

## TRANSCATHETER VENUS P VALVE IMPLANTATION AT PULMONARY POSITION- POST TOF REPAIR WITH SEVERE PR- INITIAL CASE IN PAKISTAN

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### ABSTRACT

After total correction for tetralogy of fallot (TOF), right ventricle behaves in an unpredictable manner depending on type of right ventricular outflow tract (RVOT) reconstruction and surgical expertise of infundibular muscle resection. We are reporting a 23 years old girl who underwent total correction at two years of age. RVOT was reconstructed with native pericardial patch. Gradually she developed breathlessness and occasional chest pain. Echocardiography revealed hugely dilated right ventricle (RV) with gross pulmonary regurgitation and RV dysfunction. Cardiac MRI also calculated right ventricular end systolic volume (RVESV) 57 ml/m<sup>2</sup> and right ventricular end diastolic volume (RVEDV) 157ml/m<sup>2</sup>.

We decided to implant transcatheter venus *p*-valve at pulmonary position. The procedure went successful having competent pulmonary valve and improved RV function. Total fluoro time was 36.4 minutes and total procedural time was two hours. This procedure was done first time in Pakistan with optimal results.

**Keywords:** Right ventricular outflow tract, Branch pulmonary arteries, Pericardial patch, Venus *p*-valve.

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### INTRODUCTION

Transcatheter percutaneous pulmonary valve implantation has become an effective and compliant modality for most of tetralogy correction patients needing pulmonary valve replacement after total correction almost two decades ago<sup>1-3</sup>. Melody and Sapien valves are implanted exclusively when homografts or conduits are used to repair right ventricle outflow tracts (RVOT) for total correction of tetralogy of fallot (TOF). But in many cases repaired earlier transannular patch technique was used instead of homograft which leads large and aneurysmal RVOT which requires large sized valves as compared to previously available<sup>4</sup>. In this scenario this became mandatory to have larger valve suitable for which can be implanted in native RVOT having transannular patch with significant dilatation.

For this purpose the Venus *p*-valve (Venus Med Tech, Shanghai, China) self-expandable Nitinol multi-level support frame with tri-leaflet porcine pericardial tissue valve (fig-1) designed

to be implanted in a native patched RVOT. Trials of its use have already been made<sup>5,6</sup> with promising results still pending CE certification and FDA approval<sup>7-10</sup>. We are sharing our initial experience on the technicality and effectiveness of percutaneous implantation of the venus *p*-valve at the pulmonary position in patients with native RVOT.

### CASE REPORT

A 23 year girl was admitted with chest pain and breathlessness NYHA III along with occasional tachycardia. She underwent TOF repair at the age of two years. We planned transcatheter venus *p*- valve insertion at RVOT as she had severe pulmonary regurgitation leading to gradually failing RV. Echocardiography revealed hugely dilated right ventricle (RV) with gross pulmonary regurgitation and RV dysfunction. Tricuspid annular plane systolic excursion (TAPSE) was 10mm. Cardiac MRI further elaborated RVOT, MPA and branch PA anatomy and helped to assess estimated size of the venus *p*-valve. Cardiac MRI also calculated right ventricular end systolic volume (RVESV) 57ml/m<sup>2</sup> and right ventricular end diastolic volume (RVEDV) 157ml/m<sup>2</sup>.

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Transcatheter pulmonary valve implantation was done under general anaesthesia. Heparin 100 IU/kg was used when procedure was started. Broad spectrum antibiotic was given during cath. Venous check angiograms from both femoral veins was done to assess the size and morphology of the femoral veins for suitability of later introduction of large sheaths.

Angiogram in RAO 30 with 6F pigtail through RFV at cran 15, 20ml at of 20 ml/s with 600 psi, Frame rate 15 frames/s done. Pressures of RV and the morphology of RV were noted.

