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CLINICAL CASE

Percutaneous implantation of the Venus P self-expanding pulmonary valve in children; the first case in Colombia

Implante percutáneo de válvula pulmonar autoexpandible Venus P en niños; primer caso en Colombia

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Abstract

In patients with congenital heart disease, transcatheter pulmonary valve implantation is the treatment of choice in dysfunctional right ventricular outflow tracts (RVOT). The self-expandable Venus-P valve was approved recently for use in large native tracs. This study reports the experience of the first case of successful implantation of Venus-P pulmonary valve in Colombia. Ours was a 16-year-old patient with Tetralogy of Fallot, with complete correction at 11 months of life. The patient has severe pulmonary insufficiency and functional class deterioration. Cardiac catheterization was performed to place a 34X30 mm Venus-P valve, a procedure carried out without complications, evidencing significant improvement in the diastolic pressure of the pulmonary artery, without final gradient between the right ventricle and pulmonary artery. Reports exist of experiences in Venus-P valve implant globally with favorable results; percutaneous valve placement represents decreased procedure times and hospital stays. We believe percutaneous valve replacement in pulmonary position in native RVOTs is a possible and safe option to improve pulmonary insufficiency and right ventricular dysfunction in these types of patients.

Keywords: *Pulmonary regurgitation. Pulmonary valve. Right ventricle. Venus P-valve.*

Resumen

En pacientes con cardiopatía congénita, el implante percutáneo de válvula pulmonar es el tratamiento de elección en tractos de salida del ventrículo derecho (TSVD) disfuncionales. La válvula autoexpandible Venus-P, fue aprobada recientemente para su uso en tractos nativos de gran tamaño. El objetivo de este estudio es reportar la experiencia del primer caso de implantación exitosa de válvula pulmonar Venus-P en Colombia. Paciente de 16 años con Tetralogía de Fallot, con corrección completa a los 11 meses de vida. Presenta insuficiencia pulmonar severa y deterioro de la clase funcional. Se realiza cateterismo cardíaco para la colocación de válvula Venus-P 34X30 mm, procedimiento que se lleva a cabo sin complicaciones, evidenciando mejoría significativa de la presión diastólica de la arteria pulmonar, sin gradiente final entre el ventrículo derecho y arteria pulmonar. Existen varios reportes de experiencias en el implante de válvula Venus P a nivel mundial con resultados favorables. La colocación percutánea de la válvula representa disminución en tiempos del procedimiento y estancia hospitalaria. Consideramos el reemplazo valvular percutáneo en posición pulmonar en TSVD nativos es una opción posible y segura para mejorar la insuficiencia pulmonar y la disfunción ventricular derecha en este tipo de pacientes.

Palabras clave: *Insuficiencia pulmonar. Válvula pulmonar. Ventrículo derecho. Válvula Venus P.*

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Introduction

In recent years, percutaneous valve implantation has consistently progressed, achieving today's interventions that are less invasive and have lower morbidity, compared to surgical procedures[1]. For patients with congenital heart disease, percutaneous pulmonary valve implantation is the treatment of choice for dysfunctional right ventricular outflow tracts (RVOTs)[2]. There are several balloon-expandable pulmonary valves available for implantation in conduits, native tracts and prosthetic valves. The available valves (Melody or Edwards SAPIEN) are recommended for implantation only in RVOTs made with homografts or conduits[3,4]. However, most patients with tetralogy of Fallot undergo repair with a transannular patch, which leads to very pulsatile outflow tracts that are larger than the currently available balloon-expandable valves (22 mm for Melody, 29 mm for Edwards)[3,5].

This has led to the need for a valve that can be implanted in a native RVOT and is large enough for the wide diameters of RVOTs with a patch. The self-expanding Venus P-valve (MedTech, China) is a percutaneous valve recently approved for use in larger native tracts[6].

The structure of the Venus P-valve is made up of a nitinol stent, with the leaflets and stent covered in porcine pericardial tissue. The nitinol allows the stent to properly adapt to the pulmonary trunk without compressing neighboring structures, due to its lower radial force[7]. The available valve sizes range from 28 up to 36 mm in diameter, with 2 mm increments. The Venus P-valve stent is diabolo-shaped and measures 10 mm more on the ends than in the central area. Since it is wider on the ends, the valve is ideally designed to be implanted in tubular pulmonary trunks with no distal or pulmonary artery stenosis. The central area and proximal end are covered in porcine pericardial tissue to avoid paravalvular leaks, and the distal end is not covered, thus preventing pulmonary artery occlusion. The valve is crimped onto the delivery system under ice water. Under these conditions, the nitinol softens and can be crimped onto the delivery system. The valve is attached to the delivery system using two small hooks. Once hooked and compressed, the valve is covered with the delivery system´s sheath capsule so that it enters the patient covered. The sheath is a 22 Fr for 28- and 30-mm valves, and 24 Fr for larger valves (> 30 mm). Once situated at the chosen spot in the pulmonary tree, the valve recovers its diabolo shape when the delivery system capsule is removed, and it comes in contact with the blood stream at a temperature of 36-37°C[3].

