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CASE REPORT
Valvular heart disease

A case report: transfemoral transcatheter aortic valve replacement with a dedicated valve system for severe aortic regurgitation in a patient with a left ventricular assist device

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Background Up to 30% of patients with the left ventricular assist device (LVAD) develop moderate to severe aortic regurgitation (AR) within the first year. Surgical aortic valve replacement (SAVR) is the treatment of choice in patients with native AR. However, the high perioperative risk in patients with LVAD might prohibit surgery and choice of therapy is challenging.

Case summary We report on a 55-year-old female patient with a severe AR 15 months after implantation of LVAD due to advanced heart failure (HF) as a consequence of ischaemic cardiomyopathy. Surgical aortic valve replacement was discarded due to high surgical risk. Thus, the decision was made to evaluate a transcatheter aortic valve replacement (TAVR) with the TrilogyXTä prothesis (JenaValve Technology, Inc., CA, USA). Echocardiographic and fluoroscopic control showed an optimal valve position with no evidence of valvular or paravalvular regurgitation. The patient was discharged 6 days later in a good general condition. At the 3-month follow-up, the patient showed noteworthy symptomatic improvement with no sign of HF.

Discussion Aortic regurgitation is a common complication among advanced HF patients treated with LVADSystems and associated with a deterioration in the quality of life and worsen clinical prognosis. The treatment options are limited to percutaneous occluder devices, SAVR, off-label TAVR, and heart transplantation. With the approval of the TrilogyXT JenaValve system, a novel dedicated TF-TAVR option is now available. Our experience demonstrates the technical feasibility and safety of this system in patients with LVAD and AR resulting in effective elimination of AR.

Keywords Left ventricular assist device • Aortic regurgitation • Transcatheter therapy • TAVR • Case report

ESC Curriculum 4.1 Aortic regurgitation • 4.10 Prosthetic valves

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Learning points

- Up to 30% of patients with the left ventricular assist device (LVAD) develop moderate to severe aortic regurgitation (AR) within the first year. The perioperative risk in these patients might prohibit surgical options.
- This case demonstrates the technical feasibility and safety of the Trilogy XT™ JenaValve system in patients with an LVAD and AR. The technical features of the prosthesis provide reliable valve fixation onto the native aortic valve resulting in the effective elimination of AR.

Introduction

Twenty-five to 30% of left ventricular assist device (LVAD) patients develop moderate to severe aortic regurgitation (AR) within the first year.[1] Severe AR in patients with advanced heart failure (HF) and left ventricular assist device (LVAD) results in recirculation of regurgitant blood volume and a progressive increase in HF.

Surgical aortic valve replacement (SAVR) is the treatment of choice in patients with native AR.[2] However, the high perioperative risk in patients with LVAD might prohibit surgery and an alternative choice of therapy is challenging. There are a few case reports on successful transcatheter-based therapy by transcatheter aortic valve implantation (TAVI) devices approved for the treatment of aortic stenosis; however, due to insufficient anchoring without leaflet calcification and extensive left ventricular suction, there is a high risk of acute as well as delayed TAVI embolization.[3–7] Recently, the Trilogy XT™ JenaValve system with a specific anchoring mechanism on the native leaflets has been approved in the EU and is now available as the first and only transfemoral transcatheter aortic valve replacement (TAVR) system in the world for the treatment of AR.

This case report illustrates safe transfemoral TAVR treatment of severe AR in a patient with an LVAD to treat severe AR.

Timeline

2019	Symptom onset and diagnosis of dilated cardiomyopathy
2019	Implantation of cardiac resynchronization therapy pacemaker (CRT-P)
2019–20	Recurrent cardiac decompensation despite guideline-directed medical therapy and CRT (non-responder)
October 2020	Implantation of left ventricular assist device (LVAD) HeartMate3™ as a destination therapy as well as tricuspid valve repair and epicardial pacemaker leads implantation
August 2021	Diagnosis of moderate aortic regurgitation (AR)
25 January 2022	Readmission due to decompensated heart failure caused by severe AR
23 February 2022	Transfemoral transcatheter aortic valve replacement (TF-TAVR) with Trilogy™ JenaValve prosthesis
01 March 2022	Discharge in good clinical condition
12 May 2022	Relevant improvement in clinical condition without signs for heart failure
23 February 2023	Follow-up at 12 months: the patient in fair clinical condition only with mild-to-moderate dyspnoea (NYHA II–III)

