Balloon Rupture during Pre-Dilation for Transcatheter Aortic Valve Replacement in Patients with Bicuspid Aortic Valve: Classification, Treatment Strategies, and Prevention

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Abstract: Balloon rupture during transcatheter aortic valve replacement (TAVR) is a rare but serious complication. We present two cases of balloon rupture in patients with severe aortic stenosis and type 0 bicuspid aortic valve. Three-dimensional models based on pre-procedure cardiac CT angiography were used to post hoc investigate these cases. The models revealed asymmetrical distribution of calcifications with sharp spiked features in bicuspid aortic valves. The narrow and calcified orifice resulted in uneven force distribution on the expanded balloon, leading to balloon rupture. Furthermore, we reviewed the classification and causes of balloon rupture and summarized avoidance methods and treatment options. Accurate pre-procedural anatomy evaluation and computer modeling are crucial for planning and managing TAVR procedures. Further investigation through computer simulation is needed to determine the appropriate balloon size and inflation locations to provide the reference of preparation pre-procedure.

KEY WORDS: Balloon rupture; self-expanding valve; transcatheter aortic valve replacement; bicuspid aortic valve; computer modeling.

1. Introduction

Transcatheter aortic valve replacement (TAVR) is recommended for severe symptomatic aortic stenosis in tricuspid aortic valve patients (1,2). Recent studies have shown promising outcomes for TAVR in patients with bicuspid aortic valves but complications are still a concern (3-7). Bicuspid aortic valves (BAV) have an increased risk of procedural complications due to their anatomical characteristics and the presence of calcium deposits (6,8). Balloon pre-dilation is conventionally considered a mandatory step in TAVR procedure. However, it can lead to balloon rupture, particularly in the presence of local calcification. This paper presents two cases of balloon rupture during pre-dilation in patients with BAV and severe stenosis. The causes, classification, and treatment of balloon rupture are discussed, emphasizing the importance of pre-procedural planning and risk assessment using computer models of aortic root complex.

2. Case Description

2.1 Case 1

A 74-year-old male with a history of coronary artery disease, hypertension, and gout presented with shortness of breath (NYHA class II) and syncope. Echocardiography revealed severe stenosis and mild aortic insufficiency in a BAV with an enlarged ascending aorta. Blood tests showed elevated Troponin I and NT B-type natriuretic peptide levels. Coronary angiography showed no stenosis, and cardiac CT angiography confirmed the BAV with thickened leaflets and severe calcification(Figure 1). The patient refused surgical intervention and was scheduled for TAVR after consultation with the Heart Team.

Six days later, the TAVR procedure was performed using a 26mm TaurusElite valve (Peijia Medical, Suzhou). A 20mm non-compliant TaurusAtoas balloon was used for pre-dilation with temporary pacing of 180 beat/min. During valvuloplasty, a 'waist sign' was observed alongside a calcified mass. Suddenly, the balloon burst, causing contrast leakage into the left ventricle and a rapid decrease in inflation

pressure. Despite balloon rupture, the patient remained asymptomatic. The ruptured balloon was carefully removed, although it got partially stuck at the sheath. The entire delivery system was then retrieved, and a new system was replaced. The 26mm prosthesis was cautiously pulled using a snare to avoid tearing the severely dilated ascending aorta. The prosthesis was released swiftly 5mm above the annulus into the working position. After confirming stability and minimal regurgitation through TEE, the prosthesis was fully released and securely anchored. The final mean pressure gradient was only 10 mmHg. The patient was discharged four days later. One month later, the patient reported no chest tightness or chest pain during routine activities. Ultrasound revealed an average pressure gradient of approximately 20 mmHg and a supravalvular peak velocity of 2.8 m/s with no evidence of paravalvular leakage.

