

# Unique challenges posed by a dysfunctional native right ventricular outflow tract for percutaneous pulmonary valve implantation using SAPIEN-S3 valve

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## ABSTRACT

Dysfunctional right ventricular outflow tracts after a repair for tetralogy of Fallot using a transannular patch offer limited nonsurgical opportunities due to their large dimensions. A discrete subannular narrowing between a dilated right ventricle and the enlarged pulmonary trunk was a potential anatomical target for the creation of a landing zone using a pre-stent in a young male with severe pulmonary regurgitation and moderate stenosis. Asymmetric expansion of the pre-stent in the angulated outflow tract led to distal stent embolization that was stabilized by another telescoping stent before successful valve implantation. This manuscript details the unique challenges posed by a dilated regurgitant outflow tract for implanting a pulmonary valve.

**Keywords:** AndraStent, complication, large right ventricular outflow tract, stent embolization, telescoping stent

## INTRODUCTION

Following surgical correction of tetralogy of Fallot (TOF), patients may require reinterventions to preserve right ventricular function and relieve symptoms.<sup>[1]</sup> The large dimension of the native right ventricular outflow tract (RVOT) poses unique challenges for percutaneous pulmonary valve implantation (PPVI).<sup>[2]</sup> A young male presented 17 years after surgical correction of TOF with symptomatic pulmonary stenosis and severe regurgitation. Attempts to create a landing zone in the region of the stenosis before a PPVI using a pre-stent resulted in stent embolization. This report describes the challenges posed by the dilated RVOT and strategies adopted in its management.

## CASE REPORT

A 19-year-old nonsyndromic male weighing 55 kg underwent modified Blalock-Taussig shunt in infancy followed by total surgical correction of TOF with a limited transannular patch at 2 years of age. Residual pulmonary stenosis and regurgitation led to progressive effort intolerance. Magnetic resonance imaging showed a dilated right ventricle adherent to the sternum with an indexed end-diastolic volume of 160 ml and pulmonary regurgitant fraction of 45%. An echocardiogram showed infundibular stenosis, dilated pulmonary trunk measuring 5 cm, and free pulmonary regurgitation. The narrow infundibulum was oval in cross-section measuring

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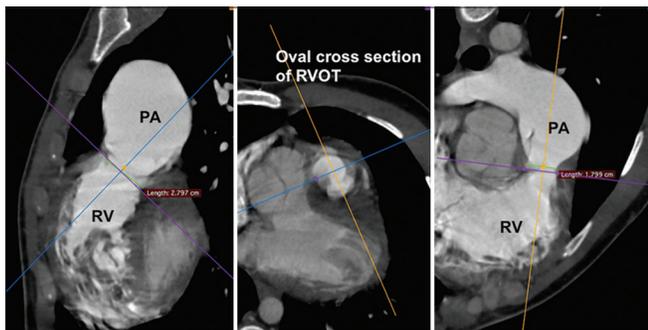
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28 mm × 18 mm on computed tomography [Figure 1]. Infundibular stenosis precluded the use of self-expanding transcatheter valves with low radial force. Moreover, the large annular dimensions limited the available options for a balloon-expandable valve.

Cardiac hemodynamics showed right atrial pressures of 8 mmHg, RVOT gradient of 55 mmHg and the ventricularized pulmonary artery pressures were 30/2 (13) mmHg. The narrow infundibulum measured 27 mm × 22 mm on right ventriculogram in orthogonal projections [Figure 2]. Balloon interrogation with a 28 mm × 6 cm semicompliant balloon did not show any waist, but the resultant hypotension indicated a complete RVOT occlusion. There was no coronary compromise or aortic root distortion during balloon interrogation. It was decided to stent the stenotic segment before SAPIEN-S3 valve implantation.

After informed consent and Heart Team discussions, a 14F FuStar sheath (Lifetech Scientific, Shenzhen, PRC) was placed across the stenosis from right femoral venous access over a Lunderquist wire (Cook Medical, Bloomington, IN, USA) after adequate heparinization. A 48-mm AndraStent XXL (AndraMed GmbH, Reutlingen, Germany) mounted on a 28 mm × 6 cm Boa balloon (PanMed US Corp, Largo, FL, USA) was positioned across the stenosis and expanded under rapid left ventricular pacing to minimize stent movement. The acute angulation of the RVOT resulted in asymmetric inflation of proximal part of the balloon and expansion of the proximal part of the stent before a melon seeding of the balloon into the right ventricle. Attempts to dilate the unexpanded distal part of the stent by advancing the balloon resulted in distal embolization of the partially expanded stent to the dilated pulmonary trunk, but its proximal expanded portion prevented its migration beyond the origin of the left pulmonary artery [Figure 3].

