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STRUCTURAL INTERVENTIONS

ADVANCED

CASE REPORT: CLINICAL CASE

First Transfemoral Implantation of a Novel Transcatheter Valve in an LVAD Patient With Aortic Insufficiency

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ABSTRACT

An 80-year-old man with a destination left ventricular assist device (LVAD) presented with decompensated heart failure. Evaluation demonstrated numerous LVAD high power spike events, significant aortic regurgitation, and hemolysis. He underwent successful aortic valve replacement with a novel transcatheter valve and LVAD pump exchange that resulted in an improvement in his clinical status. (**Level of Difficulty: Advanced.**) (J Am Coll Cardiol Case Rep 2021;3:1806–1810)
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HISTORY OF PRESENTATION

An 80-year-old man with ischemic cardiomyopathy after implantation of a HeartMate II (Abbott) left ventricular assist device (LVAD) in 2017 presented with New York Heart Association (NYHA) functional class IV symptoms. On examination, his heart rate was 82 beats/min, his mean arterial pressure was 92 mm Hg, and cardiovascular examination revealed an LVAD hum but was otherwise unremarkable. There was laboratory evidence of hemolysis (**Table 1**), and his echocardiogram demonstrated pancyclic, moderate to severe aortic regurgitation (AR). The LVAD pump speed was 9,200 rpm, and numerous high-power spike events were appreciated (**Figure 1**).

LEARNING OBJECTIVES

- To describe the evaluation of AR in patients with LVADs.
- To understand the management of AR and demonstrate the use of a novel TAVR system for patients with LVADs.

PAST MEDICAL HISTORY

The patient's additional medical history included sleep apnea, chronic kidney disease, atrial fibrillation, and a previous transient ischemic attack.

INVESTIGATIONS. Chest computed tomography angiography (CTA) was performed to evaluate the LVAD inflow and outflow cannulas, and no evidence of thrombus or obstruction was seen. Right-sided heart catheterization demonstrated the following: elevated filling pressures; mean right atrial (RA) pressure, 15 mm Hg; right ventricular (RV) pressure, 65/14 mm Hg, mean pulmonary arterial (PA) pressure, 45 mm Hg; pulmonary capillary wedge pressure (PCWP), 28 mm Hg; PA saturation, 49%;

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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cardiac output (CO), 3.2 L/min; and cardiac index, 1.6 L/min/m^2.

His transesophageal echocardiogram (TEE) confirmed pancyclic AR with a regurgitant volume of 59 mL (Video 1). An echocardiographic ramp study was performed. Baseline transthoracic echocardiogram (TTE) demonstrated an ejection fraction of 10% to 15% and a left ventricular end-diastolic dimension (LVEDD) of 6.0 cm. With higher pump speeds, there was worsening of AR and limited reduction in the LVEDD.

MANAGEMENT

After volume and medical optimization with afterload reduction, repeat right-sided heart catheterization was performed: RA pressure, 8 mm Hg; RV pressure, 34/9 mm Hg; mean PA pressure; 25 mm Hg; PCWP, 9 mm Hg; PA saturation, 63.8%; CO, 4.74 L/min; and cardiac index, 2.37 L/min/m^2. Despite the improvement in filling pressures, these conservative measurements failed to resolve the patient's symptoms and hemolysis.

Pump thrombosis and AR both increase shear stress, thus leading to hemolysis and reduced left ventricular unloading. In patients with an LVAD and AR, blood is circulating directly from the outflow cannula back to the pump, and this can result in hemolysis. Thus, it was difficult to differentiate whether pump thrombosis or AR was causing the clinical syndrome because a positive ramp study result can also be seen in both conditions. The working diagnosis was that both processes existed. The patient was a high surgical risk, and therefore the decision was made to first proceed with transcatheter aortic valve replacement (TAVR). A subsequent LVAD pump exchange could be performed using a minimally invasive approach.

Cardiac CTA demonstrated no aortic valve calcium to anchor a commercially available TAVR valve. Therefore, a novel TAVR system, the JenaValve Trilogy (JenaValve Technology, Inc.) was considered, given its ability to anchor in pure AR in the absence of calcified leaflets. The locator technology prevents migration of the device into the left ventricle after deployment, a feature that is particularly advantageous in patients with LVADs (**Figure 2**). The valve is under investigational use for native AR in the United States in the ALIGN-AR (JenaValve Pericardial TAVR Aortic Regurgitation Study; NCT04415047) pivotal trial; however, in May 2021, it received CE mark approval for treatment of both aortic stenosis and AR.

