

## Adult Heart Transplantation Following Ventricular Assist Device Implantation: Early and Late Outcomes

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### ABSTRACT

**Purpose.** The impact of prior implantation of a ventricular assist device (VAD) on short- and long-term postoperative outcomes of adult heart transplantation (HTx) was investigated.

**Methods.** Of the 359 adults with prior cardiac surgery who underwent HTx from December 1988 to June 2012 at our institution, 90 had prior VAD and 269 had other (non-VAD) prior cardiac surgery.

**Results.** The VAD group had a lower 60-day survival when compared with the Non-VAD group ( $91.1\% \pm 3.0\%$  vs  $96.6\% \pm 1.1\%$ ;  $P = .03$ ). However, the VAD and Non-VAD groups had similar survivals at 1 year ( $87.4\% \pm 3.6\%$  vs  $90.5\% \pm 1.8\%$ ;  $P = .33$ ), 2 years ( $83.2\% \pm 4.2\%$  vs  $88.1\% \pm 2.0\%$ ;  $P = .21$ ), 5 years ( $75.7\% \pm 5.6\%$  vs  $74.6\% \pm 2.9\%$ ;  $P = .63$ ), 10 years ( $38.5\% \pm 10.8\%$  vs  $47.6\% \pm 3.9\%$ ;  $P = .33$ ), and 12 years ( $28.9\% \pm 11.6\%$  vs  $39.0\% \pm 4.0\%$ ;  $P = .36$ ). The VAD group had longer pump time and more intraoperative blood use when compared with the Non-VAD group ( $P < .0001$  for both). Postoperatively, VAD patients had higher frequencies of >48-hour ventilation and in-hospital infections ( $P = .0007$  and  $.002$ , respectively). In addition, more VAD patients had sternal wound infections when compared with Non-VAD patients ( $8/90$  [ $8.9\%$ ] vs  $5/269$  [ $1.9\%$ ];  $P = .005$ ). Both groups had similar lengths of intensive care unit (ICU) and hospital stays and no differences in the frequencies of reoperation for chest bleeding, dialysis, and postdischarge infections ( $P = .19, .70, .34, .67$ , and  $.21$ , respectively). Postoperative creatinine levels at peak and at discharge did not differ between the 2 groups ( $P = .51$  and  $P = .098$ , respectively). In a Cox model, only preoperative creatinine  $\geq 1.5$  mg/dL ( $P = .006$ ) and intraoperative pump time  $\geq 210$  minutes ( $P = .022$ ) were individually considered as significant predictors of mortality within 12 years post-HTx. Adjusting for both, pre-HTx VAD implantation was not a predictor of mortality within 12 years post-HTx (hazard ratio [HR], 1.23; 95% confidence interval [CI], 0.77–1.97;  $P = .38$ ). However, pre-HTx VAD implantation was a risk factor for 60-day mortality (HR, 2.86; 95% CI, 1.07–7.62;  $P = .036$ ) along with preoperative creatinine level  $\geq 2$  mg/dL ( $P = .0006$ ).

**Conclusions.** HTx patients with prior VAD had lower 60-day survival, higher intraoperative blood use, and greater frequency of postoperative in-hospital infections when compared with HTx patients with prior Non-VAD cardiac surgery. VAD implantation prior to HTx did not have an additional negative impact on long-term morbidity and survival following HTx. Long-term (1-, 2-, 5-, 10-, and 12-year) survival did not differ significantly in HTx patients with prior VAD or non-VAD cardiac surgery.

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**H**EART TRANSPLANTATION (HTx) is considered to be an advanced therapy for end-stage heart failure. The number of people undergoing HTx has been increasing over the past several years [1]. The registry of the International Society for Heart and Lung Transplantation (ISHLT) reported an increasing number of HTx patients from 3892 cases performed in 2010 to 4096 cases in 2011 [1,2]. However, the latest advances in mechanical circulatory support (MCS) provided heart-failure patients with a new treatment regimen, including ventricular assist device (VAD) support or total artificial heart (TAH) implantation.

The number of patients on MCS as a bridge to transplantation (BTT) has been continuously increasing over the past few years as more patients with end-stage disease receive MCS therapy [1,3]. Of the 1309 patients receiving left ventricular device support as a BTT strategy from 2011–2013, 37% underwent HTx within the first year after device implantation [3]. According to the 2013 ISHLT registry report, the percentage of HTx patients with a history of left ventricular device support increased from 12% in the HTx era of 1992–2000 to 17% in the HTx era of 2001–2005, and reached 28% in the HTx era of 2006–2012 [1].

