Heart, Lung and Circulation (2014) **23,** 963–969
1443-9506/04/$36.00
http://dx.doi.org/10.1016/j.hlc.2014.04.259

ORIGINAL ARTICLE

Normalisation of Haemodynamics in Patients with End-stage Heart Failure with Continuous-flow Left Ventricular Assist Device Therapy

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Received 13 October 2013; received in revised form 9 January 2014; accepted 13 April 2014; online published-ahead-of-print 3 June 2014

Background New generation continuous-flow left ventricular assist devices (LVADs) utilise centrifugal pumps. Data concerning their effect on patient haemodynamics, ventricular function and tissue perfusion is limited. We aimed to document these parameters following HeartWare centrifugal continuous-flow LVAD (HVAD) implantation and to assess the impact of post-operative right heart failure (RHF).

Methods We reviewed 53 consecutive patients (mean age 49.5 ± 14.1yrs) with HVAD implanted in the left ventricle, at St. Vincent's Hospital, Sydney, between January 2007 and August 2012. Available paired right heart catheterisation ($n = 35$) and echocardiography ($n = 39$) data was reviewed to assess response of invasive haemodynamics and ventricular function to LVAD support.

Results A total of 28 patients (53%) were implanted from interim mechanical circulatory support. Seventeen patients (32%) required short-term post-implant veno-pulmonary artery extracorporeal membrane oxygenation. At 100 ± 61 days post-implant, mean pulmonary artery pressure and mean pulmonary capillary wedge pressure decreased from 38.8 ± 7.7 to 22.9 ± 7.7 mmHg and 28.3 ± 6.4 to 13.4 ± 5.4 mmHg respectively ($p < 0.001$). LV end diastolic diameter decreased from 71.3 ± 12.7 to 61.1 ± 13.7 mm and LV end-systolic diameter from 62.7 ± 12.3 to 53.9 ± 14.4 mm ($p < 0.001$). Aortic regurgitation remained trivial. Serum sodium increased from 133.3 ± 5.7 to 139.3 ± 2.8mmol/L and creatinine decreased from 109.1 ± 42.5 to 74.3 ± 26.2 μmol/L ($p < 0.001$). Across the entire cohort, the six-month survival/transplant rate was significantly lower for RHF patients (72.2%, n = 18) compared to those without (96.9%, n = 35, p = 0.01).

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Conclusions HVAD support improves haemodynamics, LV dimensions and renal function. Following implantation with a centrifugal continuous-flow LVAD, RHF remains a significant risk with a tendency to worse outcomes in the short to medium term.

Keywords Heart failure • Pulmonary hypertension • Heart-assist devices • Left ventricular function • Clinical outcomes • Haemodynamics

Introduction

The left ventricular assist device (LVAD) has become an important bridge-to-transplant intervention for patients with advanced heart failure refractory to inotropic therapy [1–4]. The first generation devices relied on pulsatile-flow designs, delivering blood in a physiological manner [5,6], but were limited by the requirement of highly invasive surgery and poor durability [7–10]. Subsequent continuous-flow left ventricular devices (cfLVADs) have simpler and smaller designs, and are still able to deliver up to 10L/min, equivalent to the older and larger devices [11,12]. As cfLVADs now make up approximately 99% of heart assist devices currently implanted, it is vital to understand the clinical outcomes experienced by patients supported with these devices [13].

Pulmonary hypertension, whether fixed or reversible, is a known risk factor for morbidity and mortality in heart transplant recipients. Under current guidelines, cardiac transplantation is feasible in patients where pulmonary vascular resistance (PVR) can be reduced to below pulmonary hypertension levels [14,15]. While studies show that cfLVAD support can reverse pulmonary hypertension, there is limited data with regard to third generation centrifugal cfLVADs [16–18]. Haemodynamic changes within the right ventricle (RV) should also be considered, as right heart failure (RHF) following cfLVAD implantation, increases the risk of morbidity or mortality [2,19]. The current study documents changes in clinical markers, particularly pulmonary haemodynamics, ventricular function and also systemic status following implantation with centrifugal third generation cfLVADs.

Materials and Methods

Patient Selection

The study population included 53 consecutive patients who received the HeartWare centrifugal cfLVAD (HVAD) from January 2007 through to August 2012 at St. Vincent's Hospital, Sydney, Australia. All but one patient were for a bridge-to-transplant (BTT) indication. Patients were excluded from the study if they required concomitant chronic right ventricular assist device (RVAD) support. The protocol was approved by the Human Research Ethics Committee of St. Vincent's and Mater Health Services, Sydney.

Device Management

At our local centre, following HVAD implantation, echocardiography was utilised to set pump speed with the aim that the aortic valve remained closed throughout the cardiac cycle, allowing the HVAD to provide full circulatory support. Once stable post-implant, all patients were started on a combination of warfarin, aspirin and clopidogrel.

Study Protocol

This single centre retrospective review utilised data that was collected as part of normal clinical practice. Patients that meet criteria for HVAD implantation underwent echocardiography and right heart catheterisation (RHC) to determine suitability for LVAD implantation. Once clinically stable, patients underwent repeat assessment to determine if they should be reinstated onto the cardiac transplant list. Data from patients with paired right heart catheterisation ($n = 35$) and echocardiography ($n = 39$) who survived more than 30 days were studied. Reasons for incomplete datasets for the haemodynamic and echocardiographic cohort are reported in the patient flow diagram (Figure 1). We also reviewed biochemistry ($n = 35$) in particular serum sodium and creatinine, two well-described markers of heart failure prognosis [20]. Right heart failure following HVAD implantation was defined by the requirement of temporary right-sided mechanical circulatory support with veno-pulmonary artery extracorporeal membrane oxygenation (VPA-ECMO) and/or with inotropic/nitric oxide therapy lasting greater than 14 days post-HVAD implantation, according to previous definitions [21]. All recordings (haemodynamic, echocardiographic and biochemical) were taken before and after implantation and prior to heart transplantation.

Statistical Analysis

All continuous data was presented as mean ± SD, and analysed using paired-samples t-tests. Categorical variables were analysed using chi-square tests. Statistical significance was determined at a P value < 0.05. All statistical tests were performed using EZAnalyse Software V3.0 (EZAnalyze, Boston, USA).

Results

Patients

The cohort of 53 patients (mean age 49.5 ± 14.1 years) consisted primarily of men (76%). Patient demographics and baseline characteristics are highlighted in Table 1. A total of 28 (53%) patients were implanted from interim mechanical support (22 from IABP, four on veno-arterial (VA) ECMO and two on both) and 17 (32%) patients required post-operative VPA-ECMO. Patients were categorised according to INTERMACS profile [13] (Profile 1- 'critical cardiogenic