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Branch Pulmonary Artery Valve Implantation Reduces Pulmonary Regurgitation and Improves Right Ventricular Size/Function in Patients With Large Right Ventricular Outflow Tracts

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ABSTRACT

OBJECTIVES The authors sought to assess the intermediate-term effects of percutaneous placed valves in the branch pulmonary artery (PA) position.

BACKGROUND Most patients with large right ventricular outflow tracts (RVOTs) are excluded from available percutaneous pulmonary valve options. In some of these patients, percutaneous branch PA valve implantation may be feasible. The longer-term effects of valves in the branch PA position is unknown.

METHODS Retrospective data were collected on patients with significant pulmonary regurgitation who had a percutaneous branch PA valve attempted.

RESULTS Percutaneous branch PA valve implantation was attempted in 34 patients (18 bilateral and 16 unilateral). One-half of the patients were in New York Heart Association (NHYA) functional class III or IV pre-implantation. There were 2 failed attempts and 6 procedural complications. At follow-up, only 1 patient had more than mild valvar regurgitation. The right ventricular end-diastolic volume index decreased from 147 (range: 103 to 478) ml/m^2 to 101 (range: 76 to 429) ml/m^2, $p < 0.01$ ($n = 16$), and the right ventricular end-systolic volume index decreased from 88.5 (range: 41 to 387) ml/m^2 to 55.5 (range: 40.2 to 347) ml/m^2, $p < 0.01$ ($n = 13$). There were 5 late deaths. At a median follow-up of 2 years, all other patients were in NYHA functional class I or II.

CONCLUSIONS Percutaneous branch PA valve implantation results in a reduction in right ventricular volume with clinical benefit in the intermediate term. Until percutaneous valve technology for large RVOTs is refined and more widely available, branch PA valve implantation remains an option for select patients. (J Am Coll Cardiol Intv 2018;11:541–50)

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ABBREVIATIONS AND ACRONYMS

LV = left ventricle/ventricular

MRI = magnetic resonance imaging

NYHA = New York Heart Association

PA = pulmonary artery

PR = pulmonary regurgitation

RV = right ventricle/ventricular

RVEDVIx = right ventricular end-diastolic volume index

RVESVIx = right ventricular end-systolic volume index

RVOT = right ventricular outflow tract

The advent of percutaneous pulmonary valve technology using the Melody transcatheter pulmonary valve (Medtronic, Minneapolis, Minnesota) and the Edwards Sapien transcatheter heart valve (Edwards Lifesciences, Irvine, California) has changed the therapeutic landscape for many patients with dysfunctional right ventricular outflow tracts (RVOT). Subsequent to early studies (1), the Melody valve was Food and Drug Administration approved (2–4) for implantation in dysfunctional right ventricle (RV) to pulmonary artery (PA) conduits and stented bioprosthetic valves on delivery systems that provide an outer diameter up to ~24 mm. The Edwards Sapien transcatheter heart valve, initially designed for transcatheter aortic valve replacement, can be implanted in the pulmonary position using valve sizes of 23, 26, and 29 mm (5).

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Unfortunately, these indications exclude the vast majority of post-operative patients with a dysfunctional RVOT, particularly those with a "native" or patch-augmented RVOT anatomy (6). In the absence of an RV-PA conduit or bioprosthetic valve, pulmonary regurgitation (PR) tends to be the predominant lesion, and chronic PR results in dilation and distortion of the RVOT. In most patients with this anatomy, the RVOT is too large to allow for implantation of existing balloon-expandable devices (Melody and Sapien) in the orthotopic position. Self-expanding devices such as the Harmony Valve (Medtronic) and the Venus-P valve (Venus Medtech, Hangzhou, China), which are designed to anchor within the dilated RVOT, though promising, are still in early development (7–11). In the absence of a device specifically intended for implantation into the dilated RVOT/main PA, several investigators have reported off-label implantation of commercially available balloon-expandable valves into the branch PAs as a nonsurgical alternative in high-risk patients (12–16). This technique has been shown to reduce PR in the short term (13–16), but the longer-term physiological consequences of this unique circulation have not been reported. Specifically, in the presence of a "nonvalved" RVOT/main PA segment (proximal to the branch PA valves), the effect on RV size and function in the longer term remains unknown.

The purpose of this multicenter study was to assess the technical feasibility of percutaneous branch PA valve implantation, the intermediate term function of these valves, and their impact on RV remodeling and functional status of these patients.

METHODS

PATIENTS AND PROCEDURAL TECHNIQUE. Patients who underwent attempted percutaneous implantation of a Melody or Sapien valve into a branch PA from January 2007 to May 2016 were solicited from 13 centers (10 in the United States and 3 in Europe). Institutional review board approval was obtained according to requirements at each center. Patients were included if an attempt was made to place a transcatheter valve into a branch PA unilaterally or bilaterally due to an RVOT that was deemed too large for percutaneous implantation. Patients undergoing unilateral valve implantation attempts were only included if there was no blood flow to the contralateral lung. Patients with a functionally single-lung circulation who had a percutaneous valve intended to be implanted in the RVOT were excluded, because the aim was to assess the physiological and clinical implications of a valve specifically implanted into a branch PA. Procedural implantation techniques were variable, but in general, they were similar to methods for implanting a Melody or Sapien valve in a RV-PA conduit in the cardiac catheterization laboratory. Pre-stenting of the branch PAs and choice of valve to be implanted was at the operators' discretion.

BASELINE AND FOLLOW-UP DATA. Patient demographics, New York Heart Association (NYHA) functional class, anatomic diagnosis, comorbidities,

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