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Exploring Body Mass Index Changes in Left Ventricular Assist Device Patients

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Abstract

Background: Current treatment options for end-stage heart failure, such as transplantation, can be limited by obesity guidelines. Mechanical devices such as Left Ventricular Assistive Devices (LVAD) can bridge heart failure patients to transplantation, however, after implantation; some patients may experience weight gain that precludes them from transplantation. Therefore, the objective of this study was to evaluate weight changes after the implantation of an LVAD.

Methods: A retrospective review of 130 patients receiving an LVAD were divided into two groups based on BMI at the time of implantation: obese (>30 kg/m²) and non-obese ($/m^2$). Patients were evaluated at three time points post LVAD implantation: 3, 6, and 12 months for changes in weight and BMI.

Results: The mean BMI of the overall cohort at the time of LVAD implantation was 30.3 kg/m². Patients who were not classified as obese at the time of LVAD implementation had a significant increase in BMI (2.1 kg/m2, p<0.001).

Conclusion: Weight gain after LVAD implementation is more likely in patients who are non-obese at the time of LVAD evaluation; however, obese subjects remained unlikely to lose weight one year post implantation.

Keywords

Heart failure, obesity, BMI, weight, cardiac transplantation, ventricular assist device, LVAD

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Introduction

Heart failure affects a reported 5.1 million Americans.¹ Despite advancements in medicine; a diagnosis of heart failure continues to have a poor prognosis. Likewise, obesity is a growing problem in the United States and is also an independent risk factor for the development of heart failure.²⁻⁴ Obese patients are twice as likely to develop heart failure when compared to their non-obese counterparts,⁴ and obesity limits available treatment options in those with heart failure. Mechanical assist devices, such as Left Ventricular Assist Devices (LVAD), offer an alternative option to prolong life or bridge patients to cardiac transplantation. Obesity alone is not contraindicated for LVAD placement; however, transplantation guidelines for mechanical circulatory support encourage thoughtful considerations for surgical risk and comorbidities before implanting the morbidly obese patient.⁵

After LVAD implantation, some patients can experience weight gain that may exclude them from transplantation, and many implanted obese patients fail to lose weight in order to meet BMI listing criteria for transplant.⁶⁻⁸ However, very little is known about the patterns of weight gain in patients after LVAD implantation. Therefore, the purpose of this study is to explore BMI changes in the post-LVAD population.

Patients and Methods

Participants and Study design

Prior to data collection, Institutional Review Board approval was obtained for a retrospective analysis of patients who qualified for LVAD implantation from 2009-2014. Adult participants over 19 years of age implanted with the Heartmate II device were eligible for enrollment. Patients who had a survival of less than 90 days post-implant were excluded.

Electronic medical records were used to retrospectively collect clinical, demographic and anthropometric data for patients implanted between January 2009 and December 2014.

Data Collection

Body mass index (BMI) of participants was collected at designated intervals, including time of LVAD evaluation and routine follow-up clinic visits or hospitalizations at the 3-, 6- and 12-month markers. BMI was chosen as a primary outcome as it is a standard measure used in transplant selection. Participants were categorized by BMI as defined by the World Health Organization at the time of evaluation: underweight (BMI <18.5kg/m²), normal (BMI 18.5-24.9 kg/m²), overweight (BMI 25-29.9 kg/m²) and obese (BMI <30 kg/m²).⁹

Additional baseline data was collected from the participants at their initial evaluation for LVAD and from routine follow-up clinic visits or hospitalizations at



the 3-, 6-, and 12-month intervals for comparison of BMI changes over time. Demographic data, classification of heart failure, severity of illness, psychosocial factors, and lab data represented the clinical characteristics. Demographic data collected includes subject's gender and age. Classification of heart failure and severity of illness were evaluated by obtaining information on ejection fraction, etiology of heart failure, ICU length of stay on implant, readmissions to hospital and implant strategy. Lab data included hemoglobin A1C, B-type natriuretic peptide (BNP), prealbumin, serum sodium, serum osmolality, serum creatinine, and total bilirubin.

Data was also collected on the utilization of bariatric referral over time and diuretic use.

Data Analysis

Descriptive statistics were calculated for all variables. Continuous data were represented as mean and standard deviation. Categorical data were expressed as counts and percentages. Changes between BMI at each time point were compared using either the paired t-test for normal data or the Wilcoxon signed rank test for non-normal data.

