Miyasaka et al., J Clin Case Rep 2016, 6:4
DOI: 10.4172/2165-7920.1000763

Journal of Clinical Case Reports

Case Report Open Access

Sudden Onset Massive Paravalvular Aortic Regurgitation Induced by Balloon Rupture during Transcatheter Aortic Valve Implantation: A Case Report

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Abstract

A 78-year-old woman with severe aortic stenosis underwent transcatheter aortic valve implantation (TAVI) with a balloon expandable bioprosthesis: a 23-mm Sapien XT valve (Edwards Life Sciences, Inc., CA, USA). A set of the valve and a balloon (NovaFlex, Edwards Transfemoral Balloon Catheter, Edwards Life Sciences, Inc., CA, USA) was successfully delivered to an optimal position using a 16-French expandable introducer hydrophilic sheath. Inflation of the balloon was commenced, and expansion was initially smooth. However, it ruptured immediately before completion of expansion, resulting in a rapid deterioration in hemodynamics. Even though no migration of the stent valve was observed, transesophageal echocardiography and aortography revealed massive paravalvular aortic regurgitation (AR), suggesting that AR was attributable to insufficient expansion. After post -dilatation of the stent valve using a 23-mm balloon (Edwards Transfemoral Balloon Catheter, Edwards Life Sciences, Inc., CA, USA), the patient's condition began to improve, and further aortography indicated an improvement in paravalvular AR. This case represented that balloon rupture could led to sudden onset massive paravalvular AR. Interventional cardiologists should recognize it as a significant complication in patients undergoing TAVI using a balloon-expandable bioprosthesis, with the possibility of severe cardiogenic shock.

Keywords: Novaflex; SapienXT; Complication; Transcatheter aortic valve implantation; Paravalvular aortic regurgitation; R; Shock

Introduction

Despite recent progress in its treatment, severe aortic stenosis (AS) is still characterized with both high morbidity and mortality. Moreover, surgical aortic valve replacement (SAVR), the only standard treatment option considered effective, is often intolerable in patients at high risk for surgery. Therefore, Transcatheter aortic valve implantation (TAVI), in which a bioprosthetic valve inserted through a catheter is implanted within a diseased native aortic valve, has recently emerged as another option in such cases.

The placement of aortic transcatheter valves (PARTNER) trial demonstrated that TAVI was superior to the standard medical therapy in terms of 1-year mortality in patients at high-risk for conventional surgery [1]. A randomized controlled non-inferiority trial showed that TAVI was comparable to SAVR in 1-year mortality in patients at high risk for surgery who were nevertheless considered to be candidates for surgery [2]. Moreover, a 5-years follow-up study showed that a long-term mortality between the two groups was not statistically different [3, 4].

The results of the PARTNER trial showed that TAVI was associated with a lower incidence of all-cause mortality than SAVR at 30 days (3.4% vs. 6.5%, respectively), suggesting that this procedure is safe [2]. However, severe complications have been reported during TAVI in approximately 5% of patients, with in-hospital mortality ranging from 31%-40% [5,6]. These complications include paravalvular aortic regurgitation (AR), aortic root rupture, left ventricular perforation, coronary obstruction, atrioventricular block, embolization and migration of the valve prosthesis, and vascular injury of the access site; moreover, these complications frequently require additional surgical or interventional bailout maneuvers, and are occasionally even fatal [5,6]. Thus, it is likely that TAVI needs more information to warrant its safety.

Here we report a case of massive paravalvular AR developing due to balloon rupture during inflation of a balloon expandable bioprosthesis; Sapien XT valve (Edwards Life Sciences, Inc., CA, USA). Though balloon rupture during inflation is evidently a significant concern in TAVI, little information is available on complication caused by this incidence, and to our knowledge, only two cases have been reported on it to date [7,8]. In the one case, injury of the iliac artery was seen as an adverse event associated with balloon rupture [7]. Here we describe in detail the clinical course in a patient in whom this complication occurred by balloon rupture. We presume that our finding represents a complication and recovery when severe paravalvular AR due to balloon rupture happens during TAVI.

Case Report

A 78-year-old woman with a history of severe restrictive lung disease due to nontuberculous mycobacterial infection was referred to our hospital for the treatment of severe symptomatic AS. Her condition was classified as class II based on the New York Heart Association Functional Classification [9]. A transthoracic echocardiogram revealed mild AR with severely calcified tricuspid aortic valves. Other findings comprised a peak gradient of 99 torr, a mean gradient of 62 torr, a valve area of 0.5 cm^2, left ventricular concentric hypertrophy, and a left ventricular ejection fraction of 66%. The Society of Thoracic Surgeons Predicted Risk of Mortality Score and logistic EuroSCORE were 6.4% and 7.1%, respectively [10,11].

