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Transvenous, Antegrade Melody Valve-in-Valve Implantation for Bioprosthetic Mitral and Tricuspid Valve Dysfunction

A Case Series in Children and Adults

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Objectives The purpose of this study was to report the results of percutaneous valve-in-valve therapy using the Melody valve (Medtronic, Minneapolis, Minnesota) for patients with degenerated mitral and tricuspid bioprosthetic valves.

Background Open surgery for replacement of degenerated bioprosthetic valves is associated with morbidity and mortality.

Methods Nineteen patients (median age 65 years, range 10 to 88 years; 7 males) with degenerated mitral ($n = 9$) or tricuspid ($n = 10$) bioprosthetic valves underwent transvenous valve-in-valve implantation of the Melody valve.

Results In the mitral patients, the mean Society of Thoracic Surgeons mortality score was 13.3 ± 5.6%. All patients had a prosthetic valve mean diastolic inflow gradient ≥5 mm Hg. Moderate or worse regurgitation was present in 7 of 9 mitral and 7 of 10 tricuspid patients. Implantation of a Melody valve was successful in all. Among the mitral patients, mean diastolic gradient decreased from 12.3 ± 4.6 mm Hg to 5.2 ± 2 mm Hg ($p < 0.01$). Residual regurgitation was trivial to mild in 6, mild to moderate in 2, and moderate in 1 patient. Among the tricuspid patients, mean diastolic gradient decreased from 10.0 ± 4.3 mm Hg to 5.6 ± 2.5 mm Hg ($p < 0.01$). Residual regurgitation was trivial to mild in 9 and mild to moderate in 1 patient. New York Heart Association functional class improved in 17 of 19 patients ($p < 0.01$). No periprocedural deaths, myocardial infarctions, strokes, or valve embolizations occurred. Vascular access site complications occurred in 4 patients.

Conclusions Percutaneous valve-in-valve implantation of the Melody valve in the mitral or tricuspid position for treatment of bioprosthetic valve dysfunction is feasible and can lead to significant symptomatic improvement in carefully selected high-risk patients. (J Am Coll Cardiol Intv 2013;6:598–605) © 2013 by the American College of Cardiology Foundation

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Bioprosthetic valves are frequently used for patients with acquired and congenital cardiac disease despite the valves' tendency toward earlier degeneration and valvular dysfunction (1). For patients who require treatment of degenerated bioprosthetic valves, repeat sternotomy and open surgery carry higher risk, especially in older patients with comorbid conditions (2,3). Transcatheter implantation of percutaneously delivered valves into degenerated bioprostheses (i.e., valve-in-valve therapy) has emerged as an alternative to open surgery. Reports have described valve-in-valve therapy in all 4 native valve positions (4–17), but the greatest application has been for aortic bioprosthetic degeneration.

The Melody valve (Medtronic, Minneapolis, Minnesota) is a bovine jugular venous valve designed and approved for percutaneous implantation in the pulmonary position in patients with dysfunctional right ventricular to pulmonary artery conduits and pulmonary bioprosthetic valves or homografts (18,19). Valve-in-valve Melody implantation has been reported for treatment of degenerated tricuspid bioprosthesis (5,20,21), but not for the treatment of left-sided degenerated bioprosthetic valves.

This series describes the clinical feasibility and efficacy of percutaneous implantation of the Melody valve in patients with degenerated bioprosthetic mitral or tricuspid valves.

Methods

Patient population. The study was approved by the Mayo Clinic Institutional Review Board. From July 2011 through November 2012, 19 patients underwent percutaneous implantation of the Melody valve into the mitral (n = 9) or tricuspid (n = 10) position. Patients were considered candidates for the procedure if they had significant bioprosthetic mitral or tricuspid valve dysfunction (either stenosis, regurgitation, or both) with comorbid conditions that would preclude a repeat sternotomy and valve replacement. Consultation with a cardiac surgeon occurred before proceeding with percutaneous valve-in-valve therapy. All patients or parents received detailed instruction on the potential risks of the procedure, including the off-label use of the Melody valve. Alternatives, including repeat open surgery and medical therapy, were carefully discussed. All patients or parents provided informed consent for the procedure.

Mitral valve-in-valve procedure. The mitral valve-in-valve procedure was performed in the cardiac catheterization laboratory (Fig. 1). Patients were placed under general endotracheal anesthesia. Intraprocedural imaging was performed with transesophageal echocardiography (TEE). Transseptal puncture was performed using standard techniques. The atrial septum was sequentially dilated with 14-F and 21-F dilators. A 20-F Dry Seal sheath (Gore Medical, Flagstaff, Arizona) was introduced into the right femoral vein, and an 8.5-F medium curve Agilis sheath (St. Jude Medical, St. Paul, Minnesota) was placed in the left atrium over a Torayguide guidewire (Toray Industries, Tokyo, Japan). Unfractionated heparin (100 U/kg) was administered to ensure adequate systemic anticoagulation, and the activated clotting time was monitored regularly to maintain a level >250 s.

Coronary angiography was performed to delineate the course of the left anterior descending coronary artery and its major branches before left ventricular puncture. The left ventricular apical puncture was performed with an 18-gauge needle or a One-Step Centesis Catheter (Merit Medical Systems, South Jordan, Utah) under fluoroscopic and transthoracic echocardiography guidance. A 6-F sheath was then advanced into the left ventricle over a 0.038-inch wire (22).

An exchange length 0.035-inch angled extra-support glide wire (Terumo, Somerset, New Jersey) was introduced through the Agilis sheath into the left atrium and advanced across the mitral bioprosthesis into the left ventricle. The glide wire was snared in the left ventricle and exteriorized through the left ventricular apical sheath, creating a wire rail between the right femoral vein and the left ventricular apex (Fig. 1C). In selected cases, a 5-F pacing catheter was advanced into the right ventricle via the left femoral vein. The internal diameter of the dysfunctional valve was measured with TEE, and balloon sizing performed with a compliant balloon in selected cases. Balloon sizing was not performed if it was apparent the internal diameter of the existing bioprosthetic valve would support the Melody valve. In all cases, the Melody valve was mounted onto the 22-mm Ensemble delivery system (Medtronic) and delivered antegrade via the right femoral vein, across the atrial septum, and into the dysfunctional prosthesis over the arteriovenous rail. The valve was carefully positioned across the bioprosthesis and deployed under rapid ventricular pacing using fluoroscopy and TEE guidance. The left ventricular apical puncture site was subsequently closed with a 6-mm Amplatzer Vascular Plug II (AVP II, St. Jude Medical) that expanded to fill the left ventricular apical defect. Anticoagulation was reversed with protamine, and the venous sheath site was closed with a figure-of-eight suture (23).

Abbreviations and Acronyms

ICE = intracardiac echocardiography

NYHA = New York Heart Association

STS = Society of Thoracic Surgeons

TEE = transesophageal echocardiography

Tricuspid valve-in-valve procedure. The tricuspid valve-in-valve procedure was performed in the cardiac catheterization laboratory under general anesthesia for 9 patients and conscious sedation for 1 patient (Fig. 2). Imaging was performed with intracardiac echocardiography (ICE) in 7 patients and TEE in 3 patients. The valve was delivered either through the right internal jugular vein or the right femoral vein. An extra-stiff 0.035-inch exchange length Amplatz wire was advanced into a distal pulmonary artery