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Hepatic and Renal Function with Successful Long-term Support on a Continuous Flow Left Ventricular **Assist Device**

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Introduction

Data regarding the long-term clinical effects of a continuous flow left ventricular assist device (CF-LVAD) on hepato-renal function is limited. Hence our aim was to assess changes in hepato-renal function over a one-year period in patients supported on a CF-LVAD.

Methods

During the study period 126 patients underwent CF-LVAD implant. Changes in hepato-renal laboratory parameters were studied in 61/126 patients successfully supported on a CF-LVAD for period of one year. A separate cohort of a high-risk group (HCrB) of patients (56/126) with a serum creat > 1.9 mg/dL (168 µmol/ L) (75th percentile) or a serum bil > 1.5 mg/dL (25.65 µmol/L) (75th percentile) was created. Changes in serum creatinine and bilirubin were analysed at regular intervals for this group along with the need for renal replacement therapy.

Results

Baseline creatinine and blood urea nitrogen (BUN) for the entire cohort was 1.4[1.2,1.9 mg/dL] [123.7 (106,168) µmol/L) and 27[20,39.5 mg/dL] [9.6(7.1,14.1) mmol/L] respectively. After an initial reduction at the end of one month [1(0.8,1.2) mg/dL; $88(70,105) \mu mol/L$] (p < 0.0001), a gradual increase was noted over the study period to reach $(1.25[1.1,1.5] \text{ mg/dL}; 106(97.2,132.6) \, \mu\text{mol/L}] (p = 0.0003)$. The serum bilirubin normalised from a [1(0.7,1.55) mg/dL] [17(18.8,25.7) μmol/L) to 0.9(0.6,1.2) mg/dL [15.4(10.2,20.5) μ mol/L] (p = 0.0005) and continued to decline over one year. Improvement in the synthetic function of the liver was demonstrated by a rise in the serum albumin levels to reach 4.3[4.1,4.5][43(41,45) gm/L] at the end of one year (p < 0.0001).

The baseline serum creatinine and bilirubin for the high-risk cohort (HCrB) was 1.9(1.3,2.4) mg/dL [168 (115,212) µmol/L] and 1.7(1.00,2.4) mg/dL [29(17.1,68.4) µmol/L] respectively. The high-risk cohort (HCrB) demonstrated a trend towards higher 30-day mortality (p = 0.06). While the need for temporary renal replacement therapy was higher in this cohort (16% vs. 4%; p = 0.03), only 3% need it permanently. A significant reduction in creatinine was apparent at the end of one month [1.1(0.8,1.4) mg/dL; 97(70.7,123.7) μ mol/L] (p < 0.0001) and then remained stable at [1.3(1.1,1.5) mg/dL; 115(97,132.6) μ mol/L]. Bilirubin demonstrated a 30% decline over one month and then remained low at [0.7(0.5,0.8) mg/dL; 62(44,70) μ mol/L] p = 0.0005 compared to the pre-operative baseline.

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Conclusion

Hepato-renal function demonstrates early improvement and then remains stable in the majority of patients on continuous flow left ventricular assist device support for one year. High-risk patients demonstrate a higher 30-day mortality and temporary need for renal replacement therapy. Yet even in this cohort, improvement is present over a period of one year on the device, with a minimal need for permanent haemodialysis.

Keywords

Congestive heart failure • Left ventricular assist device • Renal function • Hepatic function

Hemodialysis

Introduction

Implant of a left ventricular assist device (LVAD) has become standard therapy for patients with end-stage congestive heart failure. Continuous flow pumps are preferred to the older generation pulsatile ones as they are smaller, have lower complication rates and better long-term durability [1,2]. Prior reports on the effect of continuous flow on end-organ function are focused on device implant as a bridge to transplant in a highly selective patient population with a limited duration of support [3].

Hepato-renal function is an important predictor of long-term survival and good end-organ function is essential for long-term LVAD support. We therefore chose to study the changes in hepato-renal function while on a continuous flow LVAD support for a period of one year.

Patient and methods

126 patients underwent implant of a continuous flow left ventricular assist device (HeartMate II®, Pleasanton, CA) from January 2007 till June 2011. Out of these patients, 61 (49%) were supported for a period of one year and are the focus of this study. After Institutional Review Board approval, retrospective collection of data was done for these 61 patients. Along with clinical pre-operative variables, laboratory test results of renal and hepatic function were collected and analysed. Results were also gathered at one, six and 12 months after LVAD implant and were compared with the pre-operative value and with each other to determine the change over time. The metabolic function of the liver was assessed using total bilirubin while the synthetic mechanism was analysed with serum albumin levels. Unlike all other parameters, we chose to determine albumin levels first at six months post-operatively as patients routinely receive albumin infusion during the early post-operative period that would have a confounding influence on levels obtained at one month after LVAD implant. Renal function was assessed with the help of BUN and creatinine. Patients who were on renal replacement therapy at the time periods studied were assigned a default creatinine level of 4 mg/dL (353.6 \(\mu mol/L\)) as has been also utilised in calculation of the MELD UNOS

A separate high-risk group (HCrB) of selected 56/126 (44%) patients (40%) with the top 25 percentile values for bilirubin or creatinine was created and observed for similar changes over time.

Laboratory results are presented in both conventional units and SI units (italics).

Statistical analysis

Categorical variables are presented in percentages while continuous data is presented as mean \pm SD or median (interquartile range) after testing for normality using the Shapiro–Wilk W test. Comparison of pre-operative and post-operative continuous data is performed using the matched pairs T test or the Wilcoxon signed rank test as appropriate. Relationship of categorical variables is analysed using the Fishers exact test (two tailed). A p-value < 0.05 was considered as statistically significant.

Results

The baseline pre-operative variables are described in Table 1. The median age was 67 years [60,76] for the entire cohort and 51/61(84%) were male. An ischaemic aetiology was present in 35/61(59%) and 44/61(72%) of the implants were done as destination therapy (DT). Pre-operative optimisation in the form of an intra-aortic balloon pump was needed in 32% while 41/61(67%) were on intravenous inotropic support at the time of surgery. One-year survival for the entire cohort was $81.3 \pm 7\%$. Baseline (pre-operative) creatinine and BUN for the entire cohort was 1.4[1.2,1.9] [123.7(106,168)] and 27 [20,39.5] [9.6(7.1,14.1)] respectively.

Entire cohort

Renal function

There was a significant improvement in creatinine from preoperative values to that at one month (p < 0.0001). This trend towards improvement did not continue with a gradual decline in renal function as demonstrated by corresponding increase in creatinine and BUN levels over the latter half of the year of follow-up. The increase in creatinine from the end of one month till six months was significant (p = 0.0038) as demonstrated in Fig. 1. At the end of one year, both creatinine (p = 0.0003) and BUN (p = 0.0023) were improved compared to the pre-operative measurements.

Renal replacement therapy was required in only 2/61(3%) of patients in the entire cohort and both patients were from the HCrB cohort.

Hepatic function

There was a significant reduction in serum bilirubin from the pre-operative value of 1[0.7,1.55] [17.1(12,26.5)] to 0.9[0.6,1.2]

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