

REFERRING PATIENTS FOR LVAD THERAPY: **THE ROLE OF ECHOCARDIOGRAPHY**

Case Study:
Contilia Heart and Vascular
Center Essen
Essen, Germany

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CASE STUDY:

CONTILIA HEART AND VASCULAR CENTER ESSEN, GERMANY

CASE AT-A-GLANCE

Gender: Male

Age: 60 years old

Diagnoses: Non-ischemic cardiomyopathy, NYHA Class IV

Comorbidities: COPD II

Treatment Approach: Refer for LVAD therapy as a bridge to cardiac transplantation

Treating Facility: Contilia Heart and Vascular Center Essen, Germany

CASE HISTORY

A 60 year old male patient with advanced NYHA Class IV heart failure secondary to dilated non-ischemic cardiomyopathy presented for consideration of left ventricular assist device (LVAD) therapy. He was first diagnosed in 2010 and has since been medically treated. Within the last year, he has been admitted to our center three times due to cardiac decompensation and uncontrolled weight gain. He also reported a decrease in quality of life due to increased fatigue and worsening dyspnea. He is classified as INTERMACS¹ profile 4 (resting symptoms on oral therapy at home) and his NT-pro-BNP has risen to 12000 pg/ml from 1500 pg/ml.

Echocardiographic assessment plays an important role in screening patients for LVAD therapy as well as surgical planning. Quick accessibility and the absence of radiation make this non-invasive examination an important tool in the perioperative setting.

TTE ASSESSMENT:

According to national guidelines², a standard transthoracic echocardiogram (TTE) should be performed. A "General Standard" test including PLAX, PSAX, apical 4CH, 5CH, 2CH, as well as subcostal and suprasternal views should be obtained. A detailed assessment of left ventricular (LV) function and structure, right ventricular (RV) function, evaluation of the systolic and diastolic function, quantification of valvular abnormalities, intracardiac clots, and intracardiac shunts should be performed.

A detailed pre-operative ECHO with standardized execution is essential to reduce interobserver variability and to provide a baseline for reliable follow-up after implantation.

I. Assessment of LV function

Viewed with biplanimetric assessment, severely impaired LV function (LVEF < 30 % as stated by ESC³) allows for further evaluation for LVAD therapy. Further evaluation for restrictions to surgical access, such as (pseudo-)aneurysms and clots, should be performed. Contrast agents are a helpful tool in this regard.

II. Assessment of RV function

Since right heart failure is associated with high morbidity and mortality following LVAD implantation, a detailed ECHO evaluation of the RV is critical to the assessment for the risk of post-implant RV failure. There are five parameters we examine:

- 1) *Dimensions of the right heart.* A well-documented assessment of preoperatively right heart dimensions allows for a reliable and early sign of RV overload postoperatively. RV-diameters are obtained in the apical 4-chamber view.

- 2) *Tricuspid regurgitation (TR) and estimation of systolic pulmonary artery pressure (sPAP).* Functional TR is a frequent finding in VAD candidates and is partially improved by unloading the LV after implantation. Severe TR may contribute to RV dysfunction and needs to be identified and evaluated. Abnormalities of the valve as well as annular dilatation are factors which may determine relevant TR post implantation. By CW-doppler of the TR, we typically calculate the systolic trans-tricuspid gradient using the modified Bernoulli equation and adding the estimated right atrial pressure from examination of the caval vein.

- 3) *Tricuspid annular plane systolic excursion (TAPSE) and systolic excursion velocity (S').* TAPSE can be reliably assessed by using the M-mode at the lateral tricuspid annulus. There is data supporting poor prognosis among patients with heart failure and a TAPSE < 14 mm.⁸ In LVAD candidates, a cut off between 10 - 12 might be reasonable. S' is indicative of RV systolic dysfunction, a value < 10 cm/s is considered abnormal.⁵

- 4) *Fractional Area Change (FAC).* RV FAC ≥ 40 % is considered normal whereas a FAC between 20 - 30 % is common among LVAD candidates. An FAC < 20 % is associated with elevated risk for RV failure following LVAD implant.⁶ Also, a decrease of 10 % of FAC postoperatively is indicative of RVF.⁷

