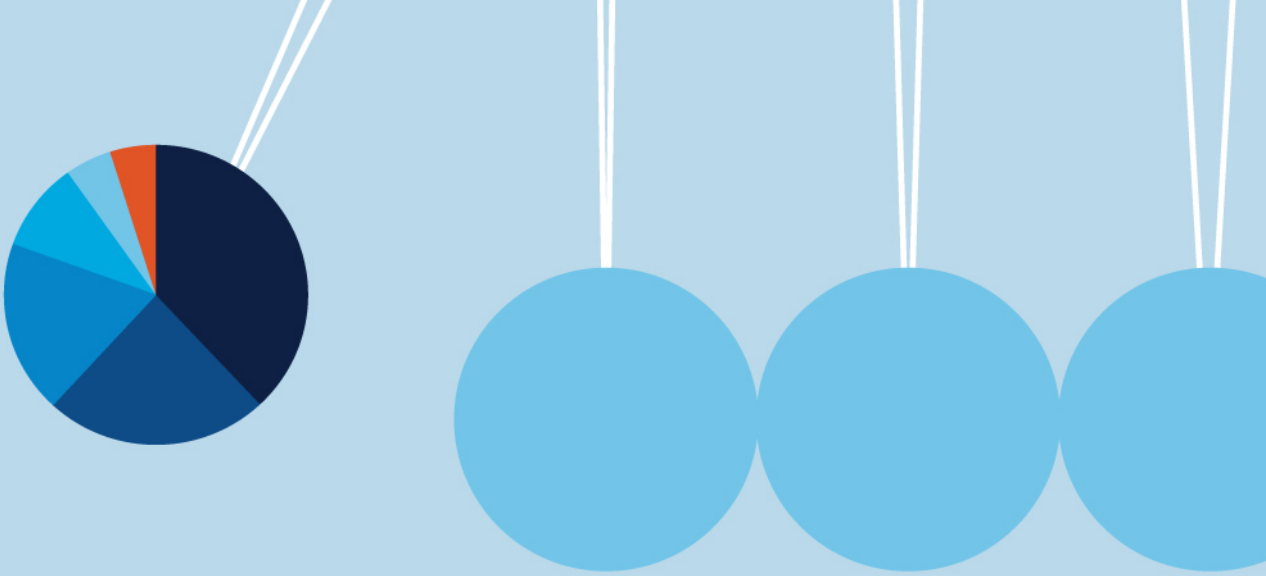

UNPARALLELED, REAL-WORLD DATA

Research on real-world patients from the Medtronic GSR showed that renal denervation (RDN) **achieved clinically meaningful, statistically significant blood pressure reductions.**[1]

REVIEW THE STUDY

[1] Mahfoud F, Mancia G, Schmieder R, et al. Three-year safety and efficacy in the Global Symplicity Registry: Impact of anti-hypertensive medication burden on blood pressure reduction. Presented at PCR e-course 2020.

Medtronic
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WILEY

CASE REPORT

Percutaneous pulmonary valve implantation in a dysfunctional Trifecta® bioprothesis after high-pressure balloon fracturing

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Abstract

A percutaneous pulmonary valve-in-valve (PPVIV) implantation in small surgical tissue valves may be limited due to the valve's initial diameter. Fracturing of the valve's integrity by high-pressure balloons may enhance the diameter and facilitate subsequent PPVIV with a large valve. To the best of our knowledge, the Trifecta® valve seemed not to be accessible for fracturing. We report a case of successful 19-mm Trifecta valve fracturing, followed by PPVIV using a 26-mm Edwards SAPIEN 3 valve in pulmonary position. By repetitively using a high-pressure balloon 5 mm larger than the labeled valve size, we were able to fracture the valve's integrity and implant a 26-mm valve thereafter. Therefore, Trifecta valve appears to be suitable for valve ring fracturing and subsequent PPVIV in certain patients.

KEYWORDS

dysfunctional biological valve, interventional valve-in-valve implantation, prestenting, Trifecta® valve

1 | INTRODUCTION

The Trifecta® valve, a trileaflet polyester-covered titanium stented pericardial valve, is designed for placement in the aortic position.[1] Some Trifecta valves have been implanted in pulmonary valve position.[2] Today, a failing bioprosthesis can be corrected via transcatheter valve-in-valve (VIV) therapy, which is also an option for children. Expanding a degenerated and stenotic bioprosthetic valve to a large diameter may not only have an immediate impact on pulmonary artery (PA) hemodynamics but also trigger long-term consequences for transcatheter valve durability.

