

# Initial experience with Edwards SAPIEN valve transcatheter implantation in native RVOT in Latvia

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Transcatheter pulmonary valve implantation has been a well-known method for more than a decade, but there are still many challenging cases when a personalized solution is needed. We report a case of a 15-year-old female patient with tetralogy of Fallot, who underwent a surgical correction during infancy. Because of progressive pulmonary regurgitation, stenosis, and right ventricle dilatation, transcatheter pulmonary valve implantation in the native right ventricle outflow tract (RVOT) using Edwards SAPIEN valve was performed. A “landing zone” was created prior to the intervention of stenting the RVOT and the right pulmonary artery.

The transcatheter approach for pulmonary valve replacement in a native RVOT is a reasonable alternative to the surgical approach.

**Keywords:** Edwards SAPIEN valve, transcatheter pulmonary valve implantation, Tetralogy of Fallot, native RVOT

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## INTRODUCTION

Twenty years ago, Bonhoeffer and colleagues reported the first in-human transcatheter pulmonary valve implantation (1). A 12-year-old male patient with stenosis and insufficiency of a prosthetic conduit between the right ventricle (RV) and pulmonary arteries (PA) was treated with a bovine jugular venous valve sutured into a stent and then crimped on a balloon (Melody® valve, Medtronic, Minneapolis, MN, United States of America). This marked a paradigm shift in treating failed RV-PA conduits. However, many patients with right ventricle outflow tract (RVOT) dysfunction do not have a conduit. In such cases, transcatheter pulmonary valve implantation (TPVI) must be performed in the native RVOT. In these patients, anchoring of the transcatheter heart valve (THV) in often non-calcified RVOT can be challenging. The first successful TPVI in a native RVOT after a surgical repair of Tetralogy of Fallot (TOF) with transannular patch was described in 2008 (2). One common way to perform this procedure is to create a “landing zone” for the THV by pre-stenting the native RVOT. Several case series have been published using the Melody valve as well as the Edwards SAPIEN valve (Edwards Lifesciences, Irvine, CA) (3). We report the first experience of TPVI in a native RVOT in Latvia.

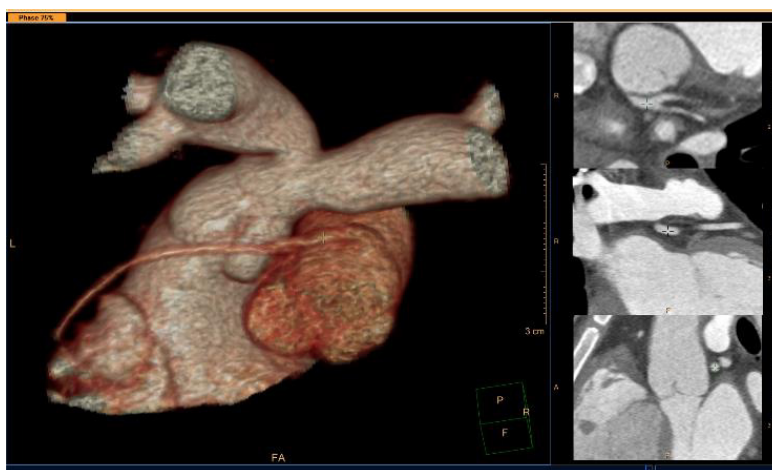
## CASE REPORT

We report the case of a patient with TOF, who at the age of five months underwent a surgical cor-

rection – the closure of a ventricular septal defect with pericardial patch, resection of infundibular stenosis and transannular patch. The postoperative period was unremarkable. The patient underwent regular follow-up in a cardiology outpatient unit. Gradually, transthoracic echocardiography (TTE) revealed progressive dilatation of the RV and tricuspid valve regurgitation (TVR) with a peak gradient of 43 mmHg. At the age of 15, the patient was still asymptomatic and was not receiving any medication. Holter monitoring did not show any arrhythmias. Cardiac MRI showed gradual RV dilatation (a 10% increase in a 3-year period). In the last MRI, the RV end-diastolic volume was 154 ml/m<sup>2</sup>, the end-systolic volume 64 ml/m<sup>2</sup>, ejection fraction 62%. Late gadolinium enhancement of the RVOT myocardium, bilateral mild proximal PA stenoses, moderate tricuspid regurgitation, and free pulmonary valve regurgitation (PVR) (42%) were observed.

