Laparoscopic sleeve gastrectomy in patients with left ventricular assist device – case series and review of literature.

Pieter Van Aelst, Ellen Deleus, Bart Van der Schueren, Bart Meyns, Katrien Vandersmissen, Matthias Lannoo

ABSTRACT

For patients with advanced heart failure, left ventricular assist device (LVAD) can serve as a bridge to heart transplantation. Patients with class II obesity are eligible for implantation of LVAD, but do not meet criteria for cardiac transplant listing. Laparoscopic sleeve gastrectomy (LSG) is proposed as weight losing modality in order to reach the NYHA criteria for listing. In our center, three patients on LVAD with need for weight reducing therapy were treated with laparoscopic sleeve gastrectomy. We reviewed our data retrospectively and compared it to the literature. Successful weight loss was achieved in all patients, without postoperative adverse events. Two out of three were listed on transplant waiting list. Our results are similar to those described in other series.

BACKGROUND

Left Ventricular Assist Device (LVAD) is a therapeutic option as bridge to orthotopic heart transplantation (OHT) in case of end stage cardiac failure. Obesity is associated with a poor outcome after OHT (1), for patients with severe obesity, it is recommended to achieve a BMI of less than 35 kg/m² before listing for OHT (1,2). Obesity is a worldwide expanding epidemic, in both developed and developing countries. (3,4) There is a strong association between obesity and heart failure: up to 35-43% of patients with heart failure are overweight or obese. (4–6) The Framingham heart study suggests that for every 1kg/m² increase in BMI the risk of developing heart failure increases by 5% in men and 7% in women. (7,8) In conclusion one can expect that more and more patients with obesity with end stage heart failure will not meet criteria for OHT due to obesity. Bariatric surgery may play a

role in inducing weight loss to improve cardiac function, even when on LVAD (8) and to reach listing criteria for OHT. (8)

Since bariatric surgery results in superior outcomes in weight loss and weight associated comorbidities compared with non-surgical interventions, this therapeutic option should be proposed to decrease morbidity while on LVAD and to increase chance for listing for OHT.(2)

Since 2014 small case series appear about performing laparoscopic sleeve gastrectomy (LSG) in patients on LVAD in order to increase their chance of being listed for heart transplantation. However experience in the field is still limited and very few medical centers have reported data about this subject.

OBJECTIVES

The purpose of our study is to evaluate the safety and efficacy of laparoscopic sleeve gastrectomy in patients with LVAD. We will report on postoperative complications, outcome after sleeve gastrectomy and whether or not listing for OHT is achieved. These outcomes will be compared to the literature.

METHODS

This is a retrospective, observational study, performed between 2016 and 2019 at the University Hospitals of Leuven, Belgium. We identified three patients with morbid obesity ($BMI > 35\text{kg/m}^2$) and end-stage heart failure with LVAD support. These were the only three patients treated with LSG while on LVAD in our center so far.

They were referred for weight loss surgery in order to improve their chance on listing for OHT. At the time of referral, all three patients were disapproved for OHT given their obesity. All patients met

international criteria to undergo weight loss surgery and received a thorough screening and multidisciplinary counseling program including endocrinological, psychological and dietary consults. All patients underwent pre-operative cardiopulmonary check-up and were approved to undergo bariatric surgery by our anesthesiology team. Two patients were on warfarin during time on LVAD, one patient was on acenocoumarol. The Vitamin-K antagonist was ceased 7 days before surgery and bridged by low-molecular-weight heparin (LMWH) in therapeutic dose. Preoperatively an abdominal x-ray (fig1.) was taken to evaluate position of the LVAD leads, they were then marked on the skin with permanent marker. At time of surgery, the anesthesia team placed an arterial line for continuous blood pressure measurement. The patients' LVAD nurse was present in the operating room for each case. She assisted with identification and protection of the subcutaneous LVAD device and drivelines, and managed LVAD settings during the case. Surgery was performed by the same highly experienced bariatric surgeon in the three cases.

Fig1: Example of abdominal x-ray that shows position of the LVAD driveline.