As a result of pre-dilation balloon burst, we analyzed the pre-procedural cardiac CT angiography. Three-dimensional computer model of aortic root clearly showed that a sharp spiked calcification with the tip luminal protrusion of 5.2 mm at anterior side (Figure 2C). The maximum and minimum diameters at each 2 mm from 2 mm below to 10 mm above the annular level (25.1, 26.9mm) and (14.8, 16.7mm), and the ratio ranged from 1.55~1.77 (Video1). Therefore, we speculate that the complete transverse rupture occurred at middle site of balloon, which could be triggered by the tightly contact of highly, asymmetric, and local sharp spiked calcification in BAV.

2.2 Case 2

A 67-year-old male with a history of coronary artery disease presented with worsening chest tightness and pain (NYHA class III). He had previously received drug-eluting stents for the left anterior descending and right coronary arteries. Echocardiography revealed severe stenosis and regurgitation in a type 0 BAV, along with mitral annulus calcification, left ventricular enlargement and reduced function (EF: 37%), thickened interventricular septum, and an enlarged ascending aorta. Cardiac CT angiography confirmed the BAV with severe stenosis and calcification, predominantly at the left coronary cusp (Figure 3). The patient was considered

high-risk for surgery but suitable for TAVR. During TAVR, balloon pre-dilation was attempted, but the balloon revealing a pinhole rupture. Finally, a 26mm TaurusElite valve was successfully implanted, and the patient was discharged after six days. Ten months later, the patient reported no chest tightness or chest pain. Ultrasound indicated an average pressure gradient of approximately 27 mmHg and a peak velocity of 2.8 m/s across the valve, with mild regurgitation.

The 3D aortic root models indicated that type 0 BAV with a severe stenotic orifice of 77.8 mm^2 and abundant calcification which had uneven or sharp surface (Figure 4B and C). The maximum and minimum diameters at each 2 mm from supra 2mm and 12 mm annulus were (25.6, 27.6mm) and (15.9, 22.0mm), and the ratio ranged from 1.25 to 1.51 (Video 3). Therefore, it is possible that balloon surface was damaged by the locally sharp calcium during the balloon is expanding against the narrow and elliptic aortic orifice. This was manifested by the presence of a pronounced 'waist sign' at the balloon shoulder during pre-dilation, where was identified a subsequent pinhole rupture of the balloon (Figure 4D).

3. Discussion

In this paper, we report two cases of balloon rupture during pre-dilation in Type 0 BAV with severe calcification. In Case 1, heavy calcification and local sharp spiked calcification were obviously related to an incomplete rupture with a large crack. In Case 2, although there were no overt signs of rupture on the balloon on the angiogram, a small pinhole was demonstrated with filling saline leakage. Three-dimensional models were used to highlight the asymmetric distribution with local sharp spiked features in BAV. This asymmetric distribution of calcification leads to a narrow and elongated orifice that produces “waist sign” on angiogram during balloon expansion. This sign indicates an uneven force distribution on the balloon after expansion. Moreover, the presence of localized spiky calcifications further induces balloon rupture.

Balloon rupture is a rare occurrence, with only a few reported cases in the

balloon-expandable valve (9-11). Balloon rupture can be classified into three types based on crack morphology: Type 1 (pinhole balloon rupture), Type 2 (incomplete rupture that is locally continuous), and Type 3 (complete rupture that tears into two or more separate parts). Balloon rupture can be caused by local sharp calcification, severe stenotic aortic valve orifice (10), or damaged by prosthesis frame or devices (9). Although the strategy of direct TAVR and post-dilation can avoid the complication of pre-dilation balloon rupture, the two patients presented here were BAV with severe stenosis and calcification. The aortic valve areas of both cases were only 55.8 mm^2 and 77.8 mm^2. Therefore, prior balloon dilatation is necessary to help facilitate the crossing of native valve and device expansion.