HTx patients on VAD support prior to transplantation have many risk factors that need to be taken into account. They are at a higher risk of bleeding due to the mechanical device and at a higher risk of infections occurring in the device, the external device pocket, or the driveline connecting the internal and external environments. In a previous analysis of 704 adult HTx patients from 1988 to 2012, we reported lower 60-day and 1-year survival rates in recipients with prior VAD compared with recipients with no previous sternotomy prior to HTx [4,5]. In the present study, we sought to compare HTx patients with a prior VAD implantation with those with other (non-VAD) prior cardiac surgery. Our aim was to examine the effects of VAD implantation in comparison with other types of prior cardiac surgery on the outcome of subsequent HTx in adults.

## METHODS

### Patients

From December 1988 to June 2012, our center performed 704 adult orthotopic heart transplantation (OHT) procedures, excluding multiple-organ and redo-cardiac transplantations; there were 345 (49.0%) recipients without prior sternotomy and 359 (51.0%) recipients with 1 or more prior sternotomies. To analyze the effect of VAD implantation prior to HTx, we divided the 359 recipients with prior sternotomies into 2 groups: HTx patients with a history of VAD implantation (VAD group,  $n = 90$ ) and HTx patients with a history of other non-VAD prior cardiac surgeries (Non-VAD group,  $n = 269$ ). Of the 359 HTx patients analyzed in this study, 5 patients in the Non-VAD group required a second HTx procedure following the analyzed one.

Of the 90 HTx patients in the VAD group, 21 patients had HeartMate I (Thoratec, Pleasanton, CA) left ventricular assist devices (LVAD), 22 had HeartMate II (Thoratec, Pleasanton, CA) LVAD devices, and 40 had Thoratec paracorporeal VAD devices

(PVAD). A total of 5 HTx patients had 2 VAD implantations: 2 patients had a HeartMate I device followed by a HeartMate II device, 1 patient had an AbioMed BVS-5000 device followed by an AbioMed AB-5000 device (Abiomed, Danvers, MA), 1 patient had a BioMedicus device (Medtronic, Fridley, MN) followed by a HeartMate I device, and 1 patient had Thoratec PVAD followed by another Thoratec PVAD. Furthermore, 1 patient had a HeartMate I left ventricular support alongside an AbioMed BVS-5000 right ventricular support and 1 patient had a HeartMate II left ventricular support alongside a BioMedicus right ventricular support. In total, there were 49 patients on LVAD support and 41 patients on biventricular assist device (BIVAD) support. No patient in this series had a TAH.

### Operative Technique and Postoperative Care

The operative technique and postoperative care after HTx and VAD implantation have been previously described [6–19].

### Data Collection and Statistics

The data were collected using the multiple databases of Cedars Sinai Medical Center and were recorded on an Excel spreadsheet. Some data points were missing from our records, most of which involved the older procedures. Patients were considered to have preoperative intra-aortic balloon pump (IABP) if they had a balloon pump within 4 months prior to HTx. The postoperative data records for dialysis, >48-hour ventilation, pneumonia, pneumothorax, abdominal surgery for mesenteric ischemia, sepsis, pacemaker placement, and postdischarge infection were collected for up to a year following HTx. Any patient whose status was unknown (prior to September 2011) was categorized under lost to follow-up. Statistical analyses were performed on the de-identified data records. The study was approved by the Institutional Review Board.

Data were analyzed statistically and the  $P$  values calculated were classified with  $P < .05$  considered to denote statistical significance. Statistical tests included Student  $t$  test, Fisher exact test, Wilcoxon rank sum test, and Chi-squared test, as appropriate. The Kaplan-Meier method was used for the survival analyses with measurements of log-rank  $P$  values, hazard ratios (HR), and 95% confidence intervals (CI). A Cox proportional hazards regression model was used to identify predictors of 60-day and long-term mortality among all of the preoperative, intraoperative, and postoperative variables collected.

## RESULTS

### Preoperative Characteristics

Table 1 shows the baseline characteristics of the HTx patients in the VAD and Non-VAD groups and their organ donors. Recipients in the VAD group were younger on average at the time of HTx ( $P < .0001$ ). They also had higher weight and body mass index (BMI) compared with recipients in the Non-VAD group ( $P = .003$  and  $P = .023$ , respectively). However, donor-to-recipient weight ratio was similar between HTx patients in both groups ( $P = .71$ ). The distribution of gender was similar between both groups as well ( $P = .16$ ). Race distribution differed between both groups ( $P = .010$ ), with more whites and less African Americans in the Non-VAD group. Interestingly, preoperative creatinine levels on average were higher in the Non-VAD group ( $P = .021$ ). In addition, there were fewer patients with a history of coronary artery disease (CAD) and more patients with a history of chronic obstructive

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