Left Ventricular Assist Device in Patients With Body Mass Index Greater Than 30 as Bridge to Weight Loss and Heart Transplant Candidacy

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ABSTRACT

Introduction. In obese patients with heart failure, weight reduction may be difficult due to physical restrictions, but may be necessary to achieve heart transplant candidacy. We report the outcomes of obese patients who underwent implantation of a left ventricular assist device (LVAD) using a pulsatile (HeartMate XVE [XVE]) or continuous flow (HeartMate II [HMII]) design and the effect on body mass index (BMI).

Methods. Of 37 patients with BMI >30 kg/m^2 who underwent LVAD implantation, 29 survived at least 30 days and were followed for weight change. In the 30-day survivors, end points of the study were continued LVAD support, heart transplant, or death. One patient underwent gastric bypass surgery and was excluded.

Results. In the 28 patients who met inclusion criteria, BMI was 35.6 ± 4.4 kg/m^2 at baseline, and at follow-up was 33.1 ± 5.5 kg/m^2 (mean BMI change −2.5 kg/m^2; $P = .063$), with a mean follow-up time of 301.6 ± 255.5 days. The XVE group showed a significant BMI reduction of 3.9 kg/m^2 ($P = .016$ vs baseline); however, the HMII group showed 0.1 kg/m^2 increase in BMI. BMI <30 kg/m^2 at follow-up was achieved in 6 patients (21%), 5 of 19 (26%) in XVE group, and 1 of 9 (11%) in HMII group. In the 14 patients (12 XVE, 2 HMII) or 50% who received a heart transplant, the mean decrease in BMI was 4.6 kg/m^2 ($P = .003$).

Conclusions. LVAD placement in patients with BMI >30 kg/m^2 provided significant weight loss in the pulsatile XVE group, but not in recipients of the continuous flow HMII. In patients successfully bridged to a heart transplant after LVAD insertion, mean reduction in BMI was 4.6 kg/m^2 ($P = .003$). LVAD implantation provides a period of hemodynamic support for obese patients with advanced heart failure, during which time opportunity may be available for weight loss. Pulsatile devices appear to be associated with greater weight loss than nonpulsatile continuous flow devices. Additional therapies may be necessary to achieve significant weight loss in recipients of the continuous flow LVAD.

MORE than 5 million Americans suffer from heart failure, with 670,000 new cases diagnosed and ~56,000 patients dying from it every year [1]. Meanwhile, obesity has become a larger global health care issue [2] and is one of risk factors for heart failure [3]. As a result, the number of obese patients with advanced heart failure has increased. Weight reduction is difficult for these patients due to physical restrictions. Due to decreased survival observed after heart transplantation, obesity is one of the

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relative contraindications for heart transplantation [4,5]. One effective treatment option for patients not eligible for heart transplant (HTx) due to obesity is implantation of a ventricular assist device (VAD). Given current circumstances, it is expected that more and more obese patients with heart failure will receive VAD in the near future. VAD may be indicated for obese heart failure patients alongside a strategy that a patient can reduce weight during support for potential heart transplantation. There have been reports that described outcomes of VAD implantation in obese patients [6–8]; however, only a few followed weight change in this patient population [9]. Our hypothesis was that placement of VAD allows obese patients with advanced heart failure to increase activity and provides an opportunity for weight loss. To determine this hypothesis, we followed outcomes of obese patients with advanced heart failure who underwent VAD implantation as a bridge to weight loss.

METHODS

From March 2007 to September 2010, 74 patients underwent LVAD implantation. All patients were assessed for eligibility for heart transplantation by the institution's heart transplant selection committee. Patients whose body mass index (BMI) was >30 kg/m^2 at the time of VAD implantation and survived 30 days after implantation were included in the study. This study was approved by the Institutional Review Board.

Left ventricular assist device was implanted as described elsewhere. In brief, the patient was placed on cardiopulmonary bypass with ascending aortic arterial cannulation and right atrial venous drainage except when closure of the patent foramen ovale or tricuspid valve procedure was intended. Tricuspid valve repair was performed for moderate and severe tricuspid regurgitation. For moderate and severe aortic insufficiency, aortic valve replacement was performed with cross clamp and cold blood cardioplegia and continuous retrograde cold crystalloid cardioplegia. After hemostasis, the chest was closed in the standard fashion. Anticoagulation with heparin was started after chest tube output was observed to be sufficiently low.

