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Review
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THE FIRST CLINICAL USE OF HEART MATE II LEFT VENTRICULAR ASSIST SYSTEM IN CROATIA AS A BRIDGE-TO-TRANSPLANT: A CASE REPORT

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Summary

Left ventricular assist systems (LVAS) are widely accepted nowadays as a successful tool for bridging the patients with end-stage heart failure to heart transplantation (BTT). The second generations of axial-flow devices, such as the HeartMate II, provide a safe and reliable, as well as an effective hemodynamic support in such patients, offering them an improved quality of life; they are furthermore associated with a very low rate of device malfunction or infection requiring device change. We report here of our first three patients with the implanted HM II LVAS as a BTT.

Key words: heart failure; LVAD; dilatative cardiomyopathy

Introduction

Currently, approximately 14 million people in Europe suffer from heart failure; this number is forecast to increase to 30 million by the year 2020 and is associated with high mortality and morbidity rates [1,2]. Nearly 40 % of heart failure patients will die within one year of their first hospitalization, whilst only 25 % of men and 38 % of women will survive more than five years following the diagnosis [2]. Heart transplan-

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tation is still the most successful treatment option for patients with advanced heart failure refractory to medical therapy. The REMATCH (Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure) trail demonstrated a survival advantage for the left ventricular assist devices (LVADs) therapy over optimal medical management for patients with advanced heart failure, who were not eligible for transplantation [3]. LVADs are nowadays widely accepted as a successful tool for bridging the patients with end-stage heart failure to heart transplantation (BTT) [4]. As a consequence of limited donor availability, waiting lists for heart transplantation (HTx) are growing as are support durations for VADs in BTT programmes [5]. Although the first generation of pulsatile devices have shown good results as BTT device, they are – to a certain extent – limited in their design and mechanical durability. These limitations include a large pump size; the need for extensive surgical dissection for implant; a larger body habitus of the recipient; and audible pump operation [5,6]. The second generation of smaller axial-flow devices that produce a continuous flow, such as the HeartMate II (HM II), provide a safe and reliable, as well as an effective hemodynamic support in patients awaiting transplantation, with improved quality of life, and are associated with a very low rate of device malfunction or infection requiring device exchange.[7] In this paper, we report our first three patients with implanted HM II left ventricular assist system (LVAS) as a BTT.

The description of HeartMate II Left Ventricular Assist System

HeartMate II LVAS (Thoratec Corporation; Pleasanton, California) is an axial-flow rotary ventricular assist system composed of a blood pump, a percutaneous lead, an external power source and a system driver with a spinning motor as its only moving part (Fig. 1). The HM II has an electromagnetic motor contained in the pump housing and creates a magnetic field that spins the rotor and imports torque to its internal bladed impeller. No compliance chamber or valves are necessary, and a single driveline exits the right lower quadrant of the abdomen. The inlet cannula is placed in the apex of the left ventricle, and the outflow cannula is anastomosed to the ascending aorta. The small, 124 mL LVAS greatly reduces the amount of dissection required to crate a nesting pocket and is placed intraperitoneally or extraperitoneally. The pump is designed to spin at 6,000 to 15,000 rotations per minute and to produce as much as 10 L/min of cardiac output.

The surgical procedure

We are describing the standard operative protocol that was – with a few differences – used in all three patient cases. A median sternotomy was performed, and a cardiopulmonary bypass (CPB) was instituted. The inflow cannula was first

