First-in-Human Experience With Transcatheter Mitral Valve-in-Valve Implantation During Left Ventricular Assist Device Placement

Gabriela Orasanu, MD*; Sadeer G. Al-Kindi, MD*; Monique R. Robinson, MBBS, DPhil; Guilherme H. Oliveira, MD; Mahazarin Ginwalla, MD; Chantal Elamm, MD; Michael Zacharias, DO; Mahmoud Farhoud, MD; Benjamin Medalion, MD; Salil V. Deo, MD; Soon J. Park, MD; Guilherme F. Attizzani, MD; Basar Sareyyupoglu, MD

Valvular disease is common in patients undergoing left ventricular assist device (LVAD) implantation. Concomitant valve surgery increases procedural complexity and cardiopulmonary bypass time and may lead to worse outcomes.1 Although mitral regurgitation is the most common mitral valve dysfunction in patients undergoing LVAD implantation, mitral stenosis (MS) is occasionally encountered. MS can lead to restricted LVAD flow; therefore, mitral valve replacement is considered to be reasonable in patients with hemodynamically significant MS undergoing LVAD implantation. We describe a successful transcatheter mitral valve replacement (TMVR) via a transapical approach with concomitant LVAD implantation in a patient with bioprosthetic MS.

Case Presentation

Our patient is a 67-year-old male with ischemic cardiomyopathy, stage D heart failure with reduced ejection fraction, and left ventricular ejection fraction 15%. He had prior 6-vessel coronary artery bypass grafting, bioprosthetic mitral valve replacement (Medtronic Mosaic porcine mitral valve, 29-mm size) for severe mitral regurgitation, and a modified endoventricular circular patch plasty (Dor procedure) for left ventricular aneurysm repair. He had cardiac resynchronization therapy and defibrillator therapy and was paced 99% but remained symptomatic with low output symptoms, as confirmed by hemodynamic assessment.

By the time of referral to our institution, he had been hospitalized multiple times in the preceding 6 months with acutely decompensated heart failure, severe ascites, and malnutrition and was maintained on home inotropic therapy with Milrinone at 0.375 μg/kg/min. Coronary angiography demonstrated patent bypass grafts. Transthoracic and transesophageal echocardiography revealed moderate bioprosthetic MS (mitral valve area = 1.43 cm², pressure half-time = 154 ms, mean gradient 9.2 mmHg, and peak gradient 19.9 mmHg), moderate tricuspid regurgitation, and mild right ventricular dysfunction.

Hemodynamic evaluation confirmed cardiogenic shock (Fick CO/CI = 4.1/2.0 L/min/m²). He was optimized with Milrinone and diuresed but could not be weaned off inotropic support. Thus, a temporary percutaneous LVAD (Impella 5.0; Abiomed, Danvers, MA) was placed via the axillary artery as a bridge to decision. He was not deemed eligible for heart transplantation because of poor renal function, poor nutritional status, and elevated pulmonary artery pressures. With temporary LVAD placement, there was hemodynamic improvement with Fick CO/CI = 6.4/3.5 L/min/m² after 10 days of therapy. Renal function normalized, and albumin was increased from 2.4 to 3.3 g/dL with nutritional support. The axillary location of the Impella device also allowed for an intensive physical therapy effort, and the patient was ambulatory preoperatively. Given the clinical improvement with better forward flow, durable LVAD placement was planned as destination therapy with concomitant mitral valve and tricuspid valve repair.

