Overexpansion of the SAPIEN 3 Transcatheter Heart Valve in a Tricuspid Aortic Valve with Huge Annulus

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Abstract

Transcatheter aortic valve replacement (TAVR) has become a treatment alternative for patients with severe aortic stenosis. As broadened indications and increasing clinical demand, the population referred for TAVR will become much more heterogeneous and anatomically challenging. Herein, we report an 88-year-old man with severe aortic stenosis and huge aortic annulus (annular area 831.8 mm²) successfully treated with overexpansion of a 29 mm Edwards SAPIEN 3 transcatheter heart valve.

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ABSTRACT

Transcatheter aortic valve replacement (TAVR) has become a treatment alternative for patients with severe aortic stenosis. As broadened indications and increasing clinical demand, the population referred for TAVR will become much more heterogeneous and anatomically challenging. Herein, we report an 88-year-old man with severe aortic stenosis and huge aortic annulus (annular area 831.8 mm²) successfully treated with overexpansion of a 29 mm Edwards SAPIEN 3 transcatheter heart valve.

Key words: transcatheter aortic valve replacement (TAVR), large annulus, overexpansion of transcatheter heart valve

INTRODUCTION

Transcatheter aortic valve replacement (TAVR) has revolutionized the treatment of symptomatic severe aortic stenosis (AS) (1). In the last decade, TAVR was approved from inoperable to low surgical risk patients based on the results of landmark randomized trials (2-5). As TAVR indications continue to expand, along with the advancement of devices and technical skills, more patients with poor vascular access or challenging anatomy once considered illegible for TAVR may be attempted.

Because of the physical limitation of currently available transcatheter heart valves (THV) sizes, AS patient with extremely large aortic annulus (ie., area > 683 mm² or perimeter > 94 mm) is contraindicated for TAVR. However, several case series have demonstrated the feasibility of over-expansion of a 29 mm SAPIEN 3 valve (Edwards Lifesciences, Irvine, CA, USA) in patients with aortic annulus area between 683~800 mm² (6-9). We report the following successful THV implantation in a severe tricuspid AS patient with aortic annulus area >800 mm², the largest in the literature to the best of our knowledge.

CASE DESCRIPTION:

An 89-year-old man with a history of hypertension and type 2 diabetes mellitus presented with shortness of breath and bilateral legs edema 2 weeks prior to evaluation. Severe symptomatic aortic stenosis was confirmed in other hospital, and the patient was referred to our institution for TAVR. Chest X-ray revealed prominent lung edema with bilateral pleural effusion. Transthoracic echocardiography demonstrated poor left ventricular systolic function (left ventricular ejection fraction: 36.4 %) and tricuspid configuration aortic valve with severe stenosis (peak velocity: 4.2 m/s; mean transvalvular pressure gradient: 41 mmHg; estimated valve area: 0.53 cm²). He was dependent on intravenous infusion of inotropic agents, and was deemed at high risk for surgical aortic valve replacement with predicted surgical mortality of 8.234 % by STS-PROM (Society of Thoracic Surgeons-Predicted Risk of Mortality) and 17.37% by EuroSCORE (European System for Cardiac Operative Risk Evaluation-II). Multidetector computed tomography (CT) showed a huge annulus measuring 37.9 × 27.8 mm in diameter and an area of 831.8 mm² (Figure 1). The measured annulus size exceeds the upper limit of both the commercially available self-expanding and balloon-expanding THV in our institution. In view of the patients age and high surgical risk, the decision was made by the heart team to proceed with TAVR by over-expansion of 29 mm SAPIEN 3 THV.

The procedure was performed under conscious sedation and right femoral access. Temporary pacemaker was placed in right ventricle via internal jugular vein. A 29 mm Edwards SAPIEN S3 THV was inserted and expanded by overfilling of the deployment balloon with 4 ml of additional volume under rapid pacing. The post-TAVR aortography revealed a well-positioned THV with mild paravalvular regurgitation (Figure 2). The maximal diameter of post-deployment THV was 32.23 mm by quantitative fluoroscopy analysis (Figure 3). The procedure was uncomplicated and there was no new conduction disturbance requiring permanent pacemaker. The patient was discharged 6 days after TAVR. The 1-month follow-up transthoracic echocardiography showed well-functioning THV (peak velocity= 1.9 m/s; mean transvalvular gradient= 7.9 mmHg; estimated valve area= 2.1 cm²) with a mild paravalvular leakage (Figure 4).

