Obesity Surgery (2020) 30:2863–2869
https://doi.org/10.1007/s11695-020-04612-2

ORIGINAL CONTRIBUTIONS

Bariatric Surgery in Patients with Severe Heart Failure

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Published online: 15 April 2020

Abstract

Purpose Obesity and cardiac failure are globally endemic and increasingly intersecting. Bariatric surgery may improve cardiac function and act as a bridge-to-transplantation. We aim to identify effects of bariatric surgery on severe heart failure patients and ascertain its role regarding cardiac transplantation.

Materials and Methods A retrospective study of a prospectively collected database identified heart failure patients who underwent bariatric surgery between 1 January 2008 and 31 December 2017. Patients were followed up 12 months post-operatively. Cardiac investigations, functional capacity, cardiac transplant candidacy, morbidity and length of stay were recorded.

Results Twenty-one patients (15 males, 6 females), mean age 48.7 ± 10, BMI 46.2 kg/m^2 (37.7–85.3) underwent surgery (gastric band (18), sleeve gastrectomy (2), biliopancreatic diversion (1)). There were no loss to follow-up. There was significant weight loss of 26.0 kg (5.0–78.5, $p < 0.001$), significant improvement of left ventricular ejection fraction (LVEF) (10.0 ± 11.9%, $p < 0.001$) and significant reduction of 0.5 New York Heart Association (NYHA) classification (0–2, $p < 0.001$). Multivariate models delineated the absence of atrial fibrillation and pre-operative BMI < 49 kg/m^2 as significant predictors (adjusted R-square 69%) for improvement of LVEF. Mean length of stay was 3.6 days and in-hospital morbidity rate was 42.9%. One patient subsequently underwent a heart transplant, and two patients were removed from the waitlist due to clinical improvements.

Conclusion Bariatric surgery is safe and highly effective in obese patients with severe heart failure with substantial improvements in cardiac function and symptoms. A threshold pre-operative BMI of 49 kg/m^2 and absence of atrial fibrillation may be significant predictors for improvement in cardiac function. There is a role for bariatric surgery to act as a bridge-to-transplantation or even ameliorate this requirement.

Keywords Bariatric surgery · Heart failure · Cardiac transplantation

Introduction

Obesity and cardiac failure are globally endemic and increasingly intersecting. Obesity is a known risk factor for the development of heart failure [1, 2] and is present in approximately one-third of heart failure patients [3]. Its association with heart failure has been attributed to increased hemodynamic load, neurohormonal activation and increased oxidative stress resulting in altered left ventricular remodelling [1]. It has been recently proposed that myocardial lipotoxicity from metabolic alterations provides a possible relation between obesity and myocardium resulting in heart failure [1, 4].

Heart failure is a major public health problem worldwide affecting at least 26 million people globally with expected increasing prevalence [5] and high mortality rate [6].

Weight loss is recommended in obese patients with heart failure for symptomatic benefit to improve exercise capacity [7], reverse metabolic derangements and normalize left ventricular diastolic function [8]. Bariatric surgery effectively produces greater and more sustained weight loss [9, 10], has been suggested to reduce left ventricular mass and improve diastolic function [11, 12] and results in lower incidence of heart failure in the obese population [13]. Amongst heart failure patients, bariatric surgery decreases rates of heart failure

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exacerbations requiring hospitalization [14, 15] and improves quality of life and patients' symptoms [16].

There is limited data on the effects of bariatric surgery in obese patients with severe heart failure and its effect prior to cardiac transplantation [8, 17, 18]. Predictive factors of improved functional and physiological variables have not been defined. Bariatric surgery in this patient group is potentially high risk; hence, it is important that predictors of a successful outcome are defined.

We aimed to determine the effects of bariatric surgery in patients with severe heart failure on several parameters including weight, cardiac function, clinical symptoms, and in-patient morbidity risk as well as ascertain its role in relation to cardiac transplantation. We also aimed to determine predictors of improvement in cardiac function and symptoms.

Materials and Methods

This retrospective study of a prospectively collected database was conducted at Alfred Health, a tertiary Australian public hospital providing state-wide bariatric and cardiac transplantation services.

