Transcatheter Mitral Valve Replacement

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KEYWORDS

• Transcatheter mitral valve replacement • Mitral valve devices • Catheter-based therapy
• Mitral regurgitation

KEY POINTS

- Transcatheter mitral valve replacement provides a reasonable alternative in high-risk surgical patients requiring mitral valve surgery.
- Several transcatheter mitral valve devices are available. Each device has a unique design and all are undergoing extensive preclinical testing before in-human use.
- The initial experience with in-human use of this novel technique shows an acceptable rate of associated morbidity and mortality in high-risk surgical patients.
- A multidisciplinary heart team approach is recommended for assessing patients' candidacy for transcatheter mitral valve replacement.
- Patients with poor ejection fraction and inadequate ventricular reserve might not benefit from this procedure.

INTRODUCTION

Mitral valve disease prevalence is on the rise worldwide. An estimated 2% of the general population has significant mitral valve disease. Around 2 million patients in the United States are affected with moderate-to-severe mitral regurgitation (MR). Incidence increases in the elderly with a prevalence of 9% in those older than 75 years of age.[1]

Given its inherent structural complexity, mastering the whole spectrum of mitral valve surgery remains a challenge to many surgeons. In the last 2 decades, the approach to mitral valve surgery has been standardized with well-described techniques for a variety of mitral valve pathologies. Specific mitral valve repair techniques have shown great results with excellent long-term outcomes.

In recent years, several approaches to mitral valve disease have been advocated that include minimally invasive surgery and catheter-based intervention. The benefits of these approaches will remain questionable until there are long-term data showing comparable results to that of the standard open techniques. However, in the high-risk surgical group, open mitral valve surgery carries increased risk of mortality and morbidity, and in some patients the surgical risk is prohibitive. Underreferral and underutilization of mitral valve surgery and intervention has also been documented.[2] The novel intervention of transcatheter mitral valve replacement (TMVR), may provide a safer and reasonable alternative to people in this category.

The most well-studied transcatheter approach to the mitral valve is the MitraClip System (Abbott Laboratory, Abbott Park, IL, USA). The randomized, controlled endovascular valve edge-to-edge repair study (EVEREST) II trial showed comparable long-term outcomes between the 2 studied groups with regard to mortality. However, there were more residual MR cases requiring mitral valve surgery in the MitraClip

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Intervent Cardiol Clin 5 (2016) 109–115
http://dx.doi.org/10.1016/j.iccl.2015.08.010
2211-7458/16/$ – see front matter

group at 1 and 4 years. Eligibility for MitraClip requires a very specific set of echocardiographic characteristics of the mitral valve, rendering it not suitable for many patients.[3]

TRANSCATHETER MITRAL VALVE DESIGN AND INITIAL EXPERIENCE RESULTS

Transcatheter aortic valve replacement (TAVR) underwent a significant improvement in the last few years, allowing application of some of its principles in the attempt to treat other valvular heart disease. Unlike the aortic valve, mitral valve catheter-based therapy has its unique set of challenges. For example, the mitral valve structure is far more complex than the aortic valve. There is an increased risk of damaging nearby structures with TMVR, including circumflex artery, conduction system, and aortic valve. Displacement of the anterior mitral leaflet (AML) may cause systolic anterior motion leading to left ventricular outflow tract (LVOT) obstruction. Physiologically, the mitral valve is constantly facing high systolic pressure requiring a more robust valve anchoring mechanism. Unlike aortic stenosis and TAVR, the lack of calcification of the mitral valve in MR patients indicates that radial force cannot be the sole mechanism of valve anchorage.

Himbert and colleagues,[4] and others, reported the use of the TAVR device SAPIEN XT (Edwards Lifesciences, Irvine, CA, USA) in the mitral position via a transseptal approach with promising initial results. This technique, however, relies on the presence of significant mitral annular calcification for a satisfactory anchoring of the valve in the mitral position.[4–6] The incidence of valve malpositioning, embolization, paravalvular regurgitation, and LVOT obstruction remains high.

The fundamental differences of the mitral valve require the development of a transcatheter system specific for its anatomy and disease state. These have undergone extensive studies in animal and cadaveric models. Both porcine and ovine models were used to demonstrate TMVR's feasibility and efficacy.[7–10] There are many TMVR systems with a variety of delivery methods, valve designs, and anchoring mechanisms at various stages of development and clinical trials. Some of these include CardiAQ (CardiAQ Valve Technologies, CA, USA), Tiara (Neovasc Inc, British Columbia, Canada), Edwards FORTIS (Edwards Lifesciences Corp, CA, USA), Tendyne (Tendyne Inc, MN, USA), Medtronic-TMV (Medtronic Inc, MN, USA), Highlife Medical-TMV (Highlife Medical CA, USA), Gorman-TMV (Trustee of University of Pennsylvania, PA, USA), and Endovalve (Micro Interventional Devices, Langhome, PA, USA). These are all trileaflet self-expanding valves with nitinol-based frames. Valve anchoring is based either on axial fixation principle, outward radial force, or a combination, depending on the design. Most have features that capture the mitral leaflets and secure the valve to the mitral annulus. Many TMVR devices have additional features to address paravalvular leakage. Most manufacturers' device designs allow fine-positioning adjustment and device retrieval before the final stage of deployment, with some allowing this even after full valve deployment. Delivery approaches include transapical, transvenous-transseptal, and transatrial. Currently, transapical is the preferred access. The delivery system size ranges from 26 F to 42 F.[7–17]

The CardiAQ valve (Fig. 1) is a trileaflet bovine pericardial valve that can be delivered transapical or transvenous-transseptal. The device design has 2 sets of opposing anchors that secure the valve to the mitral annulus. The left ventricular anchors go between the native chordae to capture the native mitral leaflets and engage the mitral annulus from the ventricular side, while the left atrial anchors stabilize the prosthetic valve and prevent it from tilting or dropping below the mitral annulus.[7,11,12] In 2012, Søndergaard and colleagues[11] reported the first in-human implant of a TMVR using the first-generation CardiAQ valve. This was performed in an 86-year-old subject with severe MR with left ventricular ejection fraction (LVEF) of 40% and Society of Thoracic Surgeons' (STS) score of 31.9%. Valve deployment used a

Fig. 1. Second-generation CardiAQ valve with the 2 sets of atrial and ventricular opposing anchors. (*Courtesy of* CardiAQ Valve Technologies, Irvine, CA, USA; with permission.)