Case Reports

Transcatheter Mitral Valve Replacement with the Edwards SAPIEN 3 Valve

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We describe the case of a 57-year-old man who had severe mitral valve stenosis and regurgitation without significant annular calcification. He was not a candidate for surgical valve replacement or repair because of his substantial comorbid conditions, overall frailty, and elevated surgical risk. He underwent successful transcatheter mitral valve replacement of his native mitral valve with compassionate, off-label use of an Edwards SAPIEN 3 valve. A search of the literature produced no other cases like ours, which represents a further evolution of the transcatheter valve implantation concept. Further studies are needed to help define accurate valve sizing, intraprocedural positioning, and long-term device stability, as well as to determine which patients might benefit from this commercially available valve. In the meantime, our findings could present a means of treating patients who have no other options. ***(Tex Heart Inst J 2017;44(4):269-73)***

Key words: *Heart valve prosthesis implantation/instrumentation/methods; mitral valve insufficiency/diagnostic imaging; prosthesis design; risk factors; transcatheter mitral valve replacement/methods; mitral valve stenosis; treatment outcome*

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In the past, the standard of care for the treatment of valvular stenosis and regurgitation has been surgical valve replacement or repair in selected patients with favorable anatomy. Transcatheter valve replacement has become an excellent alternative to surgical valve replacement when comorbid conditions and prior sternotomies heighten the patient's surgical risk, and the transcatheter approach might become even more relevant for patients who need a mitral valve replacement (MVR) when dedicated devices become available.

The Placement of Aortic Transcatheter Valve (PARTNER) trials have shown consistently favorable outcomes for transcatheter aortic valve replacement (TAVR) with the Edwards valve in patients at high surgical risk and in those with inoperable severe native aortic stenosis.[1,2] Valve-in-valve therapies performed in the tricuspid, pulmonic, mitral, and aortic positions have also been reported, with varying results.[3,4] In regard to the mitral valve (MV), favorable outcomes in patients after mitral valve-in-valve replacement are being reported more frequently,[5] and reports are emerging of mitral valve-in-ring replacement[3] and MVR in patients with severe annular calcification.[6,7] There are no reported cases of commercially available devices having been used for transcatheter valve replacement of a native MV.[3] In this report, we describe the case of a patient with severe MV stenosis and regurgitation, but without significant annular calcification, who underwent transcatheter MVR replacement with use of the Edwards SAPIEN 3 valve.

Case Report

A 57-year-old man was referred to our center for evaluation and treatment of severe mitral disease. He had a history of end-stage renal disease and had been on hemodialysis since rejection of a transplanted kidney in 1989. He had also undergone multiple percutaneous coronary interventions. He presented with extensive additional comorbidities, including chronic hepatitis C and cirrhosis. His Model for End-Stage Liver Disease score was 21. He also had ischemic cardiomyopathy with an estimated left ventricular (LV) ejection fraction of 0.30 to 0.35, a New York Heart Association (NYHA) functional class status of IV, and mild chronic obstructive pulmonary disease (forced expiratory volume in 1 s, 64%).

The patient was initially considered as a candidate for surgical MVR because of coexisting severe mitral stenosis and regurgitation. Transesophageal echocardiograms (TEEs) revealed a peak velocity of 2.48 m/s, an estimated mean gradient of 14 mmHg, and a calculated MV area of 0.88 cm^2, indexed to 0.46 cm^2/m^2 (Fig. 1). Com-

puted tomograms revealed only a focal calcification in a limited portion of the posterior leaflet and an estimated annular area of 612 mm^2. We confirmed the severity of the patient's mitral stenosis and regurgitation by direct measurement of his LV and right-sided pressures (Table I). Because the patient was highly symptomatic and had undergone multiple hospital admissions for fatigue and severe dyspnea, the heart team opted for compassionate, off-label use of an Edwards SAPIEN 3 valve (Edwards Lifesciences Corporation; Irvine, Calif). Given the patient's substantial comorbid conditions, overall frailty, and elevated surgical risk (Society of Thoracic Surgeons scores for MVR, 11% for death and 43% for morbidity or death), we thought that there were no other feasible treatment alternatives.

