BRIEF COMMUNICATION





Laparoscopic Sleeve Gastrectomy in Patients with Obesity and Ventricular Assist Devices: a Comprehensive Outcome Analysis

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Abstract

We analyzed in detail the outcomes of eight patients with ventricular assist devices (VADs) and obesity who underwent laparoscopic sleeve gastrectomy (LSG) at a single heart transplant (HT) center. This comprehensive analysis included body mass index (BMI) trends from VAD implantation to the time of LSG; BMI and percentage of excess BMI lost during follow-up; adverse outcomes; and changes in echocardiographic parameters, fasting lipids, unplanned hospitalizations, and functional status. We also identified the patients who achieved the following outcomes: listing for HT, HT, 50% excess BMI loss, and BMI < 35 kg/m^2 . Laparoscopic sleeve gastrectomy seems to be a reasonable and effective intervention to help patients with VADs and obesity to decrease excess BMI and become candidates for HT.

Keywords Laparoscopic sleeve gastrectomy \cdot Sleeve gastrectomy \cdot Bariatric surgery \cdot Heart failure \cdot End-stage heart failure \cdot Ventricular assist devices \cdot Heart-assist devices

Introduction

Obesity is a major comorbidity in patients with end-stage heart failure, not just as it poses significant cardiovascular risk but also as it is associated with worse outcomes after implantation of ventricular assist devices (VADs) and heart transplantation (HT). Hence, a body mass index (BMI) \geq 35 kg/m² represents an important contraindication for HT [1].

This represents a problem for many patients with end-stage heart failure, including those who undergo VAD implantation as destination therapy after being rejected for HT due to obesity, and those who receive a VAD as a bridge to HT but gain

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weight while awaiting transplantation, a common phenomenon after VAD implantation [2]. This has motivated programs of advanced heart failure and heart transplantation to consider bariatric surgery as a means to help patients achieve enough weight loss to become HT candidates.

Several small studies have demonstrated interesting results about the role of bariatric surgery in patients with VADs [3–5]. However, while most of these studies have tried to assess the outcomes of laparoscopic sleeve gastrectomy (LSG), they have not being able to perform inferential statistical analyses to evaluate the real significance of their results which limits their interpretation and impact in clinical practice [3, 5–7]. For this reason, this study was performed at a large academic and research center to analyze the outcomes of patients with VADs undergoing LSG.

Methods

This is a retrospective cohort of all patients with VADs who underwent LSG at Ochsner Medical Center (New Orleans, Louisiana, USA). The only bariatric surgery performed in patients with VADs in this center was LSG. These patients

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had at least grade II obesity (BMI \ge 35 kg/m²) or higher, and in most cases, obesity was a major reason for which they had been rejected for HT.

Preoperative Evaluation

All patients met selection criteria for LSG and underwent standard evaluation by our service of bariatric surgery, including psychological and nutritional assessment, and the following outpatient tests: esophagogastroduodenoscopy; electrocardiogram; chest X-ray; serum folate; H pylori screening; hemoglobin A1C; iron profile; thyroid function panel; serum folate level; serum levels of vitamins B1, B12, and D; complete blood count; and lipid, metabolic, and hepatic profiles.

Preoperative cardiovascular assessment was performed by the Advanced Heart Failure and Heart Transplant Service before being admitted for the surgery, as well as cardiac anesthesiology the day of hospital admission.

Inpatient Management

As per our protocol, each patient was admitted to the cardiovascular step-down unit under the management of the Advanced Heart Failure and Heart Transplant Service on Thursdays or Fridays to allow for, at least partial, normalization of the international normalized ratio (INR) prior to LSG. Coumadin and aspirin were held on admission, and each patient received a heparin infusion until the midnight prior to LSG. Surgeries were preferentially performed on Mondays or Tuesdays, ideally as the first case of the morning. The INR was assessed in the evening prior to the LSG, if it was > 1.5, fresh frozen plasma was administered, and INR redrawn early in the morning prior to surgery. Patients with implantable pacemakers/defibrillators had their devices reprogrammed right before and after the LSG.

Bariatric surgeons updated the heart failure attending after the surgery regarding the status of the patient and any perioperative concerns. Eight hours after the LSG, unfractionated heparin was started at 200 units/h with no titration goal unless specified by the surgeon. On the postoperative day (POD) #1, heparin was increased to 400 units/h. If no bleeding was observed by POD #2, enteric-coated aspirin was started, and the heparin infusion was titrated to achieve a goal partial thromboplastin time (PTT) of 35–45 s. On POD #3, the goal PTT was increased to 45–54 s and coumadin was restarted at 1 mg in the evening. Further coumadin doses were adjusted with the help of a transplant pharmacist.