Cardiac CTA demonstrated suitable anatomy, and the valve was implanted under an emergency use protocol with the patient under general anesthesia and TEE guidance (**Figure 3**). Transfemoral access was obtained. An 18-F dedicated sheath was advanced to the sinotubular junction. An aortogram was performed to determine the deployment view (Video 2). Next, the valve was advanced through the sheath. The locators were centered within each of the aortic cusps (Videos 3 and 4). After confirmation of the correct position, the valve was deployed without changes in LVAD speed (Video 5). The procedure was uncomplicated, requiring only 16 minutes from sheath insertion to sheath removal. TEE assessment demonstrated a well-positioned valve with closed leaflets and no evidence of transvalvular or paravalvular regurgitation (Video 6).

Given the persistent hemolysis and power spikes indicating LVAD pump dysfunction, the patient later underwent a minimally invasive LVAD pump exchange (HeartMate II [Abbott] explant, HeartMate III implant) through subcostal and left thoracotomy access. The pump rotor bearing area was noted to have thrombus present on explantation.

ABBREVIATIONS AND ACRONYMS

AR = aortic regurgitation
CO = cardiac output
CTA = computed tomography angiography
LVAD = left ventricular assist device
LVEDD = left ventricular end diastolic dimension
NYHA = New York Heart Association
PA = pulmonary artery
PCWP = pulmonary capillary wedge pressure
RA = right atrial
RV = right ventricular
TAVR = transcatheter aortic valve replacement
TEE = transesophageal echocardiogram
THV = transcatheter heart valve
TTE = transthoracic echocardiogram

DISCUSSION

AR is a frequent complication related to long-term LVAD support and progresses with increased support duration. At least moderate AR is estimated to develop in ~30% of patients who remain on continuous-flow LVAD support for 3 years and by 4% per month of support (1,2). The development of AR is associated with an increase in hospitalizations, reduced survival, and adverse left ventricular remodeling (3,4).

TABLE 1 Laboratory Evaluation

Tests	Admission	Discharge From Hospital	6 Months Follow-Up
Hemoglobin, g/dL	12.3	9.4	13.1
Platelets, 10^9/L	169	202	236
Lactate dehydrogenase, U/L	1,354	371	198
Plasma free hemoglobin, mg/dL	12.1	15	2.0
Haptoglobin, mg/dL	<20	265	223
Albumin, g/L	4.0	2.9	3.8
Total bilirubin, mg/dL	1.5	0.7	0.4
Direct bilirubin, mg/dL	0.4	0.3	<0.2
Creatinine, mg/dL	1.88	1.7	1.61
eGFR, mL/min/1.73m^2	38	47	50

eGFR = estimated glomerular filtration rate.

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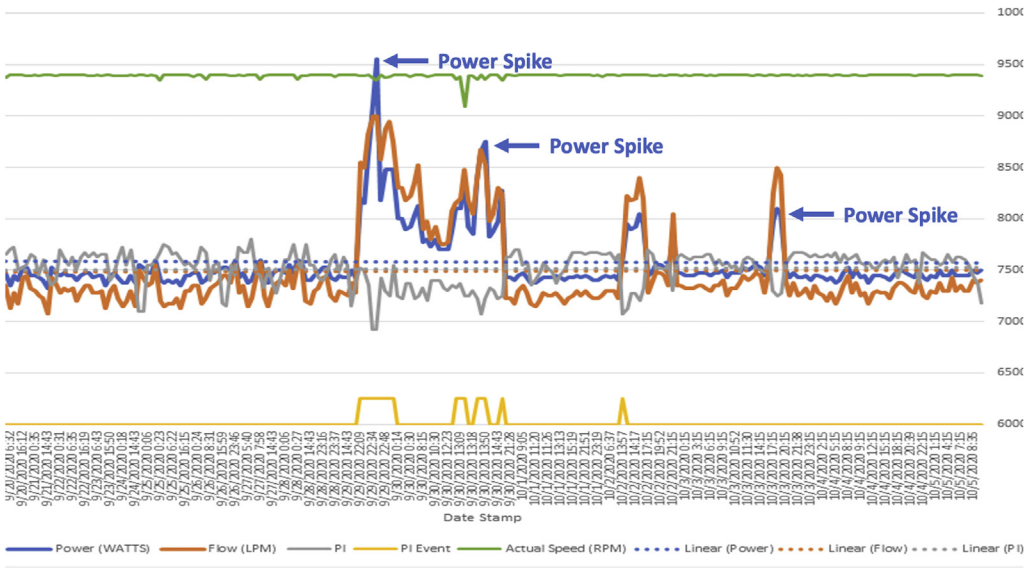
FIGURE 1 Left Ventricular Assist Device Device Evaluation