Case summary

A 55-year-old female presented to the emergency room with decreased general condition with shortness of breath at rest and weakness. The blood pressure was 78/54 mmHg, heart rate was 71 b.p.m., and oxygen saturation was 92% (room air). Physical examination revealed moderate bilateral leg oedema. Lung auscultation revealed reduced breath sounds. The past medical history of the patient was remarkable for end-stage HF due to ischaemic cardiopathy and also secondary pulmonary hypertension. The patient had a medical history of Type 2 diabetes mellitus, treated with insulin, end-stage renal disease, atrial fibrillation, and obesity with a BMI of 42.2 kg/m^2. She had already undergone cardiac resynchronization therapy with a CRT-P device, tricuspid valve repair for severe tricuspid regurgitation, and an implantation of continuous flow-LVAD as destination therapy (HeartMate3™; Abbott, St Paul, MN, USA). Current medications were aspirin 100 mg/day, phenprocoumon with INR target range 2.3–2.8, candesartan 16 mg/day, torasemid 50 mg/day, metoprolol 95 mg/day, amiodaron 200 mg/day, pantoprazole 40 mg/day, and epoetin 2000 units 3 times weekly. The haemoglobin level was 11.0 g/dL, the lactate dehydrogenase level was 242 U/L, and the NT-proBNP level was 11 600 pg/mL. Electrocardiography showed atrial fibrillation with ventricular pacing. Chest radiography revealed previously known cardiomegaly and no signs of significant pulmonary oedema (*Figure 1*). The log of the LVAD showed no markable deviations of parameters. It was then decided to hospitalize the patient due to recurrent decompensated HF.

Previously diagnosed moderate aortic regurgitation had been progressive over the last 5 months and could be identified as the main cause of cardiac decompensation (*Figure 2* and Supplementary material online, *Video S1*).

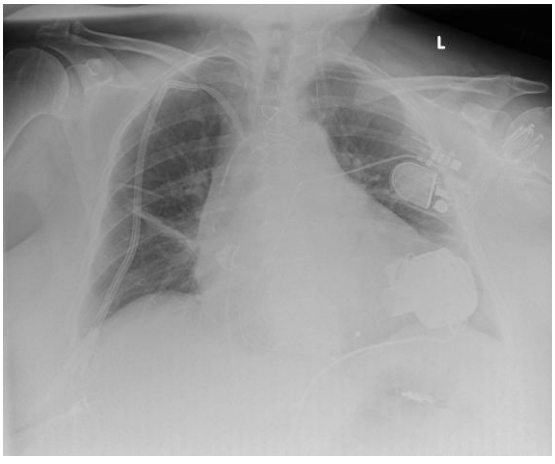

Figure 1 The chest radiography at admission (The posteroanterior view). Significant cardiac dilatation.

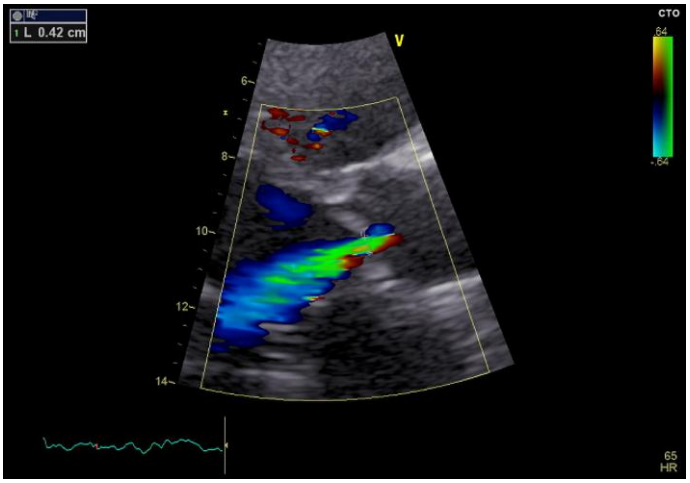

Figure 2 Severe aortic regurgitation. The parasternal long axis view, zoomed aortic valve. Image with colour Doppler, vena contracta 4.2 mm.