The objective of this study is to report the experience of the first successful implantation of a Venus P-valve in Colombia.

Clinical case

The patient was 16 years old, weighed 63 kilos and had a history of tetralogy of Fallot for which he underwent complete repair at 11 months of age. He required reintervention a few days later to reconstruct the RVOT due to a transannular patch aneurysm and residual ventricular septal defect.

He was being followed for pulmonary valve regurgitation and had experienced clinical deterioration over the last six months, developing cyanosis with exercise and progressing from New York Heart Association (NYHA) functional class I to II.

An echocardiogram showed significant right ventricular dilation (right ventricular diastolic diameter: 47 mm, Z +3-07) with free pulmonary regurgitation. Cardiac magnetic resonance imaging reported a right ventricular diameter of 58 mm (Z +3.95), with a pulmonary regurgitant fraction of 56% and a right ventricular end-diastolic volume of 172 ml/m^2. The pulmonary valve annulus was measured at 29 mm on cardiac angiography tomography, with the course of the proximal anterior descending artery 4 mm from the plane of the pulmonary valve annulus.

Based on this, the case was discussed in a multidisciplinary committee and the patient was considered to be a candidate for self-expanding percutaneous pulmonary valve implantation.

With prior informed consent, a heart catheterization was performed under general anesthesia with the patient intubated and heparinized at 100 U/kg. The right and left femoral veins and left femoral artery were cannulated. Right and left heart catheterization was performed with a right ventricular pressure of 32/2 mmHg and right and left pulmonary artery pressures of 34/4/16 and 32/2/16 mmHg, respectively, along with RVOT sizing showing a 30 mm diameter (Sizing Balloon, AGA Medical Corp., United States), with a coronary test which was negative for obstruction (Fig. 1).

With this information, a valve was chosen that was 4 mm larger than the waist of the sizing balloon and long enough to leave the distal portion at the pulmonary bifurcation and the proximal tip of the diabolo in the RV, ultimately selecting a 34 x 30 mm valve.

The valve was loaded with no difficulties. The high-support Lunderquist guidewire (Cook Medical, Denmark) was advanced to the left pulmonary artery,

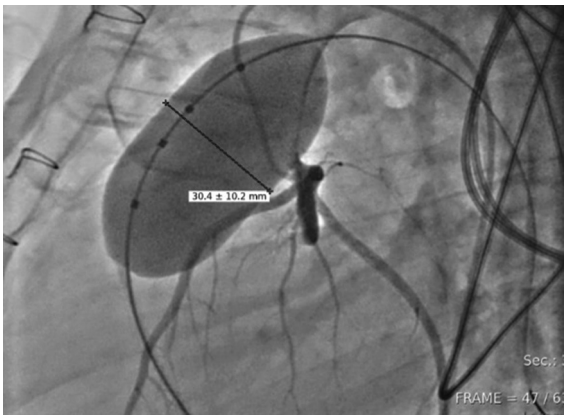

Figure 1. Coronary occlusion test with a 30 mm elastomer balloon.

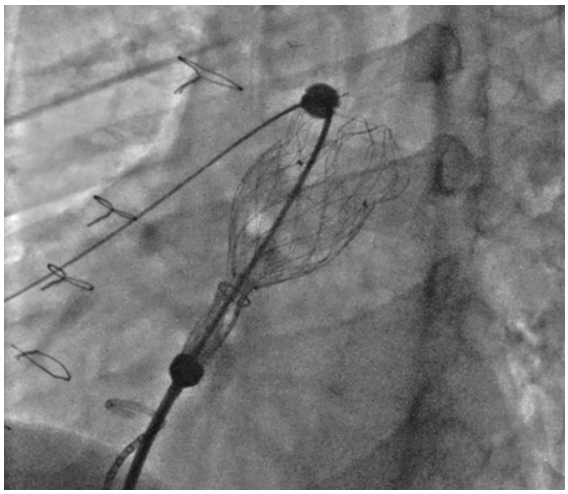

Figure 2. Initial valve deployment.

and the introducer was advanced through the artery to its origin.

Valve deployment was begun at the origin of the left pulmonary artery with serial angiographic monitoring. The initial position of the valve was not considered appropriate, and the guidewire was repositioned in the right pulmonary artery (Fig. 2). The complete valve was deployed in a controlled fashion from the right pulmonary artery, achieving an appropriate position (Fig. 3). No residual pulmonary regurgitation was found on angiography and a final coronary test showed no abnormalities. Pressures were taken after the procedure, with significantly improved diastolic pressure in the pulmonary artery, going from 4 to 14 mmHg after the procedure, with no significant gradient between the right ventricle and pulmonary artery (2 mmHg).

