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Case Report

MIGRATION AND MISALIGNMENT OF MYVAL BALLOON EXPANDABLE VALVE DURING TRANSCATETHER AORTIC VALVE IMPLATATION

Luka Rotkvić[1], Iva Mišljenčević[1], Alan Jelić[1,2], Andrija Škopljanac Mačina[1,3], Igor Šesto[1,2] and Krešimir Štambuk[1,2,3]

[1]Magdalena Clinic for Cardiovascular Diseases, Krapinske Toplice, at Faculty of Medicine, JJ Strossmayer University in Osijek, Osijek, Croatia
[2]Faculty of Dental Medicine and Health, J.J. Strossmayer University in Osijek, Osijek, Croatia
[3]Faculty of Medicine, J.J. Strossmayer University in Osijek, Osijek, Croatia

ABSTRACT – Introduction. Transcatheter aortic valve implantation (TAVI) is a treatment method for aortic stenosis with proven efficacy and recommended by professional societies in the cardiovascular field. Complications during TAVI are rare but important and potentially devastating, especially embolization or migration of prothesis.

Case presentation. We present a case of an 82-year-old patient in whom the prosthesis was displaced during implantation and later expanded in the descending aorta with a new prosthesis implanted in the aortic valve position.

Conclusion. Dislocation of the prosthesis during implantation is a serious complication. In most cases the prosthesis can be repositioned elsewhere in the aorta or perform a valve-in-valve procedure. In case of failure, the availability of cardiac surgery is important. Technological improvements, increasing operator experience and adequate periprocedural preparation minimize the risk of complications.

Key words: *aortic stenosis, transcatheter aortic valve implantation (TAVI), migration of TAVI balloon expandable valve*

Introduction

Aortic stenosis is the most common primary valve disease where thickening and narrowing of the aortic valve cause obstruction of flow in the left ventricular outflow tract.

Currently, there are two treatment options, surgical valve replacement and transcatheter aortic valve implantation. According to the ESC/EACTS guidelines, TAVI is recommended in elderly patients (> 75 years), high-risk patients (STS-PROM / EuroSCORE II> 8%) and inoperable patients (recommendation IA). (1)

Procedure-related complications include major and minor vascular complications, major and minor bleeding, regurgitation, malposition and migration of the prosthesis, coronary artery obstruction, myocardial infarction, cerebrovascular incident, conduction disturbances, acute renal failure, and death. (2, 3)

Case report

An 82-year-old man, who underwent mechanical mitral valve replacement in our institution in 2003 due to severe calcified mitral stenosis, was referred for re-evaluation and reoperation consideration due

Corresponding author:
Krešimir Štambuk, Magdalena Clinic for Cardiovascular Disease, Ljudevita Gaja 2, 49217, Krapinske Toplice, Croatia
e-mail: kresimir.stambuk@gmail.com

to severe aortic stenosis diagnosed at a regular cardiac follow up. He complained of progressive activity intolerance and angina, without syncope. His past medical history included atrial fibrillation and arterial hypertension.

Transthoracic echocardiography showed borderline dilated left ventricle with reduced ejection fraction estimated at 45% due to global hypocontractility, normal position and function of mechanical mitral valve, parameters of severe aortic stenosis in trans-systolic flow with mean pressure gradient of 45 mmHg, valve area of 0.6 cm^2, indirect parameters of pulmonary hypertension and right-sided pleural effusion. Coronary angiography ruled out significant coronary artery disease. An electrocardiogram showed an optimal rate controlled atrial fibrillation. His calculated EuroSCORE II was 17%.

ECG-gated CT was performed to analyze the potential TAVI prothesis position in relation to the mechanical mitral valve. Findings were presented to the heart team and the patient was accepted for TAVI procedure with MyVal 27.5 mm balloon expandable prosthesis. During the TAVI workup, the patient was hospitalized because of heart failure and urinary infection complicated with pseudomembranous colitis.

After the infection resolution, the patient was prepped for the TAVI procedure. He was hemodynamically and rhythmically stable, with normal vital parameters and preoperative laboratory findings. The procedure was performed in the cardiac catheter laboratory with general anesthesia.