A prospectively maintained database (MS Access, Microsoft Corporation, Redmond, WA, USA) was used to identify adult patients (age > 18 years) with significant heart failure, defined as LVEF ≤ 50% and NYHA classification ≥ 2, who underwent primary surgically induced weight loss procedure between 1st of January 2008 and 31st of December 2017.

Our clinical approach and selection of procedure have previously been described [19]. During the study period, the unit's policy was to perform laparoscopic adjustable gastric banding (LAGB) as the first line option. Follow-up protocol depending on bariatric procedure has been described by Johari et al. [20]. Baseline characteristics (age, gender, height, weight, BMI, comorbidities), pre-operative cardiac function, clinical symptoms and cardiac transplant candidacy were documented. Pre- and post-operative cardiac investigations included trans-thoracic echocardiogram or trans-oesophageal echocardiogram. If the LVEF was reported as a range, the mean value was used in the analysis. Pre- and post-operative NYHA classification was determined by a cardiologist and if a range was recorded, the mean value was used in the analysis. Length of stay and peri-operative complications were documented and categorized according to the Clavien-Dindo classification. Cardiac transplant candidacy and status were evaluated by a cardiologist during outpatient clinic appointments.

The primary outcomes were to determine the effects on weight, LVEF, NYHA classification and inpatient morbidity risk. Improvement of LVEF by 10% or reduction in NYHA classification by 1 category was considered as significant outcomes. The secondary aims were to identify the eventual outcomes of the patients who were initially listed for cardiac transplantation and identify predictors of improvement in cardiac function and symptoms. Continuous variables were expressed either as mean ± standard deviation (SD) or median (range). For intra-group comparisons, Wilcoxon signed rank test and paired *T* test were used for non-parametric and parametric paired variables respectively; *p* values < 0.05 were considered statistically significant. All analyses were performed using SPSS version 14.0 for Windows (SPSS, Inc., Chicago, IL, USA).

Results

There was a total of 21 patients. Patients' baseline characteristics, comorbidities and type of bariatric procedure undertaken are shown in Table 1. The mean age of the patients was 48.7 ± 10.0, with a majority of male patients (*n* = 15, 71%). The median pre-operative weight was 151.5 kg (108.0–285.5 kg) and median pre-operative BMI was 46.2 kg/m^2 (37.7–85.3 kg/m^2). The mean pre-operative LVEF was 32.5 ± 11.0% and median pre-operative NYHA was 2.5 (2–4). Three (14.3%) patients were on the cardiac transplant waitlist pre-operatively. All 21 (100%) patients had hypertension, 16 (76.2%) patients had obstructive sleep apnoea and 9 (42.9%) patients had atrial fibrillation. Eighteen (85.7%) patients underwent laparoscopic gastric band insertion, 2 (9.5%)

Table 1 Baseline characteristics, comorbidities and type of bariatric procedure

Characteristics	Patients (*n* = 21)
Age (years)	48.7 ± 10.0
Male gender, *n* (%)	15 (71.4)
Weight (kg), median (range)	151.5 (108.0–285.5)
BMI (kg/m^2), median (range)	46.2 (37.7–85.3)
LVEF (%)	32.5 ± 11.0
NYHA classification, median (range)	2.5 (2–4)
Cardiac transplant waitlist, *n* (%)	3 (14.3)
Comorbidities	
Hypertension, *n* (%)	21 (100)
Diabetes, *n* (%)	9 (42.9)
Hypercholesterolemia, *n* (%)	10 (47.6)
Ischemic heart disease, *n* (%)	3 (14.3)
Obstructive sleep apnoea, *n* (%)	16 (76.2)
Atrial fibrillation, *n* (%)	9 (42.9)
Gastro-oesophageal reflux disease, *n* (%)	10 (47.6)
Chronic kidney disease, *n* (%)	6 (28.6)
Bariatric procedure	
Laparoscopic adjustable gastric band, *n* (%)	18 (85.7)
Laparoscopic sleeve gastrectomy, *n* (%)	2 (9.5)
Biliopancreatic diversion, *n* (%)	1 (4.8)

BMI, body mass index; *LVEF*, left ventricular ejection fraction; *NYHA*, New York Heart Association patients underwent laparoscopic sleeve gastrectomy and 1 (4.8%) patient underwent biliopancreatic diversion.

