A Tear of the Right Ventricular Outflow Tract during Pulmonary Valvuloplasty Treated by Transcatheter Sapien Valve Implantation

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ABSTRACT_

A 74-year-old woman was treated by balloon pulmonary valvuloplasty for a symptomatic restenosis 30 years after surgical commissurotomy. The valve dilatation was complicated by a rupture of the right ventricular outflow tract, treated in emergency by a covered stent implantation. The hemodynamic situation was improved, but the free pulmonary regurgitation was leading to a symptomatic right ventricular enlargement. Because surgery was not a good option in this patient at high risk, restoration of pulmonary valve competence was performed by a transcatheter Sapien valve implantation. Transcatheter approach allowed to treat the severe complication of pulmonary valvuloplasty without risk associated with an emergent and redo surgery in a high-risk patient.

Key Words. Pulmonary Valvuloplasty; Complication; Transcatheter Valve

Introduction

B alloon valvuloplasty is a well-recognized treatment for symptomatic pulmonic valve stenosis. Tear of the right ventricular outflow tract (RVOT) is an uncommon life-threatening complication. Current indications for percutaneous pulmonary valve implantation are limited to patients who had pulmonary stenosis and/or regurgitation in a right ventricle-to-pulmonary artery conduit. However, this case shows how a covered stent into a native pulmonary valve has been considered as an acceptable landing zone for a successful transcatheter valve implantation.

Clinical Case

A 74-year-old woman was admitted in our hospital for balloon pulmonary valvuloplasty. She underwent 30 years ago a surgical commissurotomy for a stenotic bicuspid pulmonary valve. She complained of dyspnea grade New York Heart Association (NYHA) III with some chest pain and leg edema. Clinical examination revealed a systolic murmur on the pulmonary area and signs of heart failure in an overweight patient (body mass index 29). Echocardiography confirmed a significant pulmonic valve restenosis (peak gradient

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109 mm Hg, mean gradient 54 mm Hg) with mild pulmonary regurgitation, a small and hypertrophic right ventricle. The first pulmonary angiogram showed a heavy calcified native pulmonary valve and an aneurysmal short central pulmonary artery (Figure 1A). The invasive transvalvular gradient was 62 mm Hg and the pulmonic annulus was measured at 26 mm; therefore, after heparin injection, a Cristal balloon (BALT, Montmorency, France) 28 mm was manually inflated (Figure 1B), reducing the transvalvular gradient at 4 mm Hg. Immediately after balloon deflation, the systolic systemic blood pressure fell to 70 mm Hg and the patient complained of chest pain. The angiogram showed an extravasation of contrast media to the anterior part of the mediastinum, suggesting a rupture of the RVOT tissues (Figure 1C). Protamin was given in order to stop the bleeding, but the hemodynamic conditions remained unstable. Therefore, a covered Cheatham Platinum (CP) stent 39 mm (NuMED, Inc., Hopkinton, NY, USA) mounted on a Cristal balloon 28 mm (BALT) was deployed (Figure 2), and allowed to seal the leak and to stabilize the hemodynamics. The procedure was stopped, the clinical outcome was good, and the patient was discharged at day 5. Four months later, she came back in the outpatient clinic with clinical improvement but with a



Figure 1. (A) Contrast angiogram on a LAO projection showing an aneurysmal and short central pulmonary artery. (B) Balloon inflated through the native pulmonary valve: the arrow shows the bulky calcified nodule displaced in contact with the pulmonary arterial wall. (C) A leak of contrast is visualized after balloon deflation.



Figure 2. (A) A covered stent is positioned into the RVOT (the arrow shows the leak of contrast). (B) The stent deployment allowed to seal the leak.

residual dyspnea grade NYHA II; the echocardiography and the MRI showed a free pulmonary regurgitation with an enlarged right ventricle at 169 mL. Restoration of pulmonary valve competence was discussed. The patient was denied for surgery because of comorbidities (obesity, coronary artery disease, corticoid therapy for rheumatoid arthritis, diabetes, chronic obstructive pulmonary disease) and the strategy was transcatheter pulmonary valve implantation. Because of the size of the annulus (26 mm) and of the minimal diameter of the covered CP stent previously implanted (22 \times 26 mm; Figure 3A, B), a Melody