We gained transapical access by using standard surgical techniques for TAVR. A 0.035-in Amplatz Super Stiff™ guidewire (Boston Scientific Corporation; Natick, Mass) was placed in the right upper pulmonary vein, and a 16F Edwards eSheath introducer (Edwards Lifesciences) was advanced over the guidewire,

TABLE I. Hemodynamic Values Before and After Mitral Valve Replacement

Variable	Before MVR	After MVR
Right atrial pressure (mmHg)	18/13/12	17/14/15
Right ventricular pressure (mmHg)	82/12/18	62/12/18
Pulmonary artery pressure (mmHg)	78/36/56	52/24/38
Arterial partial pressure of oxygen (%)	59	75
Arterial oxygen saturation (%)	97	99.5
Fick cardiac output (L/min)	4.42	6.85
Fick cardiac index (L/min/m^2)	2.35	3.64
Mitral valve gradient (mmHg)	26	7.6
LV pressure (mmHg)	78/3/30	77/5/18

LV = left ventricular; MVR = mitral valve replacement

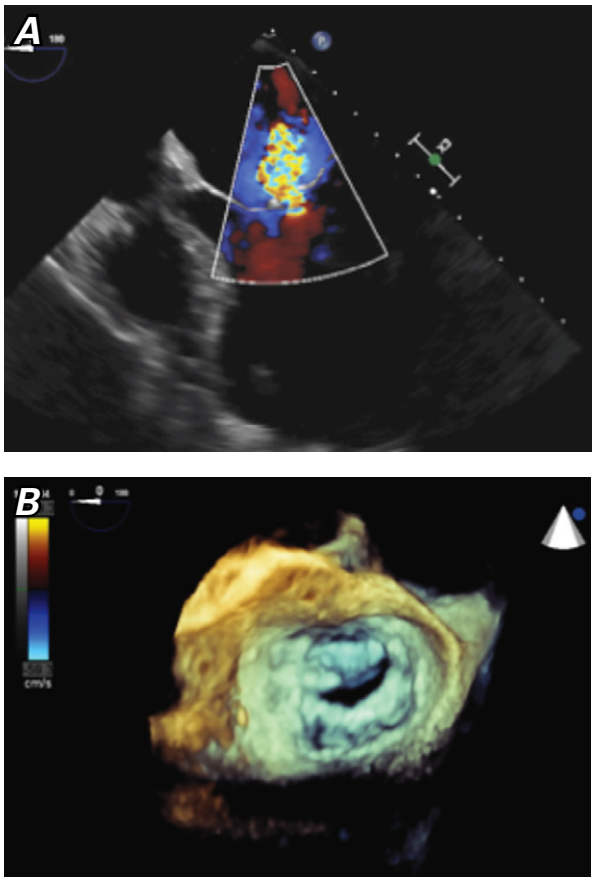


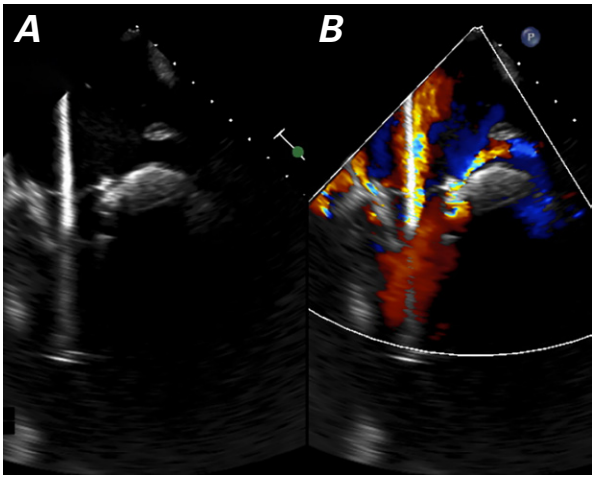
Fig. 1 *Initial transesophageal echocardiograms of the mitral valve in **A**) 2-dimensional and **B**) 3-dimensional views show a relative absence of calcification in the valve leaflets and apparatus, with the exception of a focal calcification in the posterior aspect of the annulus.*

which enabled valvuloplasty with a 20 × 45-mm TRUE DILATATION® balloon (Bard Peripheral Vascular, Inc.; Tempe, Ariz) without evidence of LV outflow tract obstruction during full inflation. The balloon was withdrawn, and a 29-mm SAPIEN 3 valve was advanced through the Edwards eSheath and deployed under rapid pacing. Transesophageal echocardiographic and fluoroscopic landmarks were used to ensure that the valve struts were properly anchored across the mitral annulus (Fig. 2). After valve deployment, TEE showed moderate paravalvular regurgitation. We then performed an additional balloon dilation, adding 1 mL to the nominal inflation volume. After 15 minutes, the patient's hemodynamic status improved significantly; there was a marked improvement in the paravalvular leaks, with only mild residual paravalvular regurgitation still present near the anterior native leaflet (Fig. 3) (Table I). The patient tolerated the procedure well and experienced no immediate periprocedural complications.

At the 2-month follow-up examination, echocardiograms revealed proper placement of the Edwards SAPIEN 3 valve in the mitral position, minimal anterior paravalvular leaks, no significant central mitral regurgitation, and a mean transvalvular gradient of 8 mmHg (Fig. 4). The patient was in NYHA functional class II and was able to walk without assistance. As of his 1.5-year outpatient follow-up (June 2017), he was being considered for a second renal transplant.