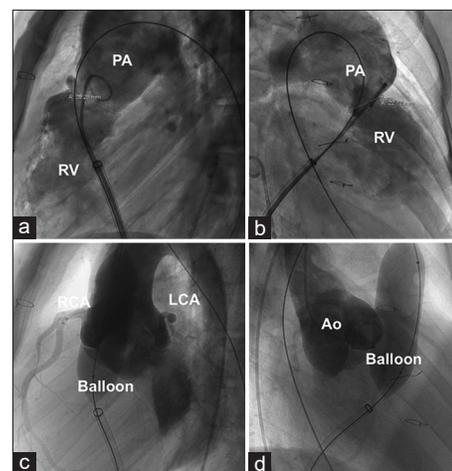
The distal end of the embolized stent was trapped by advancing and gently inflating a 25 mm × 4 cm Z-MED balloon (NuMED corporation, Cornwall, ON, USA) and brought back to the desired landing zone [Figure 4].



**Figure 1:** Multiplanar reformatted images of contrast-enhanced computed tomography in modified sagittal, axial, and coronal planes show the dilated pulmonary artery and the subannular narrowing above the right ventricle measuring 28 mm × 18 mm

However, it could not be pulled through the stenosed region. It was decided to deploy a second telescoping long stent that would relieve the annular narrowing as well as overlap the embolized stent in its distal end. After obtaining a contralateral left femoral venous access, a catheter and guidewire were advanced through the lumen of the stent into the right pulmonary artery and exchanged to an Amplatz Super Stiff guidewire that allowed a low-profile 25 mm × 6 cm Tyshak-II balloon (NuMED corporation, Cornwall, ON, USA) beyond the stent into the right pulmonary artery. This balloon was dilated to hold the expanded stent immediately above the narrowed annulus. A 57-mm AndraStent XXL mounted on 26 mm × 6 cm Z-MED balloon was advanced through the 14F right femoral venous sheath with its distal tip telescoped into the first stent. The balloon was inflated to expand the distal half of the second stent that fixed the first stent from further embolization, while simultaneously withdrawing the Tyshak balloon and the guidewire from the right pulmonary artery to prevent it getting trapped outside the second stent [Figure 5].

After upsizing the 14F FuStar sheath to a 18F Sentrant sheath (Medtronic, Minneapolis, MN, USA) in the femoral vein, the stent was flared using a spherical Coda Balloon (Cook medical, Bloomington, IN, USA) to achieve a final diameter of 26 mm [Figure 6]. Twenty-nine mm SAPIEN-S3 valve (Edwards Lifesciences, Irvine, CA, USA) crimped on a Commander Delivery System (Edwards Lifesciences, Irvine, CA, USA) needed gentle maneuvering with the formation of an alpha loop in the right atrium to disengage the nose cone from the stent [Figure 6]. The valve was expanded within the landing zone resulting in a final gradient of 5 mmHg



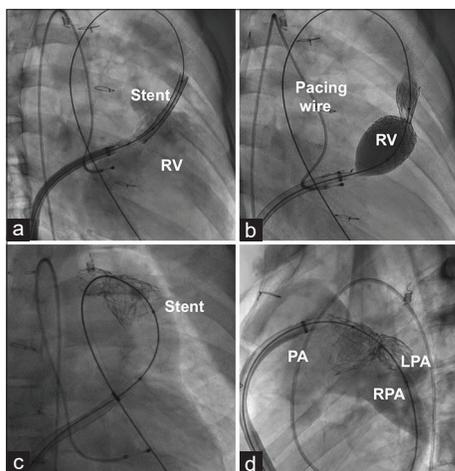
**Figure 2:** Right ventriculogram in lateral (a) and right anterior oblique (b) projections show the dilated pulmonary trunk and the subannular narrowing above the right ventricle that measured 28 mm × 22 mm. Balloon interrogation with a 28-mm balloon in left anterior oblique (c) and right anterior oblique (d) projection shows normal flows in both left and right coronary arteries and absence of aortic (Ao) root distortion

and complete absence of regurgitation. At 18-month follow-up, there was no pulmonary regurgitation, peak gradient was 14 mmHg, and the patient remained asymptomatic.

