Percutaneous pulmonary valve implantation in native outflow tracts: has the time come?

**Implante valvular pulmonar percutáneo en tracto de salida nativo: ¿ha llegado el momento?**

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**INTRODUCTION**

Right ventricular outflow tract (RVOT) disease is a common finding in children and adults with congenital heart disease and often occurs as a sequel of previous surgery. Over the past 2 decades, percutaneous pulmonary valve implantation has become more widely used and is recommended by current clinical practice guidelines as the preferred option for patients with previous conduits or bioprostheses.

However, many patients have native or patched tracts (hereafter referred to as native RVOTs) with pulmonary regurgitation as the predominant lesion. In these patients, percutaneous valve placement is more complex due to the RVOT anatomy, its dynamic behavior, larger pulmonary annulus size, and lack of a proper landing zone for the valve. Because of the differences in underlying heart diseases, previous surgical repairs, and various pulmonary artery configurations, RVOT morphology varies widely but can be categorized into 5 subtypes (figure 1).

Repaired tetralogy of Fallot serves as the paradigm, and in these cases, surgery remains the standard of care. However, the development of percutaneous procedures has enabled a larger number of patients with these substrates to be eligible for percutaneous treatment (figure 2).

Two different models of balloon-expandable valves have been authorized to treat dysfunctional bioprostheses and conduits: the Melody (Medtronic, United States) and the SAPIEN valves (XT model, Edwards Lifesciences, United States). Although they have not yet been authorized for implantation in native RVOTs, both (along with the SAPIEN S3) have been used off-label in this setting.

To address the specific characteristics of native RVOTs, several models of self-expanding valves have been developed, such as the Venus-P [Venus MedTech, China, with CE marking for use in Europe since 2022], PULSTA [TaeWoong Medical, South Korea], and Harmony valves [Medtronic, United States, with prior FDA approval]. The Alterra valve [Edwards Lifesciences] has also been used. This valve serves as a self-expanding prestent onto which a SAPIEN valve is later implanted.

The characteristics of each of these devices have already been described in detail in a previous issue of *REC: Interventional Cardiology.*

**RESULTS OF PERCUTANEOUS VALVES IN THE NATIVE RIGHT VENTRICULAR OUTFLOW TRACT**

More information has gradually become available on the favorable results and durability of percutaneous valves. The largest multicenter registry to date, with 2476 patients [82% implanted with the Melody valve and 18% with the SAPIEN device, including 16% with native RVOTs], reported an 8-year survival rate of 91.1% after implantation, and a reintervention rate of 25.1%, which is similar to the rates reported in some surgical series. Nonrandomized comparative studies and a recent meta-analysis also found similar reintervention rates. Some series report higher rates in patients implanted with the Melody compared with the SAPIEN valve, although the 2 groups were not directly comparable, with reintervention-free survival rates in patients with SAPIEN being similar to those reported in patients with surgical valves.

The SAPIEN device can be implanted with or without prestenting, depending on the patient’s characteristics, with good outcomes. The largest trial published to date included 774 patients implanted with the XT and S3 models, 51% of whom had native RVOTs (table 1).

In a study of patients with native RVOTs that included 229 candidates for the Melody valve, the device was finally implanted in 132 patients [58%]. The most common reason for avoiding implantation was a prohibitively large RVOT, followed by coronary or aortic root compression. The immediate outcomes of patients with successful implantation were good. However, the low implantation rate demonstrates the limitation of treating native RVOTs with these valves.

Self-expanding valves fill this gap by allowing treatment of larger RVOTs, as they adapt to the anatomy of the RVOT and provide more stable attachment. The series published to date indicate a very high implantation success rate—close to 100%—with good short- and mid-term outcomes and few complications (table 1 illustrates a selection of series representative of patients with native RVOTs).

Drawing comparisons between the results of surgical and percutaneous pulmonary valves is challenging because the types of patients and the anatomies treated are very different. Overall, patients undergoing percutaneous valve implantation are at higher risk and often have bioprostheses or small conduits that require smaller percutaneous valves, which is associated with a higher residual...
gradient, leading to a greater need for reintervention,\textsuperscript{4,8,9} and a higher rate of endocarditis. This aspect has traditionally led to less favorable results with the Melody series (with a maximum diameter of 22 mm), with durability being one of the issues initially identified, although more recent series have shown positive results. Only indirect comparisons can be drawn with valve procedures in the native RVOT.

