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EDITORIAL COMMENTARY

Ode to the mitral valve: “The times are a changin’”

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As Bob Dylan put it so well in 1964, “The times are a changing.” This article assures cardiac surgeons that “an event horizon” is blatantly true today, as many new mitral valve devices are threatening our well-proven surgical valve operations.¹ Badhwar et al have reviewed comprehensively the most up-to-date information regarding the transcatheter mitral valve therapies that are in play today and have given us a hint of what “could/may/will” be the future. This paper gives us direction and is the clarion call for cardiac surgeons to become engaged in this rapidly evolving parade.

Large clinical trials already have defined safety and efficacy for both transcatheter aortic valve replacement (TAVR) and mitral clip technology. Recent 2-year Placement of AoRTic TraNscathetER Valves (PARTNER II) clinical trial data showed in intermediate-risk (mean 5.8%) patients with aortic stenosis that femoral-access TAVR had less mortality/morbidity, lower gradients, and shorter hospitalizations than surgical aortic valve replacements.² Also, the SURgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) trial is making similar comparative

assessments for patients with a mortality risk of between 3% and 15%.³ Moreover, the upcoming PARTNER III trial

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Central Message

Transcatheter mitral repair and replacement devices are in evolution. If this progress recapitulates that of transcatheter aortic valve replacement, an entire new horizon in mitral valve therapy lies ahead.

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FIGURE 1. Tendyne transcatheter mitral valve. Deployed from and tethered to the cardiac apex (not approved by the Food and Drug Administration).

will compare even lower-risk patients (65 years and older with a <2% risk), who presently are the majority of our surgical patients.⁴ If long-term durability can be proven to be equivalent, then traditional surgical aortic valve replacement for most patients may go the way of the slide rule and the vacuum tube. It seems reasonable to suspect that the evolving pathway for the development of transcatheter mitral valve replacement (TMVR) could recapitulate the success of TAVR, with each generation having improved results.

Evolving mitral valve technologies must adapt to more complex cardiodynamics, changing geometry, and more flexible anatomy than the aortic valve. Nevertheless, surely a myriad of successful transcatheter repair and replacement devices will evolve to treat both degenerative and functional mitral disease. The MitraClip (Abbott Vascular, Chicago, Ill) has been shown to be safe and effective, albeit not rendering the same level of regurgitant results as surgical repairs.⁵ Nonetheless, it was approved by the Food and Drug Administration for high-risk degenerative mitral disease. As stated in the present article, transapical beating heart neochords have been shown to be effective in early clinical studies, and transcatheter annuloplasty bands have been implanted with reasonable results. Can these methods be combined to remodel the annulus and reduce leaflet prolapse? Could these replace mitral repair for degenerative disease? Even the best surgical repairs with excellent long-term durability develop progressive mitral insufficiency.⁶ Perhaps catheter-based repairs could do just as well or be “adequate” in our patient consumer’s eyes. We don’t know these answers, but we do know that future mitral therapy will become less invasive. As mentioned, these technologies will have to respond to a myriad of dynamic cardiac changes.

TMVR is another story. As discussed in this paper, TMVR devices have been acquired for 2.5 billion dollars in the last year, with few human implantations and no completed clinical trials. The Tendyne Valve (Abbott Vascular, Santa Clara,

Calif) is one of the transcatheter mitral valves that is in clinical trials currently (Figure 1). This frenzy is akin to buying a yearling racehorse for several million dollars and not knowing whether it will run successfully as a 3-year-old. The recent Cardiothoracic Surgery Network trial in which investigators compared annuloplasty alone with replacement in ischemic mitral regurgitation patients showed that within only 2 years, 58% of repairs and 4% of replacements had progressed to at least moderate mitral regurgitation.⁷ What will happen to the repair cohort at 5 years? Thus, patients with ventricular dysfunction—related mitral insufficiency and continuous remodeling might be better suited for a TMVR.

The PARTNER II trial showed greater mortality and morbidity with the transthoracic approach. It is reasonable to assume that this issue also will be true for current TMVR devices, which now are relegated to large transapical introducers (11–14 mm). Clearly, concerns regarding access, anchoring, thrombosis, left ventricular outflow tract obstruction, and paravalvular leak are daunting but will probably be overcome with an iterative development process similar to TAVR. This probably will eventually render sustainable transcatheter replacement devices.

Each of the authors is on the forefront of these technologies, and this article should encourage cardiac surgeons to become members of a heart team. Guidewire skills are at the pinnacle of necessity to remain a player in this new world. We need to develop alternate access platforms and be fully skilled at any approach that engages any of these new mitral repair or replacement devices. The following Bob Dylan lyrics are apropos for cardiac surgeons in these times!

“Then you better start swimmin’, you could sink like a stone

For the times, they are a-changin’

The slow one now will later be fast

The present now will later be past”

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