Case Reports

Use of a Melody Pulmonary Valve

in Transcatheter Valve-in-Valve Replacement for Tricuspid Valve Bioprosthesis Degeneration

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Bioprosthetic heart valves can degenerate and fail over time. Repeat surgery as a means of replacement increases morbidity and mortality rates, and some patients are not candidates for reoperation. A newer treatment, percutaneous transcatheter valve-in-valve implantation, might delay or substitute for invasive procedures. We present the case of a 51-year-old woman, a poor candidate for surgery who had prosthetic tricuspid valve degeneration and stenosis. We successfully performed valve-in-valve placement of a Melody® valve, using a procedure originally intended to treat pulmonary valve conduit obstruction or regurgitation. To our knowledge, this is among the first case reports to describe the use of the Melody pulmonary valve in transcatheter valve-in-valve replacement for prosthetic tricuspid stenosis that was otherwise not correctable. Additional data and longer follow-up periods are necessary to gain an understanding of ideal indications and selection of patients for the percutaneous transcatheter treatment of tricuspid valve stenosis. ***(Tex Heart Inst J 2014;41(5):511-3)***

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The standard treatment of cardiac valvular stenosis or regurgitation involves repair or surgical replacement with a bioprosthetic or mechanical valve. Bioprosthetic valves typically afford a lower risk of thrombotic events and less need for anticoagulation. However, these valves can degenerate and fail. Sequelae of bioprosthetic valves include primary valve failure, endocarditis, thrombosis, hemolytic anemia, and anticoagulant-related hemorrhage.[1-3] Surgery as a means of replacement increases morbidity and mortality rates, and patients often cannot undergo reoperation.

Patients with prosthetic valve degeneration are now being treated with transcatheter "valve-in-valve" replacement, with positive outcomes.[4] This procedure has been tested in the aortic position in several series.[5-7] Because removing a tricuspid bioprothesis is technically challenging and carries the risk of myocardial damage from chest reentry and cardiopulmonary bypass, the transcatheter valve-in-valve procedure can be appropriate in high-risk surgical patients.[8-12] We describe the case of a woman with tricuspid stenosis of a bioprosthetic valve, and our replacement of that valve by means of a percutaneous transcatheter valve-in-valve technique to implant a Melody® pulmonary valve (PV) (Medtronic, Inc.; Minneapolis, Minn).

Case Report

A woman undergoing hemodialysis for end-stage renal failure was diagnosed with native tricuspid valve endocarditis in October 2006. She underwent tricuspid valve replacement with a 29-mm bioprosthetic valve (Edwards Lifesciences, LLC; Irvine, Calif) and dual-chamber pacemaker insertion because of complete heart block. In May 2012, the 51-year-old patient presented at our institution with severe dyspnea at rest, progressive anasarca, recurrent ascites, and pleural effusions. Echocardiograms revealed severe bioprosthetic tricuspid valve stenosis (mean diastolic Doppler gradient, 15 mmHg) and mild regurgitation (Fig. 1). The bioprosthetic valve was calcified and had little leaflet mobility. Cardiac computed tomographic angiograms showed severe calcification and immobility of the prosthetic septal and posterior leaflets. The patient's left and right ventricular size and function were otherwise normal.

Diagnostic cardiac catheterization disclosed nothing of note; however, the patient was at excessive surgical risk (Society of Thoracic Surgeons scores, mortality 22%

and morbidity 60%). Because of the patient's clinical presentation and the severe valvular stenosis, we performed tricuspid valvuloplasty in June 2012. The baseline transvalvular gradient was 10 mmHg. The severe prosthetic calcification led to balloon rupture after the procedure on only one attempted use of a standard technique. The patient tolerated the procedure without sequelae. A postprocedural echocardiogram revealed new mild prosthetic regurgitation and severe tricuspid prosthetic valve stenosis (mean gradient, 12 mmHg at a heart rate of 83 beats/min) (Fig. 2).

The patient's symptoms persisted after the valvuloplasty. We decided to perform percutaneous valve-in-valve implantation of a Melody PV. A Lunderquist™ exchange-length stiff wire (Cook Medical Incorporated; Bloomington, Ind) was advanced into the pulmonary artery, and balloon valvuloplasty of the bioprosthetic tricuspid valve was performed with use of a 22 × 2-mm ATLAS® PTA Dilatation Catheter (Bard Peripheral Vascular, Inc.; Tempe, Ariz). Under fluoroscopic guidance, the Melody delivery system was introduced, and a 22-mm Melody valve was placed with single-balloon inflation. Intraoperative transesophageal echocardiograms confirmed satisfactory placement and seating, a normal hemodynamic spectrum, no substantial periprosthetic leak, and no abnormalities (Fig. 3). Shortly thereafter, the patient's oxygen saturation and overall hemodynamic status improved.

At the follow-up examination 3 months later, the patient's clinical improvement was dramatic, with near-resolution of her ascites, hypoxia, and dyspnea. Her functional status had improved from New York Heart Association class III to class I. She was lost to follow-up thereafter.