Twelve months post-operatively, all 21 patients (100%) were adequately followed up and their outcomes are shown in Table 2. Post-operatively, the median weight was 117.0 kg (80.0–212.0 kg) and median BMI was 38.0 kg/m^2 (28.7–63.3 kg/m^2). There was a mean weight loss of 26.0 kg (5.0–78.5 kg, $p < 0.001$) translating to a mean BMI loss of 8.0 kg/m^2 (1.8–21.9 kg/m^2, $p < 0.001$). This translate to a mean excess weight loss (EWL) of 43.8 ± 21.6% ($p < 0.001$, 95% CI 34.0–53.7) and significant mean total body weight loss (TBWL) of 19.0 ± 9.1% ($p < 0.001$, 95% CI 13.6–24.2).

Post-operatively, the mean LVEF was 42.5 ± 14.8% and the median NYHA classification was 2 (1–3.5). There was significant LVEF improvement (10.0 ± 11.9%, $p < 0.001$) and significant NYHA reduction of 0.5 classification (0–2, $p < 0.001$).

Sixteen patients (76.2%) achieved significant improvement in cardiac function—with at least 10% improvement of LVEF or reduction of NYHA classification by 1 category. From Table 3, comparing the group of patients who achieved significant improvement in cardiac function against the group of patients who did not, there was no significant difference in their baseline characteristics.

The mean length of stay (LOS) was 3.6 days (SD 4.5), with an in-hospital morbidity rate at 42.9%. The breakdown of complications as per Clavien-Dindo classification is shown in Fig. 1. There were 2 patients with classification 3b complications. One had a sleeve gastrectomy leak requiring endoscopically assisted vacuum therapy. The other had an infected gastric band which required replacement. There was no perioperative or 12-month mortality.

Univariate and multivariate analyses are shown in Table 4. A pre-operative BMI of less than 49 kg/m^2 and the absence of atrial fibrillation (AF) (Fig. 2) were identified to be significant predictors for improvement of LVEF (adjusted R-square 69%, $p < 0.001$).

Table 2 Outcomes at 12 months post-operatively

Characteristics	Patients ($n = 21$)
Weight (kg), median (range)	117.0 (80.0–212.0)
Excess weight loss (%)	43.8 ± 21.6
BMI (kg/m^2), median (range)	38.0 (28.7–63.3)
LVEF (%)	42.5 ± 14.8
NYHA classification, median (range)	2 (1–3.5)
Patients on cardiac transplant waitlist pre-operatively ($n = 3$)	
Successfully underwent cardiac transplantation	1 (33.3)
Removed from cardiac transplant waitlist	2 (66.7)

BMI, body mass index; *LVEF*, left ventricular ejection fraction; *NYHA*, New York Heart Association

Univariate analysis of reduction of NYHA classification as shown in Table 5 did not yield any predictive factors and hence multivariate analysis was not performed.

Of the three patients who were initially on the cardiac transplant waitlist pre-operatively, one patient (33.3%) successfully underwent cardiac transplantation, having had surgery whilst fully anticoagulated with implanted biventricular assist device. The patient suffered from dilated cardiomyopathy and was initially referred for bariatric surgery with a BMI of 38.5 kg/m^2. He lost 23 kg after a gastric band insertion with a resultant BMI reduction to 31.2 kg/m^2. He successfully underwent orthotopic cardiac transplantation 1.5 years after bariatric surgery. Post cardiac transplant, the patient no longer requires the biventricular assist device and maintains a healthy lifestyle.

The other two patients (66.7%), patients A and B, were removed from the waitlist post bariatric surgery. Patient A had idiopathic dilated cardiomyopathy and was referred for bariatric surgery with a BMI of 38.9 kg/m^2. He underwent a gastric band insertion with subsequent weight loss of 25.5 kg, BMI reduction to 31.3 kg/m^2, LVEF improvement of 32% (25% to 57%) and NYHA classification reduction of 1.5 (3 to 1.5). Patient B suffered from idiopathic dilated cardiomyopathy and referred for bariatric surgery with a BMI of 43.1 kg/m^2. She underwent a gastric band insertion and lost 40.1 kg with a resultant BMI reduction to 28.7 kg/m^2, LVEF improvement of 17% (22% to 39%) and NYHA classification reduction of 2 (3 to 1). Both patients were removed from the cardiac transplant waitlist due to improvements in their functional status and cardiac function.