DISCUSSION:

As the indications for TAVR are expanding, operators are faced with more complex and challenging anatomy. In the present case, we demonstrated that TAVR is feasible by over-expansion of 29 mm SAPIEN 3 THV in a tricuspid AS patient with an annulus area exceeding 800 mm². Shivaraju et al (6) first described the over-expansion technique in an AS patient with annulus area of 742 mm², with 4 mL of additional volume in the delivery balloon. Mathur et al (7) and Barr et al (8) then reported the results of TAVR in 8 patients, with aortic annulus area ranging from 691.0 mm² to 800.0 mm², using the same technique. To our best knowledge, there has been only 1 reported TAVR case with annulus area exceeding 800 mm², but in a bicuspid aortic valve (10). In contrast, our case valve was tricuspid configuration and the implant depth was at the annulus, thus resulting in the largest over-expansion of SAPIEN S3 THV ever reported.

Nominal volume 29 mm SAPIEN 3 THV deployment will definitely result in significant valve under-sizing in

our patient. Additional 4 mL volume expansion on THV deployment, according to calculation, will still result in -9.8% undersize. In our pre-TAVR planning, 5 mL additional volume post-dilatation will be performed if significant paravalvular leakage (PVL) was noted after deployment. This will reduce the estimated undersize to -6.7%. With the new frame geometry and outer skirt design of the SAPIEN 3 THV, however, even this maneuver was unnecessary. In recent analysis of SAPIEN 3 study (11), rate of PVL was low even with SAPIEN 3 THV undersized up to -5%.

The actual safe limit of over-expansion for SAPIEN 3 THV, however, are still unknown. Over-expansion may prohibit proper leaflet coaptation, increase the risk of valve dislodgement, and incur positioning challenges due to excessive frame shortening. The design of longer leaflets might allow the SAPIEN 3 THV to be more tolerant to over-expansion, and accommodate larger annulus sizes without resulting in significant central aortic regurgitation. Sengupta et al (12) reported 105 large annulus AS patients, with mean annulus area of $721.3 \pm 36.1 \text{ mm}^2$, implanted with SAPIEN 3 THV. The rate of [?]moderate transvalvular aortic regurgitation and PVL were 0% and 4.3% respectively at 1 year. Miyasaka et al (9) also demonstrated the feasibility of SAPIEN 3 THV in 30 patients with large annulus (mean annulus area $737.3 \pm 54.7 \text{ mm}^2$), with similar procedural outcomes and 1-year mortality compared to those with regular annulus (area $< 683.0 \text{ mm}^2$). These results, along with the present case experience, may provide evidence for the use of over-expanded 29mm SAPIEN 3 THV in patients with extremely large annulus. Longer term follow-up in a larger patient population is mandatory to determine its durability.

Conclusion:

We demonstrate that TAVR using over-expanded 29 mm SAPIEN 3 THV in a patient with annulus areas of 831.8 mm^2 is safe and feasible.

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FIGURE LEGEND

Figure 1. Computed tomography measurement of aortic annulus in 35% cardiac cycle demonstrating annulus area of 831.8 mm² and diameter of 37.9 × 27.8 mm.

Figure 2. Aortogram immediately obtained following 29-mm SAPIEN 3 transcatheter heart valve demonstrated well-positioned valve with mild paravalvular regurgitation.

Figure 3. Quantitative fluoroscopy analysis showed the inflow diameter of over-expanded transcatheter heart valve was 32.23 mm.

Figure 4. 1-month follow-up transthoracic echocardiography showed the well-functioning transcatheter heart valve with a mild paravalvular leakage and no transvalvular regurgitation.