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Received March 15, 2016; **Accepted** April 18, 2016; **Published** April 23, 2016

Citation: Miyasaka M, Kato S, Tada N, Tetsutaro M, Kami M, et al. (2016) Sudden Onset Massive Paravalvular Aortic Regurgitation Induced by Balloon Rupture during Transcatheter Aortic Valve Implantation: A Case Report. J Clin Case Rep 6: 763. doi:10.4172/2165-7920.1000763

Respiratory function tests revealed severe restrictive ventilatory defects, with a vital capacity (VC) of 0.91 L and %VC of 44%. Therefore, TAVI was performed via the right femoral artery using an Edwards SAPIEN valve (Edwards Life Sciences, Inc., CA, USA). A transthoracic echocardiogram revealed that the diameter of the aortic annulus was 23 mm. Contrasted computed tomography revealed that the annulus had an area of 429 mm^2 and both valvular and bulky subvalvular calcification (Figure 1).

A 23 mm Sapien XT valve (Edwards Life Sciences, Inc., CA, USA) was chosen rather than a 26 mm valve to minimize the risk of annulus rupture due to the bulky subvalvular calcification. No sign of paravalvular AR was identified during predilatation using a 20 mm balloon (Edwards Transfemoral Balloon Catheter, Edwards Life Sciences, Inc., CA, USA).

The valve was successfully delivered to an optimal position using a 16-French expandable introducer hydrophilic sheath (E-sheath, Edwards Life Sciences, Inc., CA, USA). Inflation of the balloon (NovaFlex, Edwards Transfemoral Balloon Catheter, Edwards Life Sciences, Inc., CA, USA) was commenced, and expansion was initially smooth. However, it ruptured immediately before completion of expansion, which resulted in a rapid deterioration in hemodynamics, with blood pressure showing 70/30 mmHg. Continuous infusion of norepinephrine was therefore initiated. Ventricular fibrillation then developed, but was successfully converted to a sinus rhythm by application of external electric shock.

Even though no migration was observed either during or after positioning of the stent valve, transesophageal echocardiography and aortography revealed sudden onset massive paravalvular AR and severe mitral regurgitation (MR), suggesting that the paravalvular AR was attributable to insufficient expansion and secondary MR to massive paravalvular AR occurred. After repeated dilatation of the stent valve using a 23 mm balloon (Edwards Transfemoral Balloon Catheter, Edwards Life Sciences, Inc., CA, USA), the patient's condition began to improve, and further aortography indicated an improvement in paravalvular AR.

After being transferred to the cardiac intensive care unit, the patient was treated with diuretics and placed on non-invasive positive pressure ventilation. The patient was discharged at 14 days postoperatively.

Discussion

This case shows that balloon rupture can leads to sudden onset massive paravalvular AR with cardiogenic shock, which is a rare, but significant, complication of TAVI.

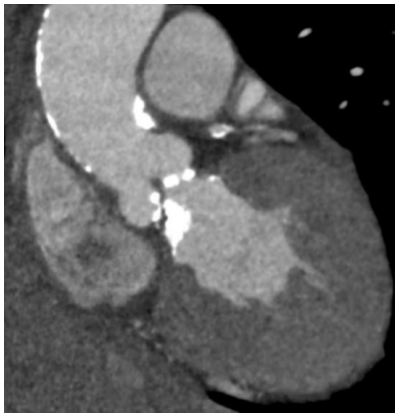

Figure 1: A bulky calcification at the left ventricular out flow tract.

Balloon rupture is a significant concern in TAVI, although little information regarding complications following balloon rupture is available. However, it is most likely that once balloon rupture occurs, which can leads to unexpected complications. In the balloon rupture, balloon rupture occurred in 3 out of 519 cases (0.58%), however adverse events occurring subsequent to this are not described in that report [12]. In one case report, however, injury of the iliac artery was mentioned as a severe adverse event associated with balloon rupture [7]. To our knowledge, no other studies to date have reported severe paravalvular AR following balloon rupture and circulatory deterioration seen in the present report. As this complication was not yet reported until this study, further studies are clearly needed to identify associated risk factors and establish optimal management.

The clinical course in this patient suggests an association between balloon rupture and the development of paravalvular AR. Paravalvular AR following TAVI results from incomplete circumferential apposition of the valve prosthesis with the aortic annulus [13]. It should be noted that the balloon ruptured at the final stage of rapid inflation, and that dilatation of the stent valve appeared to be insufficient. Furthermore, an improvement in paravalvular AR and severe MR were observed immediately after post-dilatation of the valve. These findings indicate that the severe paravalvular AR seen here was attributable to insufficient expansion of the valve prosthesis due to balloon rupture, and that severe MR occurred secondary to massive paravalvular AR.

Interestingly, bulky calcification was observed in the present patient, which may have played an important role in the development of balloon rupture (Figure 1). Earlier case reports have suggested a number of possible mechanisms underlying balloon rupture, including uneven expansion due to asymmetric calcification, manufacturing defects, damage to the balloon when crimping the valve prosthesis onto the balloon, and delivery of the valve prosthesis through a sheath and the aorta [7,8]. In the present patient, we believe that rupture may have occurred due to damage incurred when the balloon came into contact with the bulky sub-valvular calcification, although we cannot be sure.

Conclusions

Interventional cardiologists should recognize that severe paravalvular AR secondary to balloon rupture is a significant complication in patients undergoing TAVI using a balloon-expandable bioprosthesis, with the possibility of severe cardiogenic shock.

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