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Case Report

Delivery balloon rupture during transcatheter heart valve alignment procedure in extreme descending aorta tortuosity

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ABSTRACT

A 79-year-old man with a history of partial resection of the lung and the bladder due to cancer, hypertension, dyslipidemia, and heart failure, underwent transcatheter aortic valve replacement with a SAPIEN 3 (S3) valve (Edwards Lifesciences, Irvine, CA, USA). Preprocedural examination showed a bicuspid aortic valve and severe calcification of the leaflets. Computed tomography showed great tortuosity of the descending aorta. A 29-mm S3 valve prosthesis was advanced into the aorta, but a high degree of resistance was encountered in the middle of the descending aorta. The prosthesis was advanced to the level of aortic valve and an attempt was made to deploy the valve. However, the valve balloon did not expand. A balloon rupture was suspected. The balloon catheter was pulled back into the eSheath (Edwards Lifesciences), and the catheter and eSheath were removed together. Rupture of the balloon was confirmed. A new eSheath and prosthesis were prepared, with delivery supported with a Lunderquist guidewire (Cook Medical, Bloomington, IN, USA). The valve alignment procedure was performed in a straighter portion of the descending aorta. The new 29-mm S3 valve was then successfully implanted. <**Learning objective:** Rupture of the balloon during transcatheter aortic valve replacement is a rare, potentially fatal complication. A case of balloon rupture during a valve alignment procedure with successful retrieval is reported along with a review of the complication involved.>

Introduction

Transcatheter aortic valve replacement (TAVR) is an alternative to surgery to treat severe aortic stenosis (AS) in patients at high surgical risk. In specific cases in which the descending aorta is highly curved, TAVR is often attempted with a transfemoral approach [1]. Rupture of the balloon during TAVR is a rare complication but is potentially fatal. Several cases of balloon rupture due to sharp calcification of the aortic valve have been reported [2,3]. We report a case of balloon rupture during TAVR with successful retrieval, and we review this complication.

Case report

A 79-year-old man with a history of partial resection of the lung and the bladder for cancer had repeated episodes of heart failure because of severe AS. Echocardiography showed a severely stenotic, calcified bicuspid valve with an area of 0.7 cm^2, a peak velocity of 4.2 m^2/s, left ventricular diastolic diameter of 56 mm, and a low left ventricular ejection fraction of 35%. The N-terminal pro-brain natriuretic peptide level was elevated at 3567 pg/ml. The diagnosis was New York Heart Association class III heart failure due to severe AS. He also had hypertension and dyslipidemia. Diagnostic coronary angiography indicated no significant coronary artery disease. The logistic EuroSCORE and Society of Thoracic Surgeons scores were 9.0% and 5.2%, respectively. Preoperative multislice computed tomography revealed a valve annulus area of 598 mm^2 and circumference-derived diameter of 88.5 mm. There was extreme tortuosity of the descending aorta (Fig. 1A). After

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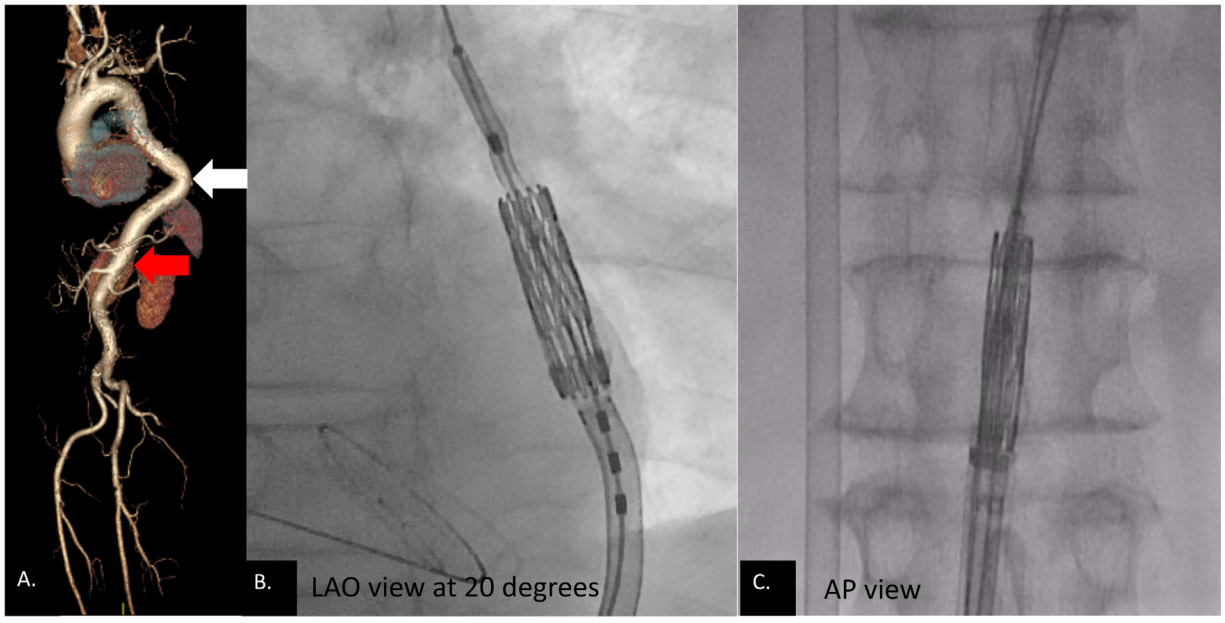