Discussion

Our study provides reassuring results on the safety and effectiveness of bariatric surgery in heart failure patients. At 12-month follow-up, we found significant weight loss of 26.0 kg, BMI reduction of 8.0 kg/m^2, EWL of 43.8%, LVEF improvement of 10.0% and NYHA reduction of 0.5 classification.

Our observed LVEF improvement was higher compared to that reported by Miranda et al. [21] and Vest et al. [11] which showed a 2% LVEF improvement over mean 4.3 years, and 5.1% LVEF improvement over mean 23 months respectively. Our observed NYHA reduction is comparable to that shown by Ramani et al. [13] with a 0.6 NYHA category reduction over a similar time period.

These results are similar to Mahajan et al. [22] who showed that intentional weight loss was associated with improvement in cardiac structure indices and myocardial function. It has been proposed that intentional weight loss decreases hemodynamic workload and improves cardiac morphology by reverse remodelling of left ventricle from decreased insulin resistance and reduction in serum leptin levels [4].

Table 3 Comparison of responders and non-responders

Variable	Patients who achieved significant improvement in cardiac function (responders)	Patients who did not achieved significant improvement in cardiac function (non-responders)	*p* value
N	16	5	
Age (years)	45.6 ± 8.4	49.6 ± 10.7	0.448
Male gender, *n* (%)	11 (68.8)	4 (80.0)	0.627
Pre-operative weight (kg), median (range)	145.0 (108.0–285.5)	151.8 (127.0–160.7)	0.934
Pre-operative BMI (kg/m^2) median (range)	46.1 (37.7–85.3)	48.2 (38.5–49.6)	0.719
Post-operative weight (kg), median (range)	108.4 (77.8–212.1)	131.0 (88.0–141.3)	0.869
Post-operative BMI (kg/m^2) median (range)	38.3 (27.1–63.3)	38.7 (30.3–44.1)	0.773
EWL (%)	44.7 ± 13.3	40.9 ± 20.0	0.742
Pre-operative LVEF (%)	26.0 ± 10.0	34.6 ± 10.8	0.730
Post-operative LVEF (%)	47.0 ± 13.3	28.2 ± 9.8	0.009
Differences in LVEF (%)	12.4 ± 12.3	2.2 ± 5.8	0.092
Pre-operative NYHA, median (range)	2.0 (2–4)	2.5 (2.5–2.5)	0.511
Post-operative NYHA, median (range)	1.0 (1–3)	2.0 (2–2.5)	0.049
Reduction in NYHA, median (range)	1.0 (0–2)	0.5 (0–0.5)	0.054

BMI, body mass index; *EWL*, excess weight loss; *LVEF*, left ventricular ejection fraction; *NYHA*, New York Heart Association

We found longer LOS of 3.6 days compared to published literature mean post-operative stay of 1.0 day [23]. We also identified an increased in-hospital morbidity rate at 42.9% compared to 0.2–10% reported in contemporary series for a normal surgical cohort [24]. This is unsurprising given the nature of our cohort of patients suffering from severe heart failure which places them at a higher risk of post-operative complications. On a positive note, there was no mortality in our cohort of patients whereas the overall 30-day post-operative mortality rate ranges between 0.2 and 0.6% in other series [25].

Notably, we identified novel pre-operative predictors for LVEF improvement, namely the absence of atrial fibrillation and a pre-operative BMI of less than 49 kg/m^2. However, they warrant further large-scale studies for a more robust predictive association.

The prevalence of atrial fibrillation in modern heart failure series ranges between 13 and 27% [26] with reportedly