The demographic and clinical characteristics of the participants were compared between the non-obese and obese groups using the independent sample t-test and Wilcoxon rank-sum for continuous data, and the Chi-square test or Fisher's exact test for categorical data, as appropriate.

All statistical analysis was performed using IBM SPSS Statistics 22. Statistical significance was measured at a p-value < 0.05.

Results

The final number of participants in the study was 130, with a total of 103 males (79%) and 27 (21%) females. The mean BMI of the overall cohort at the time of LVAD implant was 30.3 kg/m². Over 80% of participants were considered overweight (BMI of 25-29.9 kg/m²) or obese (\geq 30 kg/m²) (30% vs 51.5%, respectively).). Only one participant was categorized as underweight and less than 20% of the entire cohort was considered to be in the underweight or normal weight categories. Because of this distribution among the four BMI groups, patients were then collapsed into two BMI groups; obese (BMI \geq 30.0kg/m²) and non-obese (BMI <29.9 kg/m²). Within these categories, 51.5% of the population was considered obese (BMI \geq 30kg/m²) with 48.5% classified as non-obese (<29.9 kg/m²). Clinical characteristics for all participants observed at time of implant are presented in Table 1.



	BMI				
Variables (N)		Non- Obese (N=63)		ese (N=67)	
	Ν	Mean (S.D.)	Ν	Mean (S. D.)	P value
Age, years (130)	63	57.6 (13.2)	67	54.0 (12.4)	0.11
Initial BMI, kg/m ² (130)	63	25.2 (2.9)	67	35.1 (4.0)	<0.001
3 Month BMI, kg/m ² (124)	60	25.2 (2.8)	64	33.8 (4.3)	<0.001
6 Month BMI, kg/m ² (90)	43	26.5 (3.6)	47	34.9 (4.9)	<0.001
12 Month BMI, kg/m ² (49)	22	27.8 (3.0)	27	36.1 (4.7)	<0.001
A1C, % (120)	58	6.5 (1.4)	61	6.9 (1.4)	0.22
Prealbumin, mg/dL (122)	59	20.2 (8.3)	63	21.6 (7.9)	0.33
Initial Sodium, mmol/L (130)	63	135.8 (4.0)	67	136.2 (3.3)	0.59
Initial Osmolality, mOsm/kg (130)	63	280.0 (10.3)	67	282.0 (8.1)	0.21
Initial Creatinine, mg/dL (130)	63	1.3 (0.4)	67	1.3 (0.4)	0.88
Initial Total Bili, mg/dL (130)	63	1.8 (1.6)	67	1.4 (0.9)	0.08
Initial BNP, pg/dL (119)	56	1143.7 (794.5)	62	623.5 (617.0)	<0.001
Initial EF, % (130)	63	14.2 (6.3)	66	15.5 (6.8)	0.26
ICU Length of Stay, days (78)	37	10.0 (6.3)	41	9.2 (7.6)	0.64
Days Implanted, days (130)	63	357.8 (267.0)	67	381.7 (273.6)	0.62
Readmit at 3 months, # (126)	62	0.5 (0.8)	64	0.6 (0.8)	0.75

Table 1: Clinical Characteristics on Implant

A diagnosis of diabetes (p= 0.03) and BNP levels (p= <0.001) were significantly different between the obese and non-obese groups. As expected the obese group had more diabetics; however, there was no significant difference when comparing hemoglobin A1C levels (non-obese 6.5% vs. obese 6.9%, p=0.22). Bariatric referral was noted to be different among groups, which was to be expected.



The non-obese group had no significant BMI change between initial and 3 months measurement (p=0.787); however, they did show significant gains between initial BMI and 6 months as well as initial and 12 months measurement (1.4 kg/m², p=<0.001; and 2.1 kg/m², p=<0.001; respectively). The obese group showed significant weight loss in the initial to 3 month mark, where the non-obese group did not (1.3 kg/m²±2.6, p=<0.001 and 0.06 kg/m²±1.8, p=0.787; respectively). The obese groups showed no change from initial BMI (35.1 kg/m²) at either the 6 month (34.9 kg/m², p=0.924) or the 12 month mark (36.1 kg/m², p=0.359). These results are shown in Table 2.