The decision was made to perform the TPVI because of progressive RV dilatation, RV volume > 150ml/m<sup>2</sup> and severe PVR. Before the procedure, cardiac computer tomography (CT) was done. In CT, RVOT diameter was 26 mm and an appropriate distance between RVOT and coronary arteries was seen (Figs. 1 and 2). Therefore, RVOT stenting, preceded by transcatheter pulmonary valve implantation in the native RVOT, was performed.

Mounted on a 20 mm balloon-in-balloon catheter, RVOT stenting with a 48 mm XXL AndraStent (Andramed, Reutlingen, Germany)



**Fig. 1.** CT image showing the size of the RVOT and the distance from the left coronary artery



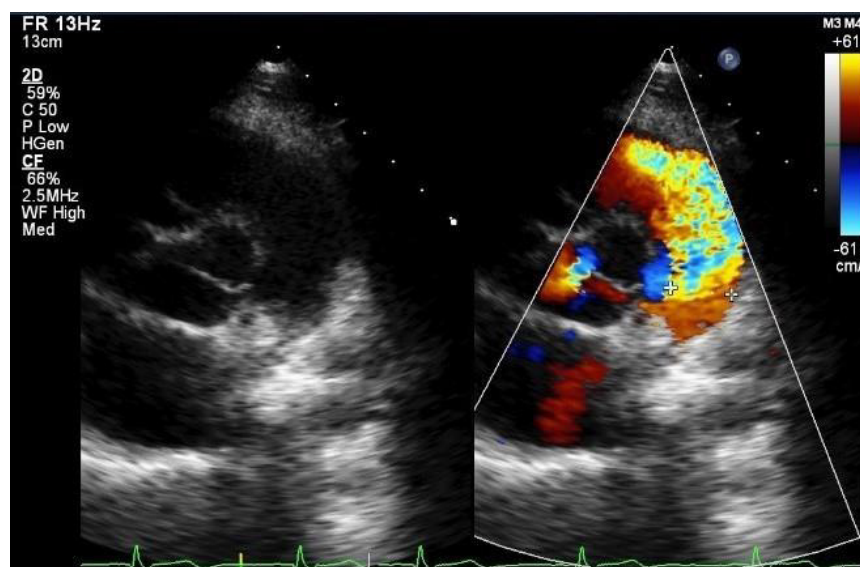
**Fig. 2.** CT image showing the shape and the size of the RVOT

was implanted successfully two months prior to re-valving in order to allow tissue in-growth and stabilization of the stent. Furthermore, the distal part of the stent was covering the proximal part of the right PA, to ensure stable position. A detailed description of the procedure with additional pictures is given in Appendix 1. Aspirin 100 mg once daily was started. After the procedure, TTE showed severe pulmonary regurgitation (Fig. 3).

A 26 mm balloon-expandable Edwards SAPIEN 3 THV (Edwards Lifesciences, Irvine, CA) was implanted in the AndraStent (Appendix 2).

Post-implantation angiography showed neither central or paravalvular pulmonary regurgitation, nor compression of the coronary arteries. After the procedure, RVOT maximal peak systolic gradient was 12 mmHg. The patient was discharged from the hospital three days after the procedure.

At 6-month post-procedural follow-up, the patient was asymptomatic and doing regular physical activities. TTE showed RVOT maximal peak systolic gradient of 22 mmHg, no pulmonary regurgitation, and mild TVR with a peak gradient of 33 mmHg. The result of the procedure was successful.



**Fig. 3.** Echocardiography image showing free pulmonary regurgitation after stent implantation

## DISCUSSION

For many years, surgical pulmonary valve implantation has been the gold standard for the treatment of free pulmonary regurgitation in the native RVOT. However, during the last decade transcatheter re-valving has been proven to be an efficient alternative to the surgical approach in degenerated RV-PA conduits, and this has led to the expansion of the technique to the native RVOT (4). This percutaneous approach has several advantages compared to surgery, which implies repeated sternotomy, cardiopulmonary bypass, and a longer recovery time. One limitation of transcatheter pulmonary valve implantation is the need for a proper landing zone for anchoring, which may not be present in the large native RVOT (5). Other limitations include issues with positioning the THV, endocarditis, and paravalvular regurgitation (5). The present case report shows how this is safe and efficient in carefully selected patients.

