JACC: CARDIOVASCULAR INTERVENTIONS VOL. 11, NO. 6, 2018
© 2018 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION
PUBLISHED BY ELSEVIER

Transcatheter Pulmonary Valve Replacement With the Melody Valve in Small Diameter Expandable Right Ventricular Outflow Tract Conduits

Shabana Shahanavaz, MBBS,[a] Athar M. Qureshi, MD,[b] Daniel S. Levi, MD,[c] Younes Boudjemline, MD,[d] Lynn F. Peng, MD,[e] Mary Hunt Martin, MD,[f] Holly Bauser-Heaton, MD, PhD,[g] Britton Keeshan, MD, MPH,[h] Jeremy D. Asnes, MD,[i] Thomas K. Jones, MD,[h] Henri Justino, MD,[b] Jamil A. Aboulhosn, MD,[c] Robert G. Gray, MD,[f] Hoang Nguyen, MD,[a,j] David T. Balzer, MD,[a] Doff B. McElhinney, MD[c,k,l]

ABSTRACT

OBJECTIVES This study sought to evaluate the safety, feasibility, and outcomes of transcatheter pulmonary valve replacement (TPVR) in conduits ≤16 mm in diameter.

BACKGROUND The Melody valve (Medtronic, Minneapolis, Minnesota) is approved for the treatment of dysfunctional right ventricular outflow tract (RVOT) conduits ≥16 mm in diameter at the time of implant. Limited data are available regarding the use of this device in smaller conduits.

METHODS The study retrospectively evaluated patients from 9 centers who underwent percutaneous TPVR into a conduit that was ≤16 mm in diameter at the time of implant, and reported procedural characteristics and outcomes.

RESULTS A total of 140 patients were included and 117 patients (78%; median age and weight 11 years of age and 35 kg, respectively) underwent successful TPVR. The median original conduit diameter was 15 (range: 9 to 16) mm, and the median narrowest conduit diameter was 11 (range: 4 to 23) mm. Conduits were enlarged to a median diameter of 19 mm (29% larger than the implanted diameter), with no difference between conduits. There was significant hemodynamic improvement post-implant, with a residual peak RVOT pressure gradient of 7 mm Hg ($p < 0.001$) and no significant pulmonary regurgitation. During a median follow-up of 2.0 years, freedom from RVOT reintervention was 97% and 89% at 2 and 4 years, respectively, and there were no deaths and 5 cases of endocarditis (incidence rate 2.0% per patient-year).

CONCLUSIONS In this preliminary experience, TPVR with the Melody valve into expandable small diameter conduits was feasible and safe, with favorable early and long-term procedural and hemodynamic outcomes. (J Am Coll Cardiol Intv 2018;11:554–64) © 2018 by the American College of Cardiology Foundation.

From the [a]Division of Cardiology, Department of Pediatrics, Washington University in St. Louis School of Medicine, St. Louis, Missouri; [b]Lillie Frank Abercrombie Section of Cardiology, Texas Children's Hospital, Baylor College of Medicine, Houston, Texas; [c]Ahmanson/UCLA Adult Congenital Heart Disease Center, David Geffen School of Medicine at UCLA, Los Angeles, California; [d]Department of Paediatric Cardiology, Centre de Référence Malformations Cardiaques Congénitales Complexes–M3C, Necker Hospital for Sick Children, Assistance Publique des Hôpitaux de Paris, Paris, France; [e]Division of Pediatric Cardiology, Lucille Packard Children's Hospital at Stanford University, Palo Alto, California; [f]Division of Cardiology, Department of Pediatrics, University of Utah, Salt Lake City, Utah; [g]Department of Pediatrics, Children's Healthcare of Atlanta, Stanford University, Palo Alto, California; [h]Division of Pediatric Cardiology, Seattle Children's Hospital, University of Washington School of Medicine, Seattle, Washington; [i]Department of Pediatrics, Yale University, New Haven, Connecticut; [j]Division of Cardiology, Department of Pediatrics, Rush University Medical College, Chicago, Illinois; [k]Department of Pediatrics, Lucile Packard Children's Hospital Heart Center, Stanford University School of Medicine, Palo Alto, California; and the [l]Department of Cardiothoracic Surgery, Lucile Packard Children's Hospital Heart Center, Stanford University School of Medicine, Palo Alto, California. Dr. Levi has served as a consultant for Edwards Lifesciences and Medtronic. Dr. Asnes has served as a proctor for Edwards Lifesciences. Dr. Jones has received research grant support and served as a consultant for Medtronic. Dr. Justino has served as a consultant for Medtronic, Edwards Lifesciences, and Abbott; on the clinical trial executive committee for Janssen Pharmaceuticals; and on the scientific advisory board for PediaStent. Drs. Boudgemline and Balzer have served as a proctor for Medtronic. Dr. McElhinney has served as a proctor and consultant for Medtronic. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Manuscript received November 28, 2017; revised manuscript received December 23, 2017, accepted January 2, 2018.