- 5) *TEI Index, or right index of myocardial performance (RIMP).* An evaluation using the TEI index seems to be concordant with invasive measures of systolic and diastolic function. A result ≤ 0.4 is normal.⁵

III. Assessment of the Valves

While aortic stenosis is not a definitive contraindication for LVAD therapy, aortic regurgitation may cause major problems by creating a circular blood flow loop between the inflow and outflow cannulas of the LVAD and restrict forward circulation. All regurgitation needs to be quantified according to guidelines, using semi-quantitative measures such as PHT and vena contracta, as well as quantitative parameters like the EROA and calculated aortic regurgitant volume with PISA. Diastolic reversal in the descending aorta is always a sign of relevant AR. Every AR more than mild should be assessed for correction.

Mitral regurgitation (MR) and stenosis are not contraindications for LVAD implantation although preoperative assessment should include an evaluation of the mitral valve (MV). MV geometry and degree of regurgitation should be assessed as the majority of VAD candidates present secondary (functional) MR. Secondary mitral regurgitation can be tolerated, since it is often significantly reduced after VAD-implantation. Although there is limited data supporting this claim, at Essen we believe a major valvular defect should be excluded. In case of a severe, primary MR as well as a severe stenosis (Pmean > 10 mmHg) a concomitant correction might be discussed.

ASSESSMENT WITH TRANSESOPHOGEAL (TEE OR TOE) ECHOCARDIOGRAPHY:

A further TOE evaluation in every patient is essential in pre-op screening to exclude intracardiac clots and shunts. Risk for clots



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is elevated in patients receiving a VAD (9-16 %).⁴ Due to elevated LA pressure, persistent foramen ovale (PFO) may not be detected during pre-op evaluation, thus an additional re-evaluation intraoperatively is suggested.

PATIENT RESULTS:

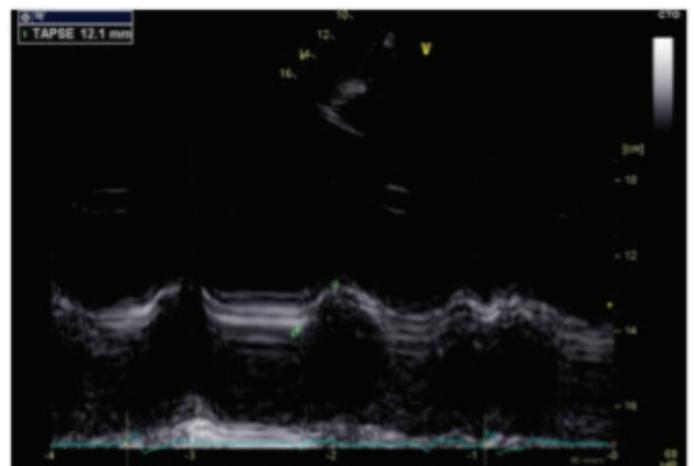
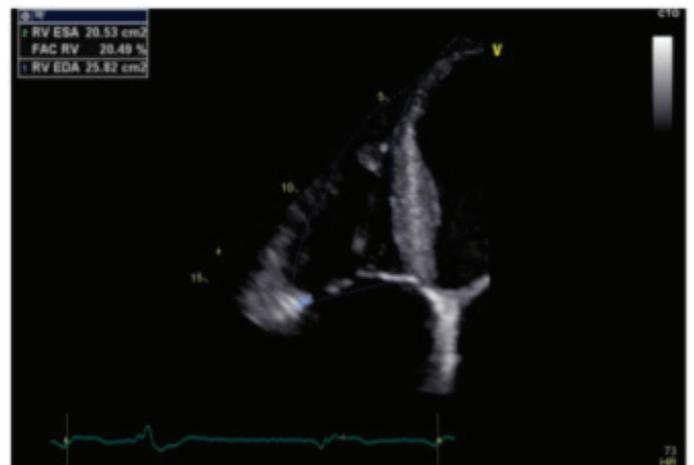
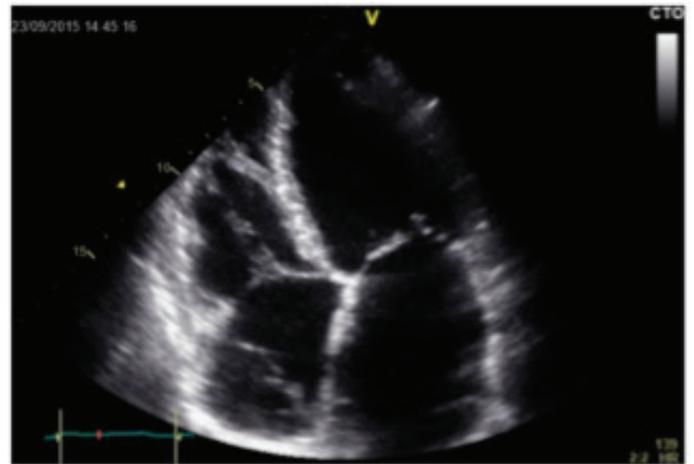
- 1) LV function was severely impaired with LVEF 10 %. The LV was dilated (LVEDD 72 mm) with general hypokinesis.
- 2) Due to LV-dilatation, the mitral valve showed secondary, moderate regurgitation with tethering of the leaflets. Valvular abnormality of the aortic valve was excluded.
- 3) Right heart chambers were also dilated (RVEDD 60 mm, RA 25 cm², RV/LV ratio 0.83). TAPSE was measured to be 12 mm in apical 4CH and S' was 10 cm/s. In this case, the FAC was 26 % and the TEI index was 1. These results indicated some RV dysfunction.
- 4) Color Doppler showed moderate TR. Systolic PA pressure was estimated to be 55-60 mmHg.