## CONCLUSIONS

Transcatheter approach for pulmonary valve replacement in a native RVOT could be a reasonable alternative to the surgical approach. The decision should be made on a case-by-case basis, considering all anatomical variations. Although at present it is an off-label method, it is used more frequently and found to be safe for a selected patient group, often after pre-stenting of the RVOT.

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## PERKATETERINĖ PLAUCIŲ ARTERIJOS EDWARDS SAPIEN VOŽTUVO IMPLANTACIJA PACIENTO DSNT: PIRMOJI PATIRTIS LATVIJOJE

### Santrauka

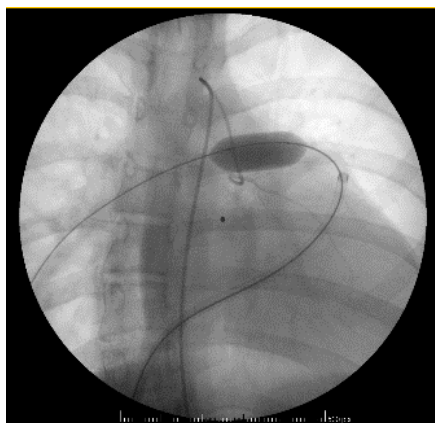
Perkateterinė plaučių arterijos vožtuvo implantacija – daugiau nei dešimtmetį žinomas metodas, tačiau klinikinėje praktikoje susiduriama su iššūkiais, kai reikia priimti individualų sprendimą. Pristatome 15 m. amžiaus pacientės, kuriai diagnozuota Fallot tetrada ir kūdikystėje taikytas chirurginis gydymas, atvejį. Esant progresuojančiai plautinei regurgitacijai, stenozei ir dešiniojo skilvelio išsiplėtimui, buvo atlikta perkateterinė plaučių arterijos Edwards SAPIEN vožtuvo implantacija pacientės dešiniojo skilvelio nutekėjimo trakte (DSNT) (angl. *right ventricle outflow tract*, RVOT). Prieš stentuoiant DSNT ir dešiniąją plaučių arteriją, buvo sukurta „nusileidimo zona“. Perkateterinis plaučių arterijos vožtuvo keitimas paciento DSNT yra tinkama alternatyva chirurginiam gydymui.

**Raktažodžiai:** Edwards SAPIEN vožtuvas, perkateterinė plaučių arterijos vožtuvo implantacija, Fallot tetrada, paciento DSNT

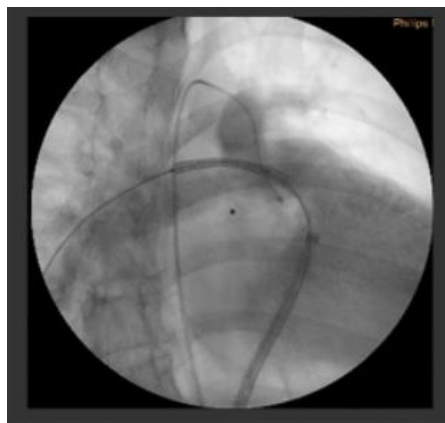
## Appendix 1

### PRE-STENTING

A femoral vein and artery were cannulated. A Lunderquist guidewire was placed in an artery of the lower pulmonary lobe. Pulmonary angiography was done using a Multi-Track catheter (NuMed Inc, Hopkinton, NY). Next, a 20 mm × 30 mm balloon was positioned in the RVOT. The balloon was inflated during simultaneous selective coronary contrast injection. The purpose of this was to confirm that there was a waist on the balloon indicating that the anchoring of the stent was possible and that there was no compression of the coronary arteries (Fig. 1). Then a balloon expandable 48 mm XXL AndraStent (Andramed, Reutlingen, Germany) mounted on a 20 mm balloon catheter was implanted in the RVOT and the right PA (Fig. 2, 3). After the stent deployment, selective coronary arteriograms were done to confirm patent flow (Fig. 4). A 7 Fr Multi-Track catheter was inserted in the PA and control PA angiography was done.