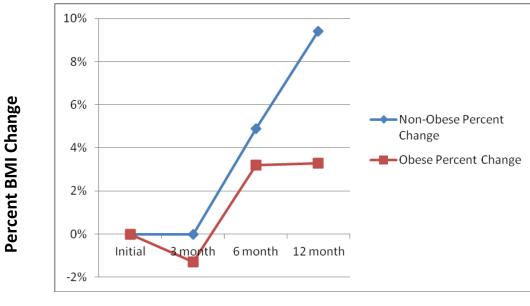
Table 2: BMI Changes Over Time*

	BMI Groups								
	Nor	n- Obese (N=	63)	Obe	se (N=67)				
Time (N)	Ν	Mean (S. D)	Ν	Mean (S. D.)				
Initial BMI (130)	63	25.2 (2.9)		67	35.1 (4.0)				
3 months (124)	60	25.2 (2.8)		64	33.8 (4.3)				
6 months (90)	43	26.5 (3.6)		47	34.9 (4.9)				
12 months (49)	22	27.8 (3.0)		27	36.1 (4.7)				
Change Over Time			P value			P value			
Initial – 3 months	60	-0.1 (1.8)	0.787	64	-1.3 (2.6)	<0.001			
Initial – 6 months	43	1.4 (2.3)	<0.001	47	-0.1 (3.3)	0.924			
Initial – 12 months	22	2.1 (1.8)	<0.001	27	0.6 (3.0)	0.359			
3 months - 6 months (90)	43	1.4 (1.9)	<0.001	47	1.2 (1.5)	<0.001			
6 months - 12 months (49)	22	0.8 (2.0)	0.66	27	0.7 (0.4)	0.125			
3 months - 12 months (49)	22	2.5 (1.6)	<0.001	27	2.0 (2.8)	0.001			

*P value by Chi-Square test



Interestingly, both non-obese and obese groups showed increases in BMI between the 3 to 6 month marks (1.4 kg/m², p=<0.001 and 1.2 kg/m², p=<0.001; respectively) and even larger, more significant BMI gains between the 3 and 12 month marks (2.5 kg/m²+1.6, p=<0.001 and 2.0 kg/m²+2.8, p=0.001; respectively). These BMI changes over time are displayed in Figure 1.





Time

Discussion

Several studies show weight gain over time in the post-LVAD patient.^{6-8, 10} However, our study shows that this BMI gain was more likely to occur in patients who are non-obese at the time of LVAD evaluation. These findings can be used to guide clinical practice and design more effective weight management strategies for post-LVAD patients and aid in preparing this patient population for cardiac transplantation.

Some evidence shows a protective and beneficial effect in the overweight and obese populations after an established diagnosis of heart failure, described as the "obesity paradox".¹⁵⁻¹⁷ This idea has shown that elevated BMI can have a protective effect and better outcomes in those who have been diagnosed with heart failure. Considering the obesity paradox and the "U"-shaped curve among BMI groups, some may consider it beneficial for the non-obese group to gain weight. However, a study by Guisado Rasco et al. shows adverse outcomes in both graft failure and mortality in post-transplant patients with a BMI >25kg/m².¹⁸ In our study the BMI gain over time is concerning even among our non-obese group as the mean BMI for this group was 25.2 kg/m² and after 1 year over 40% of the non-obese participants had a clinically significant BMI gain that increased the



average BMI to 27.8 kg/m². These significant weight gains can necessitate changes to a patients' transplant listing weight and need for careful consideration.

As might be expected, the largest BMI gains were from the 3 to 12 month mark. Although our results did not show BMI gains that would exclude non-obese patients from transplantation, these changes are especially concerning as the average implant time for both the non-obese and obese were essentially 1 year (357.8 ± 267 days vs 381.7 ± 273.6 days; p=0.62, respectively). As previously shown in Figure 1, the trend of increasing BMI in the non-obese did not plateau over time and if followed further may interfere with eligibility for transplantation.

Similar to our findings, a study by Emani et al. found that over the course of 24 months, obese and extremely obese patients post-LVAD implant showed no significant change in BMI.⁶ Our study results are comparable in the obese group as they showed no significant total change from implant to 12 months; however, these results remain disheartening for this population to bridge to transplantation as guidelines recommend a BMI of \leq 30kg/m² to qualify for heart transplantation.¹¹ Thus, obesity complicates the decision regarding eligibility for heart transplantation. The prevalence of obesity in this population is further demonstrated by the overall BMI of our cohort at implantation; which, at 30.3kg/m² is above the suggested guidelines for heart transplantation. With more than 50% of the patients in this study being obese at the time of implantation and an increase in BMI over time in the patients that were not obese, transplant options can become limited even after LVAD implantation.