Postoperative Follow-up

Patients were followed closely by the bariatric surgeons and the heart failure cardiologists for the first 3 months to cautiously adjust coumadin doses to maintain therapeutic INR levels (2–3) as food intake was expected to increase during this time.

Variables

The electronic medical charts of the patients were reviewed, and relevant data were extracted. Baseline (pre-LSG) and postoperative (post-LSG) variables, including demographics, blood levels, echocardiographic, and anthropometric parameters, such as weight and BMI, were obtained for each patient during euvolemic (homeostatic) status. Post-LSG data were obtained approximately 3 months after surgery, except for transthoracic echocardiographic data, in which case the measurements closest to 6-month post-LSG were obtained. Anthropometric data (related to BMI) were measured at multiple timepoints and compared.

Additional outcomes documented included BMI < 35 kg/m², \geq 50% of excess BMI loss (EBMIL), and a composite outcome of these two. Timing to each of these outcomes was measured. Myocardial recovery was defined as a sustained increase in the left ventricular ejection fraction to 40%, in the absence of inotropic agents.

Statistical Analysis

Numerical variables were expressed in means (\pm standard deviations) or medians (interquartile range) depending on their distribution. Categorical variables were represented in numbers (percentages). Spearman's correlation test was used to analyze the relationships between BMIs at VAD implantation and at the time of LSG, as well as the post-LSG rends in BMI over time. Paired *t* test was used to compare multiple measures of variables with normal distribution. Variables with repeated paired-measurements over time and non-normal distribution were analyzed using Wilcoxon signed-rank test. Tests were two-tailed and *p* values ≤ 0.05 were considered statistically significant. No imputations for missing data were used, so all data reported and analyzed were real patient information. StataSE 14 (College Station, TX, USA) was used to conduct all statistical analysis and elaborate all graphs.

Results

Baseline Data

Eight patients with VADs and a mean age of 43.8 (\pm 13.9) years underwent LSG between 2016 and January 2020 (Table 1). All of them had non-ischemic cardiomyopathy, and half were men. The most common VAD was the HeartMate 3 (50%). Mean BMI at VAD implantation was 37.8 (\pm 6.7) kg/m² which significantly increased to 42.7 (\pm

Table 1 Baseline, procedural and outcome characteri	stics $(n = 8)$
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Age, years	43.8 (±13.9)
Male sex, n (%)	4 (50)
NICM, <i>n</i> (%)	8 (100)
VAD types	
HeartMate 2, <i>n</i> (%)	3 (37.5)
HeartMate 3, <i>n</i> (%)	4 (50)
HVAD, n (%)	1 (12.5)
BMI at VAD implantation, kg/m ²	37.8 (± 6.7)
Weight at VAD implantation, kg	108.2 (±21.8)
Time VAD-LSG, months	29.4 (±16)
BMI at LSG, kg/m ²	42.7 (±4.5)
Weight at LSG, kg	123.3 (±20.1)

Continuous data are in means (standard deviation). Categorical data are in n (%). *BMI* body mass index, *NICM* non-ischemic cardiomyopathy, *LSG* laparoscopic sleeve gastrectomy, *VAD* ventricular assist device

4.5) kg/m² pre-LSG (p = 0.0218). There was a strong correlation between BMI at VAD implantation and pre-LSG (rho 0.881; p = 0.0039), as all patients gained weight during that time.

Perioperative Outcomes

The mean length of hospital stay was $17 (\pm 6.3)$ days, and only one patient required admission to the intensive care unit, where he stayed for 2 days for monitoring and treatment after post-LSG gastrointestinal bleeding for which he received 2 units of packed red blood cells (PRBCs) and 2 units of fresh frozen plasma. Three other patients also developed gastrointestinal hemorrhage. Two of these patients received 1 and 2 units of PRBCs respectively, and the third received 2 units of PRBCs and 5 units of fresh frozen plasma.

Three patients required rehospitalization within 30 days after discharge; one patient for VAD driveline infection, the second for ventricular fibrillation treated appropriately by her implanted cardioverter/defibrillator, and the third for syncope. The last two patients were in the group who had perioperative bleeding as mentioned above.

