Permanent Left Ventricular Assist Device for End-Stage Heart Failure: First Successful Implantation of the Axial Flow HeartMate II Rotary Pump as Destination Therapy for Heart Failure in Israel

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Despite significant advances in the management of heart failure, extremely ill patients may not be salvageable by advanced medical therapy and for them other treatment options are required, mainly heart transplantation. The main limiting factor for heart transplantation is the worldwide shortage of donor hearts. Accordingly, mechanical solutions such as left ventricular assist devices were developed to "bridge" the critically ill patient and gain time until a heart organ donor is available. Since "bridging" by LVAD has proven to be safe and effective for rather extended periods [1], the LVAD was recently approved for "destination therapy," namely, a permanent mechanical solution for patients with end-stage heart failure who are not eligible for heart transplantation or where heart transplantation is not available.

We present a patient with severe decompensated heart failure and imminent mortality who underwent implantation of a left ventricular assist device as destination therapy. The patient was the first in Israel to receive the new implantable HeartMate II device.

Patient Description

A 67 year old man who suffered from heart failure for 7 years was admitted with acute decompensated heart failure. Coronary angiography 4 years previously had shown no evidence of coronary artery disease. He had undergone implantation of a cardiodefibrillator 3 years earlier due to recurrent syncope. He had no other systemic illness, but serology for hepatitis C was positive. On examination the patient was hemodynamically unstable with signs of hypoperfusion and volume overload; blood pressure was 70/40 mmHg and sinus tachycardia 100/minute. On right heart catheterization the pulmonary capillary wedge pressure was 50 mmHg and cardiac index 1.0 L/min/M^2 [Table]. Echocardiography showed poor systolic function, dilated cardiac chambers and severe mitral regurgitation. The patient was treated with inotropic drugs and diuretics and an intra-aortic balloon pump was inserted. Over several weeks, attempts to wean him from this therapy failed as he developed repeated episodes of pulmonary edema requiring mechanical ventilation, and had several episodes of ventricular fibrillation from which he was successfully reverted.

Table 1. Hemodynamic measurements

Hemodynamic variable	Pre-LVAD	Post-LVAD (optimal)
Resting heart rate (beats/min)	80 (paced)	80 (paced)
Resting blood pressure (mmHg)	70/40	100/80
Cardiac index (L/min/M2)	1.0	3.1
Pulmonary capillary wedge pressure (mmHg)	50	17
LV end-diastolic dimension (mm)	77	54 (3 months later)
LV end-systolic dimension (mm)	72	49 (3 months later)
LA diameter (mm)	62	47 (3 months later)
Mitral regurgitation (echo) (grade)	grade 4	grade 2 (3 months later)

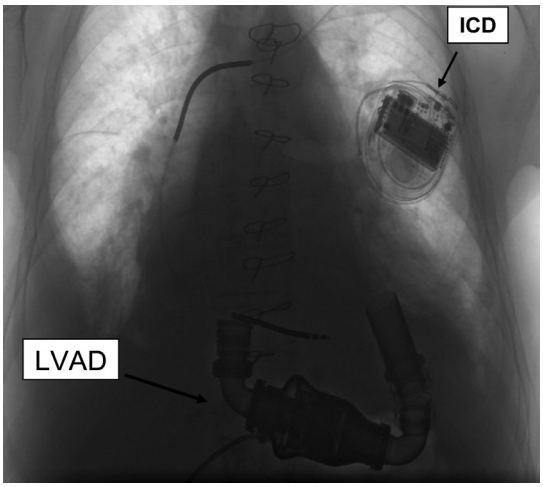
The patient was considered ineligible for heart transplantation due to his age and the relative contraindication of hepatitis C antibody. After 2 weeks dependence on an intra-aortic balloon pump, a HeartMate II (Thoratec Corporation) LVAD was implanted as destination therapy [Figure A]. Following implantation and adjustment of the device, hemodynamics improved considerably, with a striking increase in cardiac output, reduction in wedge pressure and a decrease in echocardiographic ventricular dimensions [Table]. Adjustment of the device (device set at 9200 rpm) allowed an acceptable basic aortic flow with an aortic valve opening approximately every third beat. The patient was discharged from hospital almost 12 weeks after admission (7 weeks after LVAD implantation) in good condition and able to perform daily activities without significant limitations. The anticoagulation and anti-platelet medications prescribed were coumadin, aiming for an international normalized ratio of 2-3, and aspirin.