## DISCUSSION

In selected patients with RVOT reconstructed using conduits or bioprosthetic valves, PPVI may be an acceptable alternative to surgery.<sup>[3]</sup> Large and expansile native outflow repaired with or without transannular patches is a challenging substrate for PPVI.<sup>[4,5]</sup> An eccentrically narrowed oval infundibulum causing combined stenosis and regurgitation in our patient provided a possible target for a valve landing zone. Lack of waist on a 28-mm balloon interrogation indicated the expansile nature of the outflow, though the resultant hypotension indicated a complete occlusion. Even though its strong framework prevented stent fractures and obviated pretesting, the precision needed for implanting a SAPIEN-S3 valve in the stenosis between the dilated right ventricle on one side and a dilated pulmonary trunk on the other side warranted a landing zone prestant.<sup>[6]</sup> AndraStent XXL is dilatable to large diameters and is used for pretesting large outflow tracts before PPVI.<sup>[7]</sup>

Angiography in orthogonal projections was planned for delineating the landing zone as computed tomography identified an eccentric subannular narrowing. The outflow showed marked angulation on the right anterior oblique projection. A 48-mm AndraStent XXL mounted on a 28-mm balloon was chosen to create a landing zone. However, the sharp angulated outflow

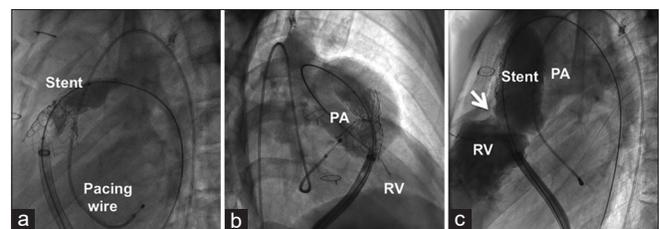


**Figure 3:** A 48-mm stent was positioned (a) across the stenosis and expanded (b) during rapid ventricular pacing. The angulation of the outflow resulted in asymmetric expansion of the stent and proximal melon seeding of the balloon. The partially expanded stent embolized into the dilated pulmonary trunk identified on right anterior oblique (c) and lateral view (d). The expanded proximal part of the stent prevented its entry beyond the origin of the left pulmonary artery. RPA: Right pulmonary artery

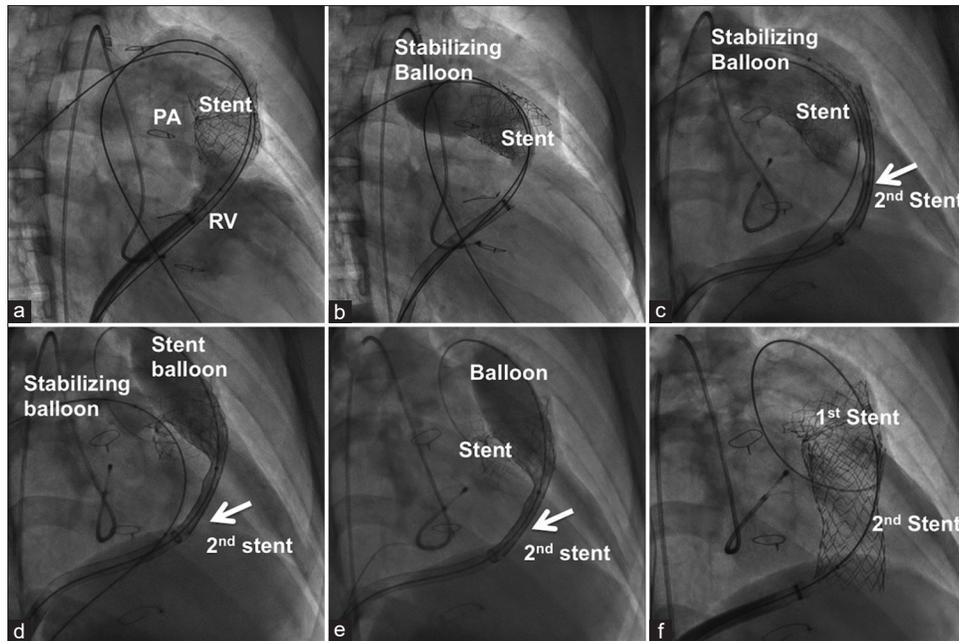
led to an asymmetric expansion of the proximal part of the stent and melon seeding of the balloon on further inflation of the balloon. Misconfiguration of an improperly crimped AndraStent is known to occur in RVOT resulting in asymmetric expansion.<sup>[8]</sup> Despite an effective rapid ventricular pacing to minimize stent movement within the regurgitant outflow, the angulated outflow did not permit a proper expansion. Severe pulmonary regurgitation also predisposes to stent embolization.<sup>[9]</sup>

Manipulation of the partially expanded stent by advancing the deflated balloon to expand its distal half resulted in its embolization. A change of balloon was not attempted as proximal migration of the partially expanded stent would have resulted in tricuspid chordal injury. Embolized large stents are parked in safe locations such as branch pulmonary arteries or pulmonary trunk. It was not feasible, as the proximal part dilated to 28 mm could not negotiate the origins of the vessels. The pulmonary trunk was dilated to 5 cm precluding a deployment there. The only available option was to overlap another long telescoping stent that trapped the embolized stent distally and widened the narrow subannular region proximally.<sup>[10]</sup>

