Rupture of the NovaFlex balloon during transcatheter aortic valve implantation and subsequent dissection of the right iliac arteries

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Abstract

We report a case with a very rare complication of transcatheter aortic valve implantation. Rupture of the NovaFlex balloon (Edwards transfemoral balloon catheter) occurred during the inflation of the Edwards SAPIEN valve, resulting in dissection of the right common and external iliac arteries during withdrawal of the balloon catheter. The NovaFlex balloon is a part of the Edwards NovaFlex XT transcatheter delivery system.

Keywords: TAVI • Complication • Balloon rupture

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has become an alternative therapy for patients with severe aortic stenosis (AS) and at high risk for surgery [1]. Despite being less invasive than open-chest aortic valve replacement, TAVI remains associated with potentially serious complications [2]. Improved understanding of the potential complications associated with TAVI might help to improve outcomes and allow wider application of this therapy.

CASE PRESENTATION

A 72-year old male patient presented to our hospital with a history of hypertension, severe chronic obstructive pulmonary disease (FEV1 < 0.6 l), coronary artery disease as well as dyspnea (NYHA class IV) and poor response to full medical treatment. His echocardiography revealed a severely-calcified AS with a valve area of 0.5 cm², the mean transvalvular gradient was 56 mmHg and the left ventricular ejection fraction was 50%. He was at high risk for surgery (logistic EuroSCORE = 18.78%). A 23-mm Edwards SAPIEN XT valve was implanted percutaneously through the right femoral artery.

The native valve seemed very calcified during and after balloon predilatation (Supplementary Video 1). During valve implantation and at the final stage of rapid fluid-inflation using the inflation device (suction kit), injection resistance diminished, and rupture of the valve-loaded NovaFlex balloon (Edwards transfemoral balloon catheter) was noted on fluoroscopy. After the deployment of the Edwards SAPIEN valve, the NovaFlex balloon could not be deflated fully and patient detriorated haemodynamically. Therefore, we pulled back the NovaFlex balloon catheter to descending aorta while applying suction. The distal part of the NovaFlex balloon could not be retracted back into the NovaFlex introducer sheath. The distal part of the NovaFlex balloon was not deflated but blood was entering the inflation device. The NovaFlex balloon was pulled back to the level of the right iliac artery together with delivery system. We felt resistance at this level and performed a surgical exploration of right common and external iliac arteries (Fig. 1a and b), and found that the balloon had ruptured and broken into two separate pieces (Fig. 1c). During withdrawal of the distal part of the NovaFlex balloon, the iliac artery was damaged and a small amount of intimal tissue came out with the balloon. Afterwards, right aortofemoral bypass graft surgery was performed immediately; an aortogram was obtained, which indicated that the valve was appropriately positioned, that there was mild paravalvular leakage and that the aortofemoral bypass graft was patent (Fig. 2, Supplementary Video 2).

A well-functioning prosthesis with an area of 1.8 cm², a peak gradient of 18 mmHg and mild paravalvular leakage was noted in a post-procedural echocardiographic assessment. The patient died from respiratory failure secondary to severe chronic obstructive pulmonary disease a month after the procedure.

There are two most commonly used valves: Edwards SAPIEN and CoreValve. Edwards SAPIEN valve is balloon-expandable and predilatation is needed before the valve replacement. CoreValve is self-expandable and it has been shown that CoreValve is effective and safe without predilatation; however, some experts prefer predilatation [3]. During TAVI procedure, there is a risk of aortic root rupture secondary to balloon predilatation, which can be avoided by not overinflating the balloon [4]. Balloon rupture is one of the known complications of the aortic balloon valvuloplasty [5]. Predilatation balloon rupture is a known complication of TAVI, but, to our best knowledge, this is the first case of the NovaFlex balloon rupture. Balloon inflation is performed using a manual injection of a 15:85 contrast/saline solution and...
the volume has to be determined before valve crimping to obtain the optimal valve diameter. Contrast/saline ratio is important to ensure easy deflation and inflation of the balloon. During preparation of the valve, the NovaFlex balloon catheter is aspirated to remove air inside. The valve is placed on the NovaFlex XT catheter and is crimped by a crimper in an appropriate location. The catheter is advanced through the NovaFlex introducer sheath inserted by a femoral access until the proximal descending aorta where it exits the sheath and the valve is placed on the balloon.

**COMMENT**

We assume that there are four possible reasons for this complication. Firstly, the balloon might have been scratched during crimping of the valve onto the balloon, resulting in decreased resistance and rupture of the balloon. We had an experienced technician prepare the balloon, who reported that there had been no problems with the procedure. Secondly, uneven expansion of the balloon due to asymmetric calcification might have caused the rupture; however, in this case, predilatation of the valve was performed with a balloon of the same brand, and no deformation was observed on the predilated balloon. Thirdly, the balloon might have been damaged during placement of the valve from the sheath onto the balloon in the proximal descending aorta. However, we did not see any sign of resistance or deformation while advancing the balloon through the sheath and placing the valve onto the balloon. Fourthly, there might have been a manufacturing defect; however, we could not examine this due to the complete rupture of the balloon during surgical removal. In conclusion, each stage of the TAVI, including valve preparation, requires meticulous attention and should be performed by experienced interventionalists. It should be kept in mind that surgical intervention may be needed at any time. These complications can be avoided by using more durable valves and improved delivery systems.

**SUPPLEMENTARY MATERIAL**

Supplementary material (Video 1 and Video 2) is available at EJCTS online.

**Video 1**: Severe calcification of the valve is seen during balloon predilation.

**Video 2**: The aortogram shows the aorta from the aortic root until the aorta femoral graft after the procedure.

**Conflict of interest**: None declared.

**REFERENCES**


