Early Outcomes With Marginal Donor Hearts Compared With Left Ventricular Assist Device Support in Patients With Advanced Heart Failure

Erin M. Schumer, MD,* Mickey S. Ising, MEng,* Jaimin R. Trivedi, MD, MPH, Mark S. Slaughter, MD, and Allen Cheng, MD

Department of Cardiovascular and Thoracic Surgery, University of Louisville, Louisville, Kentucky

Background. **The shortage of donor hearts has limited cardiac transplantation for end-stage heart failure, leading to the increased use of left ventricular assist devices (LVADs) as bridge-to-transplant (BTT) and marginal donor hearts; however, outcomes have been mixed. This study examines differences in wait list survival of patients with continuous flow LVADs and post-transplantation survival of patients receiving a marginal donor heart.**

Methods. **The United Network of Organ Sharing database was retrospectively queried from January 2005 to June 2013 to identify adult patients listed for heart transplant. Marginal donor criteria included age greater than 55 years, hepatitis C positive, cocaine use, ejection fraction less than 0.45, or donor to recipient body mass index mismatch of greater than 20%. The primary endpoint was wait list survival of patients with LVADs compared with post-transplant survival of marginal donor heart recipients using Kaplan-Meier analysis.**

Results. **A total of 2,561 and 4,737 patients received LVAD support or a marginal donor heart, respectively. The 30-day, 1-year, and 2-year survival was 96%, 89%, and 85%, for patients with LVAD support on the waiting list and 97%, 89%, and 85%, respectively, for recipients of marginal donor hearts ($p = 0.213$). Recipients of marginal hearts had worse survival than non-marginal heart recipients at 3 years ($p = 0.011$).**

Conclusions. **There was no significant difference between waiting list survival of patients with LVAD support as BTT and post-transplant survival of recipients with marginal donor hearts. There could be clinical benefits for using LVAD support as BTT to allow time for better allocation of optimal donor hearts as opposed to transplantation with a marginal donor heart.**

(Ann Thorac Surg 2015;100:522–7)

End-stage heart disease (ESHD) currently affects 5.1 million people in the United States with an estimated growth in incidence of 25% by 2030 [1]. Heart transplantation remains the gold standard treatment for patients with ESHD; however, the supply of donor organs remains limited [2]. This limited supply of appropriate donor organs has led to the development and increased use left ventricular assist devices (LVADs) as bridge-to-transplant (BTT) therapy [1–4].

Simultaneously, marginal or "extended-criteria" donor organs are being used in an effort to increase the donor organ pool [2]. While no standardized criteria exist, general consensus in the literature indicates that a donor organ is considered marginal when the donor has the following characteristics: age greater than 55 years old; hepatitis C positive; cocaine use; ejection fraction less than 0.45; or donor to recipient body mass index (BMI) mismatch greater than 20% [5, 6]. Survival outcomes are generally worse for recipients of marginal donor hearts by up to 20% at 5 years although there is evidence of similar early outcomes [7, 8]. Alternatively, outcomes for patients receiving contemporary continuous flow LVADs as support for BTT have been associated with improved patient survival and are not limited by supply [4, 9–11].

While LVADs as BTT and the use of marginal donor hearts have expanded treatment options for patients with ESHD, the best treatment option and long-term survival outcomes remain unclear [12, 13]. In an effort to help improve the decision-making process, we used the United Organ Sharing Network (UNOS) database to evaluate potential survival differences between patients on the waiting list with a contemporary continuous flow LVAD compared with heart transplant recipients of extended-criteria donor hearts.

Patients and Methods

Data were obtained from the UNOS registry for patients listed for heart transplantation from January 2005 through June 2013. The entire UNOS registry for this time period consisted of 136,498 patients. Patients were included in the study if they were listed for heart transplantation,

Accepted for publication Feb 19, 2015.

*Erin Schumer and Mickey Ising contributed equally to the study.

Presented at the Sixty-first Annual Meeting of the Southern Thoracic Surgical Association, Tucson, AZ, Nov 5–8, 2014.

Address correspondence to Dr Cheng, University of Louisville, Department of Thoracic and Cardiovascular Surgery, 201 Abraham Flexner Way, Ste 1200, Louisville, KY 40202; e-mail: allenchengcs@gmail.com.

0003-4975/$36.00
http://dx.doi.org/10.1016/j.athoracsur.2015.02.089

were 18 or greater years old, and listed after December 31, 2004 (n = 24,039). Patients were excluded if the wait list criteria were listed as refused transplantation, transferred to another center, other, condition improved, too ill for transplant, removed in error, emergency transplantation, died during transplantation, or unable to contact.