Discussion

Results of a literature search indicate that our patient is the first to have undergone a transcatheter valve replace-



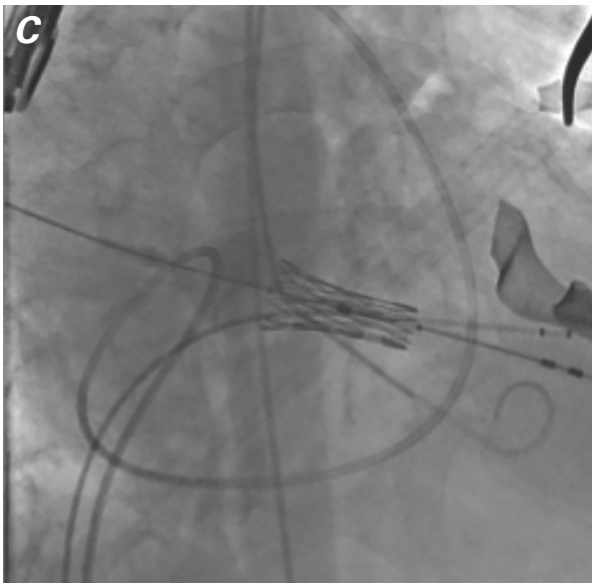


Fig. 2 *Transesophageal echocardiograms in **A**) 2-dimensional and **B**) color-flow Doppler modes and **C**) a fluoroscopic image at the time of valve deployment, obtained under rapid right ventricular pacing at the beginning of valve inflation, show the SAPIEN 3 valve in the mitral position in relationship to the native mitral annulus.*

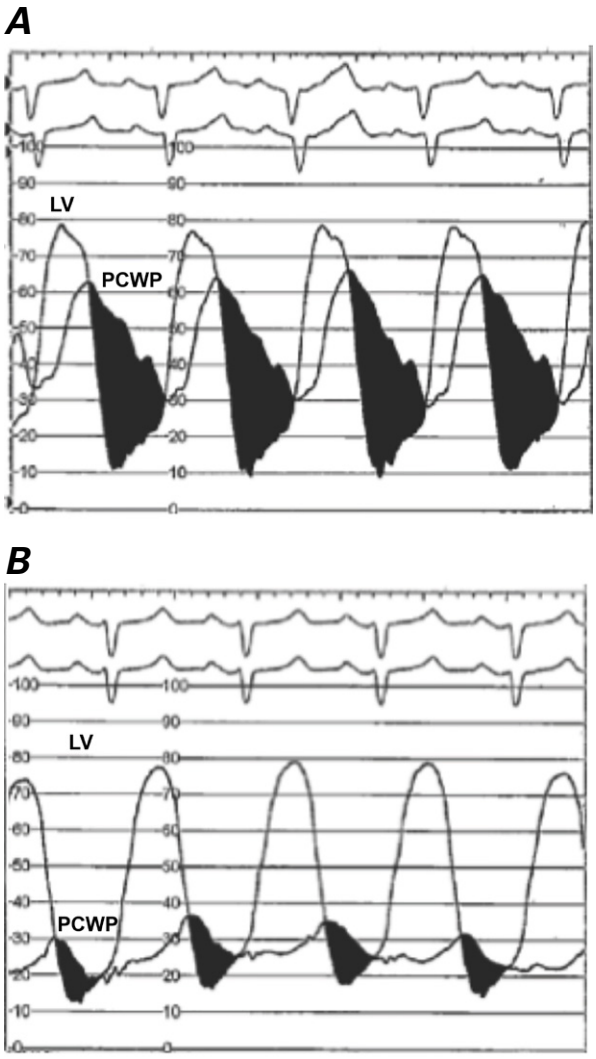


Fig. 3 *Simultaneous hemodynamic tracings of the left ventricular (LV) and pulmonary capillary wedge pressures (PCWP) (in mmHg) **A**) before and **B**) after deployment of the valve. The LV pressure was measured directly during transapical sheath delivery, and the PCWP was measured via a Swan-Ganz catheter. The marked reduction in the mean transmitral gradient and V wave were consistent with resolution of mitral regurgitation and stenosis.*

ment of a native MV with the Edwards SAPIEN 3 heart valve in the absence of significant annular calcification. This off-label use might represent the further evolution of the transcatheter valve implantation concept. Experience in transcatheter implantation of valves, other than the aortic valve, has become increasingly frequent and appears to be a valid alternative to surgery. However, the transcatheter MV experience remains restricted to the MitraClip® NT (Abbott Laboratories; Abbott Park, Ill) in selected cases of mitral regurgitation, and to the limited off-label implantation of the SAPIEN 3 valve for valve-in-valve procedures or in the presence of severe mitral annular calcification.[3,6] The development of percutaneous valves specifically for the mitral position is still in the early clinical stage.[5]