Although the focus of this study was weight gain, weight loss was also evaluated. Initial weight loss post-surgery has been reported in other studies,⁶⁻⁸ most likely due to lack of appetite, increased nutritional needs during the peri-operative period and the type of mechanical device implanted.^{6,12-14} Interestingly, despite having the same device our obese group had significant weight loss (p=<0.001) whereas the non-obese group did not. This could be attributed to poor nutrition status and poor intake being frequently overlooked in the obese population, resulting in less nutrition interventions focusing on maintaining oral intake.

As expected, diabetes was more common among the obese group. However, glucose control between groups at evaluation was not a contributing factor (p=0.22). Although the obese group had significantly more diabetic participants, hemoglobin A1C levels appeared to show good glucose control prior to LVAD implant.

B-type natriuretic peptide (BNP) is "a neurohormone secreted mainly in the cardiac ventricles in response to volume expansion and pressure overload".¹⁹ BNP is often considered a marker of disease progression in heart failure patients, with lower levels associated with less advanced disease. This is another aspect of the study that was congruent with previous research.^{2,20} Our study found lower BNP levels among the obese population as compared to the non-obese population (p=<0.001). Das et al. reported that higher BMI was independently associated with



lower BNP levels (p=<0.001).²¹ Another study by Daniels et al. showed similar results with lower BNP levels among the obese. Their study also suggests that for patients with a BMI >35kg/m² a lower cut-point of BNP (\geq 54 pg/mL) should be used to maintain a high level of sensitivity. If not, they suggest that >1 in 5 obese patients with CHF symptoms may have a missed diagnosis with a BNP level <100 pg/mL.²² Our obese group certainly would have met this criteria as the mean BNP level was 623.5pg/dL; however, this information may be very useful in earlier diagnosis, identification and treatment of heart failure among the obese population.

With an increasing number of LVAD implants and limited options for treatment in the obese population, weight loss interventions are of importance. Research is limited on specific recommendations for weight loss among the heart failure and LVAD populations.²³ However, one study involving LVAD patients shows a positive effect of nutrition counseling by a registered dietitian. Over the course of 18-months the intervention group maintained their normal BMI as opposed to the control group that had a significant BMI gain (T1: 24.0 ± 0.6 kg/m² vs. T4: 24.5 ± 1.1 kg/m², p=0.35 and T1: 23.8 ± 0.6 kg/m² vs. T4: 29.7 ± 0.8 kg/m², p=0.05; respectively).¹⁰ Newer studies have looked at the benefits and success of bariatric surgery.²⁴⁻²⁶ Although results sound promising, this option is not without substantial risk and potential complications even upon transplant as certain bariatric surgeries can cause absorptive issues with post-transplant immunosuppressant medications.²⁴

The nature of retrospective data collection contributes to the limitations of this study. Similarly, throughout the course of this study there was missing data due to participants being transplanted, expiring, or lost to follow up. Another limitation is that the vast majority of the patients in this particular study were overweight and obese. A larger study with a more equal distribution of BMI groups would provide more insight into patterns of weight change in this population. Lastly, given the relatively small sample size some p values for weight changes were not statistically significant.

A registered dietitian (RD) plays a key role in the management of dietary and lifestyle modification. Dietary modification can help patients slow, maintain or lose weight to minimize risk of LVAD complications and contribute to goals for transplantation. As seen in our study, prevention of weight gain in non-obese patients is key. Additionally, long-term individual counseling by a RD may contribute to fewer weight gains in the post-LVAD patient.¹⁰ In the obese population, identification and early weight management interventions may contribute to lower rebound weight gains after the three-month mark and a RD could provide additional resources for weight loss options. For the morbidly obese (BMI ≥35 kg/m²), perhaps an early referral to bariatric surgery is the best option for these patients to succeed with weight loss and bridge to transplantation.²⁴⁻²⁶

Our study reports finding that significant BMI gain is limited to patients in the nonobese group at the time of LVAD evaluation. We also provide supporting evidence that obese patients are unlikely to lose weight after one-year post LVAD implant.



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