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Case Report

Successful balloon aortic valvuloplasty as a bridge therapy to transcatheter aortic valve implantation during the proctoring period

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ABSTRACT

In Japan, transcatheter aortic valve implantation (TAVI) with Edwards-SAPIEN XT valve (Edwards Lifesciences Inc., Irvine, CA, USA) started in October 2013. All institutions should undergo a training period to perform TAVI independently. Balloon aortic valvuloplasty (BAV) as a bridge to TAVI during the training period should be performed with caution to avoid severe aortic regurgitation (AR) because bailout TAVI is not possible. We present a case in which BAV was successfully performed as a bridge to TAVI during the training period. The patient was an 85-year-old man with medically uncontrollable congestive heart failure due to severe aortic valve stenosis. The aortic valve area was 0.60 cm^2 with a left ventricular ejection fraction of 20%. TAVI was considered a safe but high-risk strategy owing to the unstable hemodynamic condition. We chose BAV as a bridge therapy to TAVI. The aortic annulus diameter was 25.3 mm on computed tomography scans. We chose a 20-mm balloon catheter to avoid BAV-induced AR. Transfemoral TAVI was performed successfully 16 days after BAV using a 26-mm SAPIEN XT valve. The postoperative course was uneventful. The case demonstrated BAV as a bridge therapy to TAVI can be safely and effectively performed during the training period.

<**Learning objective:** All institutions should undergo a training period to start transcatheter aortic valve implantation (TAVI). Balloon aortic valvuloplasty (BAV) during the training period should be performed with caution. The present case suggests that BAV as a bridge therapy to TAVI can be safely performed during the training period. An accurate measurement of aortic annulus diameter and the use of an undersized balloon catheter might reduce the risk of BAV-related aortic regurgitation.>

Introduction

Staged treatment is often conducted for patients with severe aortic valve stenosis undergoing transcatheter aortic valve implantation (TAVI). Several studies have demonstrated the efficacy of balloon aortic valvuloplasty (BAV) as a bridge therapy to TAVI in high-risk patients [1,2]. Compared with the past, BAV is currently conducted more frequently, with the introduction of TAVI [1,2]. One of the most serious complications after BAV is uncontrollable aortic regurgitation (AR), which often requires emergent surgical aortic valve replacement (SAVR) or TAVI [2–8]. In Japan, SAPIEN XT (Edwards Lifesciences Inc., Irvine, CA, USA) has become commercially available at limited centers in Japan. Therefore, TAVI is still in the introductory phase in most Japanese institutions. Before commencing TAVI, all institutions are required to undergo a training period. Special care is required when conducting BAV as a bridge therapy during the training period because bailout TAVI is not possible. Herein, we present a patient with severe symptomatic aortic valve stenosis who was successfully treated with BAV and percutaneous coronary intervention (PCI) to control congestive heart failure, followed by TAVI. The procedure was conducted during the training period.

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Case report

An 85-year-old man with mild exertional dyspnea was referred to our hospital for treatment of severe aortic stenosis. His brain natriuretic peptide (BNP) level was 911 pg/mL. Transthoracic echocardiography showed a severely calcified tricuspid aortic valve with a peak/mean transvalvular pressure gradient of 116/70 mmHg, and valve area of 0.60 cm^2. Left ventricular ejection fraction was 50% and trivial mitral regurgitation was observed. The patient had a history of PCI of the right and left circumflex coronary arteries and received dual antiplatelet therapy with aspirin (100 mg/day) and clopidogrel (75 mg/day). Coronary angiography revealed a moderate to severe stenosis in the middle portion of the right coronary artery (RCA). SAVR plus coronary artery bypass grafting (CABG) or PCI plus TAVI was indicated for the patient. The Society of Thoracic Surgeons (STS) risk score calculated for SAVR plus CABG was 6.3%. However, the patient refused any invasive treatments, and he was discharged from the hospital. Therefore, medical therapy was continued in the outpatient clinic.

Three months later, the patient was readmitted to the hospital because of acute exacerbation of congestive heart failure. Transthoracic echocardiography revealed that the left ventricular function was significantly reduced, with an ejection fraction of 20%. Mild mitral regurgitation was also observed. Congestive heart failure worsened despite medical treatment that included intravenous administration of inotropes, diuretics, and vasodilators. The BNP level was elevated to 5985 pg/dL, and chest radiography showed severe pulmonary congestion, cardiomegaly, and bilateral pleural effusions (Fig. 1A). The patient was deemed inoperable for SAVR plus CABG. The STS score was 12.5% at that time. TAVI was considered a possible but high-risk strategy owing to the unstable hemodynamic condition. We planned a staged procedure: first, BAV and PCI to stabilize the patient's condition followed by TAVI under safer conditions. This plan required approval by off-site proctors because our institution was still in the proctoring period. All required data were sent to the proctors, and the plan was approved after detailed discussion.