The SAPIEN 3 was designed to be deployed in a rigid structure, such as a calcified aortic annulus (for TAVR), and use has been extended to implantation into a predeployed Palmaz stent in the pulmonary position or into a degenerated bioprosthetic valve for valve-in-valve procedures in any position. Our case shows that even structures as dynamic as the mitral annulus and the subvalvular apparatus can accommodate a properly sized SAPIEN 3 valve. Our case may also serve as a proof of the concept of an alternative to surgical valve replacement in patients with mitral disease, minimal or no

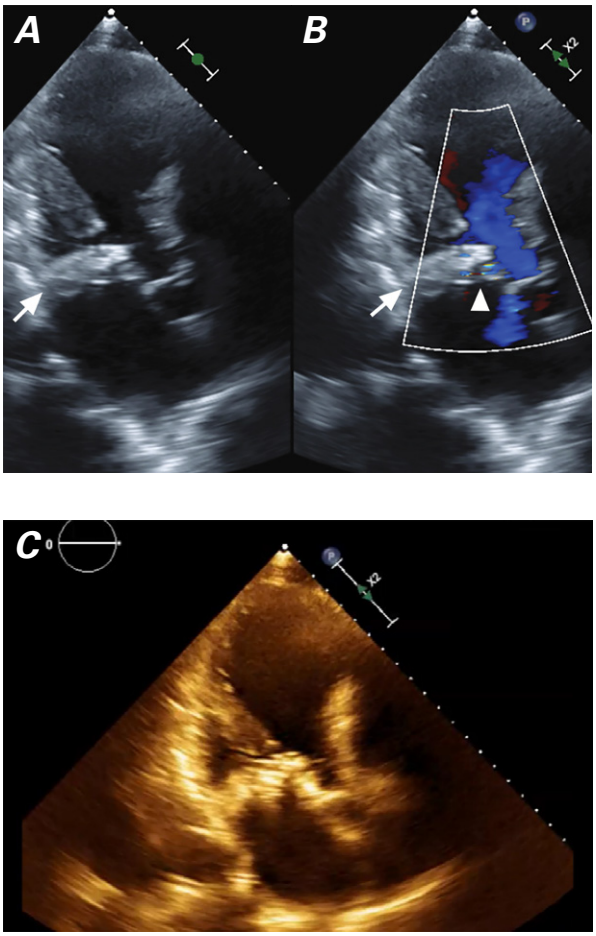


Fig. 4 *Transthoracic echocardiograms in **A**) 2-dimensional and **B**) color-flow Doppler modes obtained at 2-month follow-up show the SAPIEN 3 valve in the mitral position (arrows). There is minimal, if any, paravalvular leak, and the valve is in the correct position (arrowhead). **C**) Still frame of the echocardiogram obtained at 2-month follow-up.*

Supplemental motion image is available for Figure 4C.

annular calcification, and extensive comorbidities precluding successful surgical MVR.

As of December 2016, a feasibility trial for an Edwards percutaneous MVR device in patients not eligible to undergo surgical mitral replacement was ongoing in the United States. The study is recruiting a limited number of carefully selected patients on the basis of their clinical status and anatomy best fitting the characteristics of the device. However, widespread commercial availability of a percutaneous MV is still somewhat distant, so we must continue investigating treatments for patients with no other options. Further studies of available devices are needed to help define accurate valve sizing, intraprocedural positioning, and long-term device stability.

Selecting an appropriate treatment for our patient was challenging. We ruled out surgery because of the high risk it posed. A MitraClip was not an option because of our patient's existing mitral stenosis, and he did not qualify for enrollment in the Edwards percutaneous MVR feasibility study. Accordingly, the SAPIEN 3 was the only option. However, despite our center's substantial experience with this device, it was difficult to predict the risks of embolization, paravalvular leak, and LV outflow tract obstruction associated with using an aortic device to treat mitral disease. While planning and executing the MVR procedure, we took particular care to prevent LV outflow tract obstruction. Specifically, we confirmed our preoperative computed tomographic findings with those of intraoperative TEE performed during balloon valvuloplasty. Only after full balloon inflation and finding no evidence of LV outflow tract obstruction did we decide that a 29-mm SAPIEN 3 valve could be safely accommodated.

We opted for a transapical approach for several reasons. First, we have substantial experience in transapical access, which we have used since the early days of the first-generation Edwards SAPIEN valves and which we are currently using during HeartMate/HeartWare implantations. Second, vascular calcification made transaortic and transfemoral access prohibitive. We also excluded a transseptal approach because we were inexperienced in using the Edwards Commander transfemoral delivery system with a transseptal route.

In conclusion, we have described successful MVR with an Edwards Sapien 3 valve in a patient with mitral stenosis who was considered at very high risk for surgery. Further studies are required in more patients to confirm the feasibility of this technique.

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