Although rare, balloon rupture can complicate the procedure and increase the risk of complications, including ventricular or aortic injury, bleeding, and hemodynamic collapse. To mitigate this risk, smaller diameter balloons can be used for type 0 BAV with severe calcification. Maintaining co-axiality between the balloon and the prosthesis frame is crucial to prevent balloon damage. Manufacturers can explore the use of high-strength materials with fiber reinforcement or innovative structural designs to enhance balloon toughness. For example, the hourglass-shaped TAV8 valvuloplasty balloon (Venus MedTech., Hangzhou) (12) has been employed to reshape BAV stenosis and may be less prone to rupture due to its larger contact area for distributing balloon pressure. Overall, proactive measures should be implemented to minimize the occurrence of rupture and ensure the safety and effectiveness of TAVR.

The successful and safe removal of a ruptured balloon is critical during TAVR. For Case 1, attempts to retrieve the ruptured balloon through the sheath were unsuccessful despite repeated efforts, possibly due to the ruptured balloon portion becoming stuck at the end of the sheath. Consequently, we had to swiftly remove the entire sheath and replace it with a new delivery system (Figure 5). For Case 2, the balloon had a pinhole rupture, which could be easily removed entirely from the sheath. However, removing a balloon with a complete rupture can be challenging and may

result in serious complications, such as vascular injury. To address this issue, a right-to-left femoral loop method has been proposed (11,13), where the proximal part of the ruptured balloon is retrieved through the eSheath, while the distal part is pushed forward using a snare and pulled back with the wire through another femoral sheath. This technique helps in safely removing the ruptured balloon. If hemodynamics become unstable after balloon rupture, it is important to prioritize valve implantation before addressing the removal of the ruptured balloon to ensure normal blood flow is restored promptly and minimize the risk of complications.