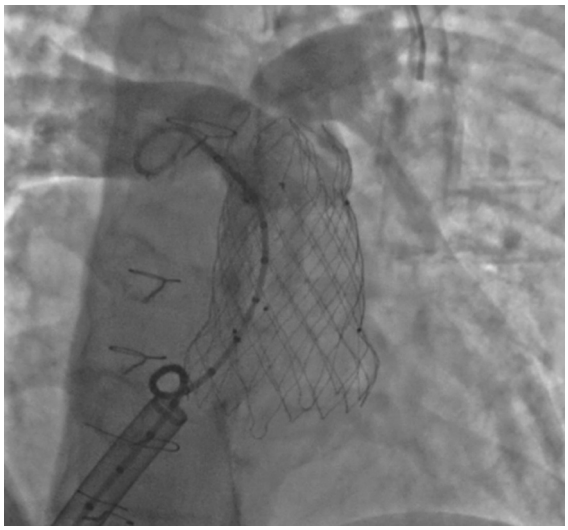

Figure 3. Final post-implant angiography.

Follow up after the procedure

One month after the procedure, the patient was asymptomatic, in NYHA functional class I, and had no cyanosis or dyspnea with activity. On physical exam, he had an oxygen saturation of 99%, with no abnormalities. The follow up echocardiogram reported trivial pulmonary regurgitation with no stenosis or paravalvular leaks, and adequate biventricular function.

Discussion

There are several reports to date of Venus P-valve implantation experiences around the world, with favorable outcomes[5,8-10]. Unlike the other available valves, Venus P-valve implantation does not require a stent to change the RVOT into a rigid conduit[11,12]. This reduces procedure time and exposure to radiation. In addition, radiopaque marks on the distal end of the straight part of the valve allow it to be precisely deployed and positioned, keeping it from protruding into the pulmonary trunk bifurcation[3].

Regarding the cost of the different expandable valves authorized by the regulatory agency in our country (INVIMA), the Melody valve (balloon-expandable) is less expensive than the Venus P (self-expanding).

However, the Melody valve is designed for "non-native" RVOTs with a diameter of up to 26 mm. For our patient, with a large RVOT, the self-expanding pulmonary valve available in this country is the Venus P-valve, which is why it was considered to be the ideal choice.

On another note, percutaneous valve implantation decreases orotracheal intubation times, intensive care unit stays and total hospital stays. As far as the cost of surgical replacement compared to the interventional procedure, percutaneous replacement is more expensive due to the cost of the valve. However, in specific cases, like that of our patient, who had already undergone two cardiothoracic surgeries, percutaneous replacement is considered to be the appropriate procedure, as it has lower morbidity and may have a lower risk of complications.

In patients with repaired or unrepaired congenital heart disease and secondary pulmonary regurgitation, the pulmonary valve may need to be replaced depending on the symptoms and hemodynamic repercussions of the regurgitation. Valve replacement candidates must undergo comprehensive assessment with an echocardiogram, cardiac magnetic resonance imaging, a stress test and a Holter electrocardiogram. When the diameter measurements are uncertain, angiography tomography may offer a more precise measurement to determine the size and length of the prosthesis to be implanted, as well as to evaluate the anatomical characteristics of the RVOT.

The selection of our patient, based on echocardiography, angiography tomography, magnetic resonance imaging and sizing balloon measurements through catheterization was effective and allowed the procedure to be successful. In our patient's case, there were no complications or hemodynamic decompensation during the procedure. An echocardiogram the next day showed a properly positioned valve with no stenosis or residual regurgitation. Furthermore, there were no local complications at the puncture sites and the patient was able to be discharged from the hospital 48 hours after the procedure.

Right ventricular volumes, right and left ventricular function and valve competence will be evaluated on follow up, as indicated in the international literature on implantation of this type of valves[8].

Based on this experience, we believe that percutaneous pulmonary valve replacement in dilated native RVOTs is a viable and safe option to improve pulmonary regurgitation and right ventricular dysfunction in this type of patient.

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical responsibilities

Human and animal protection. The authors declare that the procedures they followed adhered to the ethical norms of the responsible human experimentation committee and were in line with the World Medical Association and the Declaration of Helsinki.

Data confidentiality. The authors declare that they have followed their workplace protocols for the publication of patient data.

Right to privacy and informed consent. The authors have obtained informed consent from the patients and/or subjects referred to in this article. The corresponding author is in possession of this document.

Use of artificial intelligence to generate text. The authors declare that they have not used any type of generative artificial intelligence in drafting this manuscript nor for creating figures, graphs, tables or their respective captions or legends.

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