Postoperative Outcomes of the Largest HeartMate-II Experience in Turkey

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ABSTRACT

Introduction. HeartMate II (HMII; Thoratec Corporation, Pleasanton, Calif, United States) is a continuous-flow pump approved by the Food and Drug Administration (FDA) for bridge-to-transplantation (BTT) since 2008 and for destination therapy (DT) since 2010. Herein, we present the postoperative outcomes of HMII implantation due to end-stage heart failure in our center.

Methods. Twenty-eight patients (mean age, 51.2 ± 8.7 years; 1 female) were implanted with the HMII between August 2012 and August 2014. Indications were dilated (n = 18) and ischemic (n = 10) cardiomyopathy. The intended treatment was BTT in 24 and DT in 4 patients. Preoperative clinical status was International Registry for Mechanical Circulatory Support (INTERMACS) 2, 3, and 4 in 6, 14, and 8 patients, respectively. The procedure was performed via conventional sternotomy under cardiopulmonary bypass. Heparin, acetylsalicylic acid, and warfarin were used for postoperative anticoagulation.

Results. Mean duration of support was 326 days (median, 272). Three patients underwent heart transplantation and 22 remain on pump support. One patient died before discharge due to respiratory failure and 2 others died following a cerebral bleeding 248 and 265 days postoperatively, respectively. The survival rates at 6 and 12 months were 96% and 90%, respectively. Temporary right ventricular failure was observed in 2 patients. Two patients had pump thrombosis treated with anticoagulation management or pump exchange, whereas another patient who had aortic root thrombosis underwent reoperation for removal of the thrombus.

Discussion. Mechanical circulatory support with HMII axial flow pump seems to be effective and may provide good survival rates compared with optimum medical management and old-generation devices. Patient selection and timing of implantation are crucial for success.

LEFT VENTRICULAR ASSIST DEVICE (LVAD) implantation is a major part of the management of end-stage heart failure. According to an analysis of the International Registry for Mechanical Circulatory Support (INTERMACS), the 6-month cumulative survival for LVAD patients (those who are alive on the device, who have undergone transplantation, or who have had their device explanted due to myocardial recovery) is approximately 85%–90% [1]. In terms of quality of life (QOL), patients have better functional status after LVAD implantation [1]. The biggest contribution to this success can be attributed to the increasing experience in mechanical circulatory

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0041-1345/15
http://dx.doi.org/10.1016/j.transproceed.2015.04.046

Table 1. Demographic Data and Preoperative Characteristics of the Patients

Demographic Data	No. or Mean Value	%
Gender		
Male	27	97
Female	1	3
Etiology		
ICMP	10	36
DCMP	18	64
Diabetes	6	21
Mean T. bilirubin	1.08 mg/dL	NA
Creatinine	0.85 mg/dL	NA
Albumin	3.4 mg/dL	NA
Na	137.7 mEq/L	NA
Mean LVEDD	7.02 mm	NA
Mean LVEF	21.6%	NA
Mean SPAP	45.1 mm Hg	NA
Mean TAPSE	14.3 mm	NA
INTERMACS		
Level 2	6	21
Level 3	14	50
Level 4	8	29
Target		
BTT	24	85
DT	4	15

Abbreviations: ICMP, ischemic cardiomyopathy; DCMP, dilated cardiomyopathy; T, total; LVEDD, left ventricular end-diastolic diameter; LVEF, left ventricular ejection fraction; SPAP, systolic pulmonary artery pressure; TAPSE, tricuspid annular plane systolic excursion; NA, not available.

support (MCS). Continuous-flow (CF) pumps, which are more durable, less invasive, and require lower doses of anticoagulant therapy than earlier models, are being implanted with lower complications in the current era [2,3]. Such improvements have given surgeons the confidence to use these pumps in waiting list patients who are in poor clinical condition, and to expand the use of destination therapy (DT) [4].

HeartMate II (HMII; Thoratec Corporation, Pleasanton, Calif, United States) is an intracorporeal axial flow pump. This pump received Food and Drug Administration (FDA) approval for bridge-to-transplantation (BTT) in 2008 and for DT in 2010 [2,5].

The aim of this study is to analyze early and mid-term outcomes of LVAD (HeartMate II) implantation due to end-stage heart failure.

MATERIAL AND METHODS

This study includes all 28 patients who underwent HMII implantation due to end-stage heart failure between August 2012 and August 2014. Data was obtained retrospectively using the file scanning method. The mean age was 51.2 ± 8.7 (range, 33–67) years and only 1 patient was female. The aim of therapy at the time of implantation was BTT in 24 patients and DT in 4 patients. Patient selection was performed according to clinical state (INTERMACS level). Regarding the strategy of device selection, HMII was implanted in patients with high body surface area or with the intent of DT. The reason for DT was advanced age in 2 patients and history of peripheral vascular disease in 1 patient. Other demographic data and preoperative characteristics are shown in Table 1.

Table 2. Major Complications After LVAD Implantation

Results	No.	%	Events/Patient/Y
Re-exploration for bleeding	3	10	0.118
Hemodialysis	2	7	0.078
Prolonged ventilatory support	1	3	0.039
Right-sided heart failure (inotropic support >14 d)	2	7	0.078
Sepsis	2	7	0.078
Driveline infection	2	7	0.078
Pocket infection	3	10	0.118
Ischemic CNS event	1	3	0.039
Other thrombotic event (aortic root thrombosis)	1	3	0.039
Hemorrhagic CNS event	3	10	0.118
Pump thrombosis	2	7	0.078
Outcome			
Ongoing support	22	83	–
Tx	3	10	–
Death	3	10	–

Abbreviations: CNS, central nervous system; Tx, transplantation.

Procedure

All patients were operated on under general anesthesia using a shorter incision than conventional median sternotomy. For pump placement, an extra-pericardial intrathoracic pocket was prepared before pericardiotomy. The LVAD outflow graft was anastomosed to the ascending aorta using an off-pump technique. Left ventriculotomy was performed on the apex of the heart, 2–3 cm lateral to the left anterior descending artery (LAD). After careful examination of the left ventricle to check for thrombus, the apical cannula ring was placed using separated 3/0 pledgeted propylene sutures. De-airing was performed carefully after pump attachment to the apex, and the pump was then connected to the graft. The right lateral zone of the abdominal wall was used for the driveline exit for all patients. Covered segments of driveline were always kept under the skin and the cable was fixed to the skin with a nonabsorbable suture to prevent unwanted movement. The pump was started with low speed after weaning from cardiopulmonary bypass (CPB).

Postoperative Management

After weaning from CPB, the most important issue was the systolic function of the right ventricle (RV). Inotropic support (using dopamine, dobutamin, and norepinephrine) and pump speed were adjusted according to left ventricular filling and the position of the interventricular septum. In the event of pulmonary hypertension, inhaled nitric oxide (NO) and vasodilator agents were started just prior to weaning from CPB. One of the main goals was to maintain pulsatilty of the arterial pressure.

In the absence of bleeding, hemodynamic problems, or requirement for inhaled NO, patients were extubated on the first postoperative day (POD). Unfractionated heparin was normally started after 24 hours, based on coagulation parameters. Target activated partial thromboplastin time (aPTT) was 40–60 seconds. Acetylsalicylic acid (ASA) and warfarin were initiated on POD3. Target international normalized ratio (INR) was between 2.5 and 3.0. ASA dose was regulated according to activity as measured using an aggregometer (Roche Multiplate, Roche, Basel, Switzerland). Titration of the warfarin dose, training patients for pump care, and dressing the driveline exit site were the main goals after the intensive care period.