Initial Clinical Experience With the HeartWare Left Ventricular Assist System: A Single-Center Report

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Background. **The HeartWare ventricular assist device (HVAD) system (HeartWare International Inc, Framingham, MA) is a new centrifugal continuous-flow ventricular assist device. The aim of the present study is to review our institutional experience with this novel device.**

Methods. **We reviewed the files of 50 patients (39 men, 11 women) with a mean age of 50.6 ± 11.8 years (range, 19 to 70 years) who underwent HVAD implantation between July 2009 and November 2011. Two patients underwent HeartWare BIVAD implantation. The underlying heart diseases were end-stage ischemic heart disease (n = 12), acute myocardial infarction (n = 9), dilated cardiomyopathy (n = 27) and acute myocarditis (n = 2). Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) profiles were level 1 (n = 11), 2 (n = 5), 3 (n = 10), and 4 (n = 24).**

Results. **After a cumulative support duration of 11,086 days, Kaplan-Meier analysis revealed a survival of 82.0%, 77.9%, 75.5%, at 1, 12, and 24 months, respectively. Causes of early death were right heart failure (n = 4), multiorgan failure (n = 2), septic shock (n = 2), and major neurologic complications (n = 4). One late death occurred due to a right heart failure. Comparison between patients operated on in cardiogenic shock (INTERMACS 1 and 2) and patients who underwent elective HVAD implantation (INTERMACS 3 and 4) revealed a survival of 61.5% and 44.1% for the INTERMACS 1 and 2 group and 90.3% and 87.1% for the INTERMACS 3 and 4 group at 1 and 12 months, respectively (odds ratio, 4.67; $p = 0.003$). One patient was weaned from the system after 2 years. Eleven patients (22%) were successfully bridged to transplantation. Mean time to transplantation was 209 days (range, 72 to 427 days). Posttransplant survival at the 1-year follow-up was 90.9% (11 patients).**

Conclusions. **Our experience with HVAD shows satisfying results with an excellent posttransplantation survival. Moreover, the stratified survival based on the level of preoperative stability shows better outcomes in patients undergoing elective HVAD implantation.**

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Cardiac transplantation is still considered the gold standard in the treatment of end-stage heart failure. However, the growing incidence of end-stage heart failure worldwide and limited transplant numbers due to the lack of suitable donors have created a significant need for an alternative treatment option [1]. Mechanical ventricular assist devices (VAD) are considered to be one of the most effective and fast evolving alternatives for the treatment of acute or chronic end-stage heart failure. Nowadays in Europe, more VADs are implanted than hearts are transplanted [2].

Although the earlier pulsatile VAD designs have provided adequate cardiac output support, their large size and limited durability have hindered long-term success [1]. Moreover, pulsatile devices have design limitations that derogate their use in every day practice, such as a large pump size, requirement for extensive surgical dissection for implant, the presence of large-diameter percutaneous leads for venting air, and audible pump operation [3]. Continuous-flow devices offer a number of advantages that aid in minimizing complications associated with left VAD (LVAD) support [4]. They are small and durable and promise an optimal quality of life, avoiding bulky and noisy paracorporeal pumps [4].

This trend toward a lower-volume VAD led to the development of continuous-flow pumps with intrapericardial implantation [1–5]. Since the Conformité Européenne certification for Europe in July 2009, we integrated the HeartWare VAD (HVAD) pump (HeartWare International Inc, Framingham, MA) in our VAD program. We now report the results of a reasonable series of patients with HVAD in our institution.

Patients and Methods

The University of Münster Ethical Committee and Institutional Review Board approved the study, and patient consent was waived.

