JACC: CARDIOVASCULAR INTERVENTIONS VOL. ■, NO. ■, 2018

PUBLISHED BY ELSEVIER

Safety and Feasibility of Melody Transcatheter Pulmonary Valve Replacement in the Native Right Ventricular Outflow Tract

A Multicenter Pediatric Heart Network Scholar Study

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ABSTRACT

OBJECTIVES This study sought to determine the safety and feasibility of transcatheter pulmonary valve replacement (TPVR) using the Melody valve in native (nonconduit) right ventricular outflow tracts (nRVOT), and to identify factors associated with successful TPVR.

BACKGROUND The Melody valve is Food and Drug Administration–approved for TPVR within right ventricle-to-pulmonary artery conduits and bioprosthetic pulmonary valves. However, most patients needing pulmonary valve replacement have nRVOT and TPVR has been adapted for this indication.

METHODS In this multicenter retrospective study of all patients presenting for nRVOT TPVR, we collected pre-procedural magnetic resonance imaging, echocardiography, and catheterization data, and evaluated procedural and early outcomes.

RESULTS Of 229 patients (age 21 ± 15 years from 11 centers), 132 (58%) had successful TPVR. In the remaining 97, TPVR was not performed, most often because of prohibitively large nRVOT (n = 67) or compression of the aortic root or coronary arteries (n = 18). There were no deaths and 5 (4%) serious complications, including pre-stent embolization requiring surgery in 4 patients, and arrhythmia in 1. Higher pre-catheterization echocardiographic RVOT gradient was associated with TPVR success (p = 0.001) and larger center volume approached significance (p = 0.08). Magnetic resonance imaging anterior-posterior and lateral RVOT diameters were smaller in implanted versus nonimplanted patients (18.0 ± 3.6 mm vs. 20.1 ± 3.5 mm; p = 0.005; 18.4 ± 4.3 mm vs. 21.5 ± 3.8 mm; p = 0.002).

CONCLUSIONS TPVR in the nRVOT was feasible and safe. However, nearly half the patients presenting for catheterization did not undergo TPV implantation, mainly because of prohibitively large nRVOT size. Improved understanding of magnetic resonance imaging data and availability of larger devices may improve the success rate for nRVOT TPVR. (J Am Coll Cardiol Intv 2018;■:■–■) © 2018 by the American College of Cardiology Foundation.

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ISSN 1936-8798/$36.00 https://doi.org/10.1016/j.jcin.2018.05.051

ABBREVIATIONS AND ACRONYMS

AP = anteroposterior

BPV = bioprosthetic pulmonary valve

MRI = magnetic resonance imaging

nRVOT = native right ventricular outflow tract

PIG = peak instantaneous gradient

PR = pulmonary regurgitation

PVR = pulmonary valve replacement

RV = right ventricle

RV-PA = right ventricular to pulmonary artery

RVOT = right ventricular outflow tract

TOF = tetralogy of Fallot

TPVR = transcatheter pulmonary valve replacement

Abnormalities of the right ventricular outflow tract (RVOT) and pulmonary valve are among the most common types of congenital heart disease (1,2). Although patients typically survive the initial surgical or catheter-based intervention and lead relatively long and healthy lives, many are subject to multiple operations to replace a regurgitant pulmonary valve or to relieve residual or recurrent RVOT stenosis (3,4). Recent studies suggest that more than 50,000 people undergo pulmonary valve replacement (PVR) worldwide each year (2–4).

Transcatheter pulmonary valve replacement (TPVR) using the Melody valve (Medtronic Inc., Minneapolis, Minnesota) provides an alternative method of PVR for thousands of patients with a failing right ventricle-to-pulmonary artery (RV-PA) conduit or a dysfunctional bioprosthetic pulmonary valve (BPV) (5–10). Although the advent of TPVR initiated a paradigm shift in the care of these patients, surgical or transcatheter valvuloplasty or reconstruction of the native RVOT (nRVOT) without placement of a circumferential conduit or BPV is used to repair >75% of patients with tetralogy of Fallot (TOF) or related lesions (3,4,11). Because the Melody valve is Food and Drug Administration–approved only for implant within surgically placed RV-PA conduits or BPVs, there is a large gap between the approved use of this device and the greater need for TPVR in patients with a dysfunctional nRVOT.

As experience with the Melody valve has increased, interventional cardiologists have attempted to narrow this gap with off-label use in patients with a nRVOT (12–15). Melody valve placement in these patients is challenging because, unlike conduits, the nRVOT is typically enlarged and characterized by considerable anatomic variability and dynamic distensibility. These factors complicate the identification of candidates who are likely to have successful valve implantation before catheterization. Selection criteria, safety, efficacy, and durability of the Melody valve in nRVOT have not been systematically studied. Therefore, we sought to determine the proportion of patients presenting to the catheterization laboratory with the indication of Melody valve placement in the nRVOT who had successful TPVR and to determine patient characteristics and anatomic variations associated with successful valve implantation. In addition, we evaluated procedural safety and immediate outcomes.

METHODS

STUDY DESIGN. This was a retrospective, multicenter study of all patients presenting to the catheterization laboratory for possible Melody valve placement in the nRVOT from January 2010 through June 2016. Of the 9 Pediatric Heart Network core centers, 6 participated in the study; 5 additional centers were added based on an estimated volume of >10 attempted Melody valve implants within a nRVOT.

PATIENT POPULATION. All patients presenting to the catheterization laboratory for possible Melody valve placement in the nRVOT were included regardless of whether the valve was ultimately implanted. Exclusion criteria were: 1) prior surgical RV-PA conduit or BPV; 2) hybrid procedure with simultaneous surgical manipulation of the RVOT at the time of Melody valve placement; or 3) valve implanted in a nonpulmonary position or within the branch pulmonary arteries. Patients provided procedural informed consent to undergo TPVR. Data were collected for this study under a waiver of consent by the institutional review board at each institution. The ability to identify patients who were considered for Melody valve implantation in the nRVOT was enhanced by the fact that a humanitarian-use consent was required for use of this device during the study period. Centers were grouped according to the number of cases enrolled in the study; high volume centers had ≥20 patients and low volume centers <20 patients.

DATA COLLECTION. The treating physicians at each institution determined patient selection criteria and technical aspects of the procedure. Patient

for Medtronic. Dr. Goldstein is a proctor for Edwards Lifesciences and a consultant for Medtronic. Dr. Bergersen is a consultant for 480 Biomedical Inc. Dr. Shahanavaz is a proctor for Edwards Lifesciences and a consultant for Medtronic. Dr. Aboulhosn is a co-PI at UCLA for the Medtronic Harmony valve trial. Dr. Berman is a proctor for Edwards Lifesciences. Dr. Gillespie is a consultant and proctor for Medtronic. Dr. Armstrong is a proctor/consultant for Abbott, B. Braun Interventional Systems Inc., and Edwards Lifesciences; and has received research grants from Abbott, Edwards Lifesciences, Medtronic, and Siemens Medical Solutions USA Inc. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Manuscript received March 22, 2018; revised manuscript received May 7, 2018, accepted May 15, 2018.