The puncture and TAVI sheet (Python 14F) was placed using a transfemoral approach. After positioning the Confida wire in the left ventricle, predilatation with Mammoth 20 mm balloon was undertaken and the 27.5 mm MyVal prosthesis was planned to be implanted, but while pushing the prosthesis over the calcified valve, the prosthesis partially displaced from the balloon and the attempt to push the prosthesis through the annulus was not successful. Furthermore, we aimed to pull the prosthesis out through the sheet, but it could not enter the TAVI sheet anymore. At that point, the patient was hemodynamically stable with a balloon marker misalignment compared to the valve and delivery system that could not be placed in annulus nor withdrawn to the TAVI sheet.

Using the second transfemoral approach, the second sheet (8F) was placed and second „Confida“ wire was put in the left ventricle. After undertaking the second predilatation with a larger Mammoth 23 mm balloon, the repeated attempt to push the prosthesis over the annulus of aorta again proved to be unsuccessful (Figure 1).

In that moment we had an urgent on-site heart team meeting, considering two options - to operate the patient and to pull out the prosthesis trough iliac

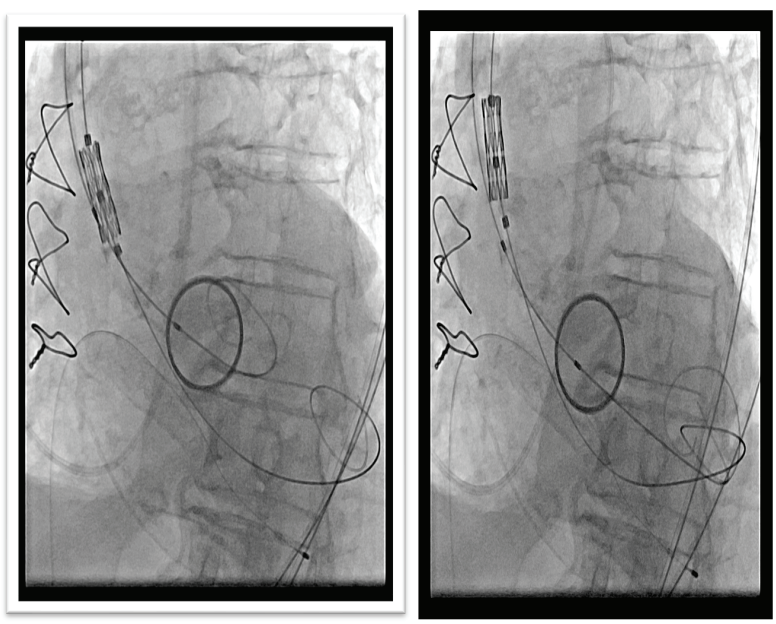

Figure 1 Migration (misalignment) of valve from the balloon while passing through the aortic annulus.

arteries or to deploy the prosthesis in the descending aorta and to continue with the procedure. The second option was chosen. According to CT measurement, the prosthesis was placed in the aorta on the place that matched the prosthesis size, and the prosthesis was expanded at the height of the diaphragm (Figure 2).

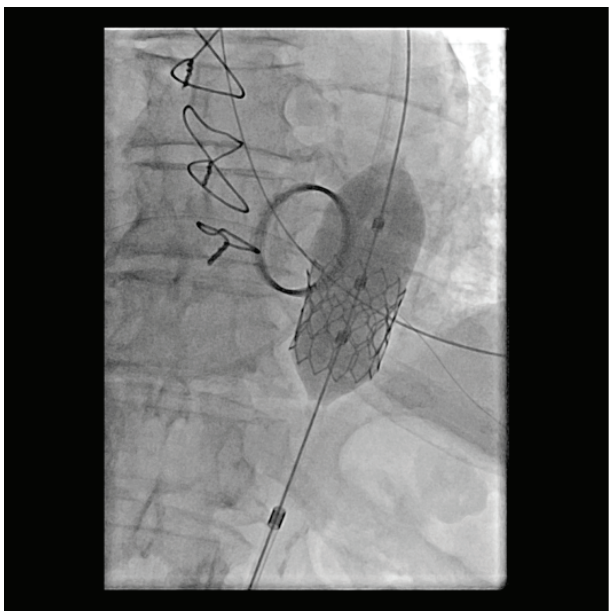

Figure 2 Deployment of valve in the descending aorta.

After that, a new MyValv 27.5 mm prosthesis was advanced through the prosthesis in the descending aorta and successfully implanted at the site of the aortic valve (Figure 3).