2 | CASE REPORT

We report on an eight-year-old boy with pulmonary atresia and subaortic ventricular septal defect (VSD) and multiple major aortopulmonary collaterals (MAPCAs). His first surgical treatment comprised MAPCA unifocalization, VSD closure, and pulmonary valve implantation using a Matrix-P-Plus-valve. Due to progressive valve degeneration, he underwent pulmonary valve replacement with a Trifecta valve (inner diameter 19 mm) in pulmonary position 2 years later.

Unfortunately, within 4 years, the Trifecta valve also exhibited increasing degeneration and combined pulmonary valve malfunction. Cardiac MRI-examinations revealed pulmonary valve insufficiency, a regurgitation fraction of about 40%, and a rapidly increasing right ventricular (RV) diameter of >140 ml/m^2 end-diastolic RV volume.

The boy presented clinically in NYHA III. Subsequent catheter examination revealed a minimal pulmonary valve diameter of 14 mm (Figure 1a,b). The RV pressure was 55 mmHg under deep conscious sedation. An additional left PA stenosis was initially handled with a Cheatham Platinum (CP)-stent®.

For safety reasons, we decided to perform a percutaneous pulmonary valve-in-valve (PPVIV) in two steps. After a coronary angiography

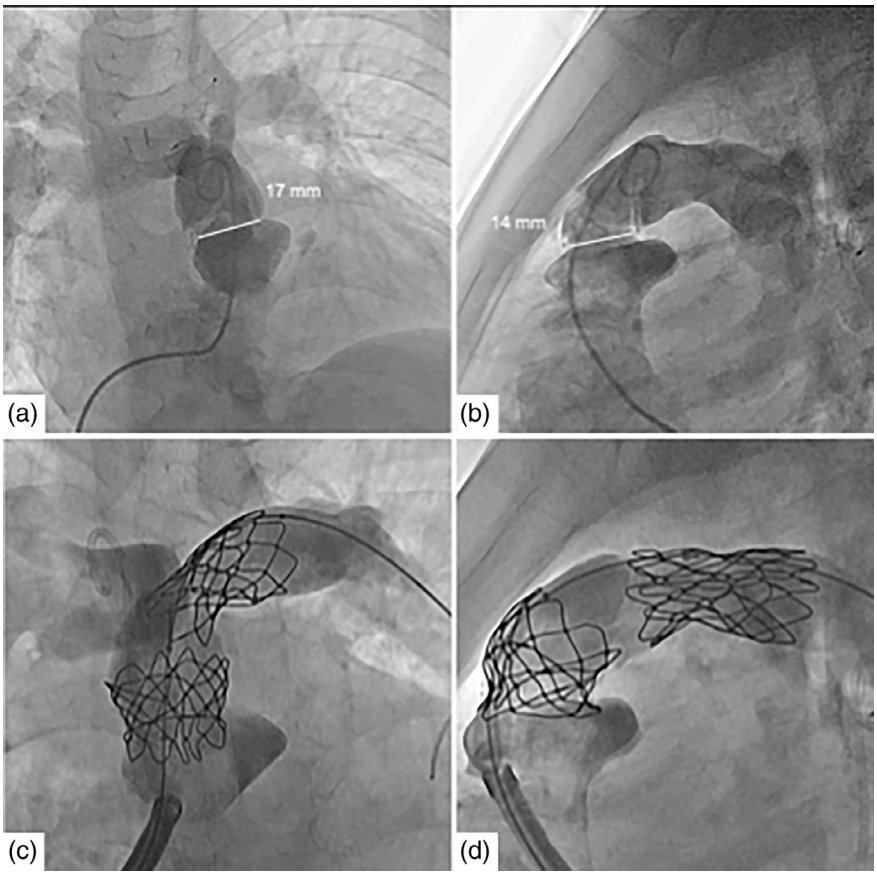

FIGURE 1 (a) and (b) Pulmonary trunk with stenotic and regurgitant 19-mm Trifecta® valve in oblique anatomic position. Minimal inner pulmonary valve diameter measures between 17 and 14 mm ((a) 30° left anterior oblique, (b) lateral 90° view). (c) and (d) Right ventricular outflow tract with pulmonary trunk and main pulmonary arteries. CP-stents® are placed in the left main pulmonary artery and above the Trifecta valve. A small notch caused by the Trifecta valve ring remains visible. ((c) 30° left anterior oblique, (d) lateral 90° view)

