

March 6, 2013

Dear Madame:

We would like to thank CMS for the opportunity to provide new data regarding patients who have been implanted with a continuous-flow left ventricular assist device (LVAD) as a bridge to transplantation (BTT) and destination therapy (DT) at non-heart transplant open-heart centers. Our study assessed outcomes of patients implanted with the HeartMate II LVAD at open-heart centers (OHCs) and, as a benchmark, compared those with that of patients implanted at heart transplant centers (HTCs). We found no significant difference in patient characteristics, survival, or quality-of-life (QoL) measures between those patients implanted in non-transplant centers and those implanted in heart transplant centers. Also, we provide a brief overview of the infrastructure needed to support these patients.

As presented at the Society for Thoracic Surgery meeting in January 2013, since 2009, the HeartMate II LVAD has been implanted in 186 patients (69 BTT and 117 DT) at 24 open-heart surgery centers. Results demonstrate that outcomes are comparable to the results of patients in the overall INTERMACS registry and other HeartMate II published studies. The 6- and 12-month survival of patients at the OHCs was 88% and 84%, respectively (Figure 1). This is comparable to the survival rates of 88% and 82% at the same intervals for 3752 patients implanted contemporaneously with the device at HTCs. Additionally, the survival rates observed in our analysis are the same as that of 3405 patients from the INTERMACS registry, as reported by Kirklin et al. in 2012.

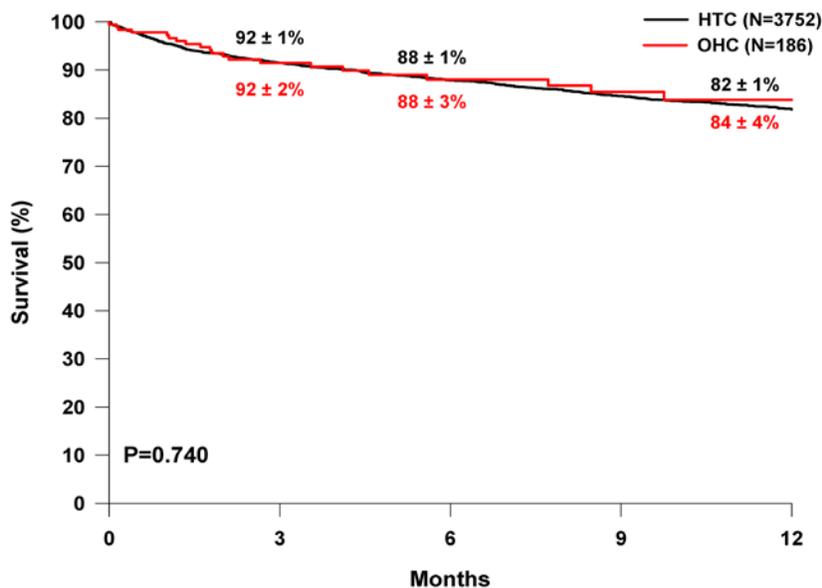


Figure 1. Kaplan-Meier survival analysis of the OHC (N = 186) and HTC (N = 3752) patients.

More patients underwent implant for DT at OHCs (63% vs. 43%), which influenced differences in demographics, transplant rate, and the percentage of patients with ongoing support. The OHC group had more patients aged greater than 70 yr (26% vs. 12%). The mean length of stay was nearly equal (OHC = 26 days; HTC = 25 days). Before implant, 54% of HTC patients were listed as INTERMACS Profile 1 and 2, compared to 41% of the OHC group. The incidence of adverse events was comparable. The 30-day mortality was 2.2% for OHC patients and 4.4% for HTC patients.

During LVAD support, QoL improved by the 3-month time point, and the improvement was maintained to 12 months (Figure 2). Similarly, the mean EuroQoL visual analog scale (Figure 2A) and the mean composite total QoL score showed sustained improvements for the 12-month time. Results of the six-minute walk tests showed an increase in distance of 230 meters for OHC patients and of 258 meters for HTC patients from pre-implant to 3 months, an improvement that was maintained by both groups (Figure 3).