**Fig. 1.** Balloon in the RVOT with a waist and normal flow in LCA



**Fig. 2.** Positioning of the bare metal stent in RVOT and the right PA



**Fig. 3.** Bare metal stent in the RVOT and the right PA during balloon inflation



**Fig. 4.** Selective LCA arteriogram after stent deployment confirms patent flow



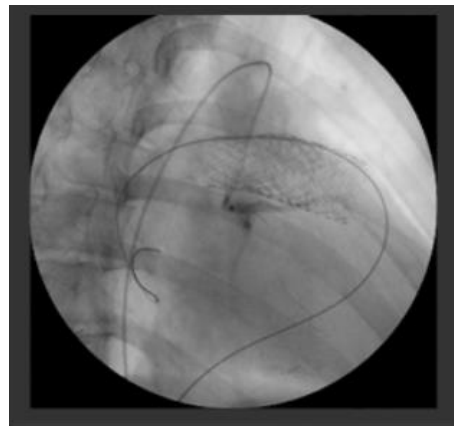
## Appendix 2

### TRANSCATHETER PULMONARY VALVE IMPLANTATION

A femoral vein was cannulated and Lunderquist guidewire placed in a peripheral PA. A long insertion sheath was positioned in the RVOT and 48 mm XXL AndraStent was implanted using the 22 mm double balloon technique (Fig. 5). Selective LAD coronarography was done after the stent implantation and normal flow in the LCA was seen (Fig. 6). RVOT angiography was repeated. The sheath in the femoral vein was exchanged for a 14Fr eSheath (Edwards Lifesciences, Irvine, CA, USA) and a 26 mm Edwards XT THV mounted on the delivery system was introduced to the RVOT (Fig. 7). The THV was deployed in the CP stent during rapid pacing 180 beat-per-minute (Fig. 8 and 9). Next, the valve position was checked by pulmonary angiogram (Fig. 10). No paravalvular leak was seen in the control angiography. The delivery system was removed and the skin closed using a figure-of-eight stitch.



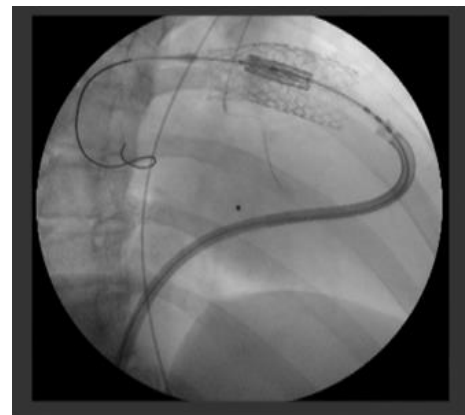
**Fig. 5.** 48 mm XXL AndraStent was implanted using the 22 mm double balloon technique



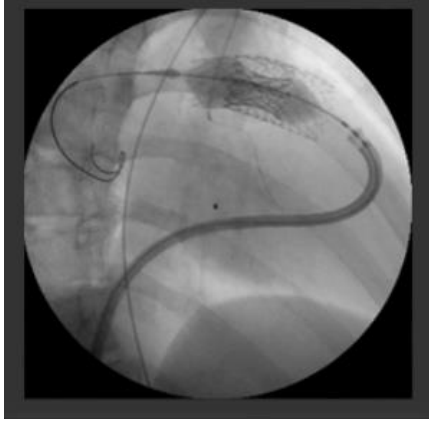
**Fig. 6.** Selective LAD arteriogram after stent implantation confirms patent flow



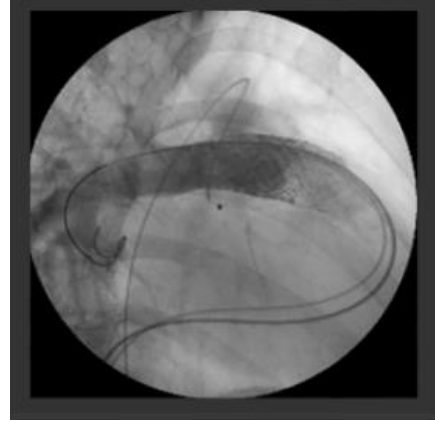
**Fig. 7.** 26 mm Edwards XT THV mounted on the delivery system



**Fig. 8.** THV deployment in the CP stent



**Fig. 9.** THV deployment in the CP stent



**Fig. 10.** Pulmonary angiogram after THV implantation