CONCLUSION:

Our findings on ECHO showing a dilated LV with severely reduced function, moderate TR and signs of pulmonary hypertension (PH) with only moderately impaired RV-function, although not meeting the critical threshold of concern for RV failure. This was confirmed with right heart catheterization which demonstrated postcapillary pulmonary hypertension with PAm_{mean} 30 mmHg and PCW 15 mmHg. Based on these results along with the overall clinical picture, repeated hospitalizations, and reduced quality of life - we decided in our interdisciplinary discussion to refer this patient to an implanting center for a HeartWare™ HVAD™ implantation.

References

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Brief Statement: HeartWare™ HVAD™ System

Indications

The HeartWare™ Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The HeartWare System is designed for in-hospital and out-of-hospital settings, including transportation via fixed wing aircraft or helicopter.

Contraindications

The HeartWare System is contraindicated in patients who cannot tolerate anticoagulation therapy.

Warnings/Precautions

Proper usage and maintenance of the HVAD™ System is critical for the functioning of the device. Never disconnect from two power sources at the same time (batteries or power adapters) since this will stop the pump, which could lead to serious injury or death. At least one power source must be connected at all times. Always keep a spare controller and fully charged spare batteries available at all times in case of an emergency. Do not expose batteries to excessive shock or vibration since this may affect battery operation. Do not grasp the driveline cable as this may damage the driveline. Do not pull, kink or twist the driveline or the power cables, as these actions may damage the driveline. Special care should be taken not to twist the driveline including while sitting, getting out of bed, adjusting the controller or power sources, or when using the shower bag. Do not disconnect the driveline from the controller or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.

Potential Complications

Implantation of a Ventricular Assist Device (VAD) is an invasive procedure requiring general anesthesia, a median sternotomy, a ventilator and cardiopulmonary bypass. There are numerous risks associated with this surgical procedure and the therapy including but not limited to, death, stroke, device malfunction, peripheral and device-related thromboembolic events, bleeding, infection, hemolysis and sepsis.

Refer to the "Instructions for Use" for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions and potential adverse events prior to using this device. The IFU can be found at www.heartware.com/clinicians/instructions-use.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.