The study population was then divided into 2 groups. Patients in the LVAD group were included if they received a continuous flow LVAD, either HeartMate II (Thoratec, Pleasanton, CA) or HVAD (Heartware, Inc, Miami Lakes, FL) at time of listing (n = 2,561). The marginal donor (MD) group includes patients who underwent heart transplantation without ever having received an LVAD and underwent transplantation with a marginal donor heart (n = 4,737). Marginal donor criteria included age greater than 55 years old, hepatitis C positive, cocaine use, ejection fraction less than 0.45, or donor to recipient (BMI) greater mismatch of 20% [5, 6]. The full algorithm for the study design is shown in Figure 1. The primary outcome of this study was comparison of survival between patients on the waiting list with a continuous flow LVAD and patients transplanted with a marginal donor heart.

All statistical analyses were completed using SPSS v. 22 (IBM, Armonk, NY). All reported results are at time of LVAD implantation for the LVAD group and time of transplantation for the MD group. The Student *t* test and χ^2 analysis were used to compare study group characteristics. Kaplan-Meier survival analysis was used to compare survival between study groups. Values are report as n (percent) or average ± standard deviation. A *p* value of 0.05 or less was considered statistically significant.

Results

Analysis included a total of 7,298 patients divided into 2 groups. There were 2,561 patients in the LVAD group and 4,737 patients in the MD group.

Similar baseline preoperative characteristics for both groups included age and pulmonary artery pressure; however, the proportion of males and diabetics, BMI, cardiac output, and wait list time were higher for the LVAD group. The MD group had a higher proportion of patients listed as UNOS status IA and higher creatinine. Demographic information for both groups is summarized in Table 1. Dilated cardiomyopathy due to all causes was the most common etiology of heart failure in both groups; 3,819 (80.62%) for the MD group and 2,419 (94.46%) for the LVAD group. The distribution of diagnoses for heart failure is shown in Table 2. The proportion of diagnoses was markedly different for these 2 populations for all diagnoses.

Annual case distribution for 2005 to 2013 is shown in Figure 2 and reflects the number of LVADs placed at time of listing and marginal donor hearts at time of transplant. With the exception of 2005 and 2013, the number of marginal donor heart transplantations remained similar.

The MD group was then further classified by marginal donor characteristics (Table 3). The BMI mismatch and donor history of cocaine use, respectively, accounted for 59.87% (n = 2,836) and 18.41% (n = 872) for classification

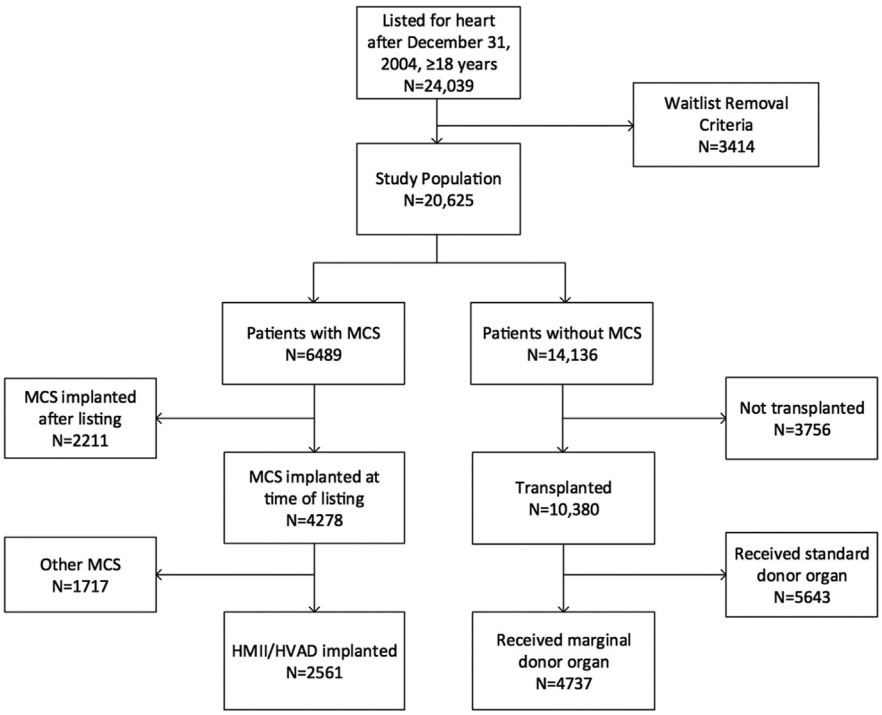

Fig 1. Flow chart of selection of patients for analysis using the United Network for Organ Sharing database. The left-ventricular assist device group, n = 2,561; marginal donor group, n = 4,737. (HMII = HeartMate II; HVAD = heart ventricular assist device; MCS = mechanical circulatory support device.)