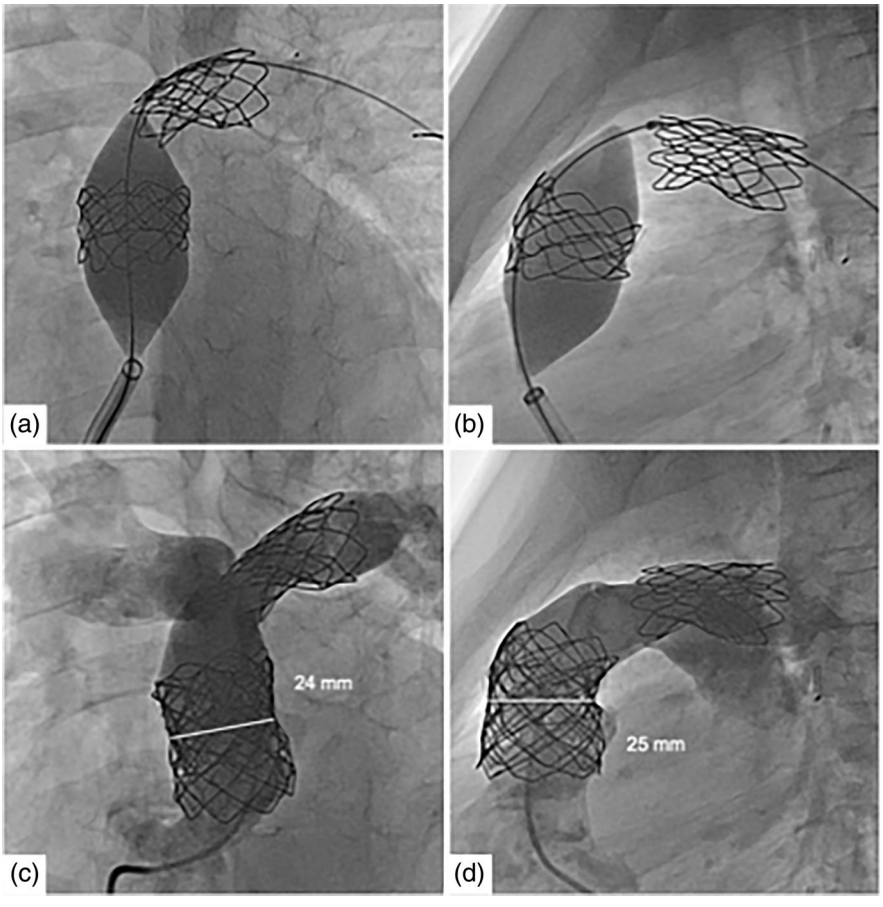

FIGURE 2 (a) and (b) Pulmonary valve dilatation with a 24-mm Atlas Gold® balloon under high pressure up to 24 atm. Two stent-braces broke up during this procedure. Post-intervention diameter is increased to 24 mm with the right-ventricular outflow tract unimpaired. ((a) 30° left anterior oblique, (b) lateral 90° view). (c) and (d) Second CP-stent® placed above the first one to stabilize and enlarge the right-ventricular landing zone. Afterwards, a 26-mm Edwards Sapien 3 valve was implanted. No parvasation or valve regurgitation is visible. The resulting inner diameters are 24 and 25 mm, respectively. ((c) 30° left anterior oblique, (d) lateral 90° view)

excluded an anatomic proximity to the right ventricular outflow tract (RVOT), we prestented the RVOT by using a 28-mm covered eight-zig CP-stent (NuMED Inc, Hopkinton, NY) (Video S1). Then, we "broke apart" the Trifecta® valve's integrity using a 24-mm high-pressure balloon (HPB) (Atlas Gold, Bard Temple) with 20 atm in two attempts. During this procedure, the minimal pulmonary valve diameter increased from 14 to 18 mm. RV pressure decreased to 40 mmHg; however, a residual notch caused by the Trifecta valve ring remained (Figure 1c,d, video S2).