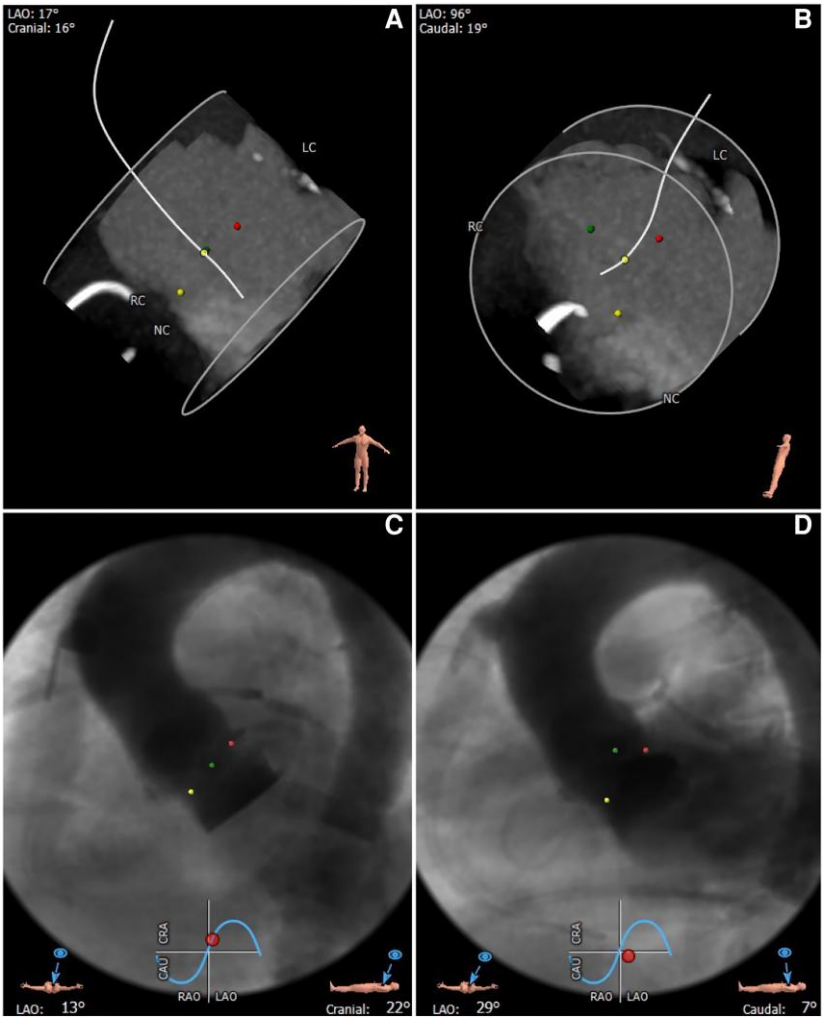

Figure 3 Pre-procedural computed tomography angiography images: (*A* and *B*) aortic annulus without calcification, (*C* and *D*) aortography, and (*E*) no significant stenosis, transfemoral access is possible.

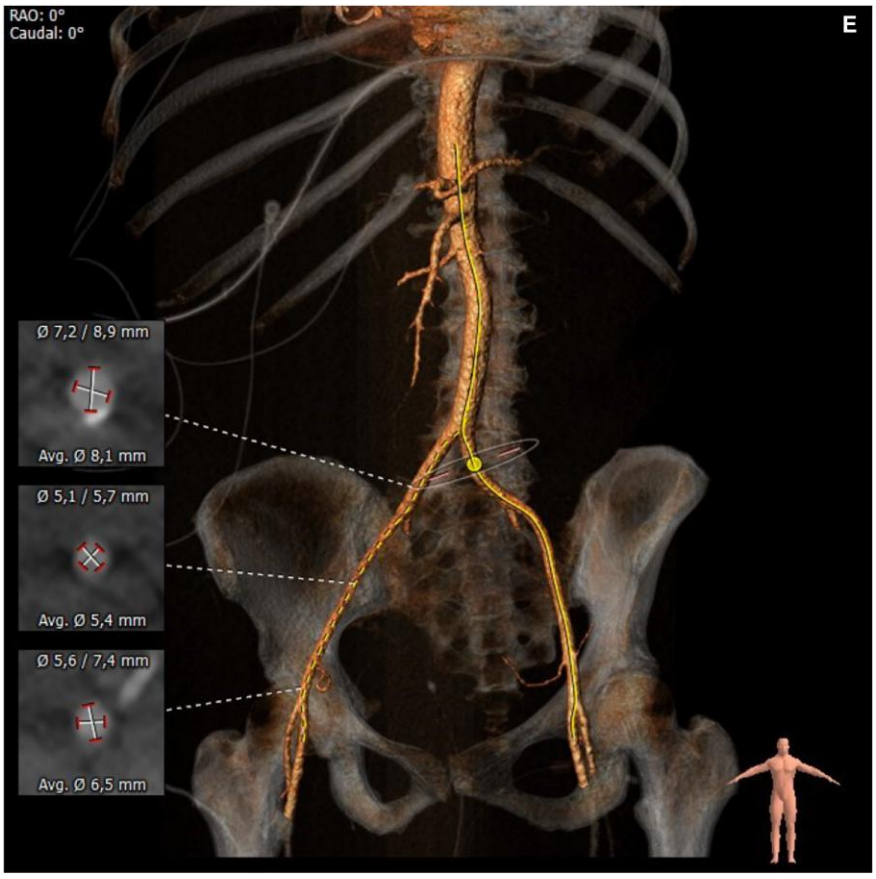

Figure 3 (Continued)