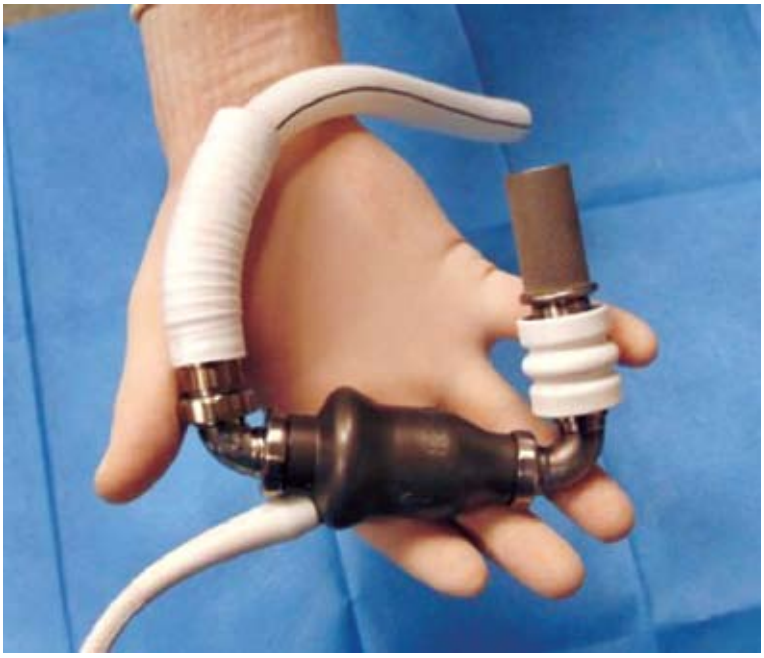

Fig. 1: LVAS

placed in the left ventricular apex after apical coring. Sutures were used to secure the sewing ring to the ventricle under direct visualization. The inlet cannula was inserted into the swing ring and secured. The outflow graft was then anastomosed via outflow conduit to the ascending aorta in an end-to-side fashion, and the pump was activated. The pump was placed parallel to the diaphragm in a previously made pocket within the muscles of the abdominal wall. Following de-airing, the patient was weaned from the CPB in the usual fashion.

Case report 1

The first HeartMate II was implanted in a 59-year-old man with a history of ischemic cardiomyopathy, glucose intolerance and renal insufficiency. Four years prior to the operation, he underwent a triple coronary artery bypass grafting with the aneurysmoraphy of the left ventricle due to two myocardial infarctions. Six months before the operation, his condition started to deteriorate due to the global cardiac decompensation and the impairment of the renal function with the New York Heart Association functional class (NYHA) III/IV. A control echocardiogram revealed an ejection fraction around 0.20, with global hypokinesis. In addition, he had extremely dilated left ventricle, dilated atria and moderate mitral regurgitati-

on. His estimated pulmonary artery pressure was 31 mmHg, pulmonary vascular resistance 1.57 wood units with an ejection fraction of the right ventricle 0.35. With aggressive conservative management, the patient was – prior to the operation – in NYHA class II with improved renal function and listed as a candidate for a heart transplant. In June 2009, he underwent the implantation of HeartMate II LVAS. Early after the operation, the patient was hemodynamically stable, however with a higher output on drainage tubes, which finally required a revision and hemostasis next morning. After the procedure, the patient was hemodynamically unstable on high-dosage inotropic agents, unresponsive to vasopressors, and with a progression to low cardiac output syndrome. Subsequently, he became rhythmically unstable and developed ventricular fibrillation, which could not be converted after multiple defibrillation and medication support. He transesophageal echocardiography revealed the akinesia of the right ventricle, with severe tricuspid regurgitation. The patient eventually succumbed to multi-organ failure on the 2nd postoperative day due to acutely developed right-heart failure. The autopsy revealed an acute myocardial infarction of the right ventricle.

Case report 2

The second HeartMate II was implanted in a 57-year-old woman with a history of dilated cardiomyopathy of unknown cause, which was diagnosed 10 years earlier. Within the last year, she was on several occasions admitted to hospital due to cardiac decompensation and minimal tolerance to any physical activity. The echocardiogram revealed an extremely dilated and hypokinetic left ventricle with ejection fraction 0.15, and severe mitral regurgitation. Her estimated pulmonary artery pressure was 45 mmHg, and her pulmonary vascular resistance was 2.7 wood units. Her right ventricle was moderately dilated with ejection fraction 0.35. The patient was listed for a heart transplant and was recognized as a candidate for HM II LVAS that was implanted in October 2009. The initial postoperative transthoracic echocardiogram revealed that the aortic valve was opening with lower pump speeds, so the pump rate was maintained at 9,500 rpm. The histological examination of the myocardial plug revealed myocyte hypertrophy, clusters of lipofuscin pigment without any sign of myocarditis. Early postoperatively, there was occurrence of gastrointestinal bleeding that was treated with endoscopical coagulation without further complications. We also noticed local infection around the percutaneous lead, with positive strains of *Corynebacterium spp* and *Staphylococcus aureus*; the infection was successfully treated with systemic antibiotics and aggressive wound care. On several consecutively preformed transthoracic echocardiographies, the ejection fraction of the left ventricle was around 0.40 with normal position and flow of inlet cannu-

la, paradoxical septal motion and moderate to severe tricuspid regurgitation. The anticoagulation treatment was started by intravenous heparin until we achieved international normalized ratio 2.5 – 3.5 with oral warfarin. The patient was given aspirin as well. No other significant clinical events occurred during the postoperative period, and she begun an aerobic exercise programme approximately 1 week following the operation. During the hospital stay, HM II was functioning properly, and the patient was a month and a half after the operation sent home. (Fig. 2) She remains in NYHA class I with no symptoms and is awaiting the transplantation more than 4 months after the implantation.