All patients who survived 30 days were discharged and followed as outpatients as needed. BMI was determined at the end-points of the study: last outpatient LVAD follow-up, the time of heart transplantation, or death. All patients underwent routine counseling on lifestyle modification, including appropriate diet and exercise. Dietary counseling was provided by registered dieticians. There was no weight loss program with standard protocol specific to the VAD program at our institution.

Continuous variables were summarized by mean ± standard deviation. Normally distributed continuous variables were compared across 2 groups by the independent samples t test. Non-normally distributed numerical variables were compared across 2 groups by the Wilcoxon rank sum test. Within group change on a numerical variable was assessed by the Wilcoxon signed rank test. Categorical variables were summarized by frequency and percent. Categorical variables were compared across groups by the Fisher exact test. A P value <.05 was considered significant. SAS version 9.1 (SAS Institute, Cary, North Carolina) was used for statistical analysis.

RESULTS

During this study period, 74 patients underwent LVAD implantation at our center. Of these, 46 patients had HeartMate XVE (XVE, Thoratec Corp., Pleasanton, Calif., United States) and 28 patients had HeartMate II (HMII, Thoratec Corp.). Of the 74 patients, 37 (50%) had a BMI >30 kg/m^2 (24 with XVE and 13 with HMII). Follow-up of the study patients is shown in Fig 1.

Of 37 patients with BMI >30 kg/m^2 at the time of LVAD implantation, there were 29 (20 XVE, 9 HMII) who survived 30 days and were followed for weight change. The 30-day mortality rate was 17% for the XVE group and and 31% for the HMII group, respectively. One patient who underwent gastric bypass surgery after implantation of an XVE device was excluded from the study.

Preoperative demographics of the study patients are shown in Table 1. No significant differences were observed except for prevalence of New York Heart Association IV patients between XVE and HMII groups.

Postoperative outcome is shown in Table 2. At follow-up, a mean BMI reduction of 2.5 kg/m^2 from baseline was observed in the entire cohort (P = .063 vs baseline). XVE group showed BMI reduction of 3.9 kg/m^2 (P = .016 vs baseline); however, HMII group showed 0.1 kg/m^2 increase in BMI. Transition of BMI before LVAD implant and at follow-up of all 28 patients is shown in Fig 2. BMI less than 30 kg/m^2 at follow-up was achieved in 6 patients (21%), 5 of 19 (26%) in the XVE group and 1 of 9 (11%) in the HMII group.

Among 28 patients in the study cohort, 14 (12 XVE, 2 HMII) or 50% were successfully bridged to heart transplantation. Mean decrease in BMI of those 14 patients was 4.6 kg/m^2 (P = .003). The XVE group showed a trend to receive more heart transplants than the HMII group during approximately the same follow-up period (close to a year). The number of patients with HMII on continuous support was significantly higher than those with XVE. Seven patients died on VAD support; 4 due to multiple organ failure, one due to device failure, one from sepsis, and one from an unknown cause.

Comparison of patients who achieved BMI >30 kg/m^2 and those who did not is shown in Table 3. No significant

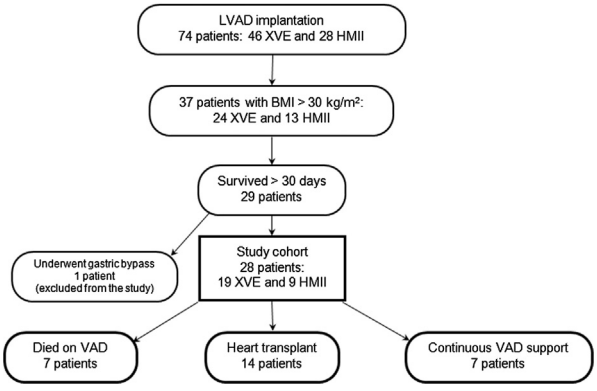

Fig 1. Follow-up of study patients. LVAD, left ventricular assist device; BMI, body mass index; XVE, HeartMate XVE; HMII, HeartMate II.

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