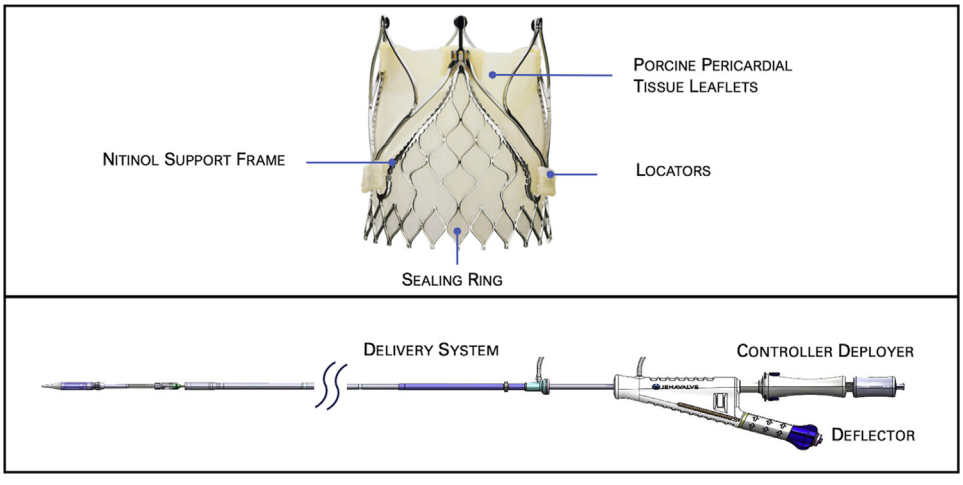


Device evaluation demonstrated numerous high-power alarms (examples indicated by **blue arrows**).

The assessment of AR in patients with LVADs is complex and requires a multiparametric approach. Traditional TTE parameters commonly underestimate the severity because regurgitant flow is typically pancyclic, thus making vena contracta and the regurgitant jet appear narrow. An outflow cannula examination, including assessment of the systolic-to-diastolic peak velocity ratio and diastolic acceleration, is often helpful to assess severity. Moderate or greater AR is indicated by a systolic-to-diastolic ratio <5.0 and/or diastolic acceleration >49.0 cm/s^2 (5).