The LSG procedures were performed according to our standard protocol. Each procedure started by carefully placing 5 ports avoiding the LVAD drivelines. There were no major changes compared to our standard trocar positions. We use two 12mm working ports in left and right flank, the remaining ports are 5-mm ports for the camera, assistant, and liver retractor. First the Angle of His is dissected and the left crus identified. At approximately 5cm proximal to the pylorus, dissection is started close to the greater curvature and the lesser sac is entered. Posterior adhesions are taken down. An

orogastric 34Fr tube is placed and LSG is performed with a powered stapling device with 60mm loads (®Echelon Flex, Johnson&Johnson). Transection of the stomach starts 5 cm proximal to the pylorus with a green load (closed staple height: 2,0mm). Then a golden load (closed staple height: 1.8mm) and approximately 4 additional blue loads (closed staple height: 1.5mm) are used to complete the LSG towards the angle of His. Then LSG is completed by first dividing the short gastric vessels and continuing the dissection along the greater curvature until the stapled specimen is completely free. An intraoperative methylene blue test is performed to evaluate possible leak. In one patient, placement of metal clips on the short gastric vessels was necessary to achieve hemostasis. There was no need to place clips on the staple line in any of our patients.

Patients were all extubated in the operation room. All patients were admitted to an intensive care unit for 24 hours observation. Therapeutic LMWH was started 6h post-surgery, vitamin K antagonist was restarted 48h post-surgery.

The electronic medical files were reviewed for information regarding date of LVAD placement, date of LSG, length of follow-up, presence of any perioperative complications, preoperative BMI, NYHA classification, percent excess weight loss, BMI at 1, 3 and 12 months and success of transplant listing.

Table 1: Patient Characteristics

	Patient 1	Patient 2	Patient 3
Sex	M	M	M
Age at time of LSG	29	46	32
Type of LVAD	Heartmate II	Heartmate II	Heart Ware
NYHA classification pre-LVAD	IV	III	III
Time interval LVAD-LSG (months)	25	49	50

Pre-operative LVEF (%)	10	1	80*
Weight pre-LVAD (kg)	/	/	107
Weight pre-LSG (kg)	146,1	127	119,5
BMI pre-LSG (kg/m ²)	36,5	42,4	37,7
INR at LSG	1,1	1,7	1,2
PT pre-LSG (sec)	12,5	18,8	13,3
Length of Hospital Stay (days)	4	6	5
Weight at 3 months after LSG (kg)	123,1	97,0	99,3
Weight at 12 months after LSG (kg)	91,0	106,8	92,0
Weight at time of listing for OHT (kg)	127,0	/	92,0
BMI at time of listing for OHT (kg/m ²)	31,8	/	29,1
Weight at time of transplantation (kg)	111,3	/	/
Follow-up (months)	30	18	12

* Patient with transposition of great arteries, treated with Senning Repair. Right ventricle serves as systemic ventricle. He suffered from irreversible right ventricle failure with preserved left ventricular ejection fraction.

RESULTS

In our center, we have performed LSG while on LVAD on three patients. All three were male. At time of LVAD placement, they were 29, 46 and 32 years old. Mean interval between LVAD placement and laparoscopic sleeve gastrectomy was 41 months. Mean follow-up after surgery was 20 months.

Weight loss was achieved in all 3 patients. Mean pre-operative BMI was 38. Mean BMI at three months and twelve months was respectively 31 and 29. INR and PT were slightly altered at time of surgery. Mean length of hospital stay was five days. They all stayed 24h in intensive care unit for

close monitoring. There were no adverse postoperative events. Vitamin K antagonists were restarted without problems. Two out of three patients were listed for OHT. To date, one patient is already transplanted. Interval between LSG and listing for OHT was 3 months. Waiting time on transplant list was only one month. At time of transplantation he had a BMI of 28. The third patient is not listed due to therapeutic non-compliance and psychological instability.

DISCUSSION

Obesity is a growing worldwide epidemic and known as a major risk factor for developing heart failure.(4) Bariatric surgery can be a valuable treatment in this population, either to prevent heart failure, or to treat heart failure.(9) An increasing amount of patients is in need for a ventricular support system as end-stage therapy for heart failure or as bridge to OHT.(10) In non-obese patients, BMI tends to rise after LVAD implantation. The BMI of patients that are already obese remains unchanged after LVAD implantation.(11) For patients with class II obesity, losing weight with diet and exercise alone is difficult.(12,13) Losing weight while on LVAD is possible but even more challenging. Review of data from the United Network for Organ Sharing (UNOS) database showed that only 15.6% of patients on LVAD with class II obesity lost enough weight to decrease their BMI group during waiting time on transplant list.(2) Exact cause (intentional or unintentional) of weight reduction in these patients is not described. But increase in exercise capacity is unlikely. The improvement in peak VO₂ is only 3-4 ml/kg/min and as such patients on LVAD support never return to normal (age-adjusted) exercise capacity, remaining with an exercise capacity similar to someone with mild heart failure (14).