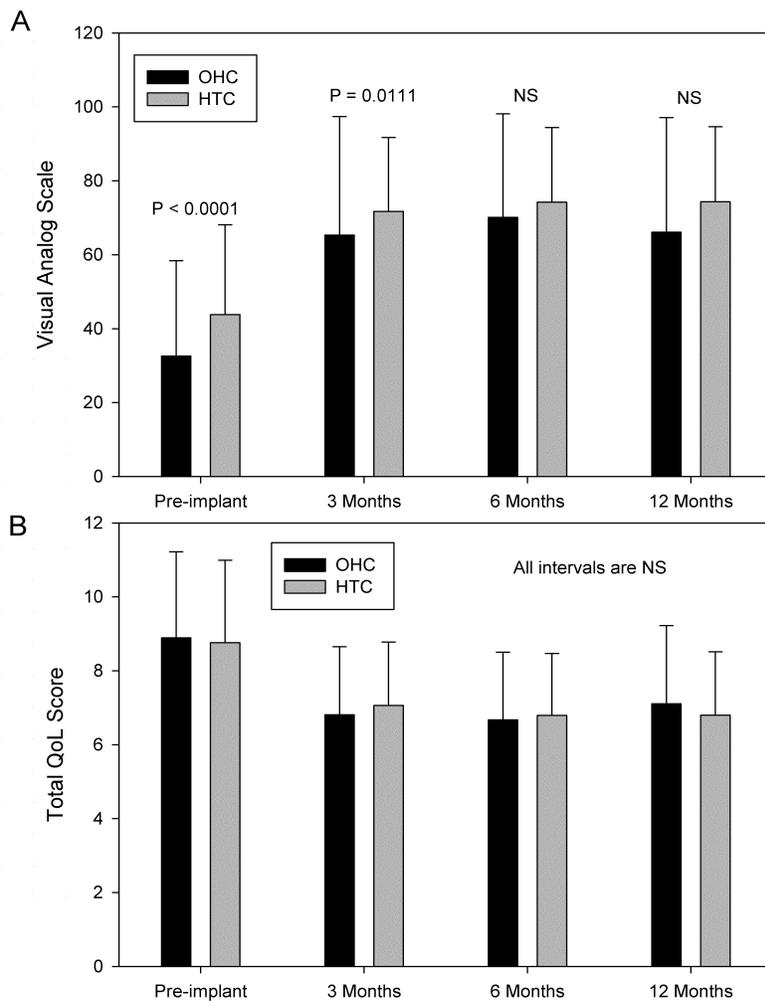


Figure 2. EuroQoL quality-of-life results displayed as visual analog scale (A) and the total composite QoL score (B). NS = not significant.

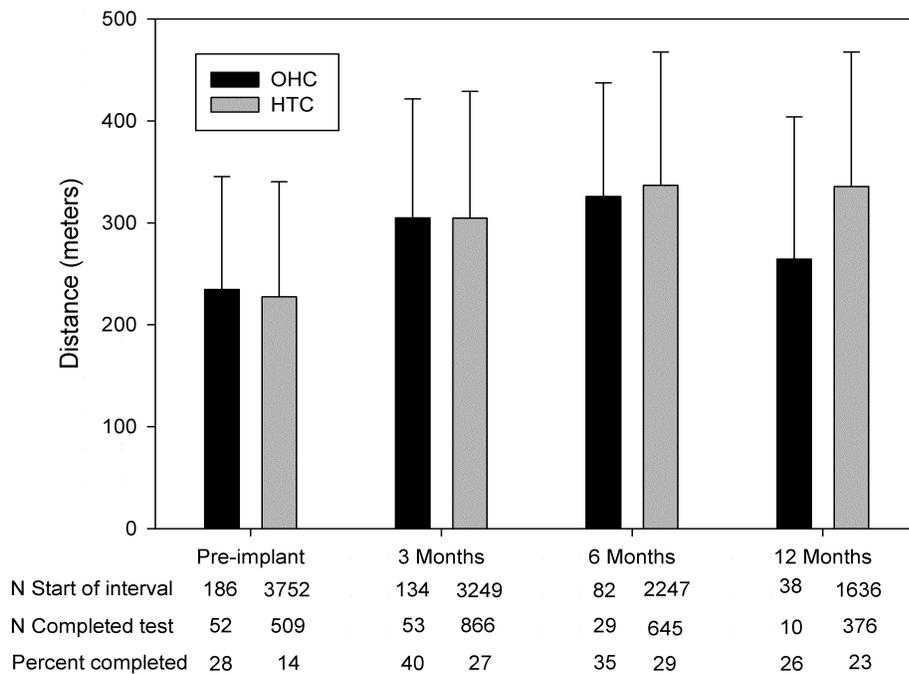


Figure 3. Equal improvement in the six-minute walk test was observed in both groups.

Establishment of a “Heart Team” is the key to success of any LVAD program and is instrumental to the responsible set up of new programs. The following is what defines the “Heart Team” in each of our non-transplant centers and does not differ from the “Heart Team” in a heart transplant surgery center other than in the ability to transplant hearts.

The OHCs have established high-quality LVAD programs with the guidance and assistance of experts at the experienced transplant-LVAD centers. Specific care protocols have been adopted from the numerous centers nationwide with many years of experience. The Heart Team includes the following: 1) cardiac surgeons trained in mechanical circulatory support technology before taking their responsibilities at open-heart surgery centers, 2) cardiologists with considerable heart failure care experience, 3) dedicated VAD nurses who now attend a VAD Coordinator Course and receive support from experienced colleagues, 4) social workers who provide a range of necessary social services, and 5) other supporting medical services such as hematology, pulmonology, nephrology, and anesthesiology are readily available as needed. The dedicated Heart Teams at open-heart surgery centers provide high-quality care for all LVAD-supported patients.

The results derived from these initial patients indicate that, with proper teams, training, and center commitment, LVAD therapy is being disseminated in a responsible way to open-heart surgery centers without any decrement in outcomes. Historically, CMS has had the wisdom to understand that it is a center’s commitment to high standards in providing VAD therapy that is paramount to patient outcomes. With the Joint Commission certification process, all centers implanting LVADs for DT must meet the same standards, establish and meet performance measurements, as well as report outcomes into

INTERMACS. These are far better methods for determining which centers should be able to provide DT than to apply a heart transplantation designation.

We would encourage CMS to continue to allow centers, regardless of transplant status, to become certified for DT, based on current Joint Commission standards and evaluation.

Thank you for your consideration.

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