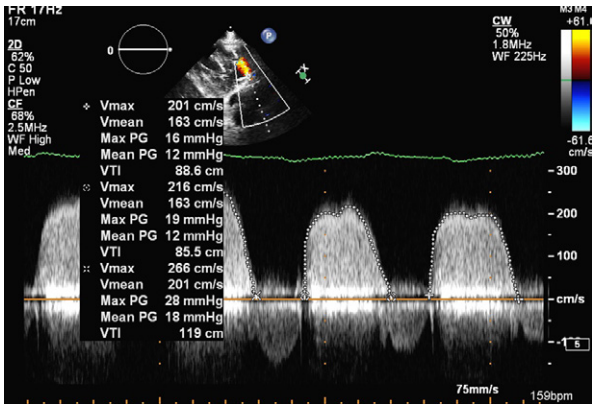

Fig. 1 *Transthoracic echocardiogram with color-flow Doppler shows severe tricuspid bioprosthesis stenosis (mean diastolic Doppler gradient, 15 mmHg) before valvuloplasty.*

Max = maximum; PG = pressure gradient; Vmax = maximal velocity; Vmean = mean velocity; VTI = velocity-time integral

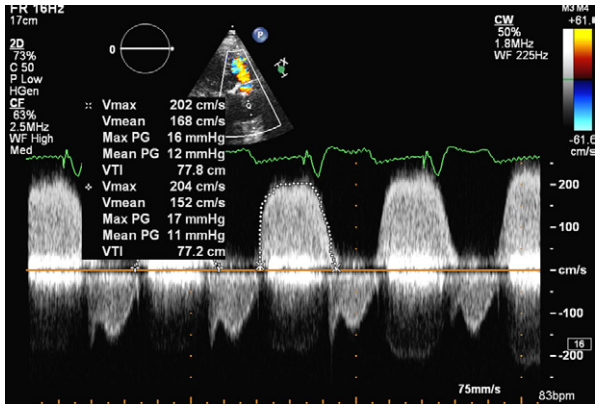

Fig. 2 *Transthoracic echocardiogram with color-flow Doppler shows prosthetic regurgitation and a mean gradient of 12 mmHg after unsuccessful valvuloplasty.*

Max = maximum; PG = pressure gradient; Vmax = maximal velocity; Vmean = mean velocity; VTI = velocity-time integral

Discussion

In 2010, the Melody valve was the first transcatheter heart valve to be approved by the U.S. Food and Drug Administration. It is indicated for pediatric and adult patients who have a regurgitant or stenotic right ventricular outflow tract conduit. In 2000, Bonhoeffer and colleagues[13] reported the first successful transcatheter PV implantation; the successor valve to the one used in that procedure is the Melody transcatheter PV. Currently, the documentation of Melody valve implantation in the tricuspid position consists of single case reports; its use for valve-in-valve therapy is apparently rare. In 2010, Roberts and colleagues[14] successfully used a 22-mm Melody PV in valve-in-valve fashion to replace a 27-mm Mosaic® tricuspid valve (Medtronic) in a 28-year-old patient who had a history of endocarditis;

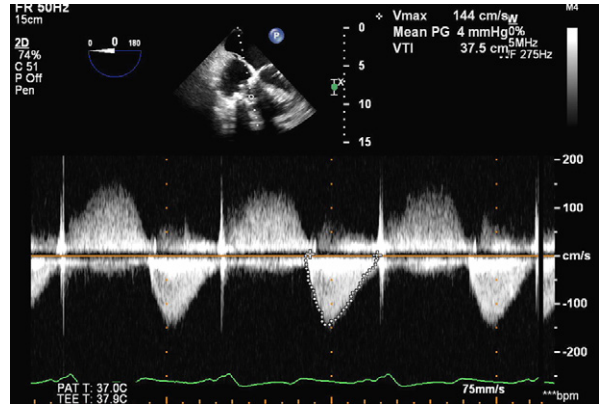

Fig. 3 *Transthoracic echocardiogram shows improvement of the transvalvular gradient to 4 mmHg after Melody valve implantation.*

PG = pressure gradient; Vmax = maximal velocity; VTI = velocity-time integral

and Riede and Dähnert[15] successfully implanted a Melody PV within a stenotic bioprosthesis in the tricuspid position, as an alternative to a 4th major cardiac surgery in a 12-year-old girl.

The initial studies of the Melody valve in its intended use were promising. The first trial, by Zahn and colleagues,[16] resulted in a procedural success rate of 93%. Short-term effectiveness was present in 83% of patients, with acceptable hemodynamic results at 6 months and symptomatic improvement in 79% of patients. No patient's symptoms worsened, and none died of relevant causes.[16] McElhinney and associates[17] reported an ongoing high rate of procedural success and encouraging short-term valve function in 122 of 124 implanted patients. Investigators have reported successful technical placement of the Melody PV in degenerated bioprosthetic valves in positions other than those for which the valve was created; however, other authors have reported early valve failure and have raised concerns about the viability of the valve in the tricuspid position.[18] The long-term effectiveness of this valve in the tricuspid position—an off-label use—remains to be determined. Further research is warranted in order to understand the role of the Melody valve in correcting tricuspid bioprosthesis failure and the long-term effects of valve-in-valve repair. To our knowledge, this is among the first case reports to describe the use of the Melody PV in transcatheter valve-in-valve replacement for prosthetic tricuspid valve stenosis that was not correctable by other means.

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