A BMI >35 kg/m² is a relative contraindication for transplantation at many centers but is a potentially modifiable factor. In these patients, LVADs may be used as a “bridge-to-listing” indication rather than the traditional bridge-to-transplant or destination therapy labels. For patients with obesity as a

transplant limitation, guideline recommendations suggest targeted strategies to assist with weight loss.(1)

Since 2013 more and more small case series are published on bariatric surgery as a valid method to lose weight while on LVAD. Although laparoscopic gastric bypass has been performed, most of the case series report laparoscopic sleeve gastrectomy as method of weight reduction surgery while on LVAD. In our series we also preferred laparoscopic sleeve gastrectomy to laparoscopic gastric bypass for two main reasons. First reason is that laparoscopic sleeve gastrectomy seems easier in terms of technicity, with lower postop bleeding rate and lower postoperative infections.(15) When on full anticoagulation therapy because of the LVAD, these short-term benefits might be of importance. A second and maybe more important reason is that the goal of the weight reduction surgery is listing for transplantation. This implicates strict use of anti-rejection therapy in the post-transplantation setting. In order to minimize risk of pharmaceutical malabsorption, laparoscopic sleeve gastrectomy is preferred to laparoscopic gastric bypass.

In our series, all patients were treated successfully, in terms of weight loss. Two patients were listed for OHT. One patient had sufficient weight reduction but was not listed because of reasons other than obesity.

Even when listing is not possible after weight reduction, there is still an indication for patients with obesity to achieve weight reduction while on LVAD. LVAD in patients with obesity is linked to more infections and more thrombosis compared to LVAD in normal weight patients. So weight reduction should lead to less morbidity. There is no difference in terms of mortality between obese and non obese patients on LVAD (2,16–18).

Tabel 2: Studies of laparoscopic sleeve gastrectomy in LVAD patients with morbid obesity

Study	N	Median length of follow-up in months (range)	Time from LVAD implantation to LSG in months (range)	LVEF (%) pre-LSG	BMI pre-LSG (range)	BMI pre-OHT (range)	Extraction LVAD without OHT	Listed for OHT	Underwent OHT	30 day morbidity (clavien-dindo)	30 day mortality *
Chaudry et al. (19)	6	22 (12-70)	50%: simultaneous 50% : median 20	NR	47,6 (+/- 3.0kg/m ²)	NR	0	6	2	2 (1 [§] , 3 ^{§§})	0
Leviner et al. (20)	1	30	13	24-40	45	NR	1	0	0	0	0
Shah et al. (21)	4	7 (5-9)	simultaneous	20	48,15 (44,4-56,4)	NR	0	1	1	1 (3 ^{§§§})	0
Jeng et al. (22)	1	71	30	15	40	29	0	1	0	0	0
Punchai et al. (23)	7	24 (2-30)	38 (14-48)	19-22	43,6 (36,7-56,7)	34,0 (24,3-46,3)	0	4	3	4 (2°, 2°, 2°, °)	0
Hawkins et al. (24)	11	NR	16 (5-32)	21	45,2 (39-58)	33,1 (26-39)	1	7	4	1 (3°)	0
Aittigrine et al. (25)	1	NR	10	20	43,8	35,3	0	1	0	0	0
Zenilman et al. (26)	6	29(7-51)	20 (9-21)	NR	41,4 (37,1-58)	26,6	0	4	3	2 (3°, 3°)	0
Greene et al. (27)	3	44	NR	15-20	49 (42-55)	30 (26-32)	0	2	2	1 (3°)	0
Our study	3	20 (12-30)	41	30 (10-80)*	38 (36,5-42,4)	29	0	2	1	0	0

OHT: orthotopic heart transplantation; NR: Not Reported

* Laparoscopic sleeve gastrectomy related mortality

§ Flank hematoma; §§ Pump thrombosis; §§§ mediastinal bleeding/tamponade; ° Staple-line bleeding;

°° Cardiac arrhythmia; °°° Dehydration

When reviewing the literature, only 9 reports on LSG in LVAD patients are available on PubMed, Google Scholar and Science Direct. (19–27) (Table 2)

All published case-series are limited in number, the largest contains 11 patients. Overall, there was a significant weight reduction in every patient. Listing for OHT was achieved in 29 (67%) cases. In two cases, LVAD could be removed due to recovery of cardiac function after weight loss. 1 patient died from LVAD complications, unrelated to LSG. 1 patient died after cardiac transplantation due to myocardial infarction. In 11 (26%) patients, listing for OHT was not reached. These patients had significant weight loss, but an extreme high start BMI, and therefore did not reach a BMI < 35 at time of publication. There is no reported mortality due to LSG, and morbidity is acceptable in light of the life saving nature of this procedure.