The severity of AR was quantified according to conventional echocardiographic parameters (vena contracts and visual estimation). Unfortunately, a novel method for grading the severity of AR, with the assessment of systolic/diastolic velocity ratio and the diastolic acceleration of the LVAD outflow cannula, could not be applied due to poor echo window to yield an accurate Doppler signal from the outflow cannula.[8]

Surgical aortic valve replacement was discarded by the Heart Team due to a prohibitive surgical risk in the presence of secondary pulmonary hypertension, severely impaired left ventricular function with a left ventricular ejection fraction of 20%, end-stage renal disease, obesity, and a logistic EuroScore II of 45.17%. The patient was also no candidate for heart transplantation as assessed by a multidisciplinary team. Thus, the decision was made to evaluate a TAVR with the Trilogy XT™ prosthesis (JenaValve Technology, Inc., Irvine, CA, USA).

The suitability of cardiac anatomy and vascular access was evaluated using 3mensio™ Structural Heart Software (3mensio Medical Imaging B.V., The Netherlands) for processing computed tomography data (*Figure 3*). No annular calcification was found and transfemoral access was possible (*Figure 3A, B*, and *E*). Transfemoral TAVR was planned under analgosedation with fluoroscopic guidance.

A 27 mm-Trilogy XT™ prosthesis was deployed after confirming the optimal position including the correct position of each locator in every single cusp (Supplementary material online, *Video S2*). During the final phase of deployment, the LVAD system was on hold and rapid pacing was applied.

Haemodynamics quickly recovered after the restart of the LVAD. The procedure time was 148 min with a radiation time of 29 min and use of 150 mL contrast media. Echocardiographic and fluoroscopic control showed an optimal valve position with no evidence of valvular or paravalvular regurgitation (*Figure 4* and Supplementary material online, *Video S3*). Due to insufficient closure of the access site with the Perclose ProGlide™ suture-mediated closure system, a graft stent had to be implanted. No other adverse effects were detected. Following a successful and incident-free recovery, the patient was discharged 6 days later in a good general condition.

At the 3-month follow-up visit, the patient showed noteworthy symptomatic improvement with no sign of HF (*Table 1*). Echocardiography demonstrated an unremarkable prosthesis with no transvalvular or paravalvular regurgitation (see Supplementary material online, *Video S4*) as well as reverse atrial remodelling. After 12 months follow-up, the patient was doing well only with mild-to-moderate dyspnoea, classified as NYHA II–III.

Discussion

Aortic regurgitation is a common complication among advanced HF patients treated with LVAD-Systems. One-third of patients develops relevant AR in the first 3 years after LVAD implantation which is associated with a deterioration in the quality of life and worsen clinical prognosis.[9] Unfortunately, adjustment of the LVAD speed does not allow to achieve a markable reduction of AR. Pump speed augmentation leads

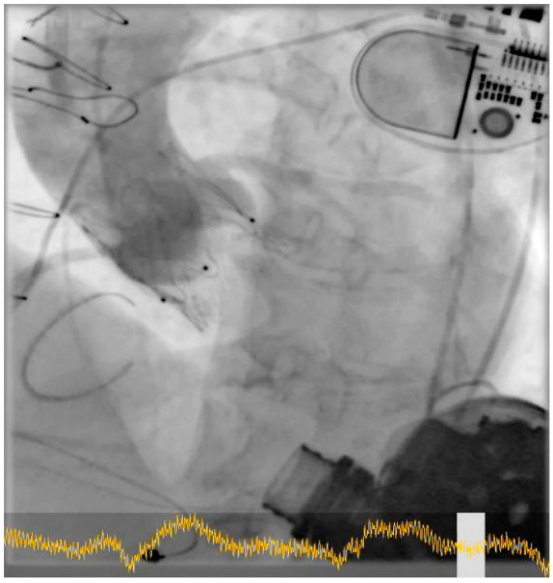

Figure 4 Fluoroscopic control: optimal valve position with no evidence of valvular or paravalvular regurgitation.

usually to the worsening of the AR. A reduction of the LVAD speed results in a decrease in transaortic pressure gradient, which in turn reduces the severity of AR.[10] However, this reduction often leads to an increase in left-sided filling pressures, flow decrease, and thereby worsening of end-organ perfusion. In the presence of AR in LVAD patients, treatment options are limited to percutaneous occluder devices, SAVR, off-label TAVR, and heart transplantation.