In the second step, 8 weeks later, we repeated the HPB dilatation using the same balloon size, this time up to 24 atm. We thus managed to increase the minimal PA diameter at the level of the valve ring to 24 mm with an unimpaired RVOT to optimize hemodynamics and to facilitate subsequent redo PPVI (Figure 2a,b, video S3). As two stent-braces broke, a second CP-stent was put in place via a 24-mm VACS III balloon (OSYPKA, Rheinfelden, Germany). Consequently, the RVOT-landing zone was stabilized and enlarged up to 25.5 mm. We then conducted the PPVIV using a 26-mm Edwards SAPIENS three-valve Edwards (Lifesciences, Irvine, CA) and achieved full balloon inflation. Our final angiography revealed an inner valve diameter of 25 mm without paravasation or valve-insufficiency (Figure 2c,d). The RV-pressure was 26/0–5 mmHg. Follow-up echocardiographic examinations, 4 and 20 weeks later, showed laminar flow in RVOT and PA (v_{max} of 1.3 m/s). His physical condition improved to NYHA I soon after intervention.

3 | DISCUSSION

To the best of our knowledge, this is the first detailed report on a successful PPVIV after fracturing a Trifecta valve and enlarging the diameter from 14 to 25 mm for excellent hemodynamics.

There is evidence that balloon-initiated valve fracturing is feasible for several different valves to facilitate transcatheter VIV-implantation.[3,4] Shahanavaz et al. showed in a multicenter study in 37 patients intentional valve fracturing in the pulmonary position.[5] in vitro bench testing demonstrated successful fracturing of the valve's ring for the following surgical valves. For example, the Mitroflow, Magna, Magna Ease, Mosaic, and Biocor Epic.[6] Allen et al. took the standard HPB approach up to 24 atm (exceeding the manufacturer's rated burst pressures) but only 1 mm larger than the labeled valve size in his investigation. However, in this setting, the Trifectas titanium ring maintained integrity and the balloon burst (employing 19- and 21-mm valves). That valve was therefore not considered breakable.[3] In a computerized model, Capelli et al., however, showed that inflation force is not just about balloon pressure, concluding that balloon diameter has a greater impact on the expansion force than inflation pressure.[6]

In our patient, we used an HPB diameter applying the same maximum pressure but substantially exceeding the labeled valve ring size of about 5 mm. This approach finally enabled us to fracture the valve's integrity. The covered CP-stent may have protected the balloon from bursting caused by the rigid titanium ring.

There have been many reports on clinical VIV-implantation inside failed bioprosthetic surgical valves in aortic position since the first clinical case by Wenaweser et al. was published in 2007.[7,8] It is generally accepted that transcatheter VIV-implantation for failed bioprosthetic heart valves is a promising alternative to surgery.[9] However, clinicians need to consider that a valve's design can trigger complications. The Trifecta valve, with its externally mounted leaflets, ensures close proximity between proximal valve tissue and the coronary ostia. A coronary-ostium occlusion has been described in aortic position in conjunction with VIV-implantation.[10]

Apart from the aortic side, there is little information about VIV implantation inside failed bioprosthetic surgical valves in pulmonary position[3] Gillespie et al. reported the largest summary in 2012.[11] In their retrospective analysis of eight centers in the United States between 2007 and 2012, a cohort of 104 patients (3–63 years) underwent a VIV implantation using a Melody valve with various types of bioprosthetic valves, for example, the Carpentier-Edwards Perimount and Medtronic Hancock Conduit. They reported a high rate of success associated with excellent short-term outcomes involving those valve types, but no fracturing of the valve rings was mentioned.

4 | CONCLUSION

We could successfully demonstrate that the Trifecta valve can be augmented via HPB dilatation for subsequent PPVIV. By using a substantially larger HPB repeatedly and under prestenting protection with a covered stent, we were able to fracture the titanium-enforced valve ring's integrity without any complications, and put a big enough valve in place thereafter. This procedure, however, depends on the anatomic situation, and is therefore only applicable for a small patient cohort. Valve fracturing with such a balloon oversizing is only suitable in pulmonary position, as the risk may be too high for injuries of structures nearby, for example, in aortic position Transcatheter aortic valve replacement (TAVR). Additionally RVOT and PA need to have an appropriate size for such a balloon. To avoid a dissection we recommend the use of a covered stent.

ACKNOWLEDGMENT

N.A.H. is proctor for Edwards Sapien PPVI.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

AUTHOR CONTRIBUTIONS

Florian Langhammer: Contributed to the clinical case, performed data interpretation, drafted the manuscript, and approved the final manuscript as submitted. **Anja Lehner:** Contributed to the clinical case and approved the final manuscript as submitted. **Nikolaus Haas:** Contributed to the clinical case and data interpretation, contributed to

drafting the manuscript, and approved the final manuscript as submitted. **André Jakob:** Conceived the work, contributed to the clinical case and data interpretation, contributed to drafting the manuscript, and approved the final manuscript as submitted.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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