Fig. 1. (A) Preprocedural multislice computed tomography demonstrating extreme tortuosity of the descending aorta. First valve alignment position (*white arrow*); second valve alignment position (*red arrow*). (B) First valve alignment procedure [left-anterior oblique (LAO) view at 20 degrees]—the delivery balloon was distorted. (C) Second valve alignment procedure [anterior–posterior (AP) view]—the delivery balloon was not distorted.

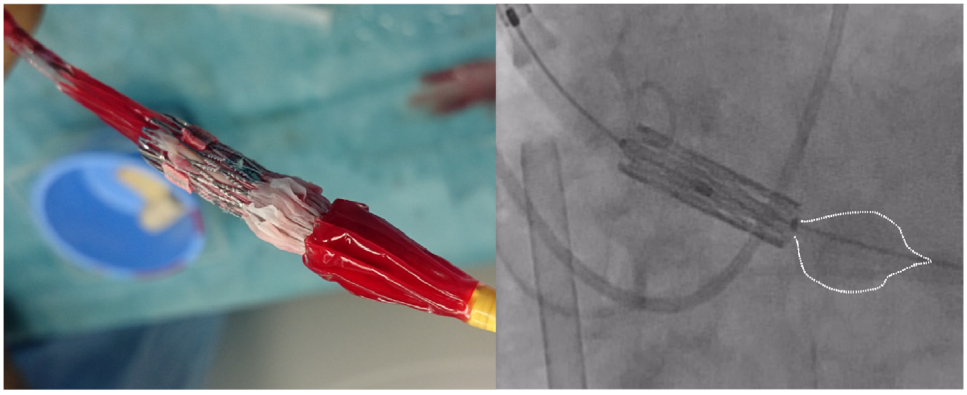

Fig. 2. Only the balloon of the distal area of the valve expanded, but the transcatheter heart valve itself did not (*white dotted line*).

discussion of various devices and approaches among the heart team, we elected to perform TAVR with a SAPIEN 3 (S3) valve (Edwards Lifesciences, Irvine, CA, USA) via the right femoral artery with surgical cutdown. Because of the patient's low ejection fraction, veno-arterial extracorporeal membrane oxygenation via the left femoral artery and right femoral vein was used.

TAVR was performed under general anesthesia with intratracheal intubation. An eSheath (Edwards Lifesciences) was used to introduce the device. Balloon aortic valvuloplasty was performed with a balloon (diameter 23 mm, length 40 mm, Zmed, NuMED Inc., Hopkinton, NY, USA) under rapid pacing. A SAPIEN Commander delivery system was advanced through the descending thoracic aorta, but resistance was met at that point. Great force was necessary to achieve valve alignment, as resistance was again encountered during that process (Fig. 1B). The prosthesis was then advanced to the level of the aortic valve and the device was deployed. However, while the balloon in the distal area of the valve expanded, the transcatheter heart valve itself did not (Fig. 2). The inflation procedure was therefore halted partway through. A valve balloon rupture was suspected, whereupon the catheter was pulled back to the eSheath and removed together with the eSheath. Inspection of the valve balloon indicated that it had indeed ruptured (Fig. 3) during the alignment procedure. The damaged unit was replaced with a new eSheath and valve, and we inserted a Lunderquist guidewire (Cook Medical, Bloomington, IN, USA) through the left femoral artery to help guide the device. This time, the valve alignment procedure was performed in the lower, straight part of the descending aorta and was completed without difficulty (Fig. 1C). The prosthesis was then successfully implanted. After the procedure, an aortogram showed no evidence of aortic injury.

Discussion

Balloon rupture during TAVR is a rare complication that is potentially fatal. Several cases have been reported in which the balloon ruptured due to a sharp spike in calcification of the aortic valve [2,3]. Because this patient did not have sharp or bulky calcification present in the aortic valve, it was surmised that the balloon rupture occurred during the alignment procedure.