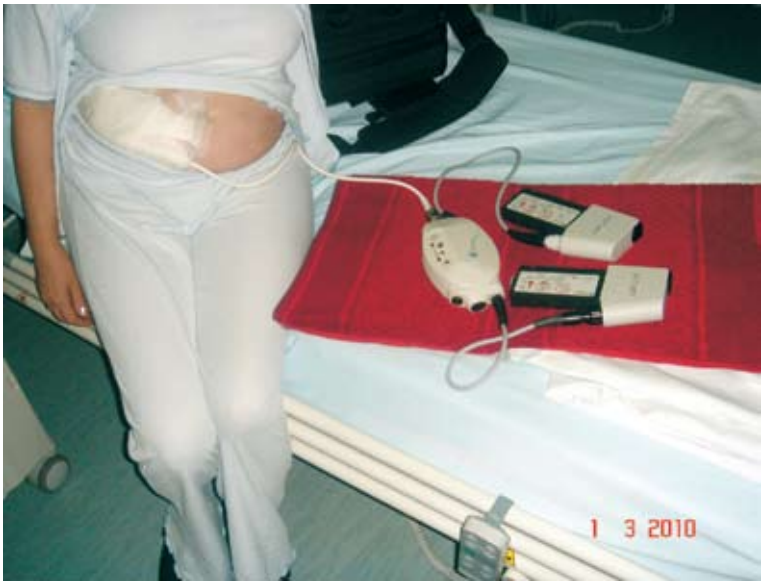

Fig. 2: Our patient with HM II

Case report 3

A 62-year-old woman with a history of hypertension, hyperlipidemia, diabetes and smoking also suffered an ischemic stroke 20 years ago, which was resolved completely. Two months prior to the implantation of HeartMate II LVAS, she was admitted to our hospital because of cardiac decompensation due to dilated cardiomyopathy of unknown cause. At that time, transthoracic echocardiography was used to reveal ejection fraction of the left ventricle around 0.20, with severe mitral regurgitation, without any apparent sign of pulmonary hypertension. A month before the implantation procedure, she was repeatedly hospitalized due to global heart decompensation and NYHA class III-IV. Despite optimal medical therapy,

the patient's clinical state started to deteriorate, and she had symptoms even while resting and with minimum exertion. In February 2010, she underwent the implantation of HeartMate II LVAS. Early after the operation, the patient was hemodynamically stable, the initial echocardiogram revealed occasional opening of the aortic valve, good position of the inflow cannula within the dyskinetic septum. Additional studies approximately three weeks after implantation revealed that the optimal pump speed was 8,800 rpm (4,4 L/min), which has been maintained since then. The patient was discharged home 4 weeks after the implantation. No adverse clinical events have occurred so far.

Discussion

A main therapeutic goal in treating patients with advanced heart failure is to enhance their quality of life and functional capabilities. Several studies showed that the implantation of a continuous-flow left ventricular assist device, as compared to pulsatile-flow device, has significantly improved the probability of survival free of stroke and reoperation due to device malfunction in patients with advanced heart failure, in whose cases the current therapy had failed, and who were ineligible for transplantation [3,8]. The continuous flow devices, such as HM II, are smaller than the previous ones and have fewer mobile parts, thereby increasing their mechanical durability. Regarding adverse events, according to *Laphor et al.*, the bleeding remains a serious problem with incidences of more than 50 %, as are infectious complications of the drive-line, as noticed in our patient group, which – when well treated – are not life-threatening [9]. Therefore, the authors suggest a less aggressive anticoagulation protocol in view of a common absence of pump thrombosis. They also concluded that the HM II, while used for BTT, might also be used for destination therapy. We have presented the first three patients in Croatia to be supported with HM II as a bridge-to-transplant. One patient succumbed an acutely developed right heart failure, whilst the other two were, without any complications, more than 4 and 1 month post-implant respectively, successfully rehabilitated.

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Sažetak

Rana klinička iskustva sa dugoročnom potporom (Heart Mate II)

Uređaji za potporu lijevom srcu (LVAS – left ventricular assist system) su danas prihvaćeni kao uspiješno sredstvo za premoštenje bolesnika u završnom stadiju zatajivanja srca do transplantacije. Druga generacija aksijalnih pumpi, kao što je HeartMate II, pruža sigurnu i učinkovitu hemodinamsku potporu takvim bolesnicima, poboljšavajući kvalitetu života. Danas su ti uređaji povezani sa niskom inicidencijom malfunkcije ili infekcije koje bi zahtijevale zamjenu. Prikazujemo naša tri bolesnika kojima je ugrađen HeartMate II LVAS kao premoštenje do transplantacije.

Ključne riječi: HeartMate II LVAS; premoštenje do transplantacije; zatajivanje srca