To facilitate potentially challenging mitral valve surgery on a high-risk patient and to shorten operative time, approval was obtained for compassionate use of an Edwards XT transcatheter valve to be placed in the mitral position via a transapical approach at the same time as LVAD implantation. He underwent Heartmate II (Thoratec, CA) LVAD implantation as destination therapy with TMVR and tricuspid valve repair. Surgically, after left ventricular apical core myomectomy on cardiopulmonary bypass, the Dor plasty patch was taken down to access the left ventricular cavity. After direct exploration of his bioprosthetic valve and center alignment, a 29-mm SAPIEN XT (Edwards, CA) transcatheter valve was deployed over a balloon catheter to the mitral position under direct vision without fluoroscopic guidance without complication. This completed mitral valve replacement in <1 minute. This...
was followed by Heartmate II device implantation. A concomitant tricuspid valve ring repair was performed through a right atriotomy. Mitral valve positioning was excellent without valvular regurgitation at the end of the procedure (Figure 1; Movie 1 in the Data Supplement).

Postoperatively, there was surgical stability, and surgical site re-exploration was not required. Repeat imaging studies at post op day 15 showed the LVAD, mitral valve, and tricuspid rings to be well seated (Figure 2A and 2B). At the time of last review, 5 months post LVAD implantation, he remains asymptomatic and fully ambulatory. Repeat echocardiography showed no evidence of mitral valve regurgitation or paravalvular leak.

**Discussion**

We describe a first-in-human successful concomitant TMVR and LVAD implantation in a high-risk patient with good outcome.

Conventional surgery for MS includes prolonged cardiopulmonary bypass, cardioplegic arrest, and left atriotomy (or transeptal right atriotomy), with a potential to increase procedural time and complications, especially when a second valve (tricuspid valve) also needs to be repaired. Transapical mitral commissurotomy has been described concomitantly with LVAD implantation in a patient who had a prior mitral valve repair. Transcatheter valves have also been used to treat degenerated aortic and mitral bioprostheses. Edwards received approval for the Conformité Européenne mark for valve-in-valve approach using the SAPIEN XT valve in 2014, and emerging reports have shown safety and efficacy of TMVR for native valves and degenerated ring annuloplasties. It was essential for us to treat bioprosthetic MS at this time of LVAD implantation not only to give the best LVAD flow postoperatively without the restriction because of stenosis, but also to show that an apical approach would be impossible in the future because of presence of LVAD.

TMVR can be implanted through transapical or transvenous/transjugular approaches. The transapical approach is the preferred method because it allows optimal alignment under fluoroscopic guidance. In our case, when the large apical ventriculotomy has already been made for LVAD placement, it allowed us to implant the valve in a direct visual approach. Direct visualization and appropriate alignment were essential to optimize valve implantation. After the valve is positioned as recommended in valve-in-valve approach (Figure 1), it is slowly deployed in a two-step inflation to allow fine adjustments for valve alignment. The success of our intervention was a result of presurgical optimization with a temporary ventricular device that allowed for renal recovery, nutritional advancement, and physical conditioning. Additionally, our novel surgical approach to mitral valve replacement using an appropriately sized transcatheter valve mitigated the surgical risk inherent in a traditional mitral valve replacement. This combined therapeutic paradigm is an attractive option for debilitated patients with advanced heart failure who require durable mechanical support.

In conclusion, transapical TMVR is an alternative option for high-risk patients with MS undergoing LVAD implantation. TMVR has the ability to decrease complications and reduce bypass and overall procedural time.

**Disclosures**

None.

**References**


**Key Words:** heart failure ■ heart valve diseases ■ left ventricular assist device ■ mitral valve ■ transcatheter mitral valve replacement
Figure 1. Transesophageal echocardiography, 2-chamber view, post implant of the SAPIEN XT (Edwards, CA) transcatheter valve. CPB indicates cardiopulmonary bypass.

Figure 2. A, Computed tomography (CT) chest without contrast. The inflow left ventricular assist device (LVAD) canula (triangle) and 29-mm SAPIEN XT (Edwards, CA) transcatheter valve (star) are visualized. B. Transthoracic echocardiogram-left parasternal long-axis view. The inflow LVAD canula (triangle) and 29-mm SAPIEN XT (Edward, CA) transcatheter valve (star) are visualized.
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SUPPLEMENTAL MATERIAL

Video: Post-implantation transesophageal echocardiogram showing the mitral prosthesis