No patient required conversion to open surgery or intraoperative abortion of the case. There were no deaths during hospital stay. Relevant perioperative data are summarized in Table 2.

Long-Term Outcomes

As early as 3 months after LSG, BMI decreased by 5.9 (\pm 2.2) kg/m² to a mean BMI of 36.8 (\pm 4.2) kg/m² (p < 0.0001), with a subsequent decrease of 1.5 (\pm 1.1) kg/m² to a mean of

Table 2Perioperative data $(n = 8)$	
Last INR pre-LSG	1.45 (±0.25)
Last PTT pre-LSG, seconds	32.9 (26.9–37.4)
POD therapeutic INR achieved, days	7.1 (±4.7)
Highest INR during the 48 h post-LSG	1.4 (1.2–1.8)
Highest PTT during the 48 h post-LSG, seconds	39.6 (37.5–66.5)
PRBC transfusions per patient, units	0.5 (0-2)
FFP transfusions per patient, units	0 (0–1)
LOS, days	17 (±6.3)
ICU LOS, days	0 (0–0)*
In-hospital adverse events, n (%)	4 (50) +
30-day adverse events \ddagger , n (%)	5 (62.5)
In-hospital mortality, <i>n</i>	0
30-day readmissions, n (%)	3 (37.5)

Continuous data are in means (standard deviation) or in median (interquartile range). Categorical data are in n (%). *Only one patient required ICU stay (2 days). +All 4 patients had gastrointestinal bleeding. ‡Included readmissions and in-hospital complications within 30 days post-LSG. *FFP* fresh frozen plasma, *ICU* intensive care unit, *INR* international normalized ratio, *LOS* length of stay, *LSG* laparoscopic sleeve gastrectomy, *POD* postoperative day, *PTT* partial thromboplastin time, *PRBC* packed red blood cells

35.3 (±4.3) at 6-month follow-up (p = 0.0057). Excess BMI decreased from 17.7 (±4.5) kg/m² to 11.8 (±4.2) kg/m² (p = 0.0001), corresponding to EBMIL of 34.3% (±11.3). This overall BMI-loss trend persisted during all follow-up (rho = -0.5937; p < 0.0001), although it was more pronounced during the first, followed by the second, quarter after LSG.

Six patients achieved the composite outcome, all of whom reached a post-LSG BMI < 35 kg/m² at 4.5 (3–18) months, with three of them reaching the said outcome at 3-month follow-up (Fig. 1). Four of these patients also experienced \geq 50% EBMIL at 12 (6–27) months (Table 3).

Three patients were listed for transplantation, one of which underwent HT at 25.3 months. Additionally, three more patients were being considered for pre-HT evaluation when the data were collected. No patient experienced myocardial recovery during follow-up (Fig. 2).

There were no deaths during the mean follow-up of 23.1 (\pm 16.4) months.

Functional, Blood Test, Echocardiographic, and Hospitalization Data

Among all the lipid variables, only triglyceride levels showed a significant change at 3 months after LSG, decreasing by 35.9 (\pm 38.4) mg/dL (from 130.5 [\pm 59.7] mg/dL to 94.6 mg/dL [\pm 29.4]; p = 0.0332). All other variables listed in Table 4 did not show any statistically significant change (p > 0.05).

Table 3Long-term outcomes (n = 8)

$BMI < 35 \text{ kg/m}^2, n (\%)$	6 (75)
Time LSG-BMI < 35 kg/m ² ($n = 6$), months	4.5 (3–18)
EBMIL ≥50%, <i>n</i> (%)	4 (50)
Time EBMIL \geq 50%, months	12 (6–27)
Composite outcome, n (%)	6 (75)
Time to composite outcome $(n = 6)$, months	4.5 (3–18)
Listing for heart transplantation, n (%)	3 (37.5)
Time LSG-Listing $(n = 3)$, months	10.1 (6.7–15.9)
Follow-up, months	23.1 (±16.4)
Mortality during follow-up, n	0

Continuous data are in means (standard deviation) or in median (interquartile range). Categorical data are in n (%). Composite outcome: BMI < 35 kg/m² or EBMIL \geq 50%. *BMI* body mass index, *EBMIL* excess BMI loss, *LSG* laparoscopic sleeve gastrectomy

Discussion

This study provides evidence of the efficacy and safety of the use of LSG in patients with VADs as well as analyses of the changes in functional, metabolic, echocardiographic, and hospitalization parameters after LSG.