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Figure

Figure 1

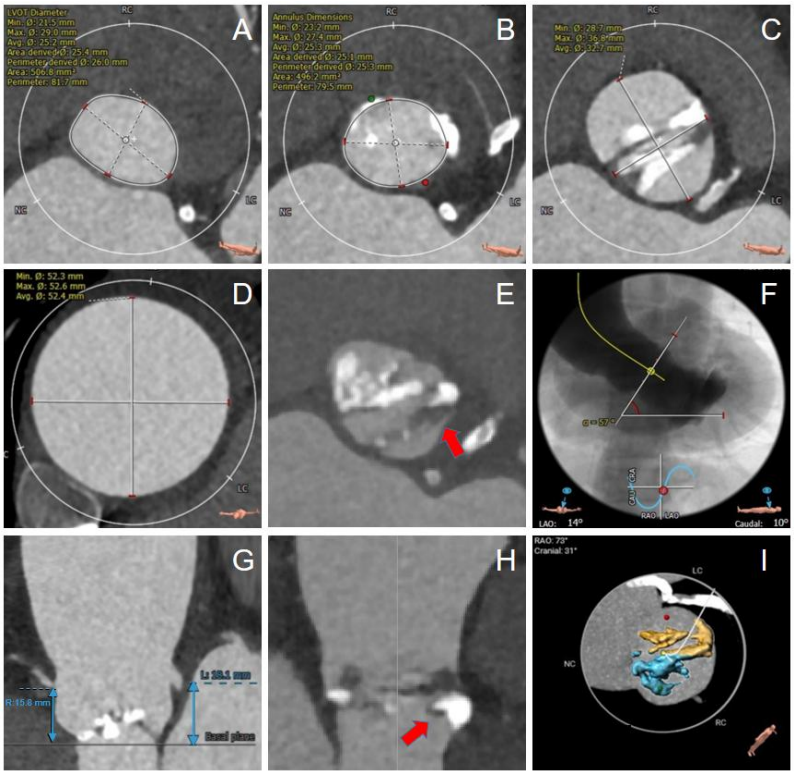

Figure 2

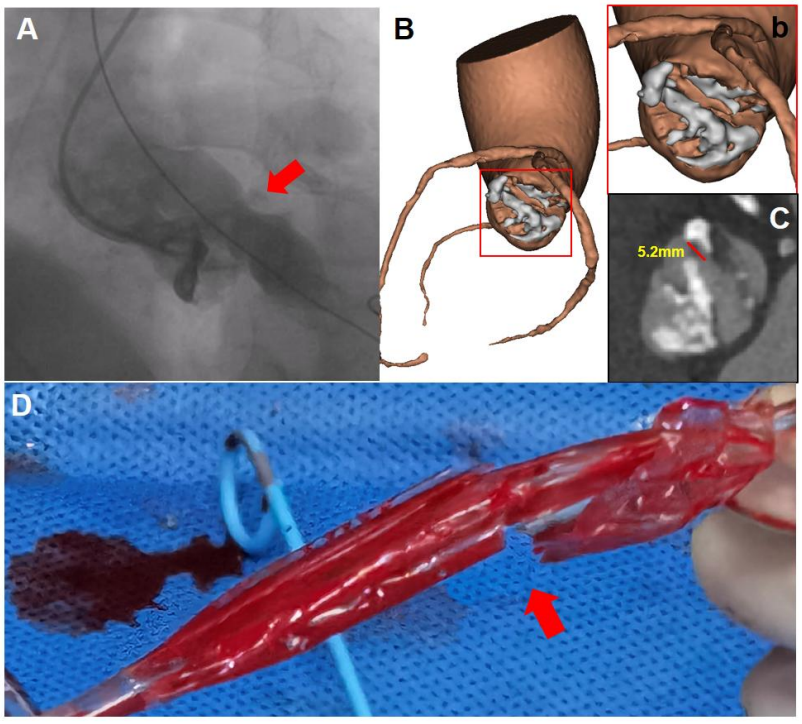