With the approval of the Trilogy XT™ JenaValve system, a novel dedicated TF-TAVR option is now available in AR patients. Transcatheter aortic valve replacement with a common prosthesis has a high risk for valve embolization[11,12] and even delayed ventricular migration of the valve particularly in patients with annulus dilatation and without annular calcification which could serve as an anchor for the prosthesis.[6]

With regard to the Trilogy XT™ JenaValve system, the unique design does not rely on calcification as anchors. Instead, the locators clip onto the native anatomy of the patients.[13] In addition, one of the frequent complications of TAVR is paravalvular leakage (PVL), which associated with poor outcome. However, the use of the current generation of prostheses in case of AR shows an incidence of PVL of 3.4%.[14] The first results of using Trilogy XT™ JenaValve system show the low rate of PVL. The ongoing ALIGN-AR trial is expected to provide the pending long-term data. The first successful implantation of this prosthesis with the predecessor of the currently approved delivery system in a patient with LVAD was published in December 2021.[13] In the case described at that time, a simultaneous operation was performed with reimplantation of the LVAD with TF-TAVR, whereas in our case, an isolated TF-TAVR was performed.

Table 1 Pre- and 3 months post-procedural follow-up data

Characteristics	Pre-procedural	3 months follow-up	Reference range
Weight (kg)	122	115	
New York Heart Association classification	IV	II	
Echocardiographic parameters			
Left ventricular end-diastolic diameter (mm)	66	62	
Left ventricular end-systolic diameter (mm)	60	56	
Indexed left ventricular end-systolic diameter (mm/m^2)	22.5	21.9	
Left ventricular ejection fraction (%)	20	20	
Diastolic septal wall thickness (mm)	10	10	
Diastolic posterior wall thickness (mm)	10	11	
Left atrial diameter (mm)	50	53	
Left atrial volume (mL)	193	111	
Left atrial volume index (mL/m^2)	84.6	49.7	
Right atrial volume (mL)	142	75	
Right atrial volume index (mL/m^2)	52	33.6	
Right ventricular basal diameter (mm)	62	45	
Tricuspid regurgitation grading	Mild	Mild	
Tricuspid regurgitation max velocity (m/s)	1.79	1.43	
Mitral regurgitation grading	Moderate	Mild-to-moderate	
Aortic regurgitation grading	Severe	None	
Pulmonal regurgitation grading	Mild	Mild	
Systolic pulmonary artery pressure (mmHg)	28	18	
Laboratory parameters			
Haemoglobin (g/dL)	11.0	10.5	12.0–16.0
NT-proBNP (pg/mL)	11 600	9670	<464
Alanine transaminase (U/L)	23	26	0–35
Aspartate transaminase (U/L)	25	26	0–35
Lactate dehydrogenase (U/L)	242	223	0–247

Our experience demonstrates the technical feasibility and safety of the Trilogy XT™ JenaValve system in patients with LVAD and AR. The technical features of the prosthesis promise reliable valve fixation onto the native aortic valve resulting in effective elimination of AR.

Conclusions

The unique design of the approved Trilogy XT™ JenaValve system has a number of objective advantages that make it a reasonable option to treat aortic regurgitation in high-risk patients with LVAD system.

Lead author biography

Since December 2019, Arseniy Goncharov is a resident at the Clinic for General and interventional Cardiology/Angiology at the Heart and Diabetes Center NRW in Bad Oeynhausen, Germany. He graduated from the Russian State Medical University in 2005 and received the MD degree in 2010. He holds a keen interest in interventional cardiology with a significant interest in cardiac intensive care.

Supplementary material

Supplementary material is available at *European Heart Journal – Case Reports*.

Slide sets: A fully edited slide set detailing this case and suitable for local presentation is available online as Supplementary data.

Consent: The patient signed written informed consent for all treatment procedures. The journal consent form has been signed by the patient. Patient information in this case report is provided anonymously in accordance with the COPE guidelines.

Conflict of interest: None declared.

Funding: None declared.

Data availability

The data underlying this article are available in the article and in its online supplementary material.

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