The observed increase in BMI from VAD implantation to LSG in every patient was not only statistically and clinically significant but the magnitude of such change correlated with the initial BMI at VAD implantation. This trend toward weight gain during VAD support has been evidenced in other cohorts and represents a major challenge in the management of these patients [2], resulting in lower rates of HT and higher incidence of complications in obese patients with VADs [2].

To reverse that natural post-VAD trend, some centers have performed laparoscopic Roux-en-Y gastric bypass, LSG, and placement of intragastric balloons in patients with VADs [3–6, 8, 9], while others have performed simultaneous VAD implantation and LSG with promising results [10]. However, most of these reports have failed, or not being powered, to provide inferential statistical analyses and assess for statistical significance of their results. For this reason, the present study is the first to analyze BMI changes during the first 3 months after LSG in this population, evidencing a statistically significant decrease of 5.9 (\pm 2.2) kg/m² during that time, as well as during the 3–6 postoperative months, and confirmed a statistically significant BMI loss trend during follow-up.

In the general bariatric population, a decrease of 20.1% EBMIL is considered a positive predictor of success after LSG, defined as persistent EBML of 50% during long-term follow-up [11]. In the present study, seven patients experienced > 20.1% EBMIL at 3-month follow-up, but only four reached \geq 50% of EBMIL. Several factors could have influenced these results, including the inherent sedentarism, and other characteristics of patients with VADs, and the fact that three patients had \leq 12 months of follow-up at the conclusion of this study.

Although the traditional definition of success of LSG based on sustained excess weight or BMI loss may be adequate for the general bariatric population, the most relevant outcomes in

Fig. 1 Trends of body mass indices. The intervals between VAD implantation (dotted line) and LSG (dashed line) varied among patients. The horizontal red line indicates BMI of 35 kg/ m². Each line represents one patient. *LSG* laparoscopic sleeve gastrectomy, *VAD* ventricular assist device



Fig. 2 Trends of percentage of excess of body mass indices. The intervals between VAD implantation (dotted line) and LSG (dashed line) varied among patients. The horizontal red line indicates 50% of baseline EBMI. Each line represents one patient. *EBMI* excess body mass index, *LSG* laparoscopic sleeve gastrectomy, *VAD* ventricular assist device



patients with VADs are HF outcomes [4, 6, 10]. Hence, reaching a post-LSG BMI < 35 kg/m², resulting in listing for

HT, receiving HT, myocardial recovery, and mortality, may represent the most appropriate outcomes.

	Pre-LSG	Post-LSG	p value
NYHA FC, n			0.5637
Ι	2 (25)	2 (25)	
II	6 (75)	5 (62.5)	
III	0	1 (12.5)*	
IV	0	0	
BNP, pg/mL	119.3 (±91.6; 42.7–195.8)	134.6 (±112.3; 40.7–228.5)	0.7289
LDH, U/L	306.5 (±90.5; 230.9–382.1)	252.9 (±132.1; 142.5–363.3)	0.0971
Total cholesterol, mg/dL	156.8 (±35.4; 127.2–186.3)	160 (± 32; 127.2–186.3)	0.9067
HDL cholesterol, mg/dL	35.5 (33.5-48.5)	43.4 (±6.7)	0.4008
HDL cholesterol/cholesterol, %	27 (±6.2; 21.8–32.1)	28.3 (±5.5; 23.7–33)	0.3857
LDL cholesterol, mg/dL	88.8 (±25.1; 67.8–109.8)	91.9 (±29.7; 70.4–120)	0.2855
Non-HDL cholesterol, mg/dL	114.9 (±29.6; 90.1–139.6)	112.9 (±30.1; 89–139.3)	0.8845
Total cholesterol/HDL	3.9 (±0.95; 3.1–4.7)	3.4 (±0.83; 3–4.6)	0.2267
Triglycerides, mg/dL	130.5 (±59.7; 80.6–180.4)	94.6 (±29.4; 70–119.2)	0.0332
LVEF, %	19.7 (± 6.9; 13.9–25.4)	19.1 (±7.6; 12.7–25.4)	0.798
RV dysfunction			0.0897
Mild	1 (12.5)	4 (50)	
Mild-moderate	1 (12.5)	2 (25)	
Moderate	4 (50)	2 (25)	
Moderate-severe	2 (25)	0	
Severe	0	0	
TAPSE +, cm	$1.2 (\pm 0.47; 0.86 - 1.64)$	$1.2 (\pm 0.26; 0.97 - 1.41)$	0.8130
Hospital admissions‡	$0.5 (\pm 0.53; 0.05 - 0.95)$	1 (±1.1; 0.11–1.9)	0.2275
Total LOS [‡] , days	1 (0-6)	5.5 (±6.6)	0.9435