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Figure 3

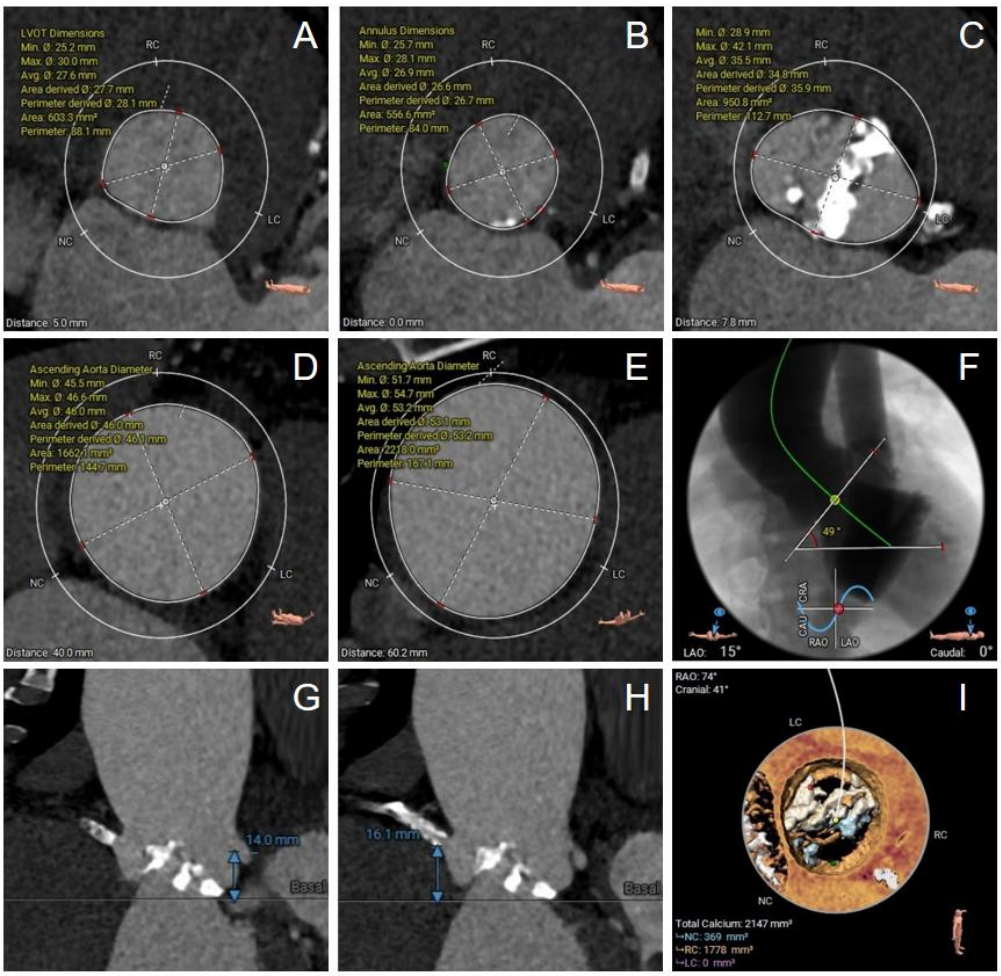

Figure 4

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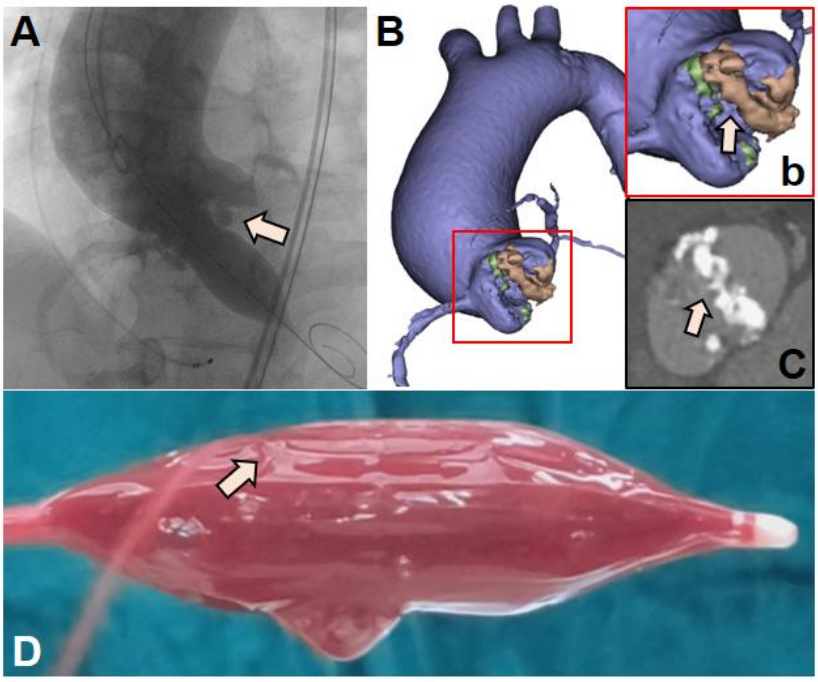