There is still little experience with LSG in this specific patient population. With our small series we show that in the hands of an experienced bariatric surgeon and after profound preparation of the patient, the procedure is feasible, safe and repeatable in different high-volume centers with LVAD experience.

We have to bear in mind that the demand for donor hearts outweighs the supply. Selection criteria for listing, as described by NYHA, should be strictly followed. Reaching a BMI of $<35\text{kg/m}^2$ is absolutely mandatory for listing.

Given the presumed increase in obesity and associated heart failure, we can expect an increased necessity for heart transplantation in patients with obesity and therefore an increased necessity for bariatric surgery in patients on LVAD. To justify it to be routinely used as weight losing modality, more knowledge and experience, especially on long-term results is required. Follow-up will remain important to verify sustained weight loss and similar long-term survival after OHT.

CONCLUSION

We conclude that laparoscopic sleeve gastrectomy while on LVAD is a safe procedure, when considering measurements to avoid wire-damage and intra-/post-operative bleeding. In our series, a successful weight loss was achieved in 100% of the patients. All three patients met the physical requirements for listing for heart transplantation shortly after the sleeve gastrectomy.

The procedure is repeatable in different centers, provided that it is performed by an experienced bariatric surgeon in a high volume center. Cardiological expertise concerning LVAD and OHT is mandatory. In most patients, listing for OHT can be reached by performing LSG. But even when listing is not reached, LVAD morbidity is probably lower.

More large series are needed to confirm these outcomes and provide long-term outcomes.

Conflict of Interest: The authors declare that they have no conflict of interest.

Ethical Approval: This is a retrospective study. For this type of study formal consent is not required.

Informed consent: Informed consent was obtained from all individual participants included in the study.

References

1. Mehra MR, Canter CE, Hannan MM, Semigran MJ, Uber PA, Baran DA, et al. The 2016 International Society for Heart Lung Transplantation listing criteria for heart transplantation: A 10-year update. *J Hear Lung Transplant*. 2016;35(1):1–23.
2. Clerkin KJ, Naka Y, Mancini DM, Colombo PC, Topkara VK. The Impact of Obesity on Patients Bridged to Transplantation With Continuous-Flow Left Ventricular Assist Devices. *JACC Hear Fail*. 2016;4(10):761–8.
3. Flegal KM, Kruszon-Moran D, Carroll MD, Fryar CD, Ogden CL. Trends in obesity among adults in the United States, 2005 to 2014. Vol. 315, *JAMA - Journal of the American Medical Association*. 2016. p. 2284–91.
4. Lavie CJ, Milani R V., Ventura HO. Obesity and Cardiovascular Disease. Risk Factor, Paradox, and Impact of Weight Loss. Vol. 53, *Journal of the American College of Cardiology*. 2009. p. 1925–32.
5. Horwich TB, Broderick S, Chen L, McCullough PA, Strzelczyk T, Kitzman DW, et al. Relation among body mass index, exercise training, and outcomes in chronic systolic heart failure. *Am J Cardiol*. 2011;108(12):1754–9.
6. Kenchaiah S, Pocock SJ, Wang D, Finn P V., Zornoff LAM, Skali H, et al. Body mass index and prognosis in patients with chronic heart failure: Insights from the Candesartan in Heart failure: Assessment of Reduction in Mortality and morbidity (CHARM) program. *Circulation*. 2007;116(6):627–36.
7. Kenchaiah S, Evans JC, Levy D, Wilson PWF, Benjamin EJ, Larson MG, et al. Obesity and the risk of heart failure. *N Engl J Med*. 2002;347(5):305–13.
8. Zhai AB, Haddad H. The impact of obesity on heart failure. Vol. 32, *Current Opinion in Cardiology*. 2017. p. 196–202.

