Transcatheter Pulmonary Valve Replacement
Current Status and Future Potentials

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KEYWORDS

• Transcatheter • Valve • Stent • Pulmonary • Regurgitation

KEY POINTS

- Transcatheter pulmonary valve replacement has evolved into an attractive alternative to surgery in older children and adults with dysfunctional ventricular-to-pulmonary artery conduits.
- The learning curve with initial valve design has led to significant improvements to both valve design and procedural approach.
- Indications for implantation are evolving; however, a more aggressive approach may now be possible to prevent the longer-term effects of chronic right ventricular pressure and volume loading.
- Simplification of follow-up protocols may reduce both financial and time burden to patients.
- Future endeavors will focus on a percutaneous valve for the dilated native right ventricular outflow tract and tissue engineering that may promote valve growth and longevity.

INTRODUCTION

Endeavors in congenital heart disease are mirroring (often preceding) efforts in adult cardiology in providing less-invasive, but equally effective alternatives to surgery. In the context of transcatheter pulmonary valve replacement (tPVR), battle lines were drawn when Bonhoeffer and colleagues[1] reported successful transcatheter delivery of a valved stent into a 12-year-old boy with stenosis and insufficiency of a prosthetic conduit from the right ventricle to the pulmonary artery more than 10 years ago. This delivery set the platform for nonsurgical replacement or repair of other heart valves, which is proving to be the most exciting advancement in the treatment of valve disease in many years. In less than a decade, tPVR has evolved rapidly through the inevitable technical learning curve and design modifications to establish itself as an acceptable therapy for right ventricular (RV)-to-pulmonary artery conduit and bioprosthetic valve dysfunction. Limitations remain related to valve size in patients with native outflow tracts, and although tPVR has been described with both established and novel approaches in this setting,[2–5] surgery remains the preferred approach in most cases. Extensive data collection through early clinical experience and clinical trials was necessary to prove safety and efficacy of the approach. Evolving data from these studies have shown beneficial effects of tPVR in right ventricular (RV) volume reduction,[6] left ventricular filling properties,[7] exercise capacity,[8] and electrical remodeling.[9] This review discusses the evolution of tPVR,

Disclosure: Dr Hijazi is a non-paid consultant for Edwards Lifesciences, the company that manufactures the Edwards Sapien THV. He is also a consultant for Colibri and has stock options. Dr Kenny has no conflict of interest related to this study. This is an original manuscript and has not been previously published or submitted to another journal.

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Intervent Cardiol Clin 2 (2013) 181–193
http://dx.doi.org/10.1016/j.iccl.2012.09.008
2211-7458/13/$ – see front matter Published by Elsevier Inc.

the attempts and challenges to establishing itself as an acceptable and cost-effective alternative to surgery, and possible future endeavors in this field.

PROCEDURAL EVOLUTION

Initial work in animals was reported in 2000 by Bonhoeffer and colleagues,[10] in an ovine model with successful valve delivery in 7 of 11 attempts. Valve design consisted of a section of fresh bovine jugular vein attached to a platinum iridium stent. Initially, the stent was expanded to a radial diameter of 18 mm, and the length of jugular vein was sutured to span the entire axial length of the stent. The valved stent was then hand crimped onto the inflatable portion of an 18- to 22-mm balloon catheter. Five valves were delivered in the desired location, and macroscopic review after explantation at 2 months showed transparent, mobile, and competent valves in 4 of these. One stent was slightly stenotic and showed macroscopically visible calcifications. Reported experience in humans followed,[11] with the first detailed clinical study reporting on 59 consecutive patients with right ventricular outflow tract (RVOT) dysfunction associated with stenosis or significant pulmonary insufficiency, leading to RV dilatation or RV failure.[6] Successful valve implantation was achieved in 58 patients. Three patients required acute surgical intervention because of stent dislodgment or conduit rupture. During a mean follow-up of just less than 10 months, there was no mortality; however, device-related complications were seen in 14 of the 56 patients (25%). These included in-stent stenosis, referred to as the *hammock effect* in 7 because of lack of apposition of the valve to the stent. This observation led to a change in device design with suturing of the whole length of the bioprosthetic valve tissue to the stent. Stent fracture, which has continued to be clinically relevant for this valve (Medtronic Melody Valve [Medtronic Inc, Minneapolis, MN]) (**Fig. 1**) was noted in 7 patients, with one patient undergoing a second valve-in-valve implantation. Overall freedom from surgical explantation for valve failure was 83% at 12 months.

More recent studies with the Melody Valve have found improved outcomes with reduction in adverse events.[12,13] Further follow-up data from Bonhoeffer's group after the initial report showed reduction in procedural complications from 6% to 2.9%.[12] Recently, a multicenter US clinical trial evaluating the Melody Valve found impressive medium-term outcomes in 124 patients with dysfunctional right ventricular-to-pulmonary artery conduits. Freedom from Melody Valve dysfunction or reintervention was almost 94% at 1 year.[13] An alternative transcatheter pulmonary valve has also become available, achieving CE marking in the European Union and undergoing trials in the United States. The Edwards SAPIEN transcatheter heart valve (Edwards Lifesciences LLC, Irvine, CA) (**Fig. 2**) was initially introduced as a transcatheter alternative to surgical valve replacement in elderly patients with severe aortic stenosis.[14] Reports describing implantation in the pulmonary position for RVOT conduit dysfunction, mirroring valve efficacy and durability in the aortic position, have followed.[15] Recently, a multicenter international clinical trial found effective reduction of RVOT gradient (27 mm Hg–12 mm Hg [$P<.001$]) with improvement in clinical symptoms and maintenance of pulmonary valvar competence at 6-month follow-up.[16]

INDICATIONS

Defining objective parameters of when to replace the pulmonary valve in the setting of chronic pulmonary regurgitation has been difficult. With

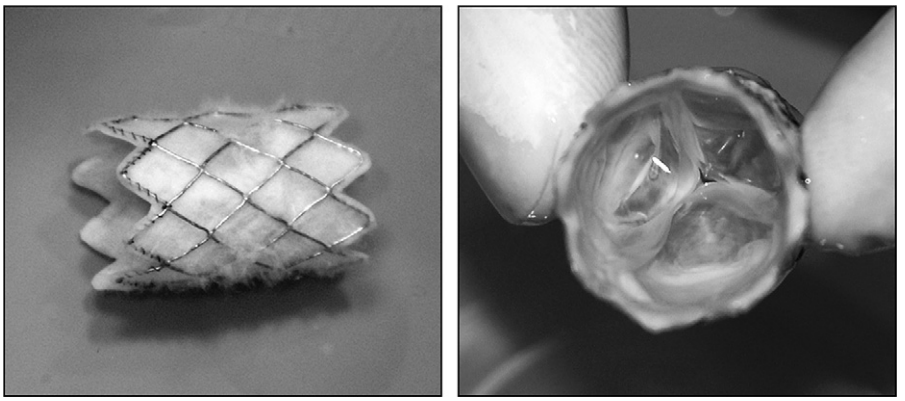

Fig. 1. The Medtronic Melody valve seen in 2 different views. (*Courtesy of* Medtronic, Mounds View, MN; with permission.)