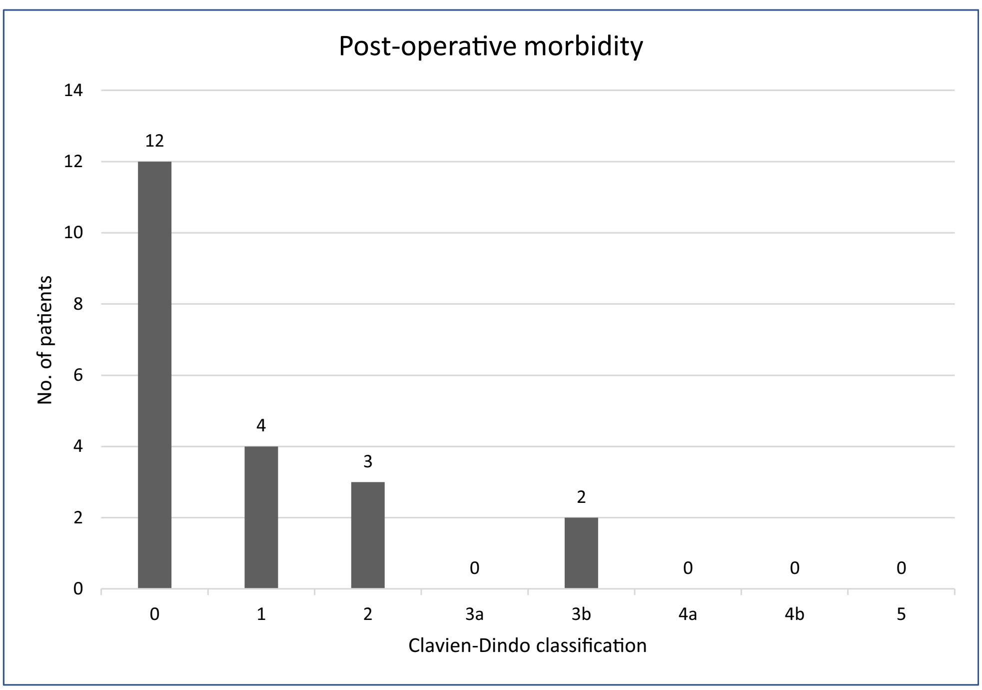

Fig. 1 Post-operative inpatient morbidity, categorized according to Clavien-Dindo classification. Majority (57%) of patients had no complications, whilst the remaining patients had complications between grades 1 and 3b

Table 4 Univariate and multivariate analysis—LVEF improvement

Variables	Univariate analysis		Multivariate analysis	
	Coefficient ± standard error	*p* value	Coefficient ± standard error	*p* value
Age	− 0.08 ± 0.28	0.766	–	0.312
Gender	− 0.19 ± 6.13	0.975	–	0.228
Pre-operative BMI	− 0.48 ± 0.23	0.046	−15.73 ± 3.68	*0.001*
Post-operative BMI	− 0.54 ± 0.26	0.056	–	0.110
EWL	0.14 ± 0.12	0.284	–	0.865
Bariatric procedure	− 6.51 ± 5.45	0.248	–	0.160
Diabetes	− 5.01 ± 5.31	0.358	–	0.247
Hypertension	–	–	–	–
Hypercholesterolaemia	10.99 ± 4.73	0.032	–	0.092
Ischaemic heart disease	8.27 ± 7.44	0.281	–	0.232
Obstructive sleep apnoea	− 2.62 ± 6.23	0.682	–	0.579
Atrial fibrillation	− 8.55 ± 5.06	0.109	− 11.07 ± 3.68	*0.008*
Chronic kidney disease	− 15.50 ± 4.71	0.004	–	0.882

BMI, body mass index; *EWL*, excess weight loss. Note: Italic values demonstrating statistical significance

increasing prevalence according to its severity (up to 50% in patients with severe heart failure) [27]. Atrial fibrillation impairs cardiac function via multiple mechanisms [28], including decreasing cardiac output, unsatisfactory ventricular filling and activation of neurohormonal vasoconstrictors. This pathophysiology may account for the reduced response to weight loss that we observed.

An elevated BMI is associated with an increased risk of heart failure [1] and affects cardiac remodelling due to left ventricular hypertrophy and cardiac adiposity [29]. Antonini-Canterin et al. [30] identified that grade 4 obesity (BMI > 50 kg/m^2) has a worse impact on cardiac remodelling and left ventricular diastolic function compared to morbid obesity (BMI 40–49 kg/m^2). This was attributed to insulin resistance which may induce myocardial hypertrophy via several mechanisms including growth stimulating effect of insulin or via increased circulating blood volume [29].