Another injection with same catheter and projection in the main pulmonary artery was carried out. LAO 90 projection with pigtail in the MPA to see degree of stenosis and regurgitation, to estimate the shape and size of RVOT, narrowest pulmonary valve point, MPA size, take off of the LPA and to estimate length of the desired valve. The catheter is advanced to LPA to see the gradient across RVOT.

LOKUM Lunderquist extra-stiff guide wire 260 cms 0.35 wire" with 10 cms PTFE coated straight tip (Cook Medical, IN, USA) was parked deep in the one of the branch of left pulmonary artery using 6F MP from LFV as RFV showed small caliber not suitable for large sheath. Via LFA 6F pigtail was placed in the LV to assess LVEDP. The catheter was then pulled back to aortic root for a later coronary angiogram during RVOT balloon inflation. Using the same (left) groin, another 6F pigtail is passed in the femoral vein and placed in the RV for check angiograms.

Balloon interrogation with 34mm diameter/4cm long, 75cm shaft length Amplatzer TMSD Sizing Balloon Catheter (St. Jude Medical, MN, USA) was done over the Lunderquist wire and placed across the pulmonary valve deep in the main pulmonary artery. The balloon was then inflated using a contrast dilution of 1:5 and using a T tap at the end. Two syringes 50 ml each were used with a two way tap at the balloon end. Enough contrast was injected into the balloon so that it completely occluded the RVOT and was fixed in the main pulmonary artery without any

bobbing to and fro motion and was still at the end of inflation. A simultaneous injection was then given in the arterial root pigtail at 20ml and 20ml/s; 600 psi at LAO 90 projection. Patency of

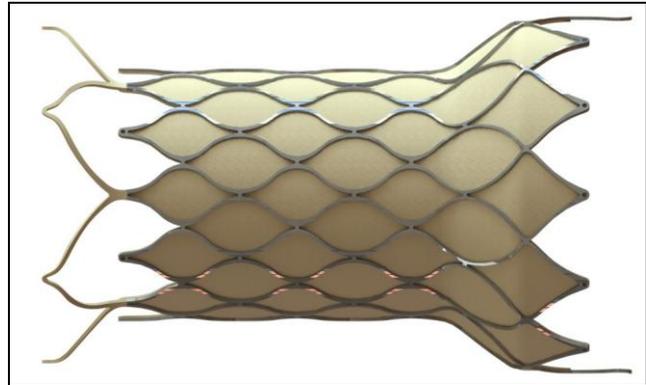


Figure-1: The Venus *p*-valve TM.

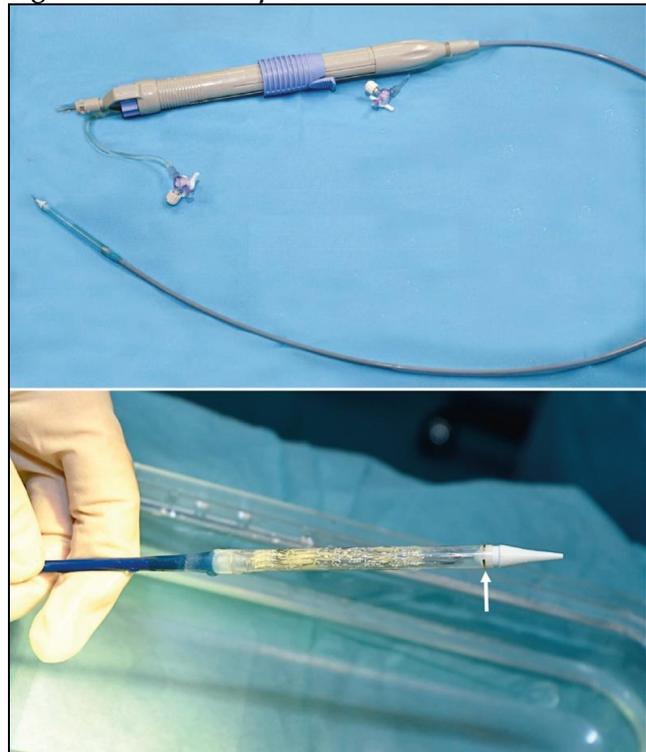
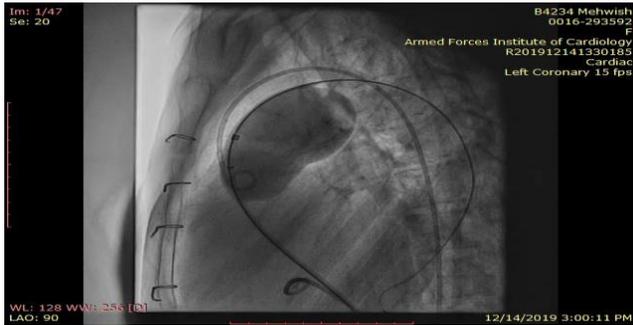