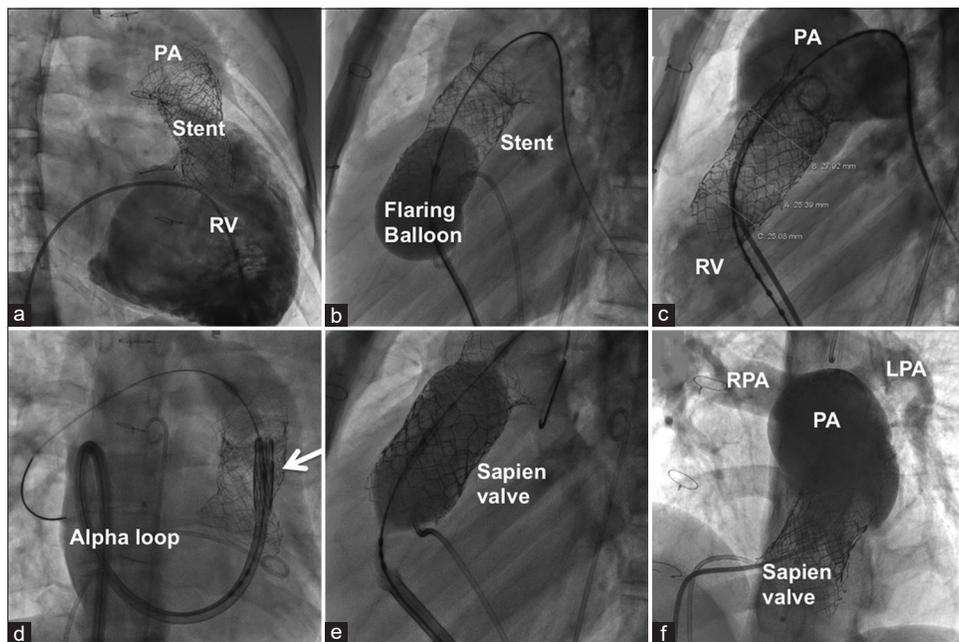
Once the proximal part of the prestant was flared, a little maneuvering with an alpha loop in the right atrium prevented interference of the nose cone of the valve delivery system with the stent. The use of long 24F sheaths across the prestents in RVOT would prevent such interference but was not available.<sup>[4]</sup> The unique challenges posed by a native RVOT anatomy for a PPVI in this case included (i) a relatively large landing zone measuring 28 mm, (ii) lack of waist on an interrogating balloon that failed to give confidence to the operator about the adequacy of the diameter of the prestant, (iii) markedly dilated right ventricle and pulmonary trunk on either side of the stenosis that warranted a great deal of precision in the landing zone stent, (v) angulated outflow that prevented uniform balloon and stent expansion resulting in embolization, (vi) markedly dilated pulmonary trunk and relatively smaller branch pulmonary arteries that did



**Figure 4:** The embolized stent was trapped by advancing a balloon through its lumen and gentle inflation and pulled back from the dilated pulmonary trunk to the subannular region on lateral view (a) and right anterior oblique (b) views. However, the expanded stent could not be pulled into the narrow subannular region (arrow) above the right ventricle (c)



**Figure 5:** A catheter and guidewire advanced from left femoral vein (a) through the expanded stent lumen allowed passage of a balloon, which was inflated distally to stabilize the stent immediately above the stenosis (b). A second stent was telescoped partially into the lumen of the first stent (c). The second stent was gradually expanded to hold the previous stent (d) as the stabilizing balloon and guidewire were removed (e). The expanded second stent stabilized the first stent (f)



**Figure 6:** Stents in the right ventricular outflow relieved the gradients. (a) After flaring the lower end (b), the landing zone measured 26 mm on lateral projection (c). The Commander delivery system was maneuvered across the lower end of the stent with a large alpha loop in the right atrium (d) to advance the SAPIEN-S3 valve (arrow) into the landing zone. After full expansion of the valve (e), there was no regurgitation from the dilated pulmonary trunk into the right ventricle (f). The left and right pulmonary arteries were shown in the final angiogram

not permit safe parking of the embolized stent, (vii) need for a long telescoping overlapped stent to secure the embolized stent, (viii) flaring of the lower end of the stent protruding into the right ventricle to avoid interference with the valve delivery system.

## CONCLUSIONS

A dilated native outflow tract offers considerable challenges for PPVI due to its large dimensions. Careful planning, strategies at hand to tackle complications,

and availability of adequate catheterization laboratory hardware are vital to complete a procedure successfully.

#### Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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#### Conflicts of interest

There are no conflicts of interest.

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