Postprocedurally, the patient spent a short time in the Intensive Care Unit, where he remained hemodynamically and rhythmically stable throughout the entire time. Transthoracic echocardiography confirmed proper position and function of the TAVI prosthesis with a maximum trans-systolic gradient of 18 mmHg and mild regurgitation. CT scan showed a supradiaphragmally positioned vascular prothesis in the descending aorta, with preserved lumen of the aorta. The course of hospitalization was complicated by development of pseudoaneurysm of the left femoral artery, which was resected after unsuccessful conservative treatment with the installation of hemostatic sutures to the left common femoral artery.

The patient was discharged after 22 days of hospitalization in good condition. At follow up after 1 month, 6 months and after 1 year the patient was satisfied and did not complain about any exertional dyspnea, angina, or claudication. His artery pressure and heart rate were in the normal range. On transthoracic echocardiography there was an improvement in the ejection fraction of the left ventricle (estimated at 50%), with proper function of the TAVI endoprosthe-

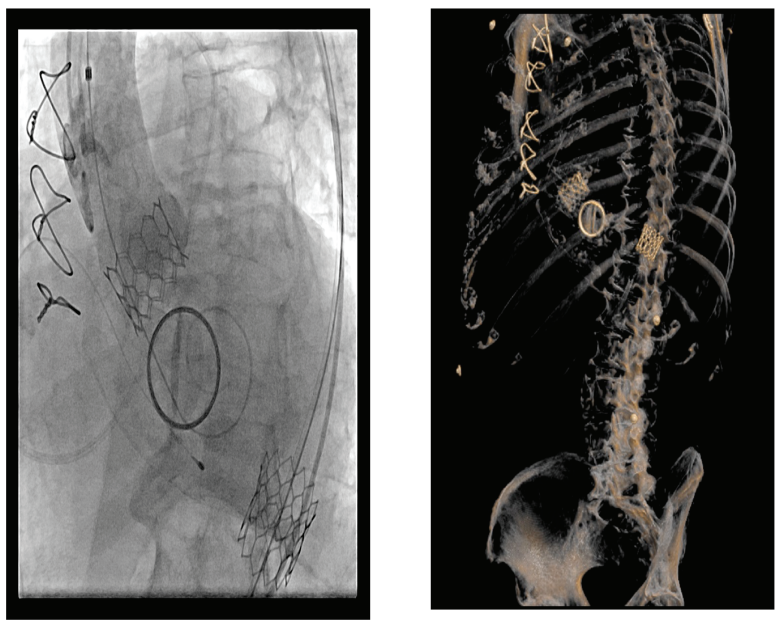

Figure 3 Position of all three valves. A. Angiographic view B. CT scan

sis and mechanical mitral valve. The Doppler showed triphasic flow in arteries of the lower extremities.

Discussion

Transcatheter aortic valve implantation has repeatedly proven to be an excellent treatment strategy for severe aortic stenosis, especially in elderly, high-risk, and inoperable patients. (4)

Adequate pre-procedural preparation of patients is necessary for the success of the procedure. ECG-gated CT is the "gold standard" today that provides 3D visualization of the heart, valvular apparatus, ascending aorta, coronary arteries, and peripheral vascular access. (5, 6) Peri-procedural use of transesophageal echocardiography provides real-time imaging guidance, helps in optimal positioning of prothesis and allows *ad hoc* prediction and management of complications such as regurgitation and malposition of prothesis. (7)

To minimize the risk of complications, all patients must be presented to the heart team and all decisions must be made by consensus. Cardiac and vascular surgery backup within the center where TAVI is performed is important, if needed for surgical management of complications.

Malposition, migration and embolization of the prosthesis are rare but can be fatal complications of the procedure. Unlike surgical valve replacement where the valve is sutured to the aortic annulus, in transcatheter implantation the prosthesis is anchored and held by friction between the prosthesis and the annulus. Subexpansion of the prosthesis or wrong positioning can lead to malposition and migration. (8) Consequences can be minimal such as repositioning the prosthesis in the ascending or descending aorta, or more complicated as obstruction of flow and loss of function of vital organs.