Continuous data are in means (standard deviation; 95% confidence interval) or in median (interquartile range). Categorical data are in n (%). *During decompensated heart failure. +An objective parameter for assessing RV function. ‡Corresponds to all hospital admissions, and LOS of all hospitalizations combined, respectively, during the 6 months immediately before and after LSG. *BNP* B-type natriuretic peptide, *HDL* high-density lipoprotein, *LDH* lactate dehydrogenase, *LDL* low-density lipoprotein, *LOS* length of stay, *LSG* laparoscopic sleeve gastrectomy, *LVEF* left ventricular ejection fraction, *NYHA FC* New York Heart Association Functional Class, *RV* right ventricular, *TAPSE* tricuspid annular plane systolic excursion

Table 4 Changes in functional,
blood test, echocardiographic,
and hospitalization data (n = 8)

In this study, six patients achieved postoperative BMIs $< 35 \text{ kg/m}^2$, three were listed for transplantation, and one underwent HT. These rates are lower than observed in similar cohorts of patients with VADs, where the rates of listing and HT were 42–64% and 36.6%, respectively [4, 6]. However, three patients were considered for pre-HT evaluation at the conclusion of our study. Also, the follow-up of three of our patients was significantly shorter than in those cohorts, in one of which the median interval between LSG and HT was 10 months, with 10 of 11 patients being followed for at least 1 year [4]. In the other study, three patients underwent HT between 12 and 24 months after LSG [6].

Regarding all the parameters listed in Table 4, only serum triglyceride levels showed a statistically significant decrease at 3 months after LSG, probably due to a combination of dietary improvement and weight loss.

Finally, although four patients developed postoperative gastrointestinal bleeding, and three patients experienced readmission within 30 days, there were no deaths during followup, and there was no statistically significant difference in the number of hospital admissions or number of days of hospitalization between the 6 months before and after LSG. This overall positive experience has led to a growing interest in this center to perform LSG in patients with VADs and grade II obesity.

Despite these promising results, large multicenter prospective cohorts and/or clinical trials are needed to provide more information and help to improve both selection criteria as well as perioperative and long-term protocols to achieve the best outcomes for these patients.

Limitations

This cohort study includes the most comprehensive statistical analysis of changes in the most important anthropometric, functional, blood test, and hospitalization parameters in this population. However, this study is a single-center, single-arm retrospective cohort, hence, generalizations to large populations of patients with VADs, or extrapolations to other groups with end-stage HF warrant caution and integration of clinical judgment, taking into account the little available literature of bariatric surgery in patients with VADs.

This study had a BMI of $< 35 \text{ kg/m}^2$ as postoperative outcome because that is the cutoff for HT in our program and in many others. However, some centers may have lower BMI cutoffs; hence, in such context, some of our results should be analyzed carefully.

Although multiple factors could have influenced the results observed in this cohort, such as comorbidities, age, BMI at VAD implantation, and baseline BMI prior to LSG, our study was not powered to analyze the effect of each of these variables. Nevertheless, we do recommend future larger studies to consider such analysis. The focus of this study was to address outcomes after LSG, so it was not feasible to analyze in more detail BMI trends between VAD implantation and LSG. This seems to represent a critical period for weight gain in this population and should be explored in future studies to investigate potential benefits of earlier LSG prior to significant weight gain.

Conclusions

Laparoscopic sleeve gastrectomy seems to be a reasonable and effective intervention to help patients with VADs and grade II obesity lose enough weight to improve their candidacy for HT. Although there were no deaths during follow-up, morbidity remains higher than in the general bariatric population, which warrants special considerations.

The significant BMI gain between VAD implantation and LSG warrants attention and consideration of early weight loss interventions, including LSG.

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Compliance with Ethical Standards

Conflict of Interest SAM is a paid speaker for United Therapeutics Corporation and Bayer. All other authors declare no conflicts of interest.

Ethical Approval Statement For this type of study formal consent is not required.

Informed Consent Statement Informed Consent does not apply.

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