Figure 5

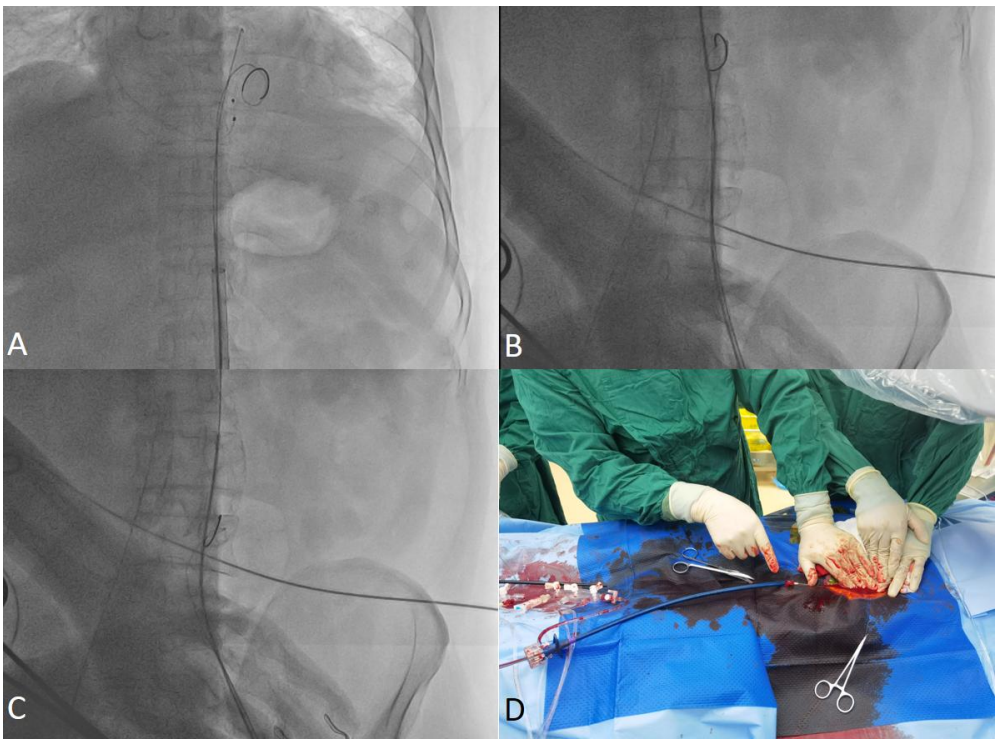

Figure legend

Figure 1. Pre-procedural CT assessment of aortic valve dimensions (Case 1).

(A) LVOT at 5mm below annulus; (B) aortic valve annulus; (C) sinus of Valsalva; (D) enlarged ascending aorta at the maximum cross-section; a sharp spiked calcification at anterior LVOT in the cross-section view (E) and longitudinal view (H); (F) aorto-ventricular angle; (G) heights of left and right coronary ostium; (I) 3D calcification volume and distribution.

Figure 2. Balloon burst during pre-dilation (Case 1).

(A) Balloon waist sign on the anterior side compressing with a calcified mass (arrow). (B) Three-dimensional reconstruction of BAV and highly, asymmetric calcification with a sharp spiked calcification at anterior LVOT in zoom view (b, arrow) and CT image (C, arrow). (D) Complete transverse rupture of the balloon (arrow).

Figure 3. Pre-procedural CT assessment of aortic valve dimensions (Case 2).

(A) LVOT at 5mm below annulus; (B) aortic valve annulus; (C) sinus of Valsalva; (D) ascending aorta at 40mm above annulus; (E) maximum ascending aorta; (F) aorto-ventricular angle; heights of (G) left and (H) right coronary ostium; (I) calcification volume and distribution.

Figure 4. Pinhole balloon rupture during pre-dilation (Case 2).

(A) Balloon waist sign at proximal shoulder contacted with a calcified mass (arrow). (B) Three-dimensional reconstruction of BAV and highly, asymmetric calcification at left (brown) and right sinuses (green), with a uneven or sharp surface at left sinus in zoom view (b, arrow) and CT image (C, arrow). (D) Pinhole balloon rupture identified with filling saline leakage (arrow).

Figure 5. Key steps of our retrieval approach (Case 1).

(A-C) the ruptured balloon was retrieved to the sheath with the wire; (D) remove the entire sheath out of the body.

Online video legend

Video S1. A sharp spiked calcification was observed at the left side of left ventricle outflow tract in this severe stenotic bicuspid aortic valve computed tomography (Case 1)

Video S2. Balloon rupture and the contrast injected into the left ventricle during pre-dilation (Case 1)

Video S3. Cross-sectional views of the calcification distribution in aortic root (Case 2)

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