**PROCEDURAL PLANNING**

Multimodal imaging modalities, especially magnetic resonance imaging and computed tomography, are crucial for patient selection and procedural planning. Key aspects include measurement of the RVOT and the pulmonary annulus, and assessment of both the RVOT and the coronary anatomy. Recently, computed tomography guidelines for RVOT assessment\textsuperscript{17} have been published with detailed information on the measurements that should be taken, and the cardiac cycle phase.

**POTENTIAL PROBLEMS**

Valve or stent migration or embolization is a potential complication in patients with large RVOTs due to the lack of an adequate landing zone, with incidence rates between 0% and 4.5%,\textsuperscript{11,10,18} and consequently proper valve sizing is of paramount importance.

Stent fractures can lead to loss of integrity and contribute to prosthetic valve dysfunction. Nonetheless, the implications of the occasional finding of an isolated strut fracture remain unclear.

Tricuspid valve injury has been reported in 3% to 6% of patients.\textsuperscript{10} However, this rate has dropped significantly with the use of DrySeal introducer sheaths (W.L. Gore & Associates, United States).\textsuperscript{10}

Coronary compression is a rare complication nowadays, because coronary angiography is simultaneous and systematically performed during RVOT balloon inflation testing. However, it can be a reason for not performing percutaneous implantation in nearly 3% of patients.\textsuperscript{11}

A higher incidence of infective endocarditis has been reported, especially after Melody valve implantation,\textsuperscript{4,8,9} with a higher risk when smaller valves are implanted and there is a greater residual gradient. The risk involved with other types of device such as the SAPIEN—whether because of its different composition (bovine jugular vein graft in the Melody compared with bovine pericardium in the SAPIEN) or because of its larger size—is much lower\textsuperscript{9} and seems comparable to that of surgical series.

Self-expanding valves are larger, and the proximal end often remains inside the RVOT, which could increase the risk of ventricular arrhythmias. The incidence of nonsustained ventricular tachycardia varies widely (between 0.6% and 40%\textsuperscript{11,12,20}, although it is usually a transient phenomenon during the early postimplantation
phase, and its long-term implications remain unclear. Of note, when comparing surgical with percutaneous pulmonary valve replacement, the early incidence of arrhythmias was lower in the latter. A potential caveat is that catheter access to the arrhythmic substrate can be limited after valve implantation.

The presence of the valve metal mesh with or without previous stents inside the RVOT can pose additional challenges for the surgeon if surgical valve replacement is subsequently required. This is a relative problem, because surgical pulmonary valve replacement also increases the risk of future reinterventions related to resternotomy.

**Benefits of Percutaneous Valve Implantation**

The possibility of performing percutaneous pulmonary valve implantation offers clear advantages: the procedure is much less...
invasive, length of stay is shorter, recovery is faster, the mortality rate is very low (from 0.2% to 0.8%), and the cost-effectiveness ratio is more favorable. In patients at high surgical risk, it might be the only available treatment option. The path followed by its ‘left-sided relatives’—transcatheter heart valves in the aortic position—illustrates that the threshold for the use of percutaneous techniques is decreasing as more experience is gained and technology becomes further refined. In cases of intermediate or low risk, percutaneous valve implantation may delay or avoid the need for surgery in patients who often require multiple interventions during their lifetime. This concept of avoiding sternotomies is relevant due to the added risk of further surgeries and for patients who are candidates for heart transplants. The decision on the best approach to valve implantation in each patient should be made by a multidisciplinary heart team, including health professionals experienced in these types of heart disease.

CONCLUSIONS

Percutaneous pulmonary valve implantation is particularly challenging in patients with native RVOTs. Nonetheless, it is a feasible option that is being used with a high success rate and few complications. However, appropriate candidate selection is essential. Several models of self-expanding valves have been specifically developed for this purpose, with good short- and mid-term results, allowing the treatment of patients with large RVOTs that were previously not amenable to balloon-expandable devices. The latest information suggests that the durability of percutaneous valves may be comparable to that of surgical bioprostheses, although long-term data are lacking, especially with the latest models. Although more studies and follow-up are necessary, percutaneous techniques are already an option for many patients and will likely become an alternative to surgical treatment in the near future.

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CONFLICTS OF INTEREST

None declared.

REFERENCES