The patient is maintaining good health 12 months after implantation and is in New York Heart Association Functional Class 1 after a graded but intensive rehabilitation program. The driveline exit wound is managed daily by the primary care team and is supervised by our heart failure clinic team.

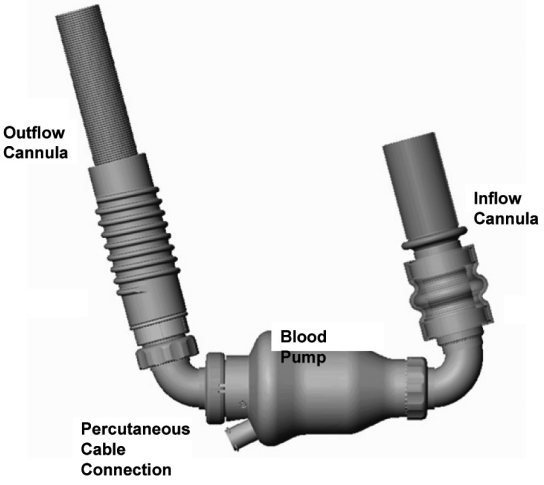
Comment

As the prevalence of heart failure increases and the shortage of donor hearts continues, the option of LVAD as desti-

LVAD = left ventricular assist device



[A] Chest X-ray, showing left ventricular assist device (LVAD) (HeartMate II) in supra-diaphragmatic position. The implantable cardioverter defibrillator (ICD) is also seen.



[B] Heartolate II implantable device

nation therapy will continue to evolve. Both in Europe and in the United States, specific LVAD devices have been approved for implantation in these patients as destination therapy. In the REMATCH trial [2], end-stage heart failure patients who had "optimal medical therapy" without LVAD had very poor survival rates, in the order of 75% mortality rates at 12 months. In contrast, in the "post REMATCH trial," one year survival in LVAD patients was more than 60% [1]. Improving patient selection and improved mechanical devices may have allowed for this trend and for long-term further improvement [3]. While most of the literature relates mostly to the older generation of the pulsatile HeartMate devices (VE LVAD), this current device, the HeartMate II, represents a new generation of axial flow device. Through the rotation of a single moving part, the HeartMate II pumps blood from the left ventricle apex through an inlet and to the ascending aorta through an outflow canula. An external, belt-worn system controller and battery [Figure B] are attached to the implanted pump via a small, flexible percutanous cable. The HeartMate II is a smaller device than the older generation of pulsatile flow devices and is less associated with mechanical dysfunction. In spite of technological progress, LVAD implantations are still associated with high morbidity and mortality, mainly bleeding, infection and thromboembolic events for which patients require both anticoagulation and anti-platelet therapy [4,5]. The cost of the device (approximately US$ 75,000) is a major limiting factor in the wider application to the gravely ill heart failure population. On the other hand, it is difficult to ignore the very poor outcome and high early mortality of end-stage heart failure without this mechanical solution. The Israeli National Council for Prevention and Treatment of Heart Diseases has recently recommended including the HeartMate II LVAD in the national basket of health services and has set up guidelines for patient selection with the aim of balancing medical, ethical and financial aspects of such therapy.

In summary, we present a patient who exemplifies a new challenge in the treatment of end-stage heart failure patients. As technology will improve, the LVAD as destination therapy may be a practical and feasible solution for some of these patients. Guidelines are being developed to recommend proper selection of patients who may benefit from this novel therapy.

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To confront a person with his own shadow is to show him his own light

Carl G. Jung (1875-1961), Swiss psychiatrist, influential thinker, and founder of analytical psychology. Jung's unique and broadly influential approach to psychology emphasizes understanding the psyche through exploring the worlds of dreams, art, mythology, world religion and philosophy