ISSN 1936-8798/$36.00 https://doi.org/10.1016/j.jcin.2018.01.239

In 2010, the Melody transcatheter pulmonary valve (TPV) (Medtronic, Minneapolis, Minnesota) was granted HDE approval by the U.S. Food and Drug Administration for the treatment of dysfunctional right ventricular outflow tract (RVOT) conduits. In reports of trial patients and other cohorts, TPV replacement (TPVR) has been shown to restore pulmonary valve function and extend the life span of various surgical conduits and pulmonary valves (1–7). Until early 2017, the instructions for use for the Melody valve followed the U.S. investigational device exemption (IDE) trial in specifying that the RVOT conduit must have been ≥16 mm at the time of surgical implant (8). Accordingly, there are limited published data on TPVR into smaller RVOT conduits, which are generally embedded within larger series (4,9–11). Although the IDE trial required that conduit diameter measured 14 to 20 mm by sizing balloon after initial predilation (8), the instructions for use does not specify criteria for actual conduit size at the time of TPVR.

SEE PAGE 565

This disparity is noteworthy, as the original size of the implanted conduit may or may not correspond to its diameter at the time of TPVR. As documented recently, many RVOT conduits, homografts, and valved bovine jugular vein conduits in particular become substantially narrowed in situ, whereas others may enlarge after implant (1,3). Moreover, homograft conduits tend to lose the mural structure and mechanical behavior of arteries and become less compliant over time, such that the originally implanted size may not reflect the expected capacity of the remodeled conduit to expand (12–14). Thus, it is not clear that small original conduit diameter should be an a priori exclusion criterion for TPVR. Considering these factors, the purpose of this multicenter study was to evaluate the procedural characteristics and outcomes of TPVR in patients with an expandable RVOT conduit that was ≤16 mm at the time of surgical implant to determine whether efficacy and safety were similar to published data on implants in larger conduits.

METHODS

PATIENTS. All patients with an expandable RVOT conduit who underwent percutaneous catheterization for intended TPVR at 9 participating institutions from January 2010 to March 2017 were reviewed, and those whose original (implanted) conduit diameter was reportedly ≤16 mm were analyzed for this study. Expandable conduits were defined as those composed of biological tissue without a rigid frame, specifically, homografts and valved bovine jugular vein (Contegra, Medtronic) conduits. Synthetic tube grafts, composite conduits, and stented pulmonary valves were excluded, as were any type of biological graft >16 mm at implant. Ring-supported Contegra conduits were considered eligible because the expandability is unknown.

Written informed consent was obtained for clinical percutaneous catheterization and TPVR. Institutional review board approval for retrospective data collection and analysis was obtained at each of the participating centers.

Pre-catheterization data included demographic, diagnostic, and historical information. Standard measures were recorded from pre- and post-implant imaging studies, including echocardiography and magnetic resonance imaging if applicable. Pulmonary regurgitation (PR) was evaluated qualitatively by spectral and color Doppler ultrasound, and categorized as either moderate-severe or mild or less. The underlying hemodynamic indication for TPVR was classified as PR (moderate or severe), stenosis (maximum Doppler gradient ≥50 mm Hg, mean Doppler gradient ≥35 mm Hg, or peak invasive gradient ≥30 mm Hg), or combined stenosis and PR. The narrowest angiographic conduit diameter in any projection was measured, and the degree of conduit calcification was graded as heavy (extensive, circumferential) or minimal or none. Acute post-implantation hemodynamic data and final conduit size were recorded. Longer-term outcomes, including death, RVOT reintervention, and endocarditis, were specifically ascertained, along with attributed causes. The mean Doppler RVOT gradient was not available as often as maximum gradient, so only the latter is reported.

TPVR PROCEDURE. TPVR was performed following general techniques that have well described (1,5,6), but specific technical measures were at the discretion of the implanting physician. The number and type of prestents implanted before TVPR were recorded. Ratios were calculated of balloon sizes to original implanted, narrowest angiographic, and final post-TPVR conduit diameters, and of angiographic or implanted and final or implanted conduit diameters. The narrowest angiographic/implanted diameter ratio was used as a marker of shrinkage from the time of surgical implant to catheterization, whereas balloon/angiographic or implanted diameter ratios and final post-TPVR/angiographic diameter ratios were indices of the aggressiveness of dilation and conduit expansion.

ABBREVIATIONS AND ACRONYMS

CI = confidence interval

IDE = investigational device exemption

OR = odds ratio

PR = pulmonary regurgitation

RVOT = right ventricular outflow tract

TPV = transcatheter pulmonary valve

TPVR = transcatheter pulmonary valve replacement

Download English Version:

https://daneshyari.com/en/article/8663919

Download Persian Version:

https://daneshyari.com/article/8663919

Daneshyari.com