Some of the predisposing factors for prothesis malposition are an inaccurate assessment of the annulus dimension, incorrect implantation of the prosthesis, the presence of a mechanical mitral valve or extensive calcifications of the mitral valve apparatus. Depending on the type of prosthesis used and hemodynamic status of the patient, an attempt can be made to reposition the prosthesis percutaneously in the ascending or descending aorta or to perform a valve-in-valve with a new prosthesis. In case of failure, conversion to open heart surgery and surgical removal of the prothesis is indicated. (9)

According to the TRAVEL (Transcatheter heart Valve Embolization and Migration) registry, which analyzed almost 30 000 TAVI procedures, migration or embolization of the prosthesis was reported in 0.92%, most of them in the ascending aorta and a small part in the left ventricle, with an increased risk of death, stroke and open heart surgery (10). Risk factor for embolization and migration of the valve are use of self-expanding valve, first-generation prostheses and the existence of a bicuspid aortic valve. Self-expanding valves are usually managed with snare for reposition while balloon-expandable valves are mostly managed with balloon. (10, 11) During this maneuver it is crucial to maintain coaxial wire position to prevent balloon-expandable valve from inversion. Most cases were managed with implantation of the second prothesis in correct position. (12)

We presented a case with partial migration of valve and misalignment with the balloon marker that could lead to serious complication. To the best of our knowledge, there was only one similar case published in literature (with Edwards SAPIEN 3 valve) where the balloon-expandable aortic valve partially migrated from the balloon during the manipulation through the TAVI sheet using a transaortic approach. While deploying, the valve embolized in the ascending aorta. (13) In our case, the "broken" valve and delivery system did not enter the predicted position on aortic valve and maybe that stopped further embolization of the valve in the ascending aorta or in the left ventricle. The complication was resolved with valve deployment in the descending aorta as it was already described in literature. (14)

The exact reason of migration is not known. The possible reasons could be a mistake in valve crimping or pushing the valve too hard trough the heavily calcified aortic annulus. This case shows the importance of pre-procedural CT evaluation and on-site decision-making of the heart team.

Conclusion

In TAVI, it is necessary to anticipate possible complications and plan their management before the procedure, in agreement with heart team and with surgery backup. Careful and detailed periprocedural preparation using ECG-gated CT and supplementary methods such as TEE can minimize measurement errors. Some complications, like embolization or migration of the valve can be treated percutaneously, by repositioning the prosthesis elsewhere in the aorta or performing a valve-in-valve procedure.

In our case the prosthesis migration was successfully resolved by retracting and expanding the prosthesis in the descending aorta in accordance to previously done measurements and angiographic verification of aortic thoracic branches proximity. TAVI procedure like any other skill requires a certain learning curve. Thus, the success rate and resolving complications depend on center excellence as well as operator experience.

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Sažetak

MIGRACIJA I POMAK MYVAL BALON EKSPANDIRAJUĆE VALVULE TIJEKOM TRANSKATETERSKE IMPLANTACIJE AORTNOG ZALISTKA

L. Rotkvić, I. Mišljenčević, A. Jelić, A. Škopljanac Mačina, I. Šesto i *K. Štambuk*

Uvod. Transkateterska implantacija aortnog zalistka (TAVI) je metoda liječenja s dokazanom učinkovitosti u liječenju aortne stenoze te je preporučena od strane stručnih kardioloških društava. Komplikacije tijekom TAVI-a su rijetke, ali su vrlo važne i potencijalno fatalne, pogotovo embolizacija ili migracija umjetnog zalistka.

Prezentacija slučaja. U 82-godišnjeg bolesnika došlo je do pomaka proteze tijekom zahvata koja je kasnije ekspandirana u silaznoj aorti. Nova proteza je postavljana na mjesto aortnog zalistka.

Zaključak. Dislokacija proteze tijekom implantacije umjetnog zalistka je ozbiljna komplikacija. U većini slučajeva sami umjetni zalistak se može repozicionirati na drugo mjesto u aorti ili se može postaviti novi zalistak u već postavljeni zalistak. U slučaju neuspjeha, potrebna je dostupnost kardijalne kirurgije. Tehonološki napredak, iskustvo operatera i adekvatna periproceduralna priprema smanjuju rizik komplikacija.

Ključne riječi: *aortna stenoza, trnaskateterska zamjena aortnog zalistka, migracija TAVI balon ekspandirajućeg zalistka*