After obtaining the approval of our institutional human ethics committee and the written informed consent, BAV and PCI were conducted under local anesthesia. Three introducer sheaths were placed: a 12-F introducer sheath in the left femoral artery, a 5-F introducer sheath in the right femoral artery, and a 7-F introducer sheath in the right femoral vein. First, we conducted right heart catheterization, which showed a mean right arterial pressure of 14 mmHg, mean pulmonary arterial pressure of 36 mmHg, and mean pulmonary wedge pressure of 31 mmHg. Cardiac output, determined by using the Fick method, was 2.35 L/min (cardiac index = 1.49 L min^{-1} m^{-2}). A 5-F Amplatz Left 1.0 diagnostic catheter and a 0.035-inch straight guidewire were used to cross the stenotic aortic valve. Simultaneous pressure tracing demonstrated a mean pressure gradient of 51 mmHg across the aortic valve, and the aortic valve area was 0.32 cm^2, as calculated by using the Gorlin formula (Fig. 2A). The aortic annulus diameter was approximately 25 mm on computed tomography scans (Fig. 3). We chose a 20-mm Maxi-LD balloon catheter (Cordis Corporation/Johnson & Johnson, Bridgewater, NJ, USA) for BAV to avoid BAV-induced AR. After placing a 0.035-inch extra-stiff guidewire in the left ventricle, the balloon catheter was delivered retrogradely, and

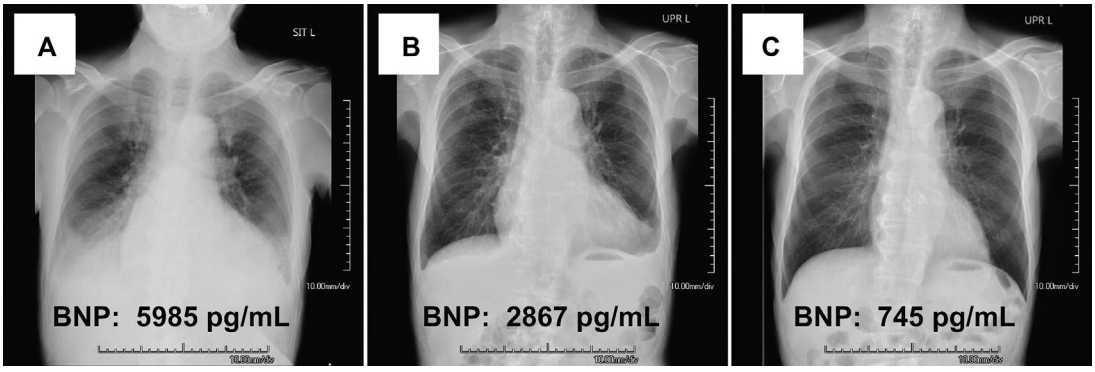

Fig. 1. Changes on chest radiographs and in the brain natriuretic peptide (BNP) level. (A) A chest radiograph before balloon aortic valvuloplasty (BAV) showing cardiomegaly, bilateral pleural effusions, and pulmonary congestion. (B) A chest radiograph after BAV showing signs of improvement; no pleural effusion can be observed, but cardiomegaly and pulmonary congestion are still present. (C) The chest radiograph after transcatheter aortic valve implantation shows almost normal findings.

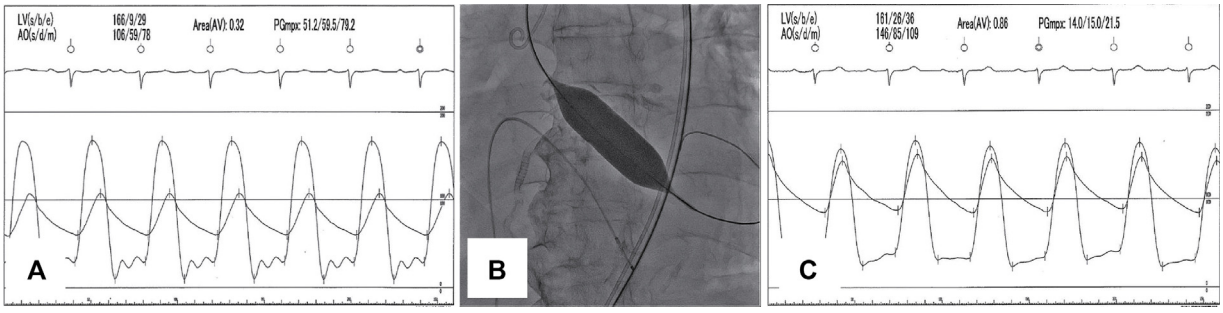

Fig. 2. Fluoroscopic image during balloon aortic valvuloplasty (BAV) and simultaneous pressure tracings from the left ventricle and aorta. (A) The pressure tracing before BAV showing a mean pressure gradient of 51 mmHg and aortic valve area of 0.32 cm^2. (B) Balloon inflation with a 20-mm balloon catheter under rapid right ventricular pacing. (C) The pressure tracing after BAV showing a mean pressure gradient of 14 mmHg and aortic valve area of 0.86 cm^2.