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Abbreviations and Acronyms

ACE = angiotensin-converting enzyme
BIVAD = biventricular ventricular assist device
CNS = central nervous system
COPD = chronic obstructive pulmonary disease
ECMO = extracorporal membrane oxygenation
GI = gastrointestinal
HVAD = HeartWare Ventricular Assist Device
IABP = Intraaortic balloon pump
INTERMACS = Interagency Registry for Mechanically Assisted Circulatory Support
LVEF = left ventricular ejection fraction
MELD = Model for End-Stage Liver Disease
MOF = multiorgan failure
RV = right ventricle
RVAD = right ventricular assist device
SD = standard deviation
VAD = ventricular assist device

Study Population

Between July 2010 and November 2011, 53 HVAD pumps were implanted in 50 patients (39 men, 11 women) who were a mean age of 50.6 ± 11.82 years (range, 19 to 70 years). Baseline demographic data as well as preoperative risk factors are summarized in Table 1. All patients had New York Heart Association class IV symptoms. Nine patients (18%) on our transplant waiting list had to undergo urgent VAD implantation due to progressive organ deterioration. The underlying heart diseases were end-stage ischemic heart disease (n = 12), acute myocardial infarction (n = 9), dilated cardiomyopathy (n = 27), and acute myocarditis (n = 2). The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) profiles were level 1 in 11 patients, level 2 in 5, level 3 in 10, and level 4 in 24.

Table 1. Preoperative Baseline Patient Data

Variables	Mean ± SD or No. (%) (n = 50)
Baseline characteristics	
Age, years	50.62 ± 11.820
Female sex	11 (22)
Body surface area, m^2	1.99 ± 0.27
Body mass index, kg/m^2	26.63 ± 5.82
Hypertension	38 (76)
Diabetes mellitus	7 (14)
Chronic obstructive pulmonary disease	6 (12)
Hyperlipidemia	28 (56)
Preoperative stroke	4 (8)
Peripheral vascular disease	5 (10)
Underlying heart diseases	
Dilated cardiomyopathy	27 (54)
Ischemic cardiomyopathy	12 (24)
Postcardiotomy failure	4 (8)
Acute myocardial infarction	9 (18)
Myocarditis	2 (4)
Preoperative LVEF	0.228 (0.17)
Atrial fibrillation	9 (18)
Implantable cardioverter-defibrillator	24 (48)
Preoperative ECMO	5 (10)
Preoperative intraaortic balloon pump	2 (4)
Previous open heart operation	10 (20)
Preoperative medications	
Intravenous heparin (%)	12 (24)
Phenprocoumon	20 (40)
Acetylsalicylic acid	13 (26)
Clopidogrel	7 (14)
Digitalis	5 (10)
Diuretics	26 (52)
β-Blocker	26 (0.52)
Calcium antagonist	1 (0.02)
ACE inhibitor	25 (0.5)
Antiarrhythmic agent	12 (0.24)
INTERMACS	
1	11 (22)
2	5 (10)
3	10 (20)
4	24 (48)

ACE = angiotensin-converting enzyme; ECMO = extracorporeal membrane oxygenation; INTERMACS = Interagency Registry for Mechanically Assisted Circulatory Support; LVEF = left ventricular ejection fraction; SD = standard deviation.

Device and Implantation Technique

The HVAD is a continuous-flow device consisting of an internal centrifugal-flow blood pump with a percutaneous lead that connects the pump to an external system controller and power source. The pump is designed to draw blood from the left ventricle and propel it through an outflow graft connected to the patient's ascending aorta. The device generates blood flow of up to 10 L/min.

With a displaced volume of only 50 cm^3, the HVAD pump is designed to be implanted in the pericardial space, directly adjacent to the heart (Fig 1). The HVAD pump has only one moving part, the impeller, which spins at rates between 2,400 and 3,200 rpm. The impeller is suspended within the pump housing through a combination of passive magnets and hydrodynamic thrust bearings. This hydrodynamic suspension is achieved by a gentle incline on the upper surfaces of the impeller blades. When the impeller spins, blood flows across these inclined surfaces, creating a "cushion" between the impeller and the pump housing. There are no mechanical bearings or any points of contact between the impeller and the pump housing. The pump's inflow cannula is integrated with the device, ensuring proximity between the heart and the pump itself.