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The Effect of Continuous-Flow Left Ventricular Assist Device Duration on Postoperative Outcomes

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Background. This study evaluated the effect of continuous-flow left ventricular assist device (CF-LVAD) duration on postoperative outcomes in heart transplant patients.

Methods. United Network of Organ Sharing heart transplant follow-up data from 2005 to 2015 were obtained. Patients supported by CF-LVADs who subsequently underwent cardiac transplantation were studied. The study population was divided into three groups by CF-LVAD duration of less than 1 year, 1 to 2 years, and more than 2 years. Multivariable Cox regression analysis was used to identify predictors of overall postoperative graft survival. Kaplan-Meier survival functions were used to estimate actuarial survival at 1, 2, and 5 years after transplant. The association between CF-LVAD duration and postoperative acute rejection episodes before and after hospital discharge was assessed.

Results. Of 21,336 recipients, 4,382 had CF-LVADs before cardiac transplantation: 2,603 (59.4%) had CF-LVADs for less than 1 year, 1,178 (26.9%) for 1 to 2

years, and 601 (13.7%) for more than 2 years. Donor age, high body mass index, dialysis dependence, and poor functional status at transplant were significant predictors of poor posttransplant graft survival. CF-LVAD duration was associated with increased incidence of acute rejection before hospital discharge (odds ratio, 1.14; 95% confidence interval, 1.02 to 1.28; $p = 0.019$). Duration was not related to acute rejection episodes after discharge. There was no difference in survival among patients with increasing time durations (hazard ratio, 1.01; 95% CI, 0.89 to 1.15; $p = 0.824$). Graft survival at 1, 2, and 5 years among patient groups was not significantly different ($p = 0.824$ by log-rank test).

Conclusions. Duration of CF-LVAD support does not affect posttransplant graft survival. Longer duration of support increases acute rejection episodes; however, this may not translate into diminished survival.

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Orthotropic heart transplantation continues to be the gold standard treatment for advanced heart failure (AHF). The scarcity of organs and the rise in AHF patients in the past decade have led technologic advances in mechanical circulatory support technology. Hence, the continuous-flow left ventricular assist device (CF-LVAD) has emerged as a promising outcome of the mechanical circulatory support technology evolution. The role of CF-LVADs as a bridge to heart transplantation (BTT) therapy has been associated with improved survival and outcomes in AHF patients awaiting heart transplant [1, 2].

As the use of CF-LVADs has increased, so has the number of associated challenges and complications. The

increase in CF-LVAD usage been explained not only by the parallel increase in the number of AHF patients but also by several factors, including patient body size, blood type, graft incompatibility, and the rise in organ shortage [3]. These factors have led to the extended duration of CF-LVAD support, and concerns have arisen regarding the adverse effects of prolonged CF-LVAD therapy.

Previous studies have reported unfavorable short- and long-term posttransplant outcomes in patients who are supported with a CF-LVAD for a longer period [3, 4]. An example is the poor posttransplant hemodynamics that is seen in patients who stay on LVAD therapy for more than 1 year [5]. Moreover, patients who are

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exposed to prolonged CF-LVAD therapy may have an increased risk of device-related complications such as bleeding, thrombosis, device-related infections, and device malfunction [6].

Several questions have arisen regarding the optimal timing for heart transplantation for patients in whom CF-LVAD support is initiated. Answers have been limited by several factors that are mainly not under the full control of the transplant team alone. Existing policies are based on past evidence generated with data published on patients who were supported with pulsatile-flow devices for BTT therapy [7]. The decision to proceed with heart transplantation after an optimal duration of LVAD support or device-related complications arises has therefore been challenging, especially in this modern BTT era, thus warranting further investigation. The expectation is that future policies could be adjusted according to newly reported outcomes in patients undergoing CF-LVAD therapy. The present study used the United Network for Organ Sharing/Organ Procurement and Transplantation Network (UNOS/OPTN) registry to examine the effect of CF-LVAD duration on posttransplant outcomes, specifically, graft survival and acute rejection episodes before and after hospital discharge among BTT patients who finally underwent heart transplantation.

Material and Methods

Data Collection

This study is a retrospective analysis of deidentified data from the UNOS/OPTN registry. The data were provided by the UNOS data use agreement. In brief, the protocol supports work by health resources and instills responsibility and integrity of the data into the hand of authors alone, without reflecting the views and policies of third parties.

The UNOS/OPTN registry was queried for data on patients who were listed for transplant in the UNOS network and their follow-up between January 2005 and September 2015. The need for Institutional Review Board approval for this study was waived due to the deidentified nature of the data set.

Study Population and Methods

The present analysis included CF-LVAD patients who were listed for a heart transplant and subsequently underwent orthotopic heart transplantation (OHT) within the study period. Patients were excluded if they (1) were 12 years or younger, (2) had undergone a multiorgan transplant, or (3) were supported with total artificial hearts or extracorporeal or percutaneous LVADs. Other exclusion criteria were the use of biventricular assist devices and right ventricular assist devices.

Device duration was calculated by dividing the total time in days from CF-LVAD implantation to OHT by 365 days/(1 – year). Patients were categorized into three main groups according to the duration of CF-LVAD support: group I, less than 1 year; group II, 1 to 2 years; and group III, more than 2 years.

Functional status of patients was determined by using the Karnofsky performance score. Its utility has been described in detail elsewhere [3]. In brief, Karnofsky performance scores ranged from 0 to 100, with higher scores representing functional independence. For this study, patients with scores of 60 or higher were classified as functionally independent.

CF-LVAD patients with calculated panel reactive antibodies exceeding 10% before transplant were classified as allosensitized. The association between CF-LVAD duration and allosensitization was assessed by comparing the incidence of sensitization among the three support duration groups.

The primary outcome measure was actuarial post-transplant survival, which was defined as an absence of death resulting from any other cause. Survival data were extracted for all patients at defined periods of 1 year, 2 years, and 5 years. Deaths with graft function were also regarded as death from all causes and included as a primary end point. Acute rejection before and after hospital discharge after transplant was used as a secondary outcome measure.

Statistical Analysis

Data are presented as mean $\pm$ SD for continuous variables and percentages or numbers for categorical variables. Baseline clinical characteristics of recipients, donors, and other transplant-specific factors at the time of OHT were calculated. Donor and recipient variables reported in Table 1 were analyzed by logistic regression to identify factors contributing to overall survival after transplantation. Cox proportional hazards models were used to estimate predictors of overall all-cause mortality.

For the multivariable analysis, all variables that had a p value of less than 0.20 were included in a final multivariable model. The variable of device duration was forced into the final model. Univariate and multivariate logistic regression models were used to investigate predictors of acute rejection episodes after the transplant, before and after hospital discharge. Unadjusted survival rates among patient groups were derived by using the Kaplan-Meier survival function and compared using log-rank tests. All analyses were performed with Stata 14 (2015 release) software (StataCorp, College Station, TX). The tests were two-tailed, and a p value of 0.05 or less was accepted as statistically significant.

Results

From 21,336 recipients who were identified in the UNOS registry, we analyzed 4,382 patients who underwent pretransplant CF-LVAD placement and subsequently underwent cardiac transplantation.

Of the 4,382 patients that were included in the final analysis, 59.6% were supported by a CF-LVAD for less than 1 year, 26.9% between 1 and 2 years, and 13.7% for more than 2 years before OHT. The mean device support duration was 1.1 ± 0.9 years. Baseline demographic and clinical characteristics of all patients enrolled into the study are listed in Table 1. The study cohort was

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