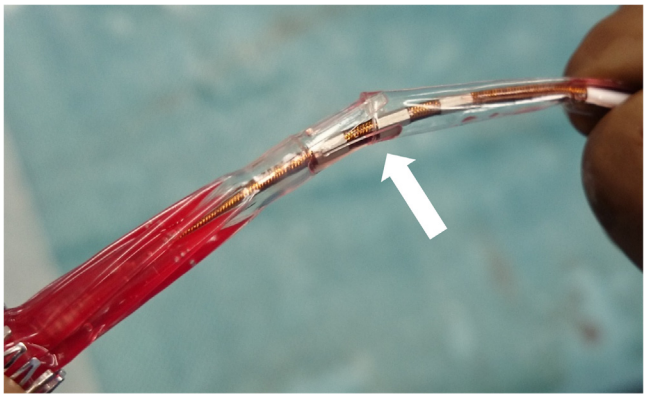

Fig. 3. The 29-mm valve balloon is seen to be ruptured after withdrawal (*white arrow*).

In patients with a highly tortuous aorta, it is difficult to pass the device through the aorta because of high resistance. In this case, the transcatheter heart valve was successfully passed with support by a Lunderquist guidewire inserted via the femoral artery opposite the eSheath. Although these guidewires can help straighten tortuous vessels, there is also the possibility of vascular injury due to the guidewire itself. A previous case study noted vascular dissection and vascular rupture in a highly tortuous aorta [4]. Extensive aortic dissection led to severe visceral ischemia and the death. Even if the prosthesis can be passed all the way to the aortic valve, the device operability is often significantly compromised. Therefore, in patients with a highly tortuous aorta, alternative approaches should be considered.

The Medtronic CoreValve Evolut R (Medtronic, Minneapolis, MN, USA) 34 mm, which would have matched the patient's valve annulus and diameter, is still not available in Japan. Moreover, at that time in Japan, use of the SAPIEN XT was not indicated for bicuspid valve procedures, with the only method available for use of the SAPIEN XT being a transapical approach. Currently, the S3 valve is available for delivery through either the apex or ascending aorta. A transascending aortic approach would be safer in patients with low ejection fraction than a transapical approach, because any myocardial damage can be avoided with its use. A previous case study reported an S3 valve had been deployed with the transsubclavian approach [5], but our patient's subclavian artery was too narrow for the device to pass through. For these reasons, the decision was made to perform S3 TAVR via the femoral artery.

The SAPIEN Commander delivery system reduces the valve's profile by shifting the position of the prosthetic valve and the delivery balloon. It is therefore typically necessary to perform a valve alignment procedure in the descending aorta to place the prosthetic valve on the delivery balloon. Since the delivery balloon is expanded and deflated several times, it can become wrinkled. When the valve is properly crimped and alignment can be done in a linear area of an aorta, the delivery balloon will not be pinched by the pusher unit. Unfortunately, in this case, the delivery balloon and the pusher unit were angled. We therefore concluded that the delivery balloon was pinched by the pusher unit, stressing the most fragile part of the balloon and tearing it by the force of the shaft. Having the eSheath positioned lower in the aorta on the second attempt allowed the device to be straight enough for the alignment procedure.

When such alignment is carried out, the potential for balloon rupture should always be considered. The balloon should not be withdrawn using excessive force, and visual confirmation should be maintained of the balloon via fluoroscopy. The alignment procedure was carried out using a left-anterior oblique view at an angle of 20°. The alignment procedure is typically performed with an anterior–posterior cranial view. However, because this case was marked by a tortuous aorta, the anterior–posterior cranial view was not suitable. The left-anterior oblique view was suitable for the alignment procedure in this particular case. In general, when great force is necessary to achieve valve alignment or the delivery balloon becomes distorted, balloon rupture should be suspected. A rupture is also indicated if there is return of blood into the inflation device with balloon deflation. Fortunately, the delivery balloon in this case did not expand at all (Fig. 2), allowing the valve to be withdrawn into the eSheath for removal. If the valve had not fit into the eSheath, a wide incision from the iliac artery to the femoral artery would have been necessary to remove it.

In conclusion, the major problem in this case was that the alignment procedure was not halted despite the resistance encountered during the heart valve alignment procedure. Careful attention must be paid to any complication that might arise in this procedure. As seen in this case, one such complication can be balloon rupture during the alignment procedure. Our experience in this case leads to the following recommendations: that valve alignment be performed not in the tortuous portions of the descending aorta but in a relatively linear part of the vessel; that the balloon not be pulled aggressively during the alignment procedure; and that the balloon be deflated and negative pressure be created if balloon rupture is suspected.

Acknowledgments

None.

Conflict of interest

None.

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