9. Kindel TL, Strande JL. Bariatric surgery as a treatment for heart failure: review of the literature and potential mechanisms. *Surg Obes Relat Dis*. 2018;14(1):117–22.
10. Gustafsson F, Rogers JG. Left ventricular assist device therapy in advanced heart failure: patient selection and outcomes. Vol. 19, *European Journal of Heart Failure*. 2017. p. 595–602.
11. Emani S, Brewer RJ, John R, Slaughter MS, Lanfear DE, Ravi Y, et al. Patients with low compared with high body mass index gain more weight after implantation of a continuous-flow left ventricular assist device. *J Hear Lung Transplant*. 2013;32(1):31–5.
12. Bray GA, Frühbeck G, Ryan DH, Wilding JPH. Management of obesity. Vol. 387, *The Lancet*. 2016. p. 1947–56.
13. Sjöström L. Review of the key results from the Swedish Obese Subjects (SOS) trial - a prospective controlled intervention study of bariatric surgery. Vol. 273, *Journal of Internal Medicine*. 2013. p. 219–34.
14. Mancini D, Goldsmith R, Levin H, Beniaminovitz A, Rose E, Catanese K, et al. Comparison of exercise performance in patients with chronic severe heart failure versus left ventricular assist devices. *Circulation*. 1998;98(12):1178–83.
15. Guerrier JB, Dietch ZC, Schirmer BD, Hallowell PT. Laparoscopic Sleeve Gastrectomy Is Associated with Lower 30-Day Morbidity Versus Laparoscopic Gastric Bypass: an Analysis of the American College of Surgeons NSQIP. *Obes Surg*. 2018;28(11):3567–72.
16. Khan MS, Yuzefpolskaya M, Memon MM, Usman MS, Yamani N, Garan AR, et al. Outcomes Associated with Obesity in Patients Undergoing Left Ventricular Assist Device Implantation. *ASAIO J* [Internet]. 2019 Jun [cited 2019 Nov 12];1. Available from: <http://insights.ovid.com/crossref?an=00002480-9000000000-98662>
17. Akay MH, Nathan SS, Radovancevic R, Poglajen G, Jezovnik MK, Candelaria IN, et al. Obesity Is Associated with Driveline Infection of Left Ventricular Assist Devices. *ASAIO J* [Internet]. 2019

[cited 2019 Nov 12];65(7):678–82. Available from:

<http://www.ncbi.nlm.nih.gov/pubmed/30398982>

18. Lee AY, Tecson KM, Lima B, Shaikh AF, Collier J, Still S, et al. Durable left ventricular assist device implantation in extremely obese heart failure patients. *Artif Organs* [Internet]. 2019 Mar [cited 2019 Nov 12];43(3):234–41. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/30357882>
19. Chaudhry UI, Kanji A, Sai-Sudhakar CB, Higgins RS, Needleman BJ. Laparoscopic sleeve gastrectomy in morbidly obese patients with end-stage heart failure and left ventricular assist device: Medium-term results. *Surg Obes Relat Dis*. 2015;11(1):88–93.
20. Leviner DB, Keidar A, Ben-Gal T, Medalion B. Cardiac function recovery following LVAD implantation and bariatric surgery in a morbidly obese patient. *J Card Surg*. 2014;29(5):740–2.
21. Shah SK, Gregoric ID, Nathan SS, Akkanti BH, Kar B, Bajwa KS. Simultaneous left ventricular assist device placement and laparoscopic sleeve gastrectomy as a bridge to transplant for morbidly obese patients with severe heart failure. Vol. 34, *Journal of Heart and Lung Transplantation*. Elsevier USA; 2015. p. 1489–91.
22. Jeng EI, Aranda JM, Ahmed M, Klodell CT. Left ventricular assist device and bariatric surgery: A bridge to heart transplant by weight and waiting time reduction. *J Card Surg*. 2016;31(2):120–2.
23. Punchai S, Nor Hanipah Z, Sharma G, Aminian A, Steckner K, Cywinski J, et al. Laparoscopic Sleeve Gastrectomy in Heart Failure Patients with Left Ventricular Assist Device. *Obes Surg*. 2019;29(4):1122–9.
24. Hawkins RB, Go K, Raymond SL, Ayzengart A, Friedman J. Laparoscopic sleeve gastrectomy in patients with heart failure and left ventricular assist devices as a bridge to transplant. *Surg Obes Relat Dis*. 2018;14(9):1269–73.

25. Aittigrine S, Tozzi P, Hullin R, Yerly P, Regamey J, Rösner L, et al. Laparoscopic sleeve gastrectomy for class III obesity in a patient with a left ventricular assist device (LVAD) Heartmate III. *Surg Obes Relat Dis*. 2019;15(8):1420–1.
26. Zenilman AL, Camacho DR, Choi J. Scientific Session of the 16th World Congress of Endoscopic Surgery, Jointly Hosted by Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) & Canadian Association of General Surgeons (CAGS), Seattle, Washington, USA, 11-14 April 2018: Post. *Surg Endosc*. 2018;32:130–359.
27. Greene J, Tran T, Shope T. Sleeve Gastrectomy and Left Ventricular Assist Device for Heart Transplant. *JSL S J Soc Laparoendosc Surg*. 2017;21(3).