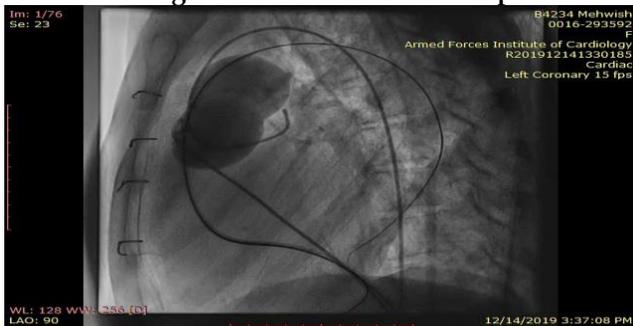
Figure-2: The Venus *p*-valve delivery system. note the handle with a knob for slow and controlled release of the valve and the distal capsule with a crimped and loaded valve inside. The arrow signs a distal radiopaque mark to be shifted to ICU.

the coronary arteries was checked and any compression of the arteries during balloon inflation of the RVOT was noted. In the same projection (LAO 90) a repeat angiogram was taken with

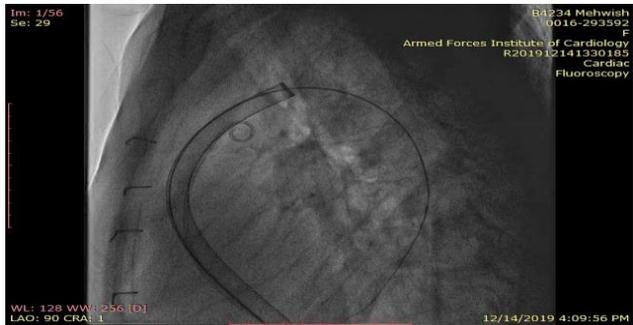
20ml contrast at 20ml/s at 600 psi; using the 6F pigtail placed in the RV cavity. Complete occlusion of the RVOT was achieved at maximum inflation of the sizing balloon (fig-3). No contrast was seen in the main pulmonary artery. The procedure was then repeated in the RAO 30, Cran 15



**Figure-3: LAO 90 view showing complete occlusion of rvot with full inflation of balloon. This helped to estimate sizing of valve at the narrowest point.**



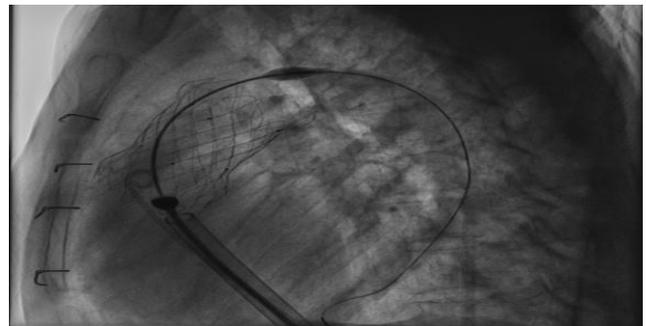
**Figure-4: LAO 90 view showing LCA catheter away from full inflated balloon.**