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valve (Medtronic, Minneapolis, MN, USA) was considered as not appropriate; therefore, a percutaneous Sapien 26 mm valve (Edwards Lifesciences, Irvine, CA, USA) implantation was attempted. The angiogram confirmed the major pulmonary regurgitation (Figure 3C); two additional stents, Andra stent 43 mm (Andramed GmbH, Reutlingen, Germany) and CP stent 45 mm (NuMED, Inc.), were implanted in the RVOT in order to reduce the diameter of the landing zone. A 24-French sheath was inserted into the femoral vein, and a Sapien valve 26 mm (Edwards Lifesciences) was delivered using a Ret-



Figure 3. Dimensions of the covered stent on an anteroposterior (A) and LAO (B) projection. (C) Sapien valve implantation: angiogram shows a severe pulmonary regurgitation through the covered stent; (D, E) Sapien valve positioning and deployment; (F) final angiogram shows the good position of the Sapien with no significant residual pulmonary regurgitation.

roflex III delivery system (Figure 3D, E): the residual gradient was measured at 7 mm Hg with a trivial regurgitation at the end of the procedure (Figure 3F). The femoral vein was closed using the Prostar XL device (Abbott Vascular, Santa Clara, CA, USA). The clinical outcome was excellent and the patient was discharged at day 2. At 30-day follow-up, the patient was in class NYHA I and the peak transvalvular gradient was at 9 mm Hg with a trivial pulmonary regurgitation.

Discussion

Current indications for percutaneous pulmonary valve implantation are limited to patients who had pulmonary stenosis and/or regurgitation in a right ventricle-to-pulmonary artery conduit.¹ However, failed surgical bioprosthesis and RVOT patch have been reported as "acceptable landing zone" for a transcatheter pulmonary valve implantation.^{2,3} Native pulmonary valve is an off-label indication for Sapien valve implantation because of the need of a rigid target zone to safely anchor the balloonexpandable valve-carrying stent and prevent a valve migration. In the present case, the native valve was stented as a bailout treatment of RVOT rupture during balloon dilation. This complication is rare in the setting of congenital pulmonary balloon valvuloplasty with a ratio balloon/annulus of 1.2.4 However, some authors suggest that balloon oversizing may produce RVOT damage. In our patient, the heavy calcification of the native valve and the chronic corticoid therapy would be identified as risk factors for RVOT rupture. The present case illustrates the need to perform the procedures of pulmonary valvuloplasty in a catheterization lab with a great experience in the use of bailout equipment (covered stents, large balloons, and sheaths) and suggests that the ratio annulus/ balloon would be reduced close to 1 in this kind of adult patients.

After the preparation of the landing zone with prestenting, and because surgery was not a good option for this patient, a percutaneous valve implantation was attempted. Two devices are available for a transcatheter delivery in a pulmonary position: the Melody system, using retractable 22F sheath that covers and protects the valve until deployment, with potentially more deliverability than the bulkier 24F Sapien system, using not covering sheaths.

Outflow tract size is of crucial importance in considering whether a Melody valve (used in conduits measuring up to 22 mm) or Edwards Sapien valve (available sizes 23 and 26 mm) can be selected. In the present case, the dimension of the covered CP stent was 22×26 mm, precluding an implantation of a Melody valve. In order to prevent embolization, two additional stents were implanted reducing the size of the landing zone and allowing to create a rigid target zone for a successful 26-mm Sapien valve implantation.

This case illustrates that a life-threatening complication like RVOT tear during balloon valvuloplasty can be successfully treated by transcatheter stent and valve implantation, preventing the high risk of a redo and emergent surgery.

Conclusion

To the best of our knowledge, this is the first case of a Sapien valve implantation in a native pulmonary valve in order to treat a RVOT rupture during valvuloplasty. Emergency covered stent placement followed by further elective bare metal stents implantations created a landing zone for a successful transcatheter pulmonary valve implantation. Transcatheter approach allowed to treat the severe complication of pulmonary valvuloplasty without risk associated with an emergent and redo surgery in a high-risk patient.

Authors Contribution

J. Kefer: operator during the procedures, author of the paper; M. Gewillig: operator during the procedures and review of the paper; T. Sluysmans: operator during the procedures and review of the paper.

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