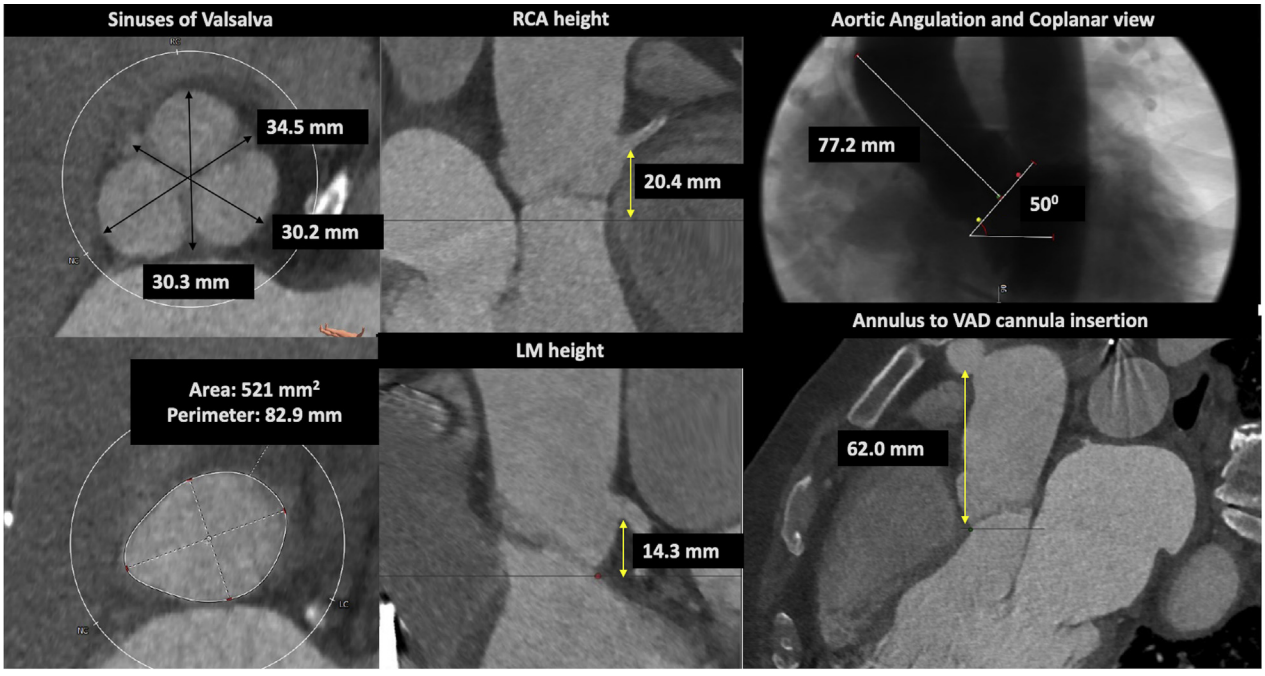
The optimal management of LVAD-associated AR remains unknown. Medical management focuses on volume optimization and afterload reduction. LVAD device management should target the lowest possible

FIGURE 2 JenaValve Trilogy Transcatheter Heart Valve System



The valve consists of a nitinol frame with porcine pericardial leaflets. The delivery system has a deflector that allows for coaxial alignment and a controller knob that facilitates axial rotation of the valve to align the radiopaque locators in the middle of each coronary cusp.

FIGURE 3 Preprocedural Cardiac Computed Tomography Angiography Analysis



Preprocedural cardiac computed tomography angiography demonstrated an annulus perimeter of 82.9 mm, corresponding to a 27-mm valve. The aortic angulation was 50° with adequate distance to the ascending aorta. LM = left main [coronary artery]; RCA = right coronary artery; VAD = ventricular assist device.

pump speed because the development of a reverse transaortic pressure gradient will result in worsening of AR. Surgical treatment options include aortic valve replacement; however, the operative mortality in these patients is significant. There is limited experience with off-label TAVR for AR in patients with LVADs. Single-center studies have demonstrated variable rates of periprocedural mortality and valve migration requiring implantation of a second TAVR device (6,7). The novel transcatheter heart valve (THV) used in this patient has a unique design compared with most other TAVR systems; the locator technology aids with anchoring and prevents ventricular embolization, perhaps making it a more optimal THV in patients with LVADs. A first generation of this valve has been successfully implanted transapically in this clinical setting (8). An alternative transcatheter approach is aortic valve closure with an Amplatzer Septal Occluder (Abbott); an improvement in hemodynamics has been observed with this approach; however, this makes patients pump dependent and vulnerable if there is pump malfunction or failure (9). Finally, if the patient is a transplant candidate, urgent heart transplantation can be considered.

FOLLOW-UP

The patient demonstrated symptomatic improvement after TAVR and LVAD exchange. At 6-month clinical follow-up, he described NYHA functional class II symptoms, and his laboratory test results demonstrated resolution of hemolysis. On 6-month TTE, the prosthesis was stable without any paravalvular or transvalvular AR.

CONCLUSIONS

The use of commercially available TAVR devices is challenging because of issues with valve anchoring. This first case example demonstrates that this novel THV may be a feasible option for TAVR in the patients with LVADs.

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Dr Khalique is part of a core laboratory contracting with JenaValve but has not received any direct compensation; has received consulting fees from Abbott Structural and Boston Scientific; and has received Speakers Bureau fees from Edwards Lifesciences. Dr George has received consulting fees from Cardiomech, Mitremedical, Atricure, Vdyne, Valcare Medical, DurVena, MITRx, and Johnson & Johnson. Dr Leon has reported institutional clinical research grants

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KEY WORDS aortic regurgitation, TAVR

APPENDIX For supplemental videos, please see the online version of this paper.