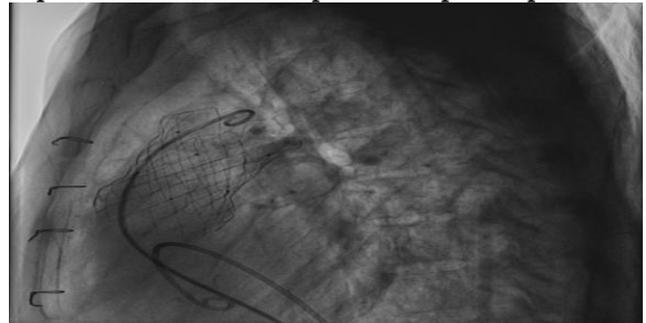
**Figure-5: A 24 french sheath placed at the proximal LPA.**

projection and check angiograms in the aortic root and in the RV cavity were repeated. Coronary compression in this new position was then ruled out during maximum compression of the sizing balloon using diluted contrast; injecting 80 ml with two 50 ml syringes attached to the T tap (fig-4).

Predilating the left groin using 24 F Venus *p*-valve sheath dilator, repeated angiograms taken in LAO 90 and RAO 30 cranial 15, to keep distal end of sheath in to proximal LPA or along the anterior border of the trachea and so adjusted to avoid distal RPA origin. 6F pigtail placed in the RV was then advanced into the MPA for later injections and pressure measurements. We selected Venus *p*-valve “shaft length 20 mm and with dia-



**Figure-6: The self expanding valve is completely exposed from the sheath placed at optimal position.**



**Figure-7: Check angiogram showing competent valve at pulmonary position.**

meter of 34 mm” (fig-1). After rinsing with large amount of normal saline, the valve was manually crimped under cold normal saline onto a 22 French delivery system. Then, the whole system assembly was passed through a 24 French or larger Check-Flo® Performer Extra Large Introducer (Cook Medical, IN, USA), and placed at the proximal LPA (fig-5). Once in the optimal position, the valve was very slowly implanted by clockwise rotation of the releasing knob. Frequent pulmonary angiograms via pigtail catheter are performed to ensure a proper valve position until the valve was completely exposed (fig-6). After the valve deployment, the RV/ PA pressure and

MPA angiography are repeated. The flair end of the valves was adjusted in the pain pulmonary artery and repeated check angiograms were taken in LAO 90 and RAO 25 making sure that the branch Pas remained unobstructed (fig-7). Repeated check angiograms were then taken and pressures recorded. Using a wire the pigtail in the PA was then gradually withdrawn. While withdrawing the 24 F sheath probably diaphragm of the sheath was damaged causing profuse bleeding, the sheath was immediately withdrawn with compression at the sheath site. Due to heavy bleeding, two units of blood were immediately replaced and she was resuscitated successfully to be shifted to ICU.

## DISCUSSION

This was our initial experience of venus *p*-valve implantation in a patient in whom pericardial patch was used to reconstruct RVOT, with very favourable results. However case selection and technical expertise is key for the success.

## RECOMMENDATIONS

- Injection Heparin 5000 IU every 6 hrly
- Injection Meropenem 500 mg 8 hrly
- Inj Amikin 500 mg BD
- Tab loprin 150 mg OD indefinitely
- Tab Lowplat 75r mg OD for six months
- Tab paracetamol 2 tabs 8 hrly for 3 days
- Repeat ECHO after 24 hrs
- Ultrasound abdomen after 24 hrs for retroperitoneal bleed.
- Care of the access site.
- Follow up after 2 weeks, 3 months, 6 months, then 1 yearly
- MRI and fluoroscopy after 3 months to asses changes in the RV EDV/RV function and fracture of valve stents.
- Avoid Estrogen for contraception, use only progesterone to avoid thrombosis.

## CONCLUSION

Venus *p*-valve is very effective and practical solution for Severe PR and failing RV post total correction. However we need to do more cases for more experience and data for future management of this category of patients.

## CONFLICT OF INTEREST

This study has no conflict of interest to be declared by any author.

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