an established treatment modality for high-risk and inoperable AS patients. Despite being less in-

---

**Figure 1.** Fluoroscopic image of embolization of Edwards SAPIEN prosthesis.

**Figure 2.** (A) In TTE, the part of the Edwards SAPIEN prosthetic valve holding to the LVOT is observed. (B) In TEE, the embolized prosthetic valve was observed in the native aortic valve and LVOT.
Proximal embolization of Edwards SAPIEN prosthesis in transcatheter aortic valve implantation is associated with the potential for serious complications such as valve embolization. Ventricular embolization of the prosthesis is a rare but life-threatening complication that requires immediate diagnosis and treatment. It usually necessitates conversion to open heart surgery to remove the embolized valve and perform conventional aortic valve replacement. There are a number of factors that contribute to the embolization of the balloon-expandable valve to the left ventricle, including suboptimal positioning, undersizing of the prosthesis in respect to the annulus size, and minimal calcification of the native aortic valve leaflets. Although temporary failure of pacing during implantation is a common cause of prosthetic embolization, less frequent causes of embolization include post-cardiopulmonary resuscitation, post-dilation, and displacement during insertion of a balloon or new prosthesis while attempting post-dilation.

There are a number of factors that contribute to the embolization of the balloon-expandable valve to the left ventricle, including suboptimal positioning, undersizing of the prosthesis in respect to the annulus size, and minimal calcification of the native aortic valve leaflets. Although temporary failure of pacing during implantation is a common cause of prosthetic embolization, less frequent causes of embolization include post-cardiopulmonary resuscitation, post-dilation, and displacement during insertion of a balloon or new prosthesis while attempting post-dilation. In our patient, several factors might have played a role in the valve embolization into the LVOT. Although the coplanar view was accurate, the pelvis was deployed rather low. An aortography at the time of valve implantation might have alerted us to affix the prosthesis higher in the annulus, resulting in optimal placement. Another potential factor is the minimal calcification (Video 3); furthermore, apposition without calcification lacks the strength to stay in the annulus. The third potential factor that should be taken into consideration is the accurate sizing of the prosthesis, which requires precise measurement of the aortic annulus using three-dimensional imaging modality. Most frequently, multislice computed tomography (CT) is used for this purpose. In our patient, multislice CT was not performed to evaluate dimensions and calcification of the aortic valve and aorta due to lack of support from the radiology department in our center. Thus, we used 2D TEE and arch aortography with abdominal aortography for evaluation of the aortic root, aortic annulus, valve calcification, and coaxial plane angle of valves and iliac arteries.

Malpositioning is a common cause of prosthetic valve embolism. The rate of valve malpositioning ranges from 2.0% to 5.3% for the Edwards SAPIEN valve, this relatively large range can be attributed to the learning curve of operator experience. The most common reason for ventricular embolization is the malpositioning of the valve, especially placing the valve too ventricularization. In addition, inadequate visualization of the valve plane (non-coaxial position) can lead to ventricular embolization.

Incorrect measurement of the aortic annulus and incorrect selection of valve size are other causes of prosthetic valve embolism. Aortic annulus:valve prosthesis ratio should be at least 1:1.

The absence of a direct view of the aortic root and valve remains a challenge for transcatheter approach. Among imaging modalities available for the evaluation of patients prior to TAVI, CT plays a central role in patient selection. CT reliably detects the dimensions of the aortic root, including size of the aortic annulus, degree of valve calcification, and morphology of the access routes, providing a more accurate measurement of the aortic annulus than 2D TEE. Additionally, CT is the only imaging modality that allows risk assessment for paravalvular leakages based on the calcification of the aortic valve. Accurate measurement of the oval-shaped annulus should be performed in the transverse plane and perpendicular to the aortic root axis. Two-dimensional TEE has been used to measure aortic annulus diameter and for valve sizing; however, 2D TEE annular measurement may underestimate actual annular size, as the 2D technique provides only a sagittal view of the aortic annulus. The sole use of 2D TEE in our case may be responsible for a lower measure for the aortic annulus. Valve size choice and placement according to aortic annulus measurement by both 2D TEE and CT could be a more appropriate approach.
In contrast to ventricular embolization, transcatheter management of distal aortic embolization of Edwards SAPIEN valve is possible. The embolization prosthesis may be redeployed in the descending aorta without the need for removal by surgery.\(^9\),\(^10\) However, ventricular embolization of Edwards SAPIEN valve is a rare and severe complication of TAVI, usually necessitating conversion to open heart surgery. Although our patient remained stable for months after ventricular embolization, conservative management cannot be advocated, as the risk of valve loosening in the left ventricle with dire consequences is significant. While we recommended open heart surgery for removal of the prosthesis, the patient and his family adamantly refused surgery. Fortunately, the fully deployed valve remained in the LVOT; though one end was not touching the myocardium, the other was holding to the LVOT and continued to function competently, thus preventing hemodynamic problems.

Finally, the precise positioning of the valve, appropriate valve selection, and route of administration of the procedure are crucial for reducing the risk of valve migration. In the insertion of an aortic valve via catheter, the key factors for proper placement and fixation are appropriate size, choice of valve, proper alignment of the valve, and correct position placement.

In conclusion, the experience of the operator must be emphasized, as the learning curve is extremely important to reduce the complication rate. Accurate measurement of the aortic annulus is crucial for precise valve sizing in patients undergoing TAVI. As a result, patients should be evaluated carefully before TAVI.

**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


**Keywords:** Edwards-Sapien; proximal valve embolization; transcatheter aortic valve implantation.

**Anahtar sözcükler:** Edwards-Sapien; proksimal kapak embolizasyonu; transkateter aortik kapak yerleştirilmesi.