Outcomes and Readmissions After Continuous Flow Left Ventricular Assist Device: Heartmate II Versus Heartware Ventricular Assist Device

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ABSTRACT

Introduction. Donor organ shortage is still a problem for heart transplantation. Only 10% of patients in waiting list undergo heart transplantation. Over the last 5 years, 2 different continuous flow pumps, the HeartMate II and the HeartWare, have been successful clinically in the alternative treatment of patients with end-stage heart disease.

Methods. Fifty-five patients underwent left ventricular assist device implantation between 2011 and 2014. Patients were followed on pump support for complications and intraoperative outcomes. Potential device-related complications include infections, bleeding liver dysfunction, renal dysfunction, right ventricular failure, stroke, thromboembolism, gastrointestinal bleeding, and wound infection.

Results. The only preoperative significant difference between groups in the study was age; the Heartmate II group were significantly older than Heartware group. There were no differences in gender, body mass index, or body surface area. The Heartware has a better 1-year survival rate, although the difference was not significant. Patients with Heartmate II had a higher incidence of gastrointestinal bleeding and driveline infection. The Heartware group had a higher incidence of stroke and pump thrombosis.

Conclusions. The Heartmate II and Heartware are comparable in most respects such as survival, intraoperative features, and major complications.

HEART failure (HF) is a major public health issue, with a prevalence of >5.8 million in the United States and >23 million worldwide; the prevalence is increasing. Every year in the United States, >550,000 individuals are diagnosed with HF for the first time. Despite advances in therapy and management, HF remains a deadly clinical syndrome. In the United States, 1 in 8 deaths has HF mentioned on the certificate, 20% of which have HF as the primary cause of death. Based on the Framingham Heart Study, the 30-day mortality is around 10%, the 1-year mortality is 20%–30%, and the 5-year mortality is 45%–60% [1]. After hospitalization, the prognosis worsens. From a community study in Worchester, the 5-year mortality was >75% after the first hospitalization for HF [2].

Despite developments in medical and surgical therapy, heart transplantation remains the gold standard therapy for patients with end-stage HF. However, donor organ shortage is a problem in heart transplantation. Only 10% of patients in waiting list actually undergo heart transplantation [3].

Over the past 20 years, major advances have been made in the development of new mechanical technologies, both to support the failing heart until a transplant occurs and to serve as permanent cardiac support when cardiac transplantation is not an option. Over the last 5 years, 2 different

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continuous flow pumps, the HeartMate II (HMII; Thoratec Corp., Pleasanton, CA) and the HeartWare Ventricular Assist Device (HVAD; HeartWare, Inc., Miami Lakes, FL) have been successful clinically in the alternative treatment of patients with end-stage heart disease, not only as bridge to transplant but also for chronic support [4].

This paper compares outcomes between Heartware and HMII devices within a single institution.

METHODS

We enrolled 55 patients who underwent left ventricular assist device (LVAD) implantation between 2011 January and 2014 August at Akdeniz University Hospital in Turkey. Thirty-five patients underwent HVAD implantation and 20, HMII. Device selection was based on patient characteristics and surgeon preference.

First HVAD implantation was performed in January 2011 and the first HMII was implanted August 2012. Thirty-five patients received the device as bridge to transplantation and 20 as destination therapy.

Before surgery, a triple drug regimen consisting of vancomycın, levofloxacinan, and fluconazole infection prophylaxis were administered to all patients and limited 48 hours after surgery.

LVAD implantations were performed through a median sternotomy, with cardiopulmonary bypass, through cannulation of ascending aorta and right atrium on beating heart without cardioplegic arrest.

Intravenous heparin application to maintain the activated partial thromboplastin time between 50 and 70 seconds was administered after 24–48 hours according to chest tube drainage. After chest drain removal and tolerance of oral medication 300 mg of aspirin and warfarin administered to maintain a target international normalized ratio (INR) between 2 and 3 for both devices.

Table 1. Clinical Characteristics of Patients Before Left Ventricular Assist Device Implantation

	All Patients (n = 55)	Heartware (n = 35)	Heartmate II (n = 20)	*P*
Gender				1
Male	48	31	18	
Female	7	5	2	
BMI	25.83 ± 4.34	25.49 ± 4.61	26.42 ± 3.86	.436
BSA	1.87 ± 1.77	1.86 ± 0.17	1.89 ± 0.18	.542
Age	49.84 ± 10.82	47.43 ± 10.782	54.05 ± 9.79	.028
Diagnosis				.759
DCMP	29	19	10	
ICMP	26	16	10	
Mean follow-up time	417.55 ± 281.85	495.06 ± 298.36	281.90 ± 198.85	.012*
Purpose of implantation				.03
BTT	35	26	9	
DT	20	9	11	
INTERMACS				.03
1	3	2	1	
2	21	13	8	
3	30	19	11	
Echocardiographic evaluation				
EF	22.31 ± 4.03	23.60 ± 5.45	20.00 ± 3.81	.682
LA dimensions	5.18 ± 0.77	5.42 ± 0.82	5.4 ± 0.55	.073
LVEDD	6.88 ± 0.85	6.88 ± 1.29	7.06 ± 0.66	.226
LVESD	6.12 ± 0.86	6.04 ± 1.25	6.4 ± 0.66	.387
PAP	51.69 ± 14.12	49.32 ± 7.86	50.86 ± 19.85	.082
TAPSE	16.21 ± 3.22	14.00 ± 3.39	14.2 ± 2.9	.551
RVFAC	32.76 ± 12.15	31.40 ± 12.44	31.2 ± 13.1	.730
Laboratory tests				
Hemoglobin	12.00 ± 1.86	12.38 ± 2.98	12.22 ± 2.16	.337
Platelets	248,874 ± 103,993	271,400 ± 113,654	198,820 ± 117,948	.336
BUN	26.09 ± 14.99	27.20 ± 15.93	39.80 ± 29.67	.820
Creatinine	1.19 ± 0.48	1.08 ± 0.48	1.81 ± 0.82	.416
Serum Na	136.62 ± 4.68	138.8 ± 1.67	132.6 ± 6.8	.580
Serum K	4.38 ± 0.62	4.00 ± 0.43	4.82 ± 0.45	.400
Serum total protein	6.05 ± 0.78	5.93 ± 1.15	6.08 ± 1.17	.937
Serum albumin	3.46 ± 0.58	3.30 ± 0.39	3.44 ± 0.51	.859
Serum direct bilirubin	1.23 ± 1.35	2.44 ± 1.25	1.95 ± 2.00	.195
Serum total bilirubin	1.83 ± 1.76	3.58 ± 1.69	2.57 ± 1.83	.294
ICU stay	12.6 ± 10.7	10.4 ± 3.3	11.6 ± 5.1	.294
Total duration of hospitalization	33.0 ± 29.7	32.2 ± 10.7	62.6 ± 79.3	.164

Abbreviations: BMI, body mass index; BSA, body surface area; BTT, bridge to transplant; BUN, blood urea nitrogen; DCMP, dilated cardiomyopathy; DT, destination therapy; EF, ejection fraction; ICU, intensive care unit; ICMP, ischemic cardiomyopathy; LA, left atrium; LVEDD, left ventricular end-diastolic diameter; LVESD, left ventricular end-systolic diameter; PAP, pulmonary arterial pressure; TAPSE, tricuspid annular plane systolic excursion; RVFAC, right ventricular fractional area change.
*Indicates significant value.