Cardiac transplantation has been established as the most durable therapy for patients with severe heart failure, with a median survival of 10.7 years [31] and a 5-year survival rate of 72.5% [32]. However, morbid obesity (BMI > 30 kg/m^2) has been identified as an independent risk factor for mortality post cardiac transplant [33, 34] and is an exclusion criteria for cardiac transplantation [35]. Additional therapies and specific

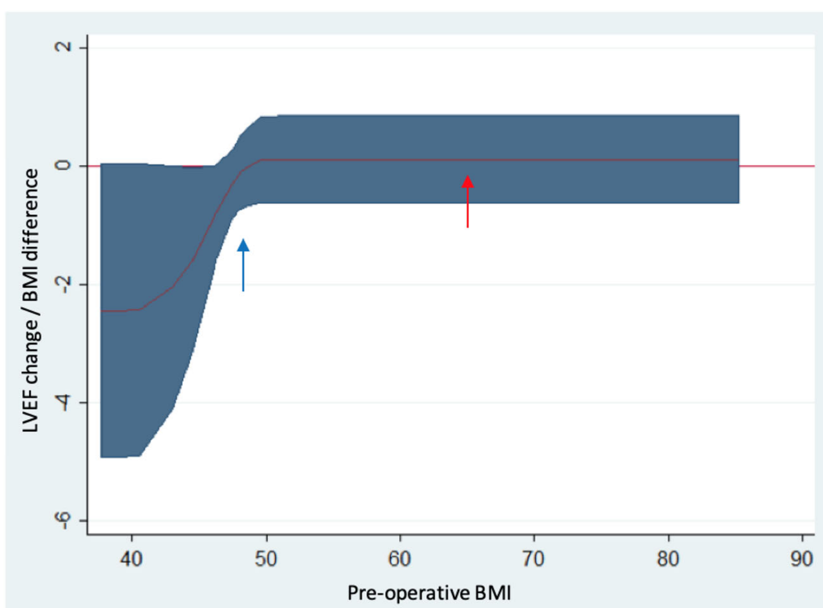

Fig. 2 Change in LVEF stratified by pre-operative BMI. The magnitude of change in LVEF (red line) is plotted against initial BMI (x-axis), with error bars noted in blue. Rate of LVEF change was maximal when pre-operative BMI was less than 49 kg/m^2 (blue arrow). A reduction in efficacy was noted starting from a BMI > 50 kg/m^2, with limited change observed (flat portion of red line—red arrow)

Table 5 Univariate analysis—NYHA reduction

Variables	Univariate analysis	
	Odds ratio ± standard error	*p* value
Age	1.02 ± 0.05	0.733
Gender	2.29 ± 2.31	0.413
Pre-operative BMI	1.05 ± 0.05	0.337
Post-operative BMI	1.03 ± 0.05	0.655
EWL	1.02 ± 0.02	0.281
Bariatric procedure	2.19 ± 2.29	0.452
Diabetes	2.80 ± 2.57	0.262
Hypertension	–	–
Hypercholesterolaemia	0.83 ± 0.73	0.835
Ischaemic heart disease	–	–
Obstructive sleep apnoea	0.67 ± 0.69	0.697
Atrial fibrillation	0.57 ± 0.51	0.530
Chronic kidney disease	0.88 ± 0.85	0.890

BMI, body mass index; *EWL*, excess weight loss

weight loss strategies have been advocated for those endeavouring to lose sufficient weight to qualify for cardiac transplantation [36, 37].

The three patients in our study who were waitlisted for cardiac transplantation all achieved excellent outcomes. Their successful weight loss post bariatric surgery resulted in either a suitable target weight to undergo cardiac transplantation or improvements which ameliorated the requirement altogether. This significant outcome broadens the pool of available data from pre-existing observational studies [16, 38] and supports the premise that bariatric surgery is a potential treatment for end-stage heart failure or bridge-to-transplantation.

There are several limitations to this study. Firstly, there is the potential for selection bias due to a lack of an overlapping cohort group for comparison. Secondly, accurate measurements of LVEF via trans-thoracic or trans-oesophageal echocardiograms are challenging in people with obesity [39], although meaningful values were obtained in all. Furthermore, the echocardiograms were performed by different doctors, resulting in the limitation of interobserver variability. Thirdly, the sample population in this study is relatively small and therefore, the power to detect modest differences in outcomes is limited. Lastly, majority of the bariatric procedures performed in this study were LAGB, reflective of our Unit's treatment pathway at that time. More recently, sleeve gastrectomy and gastric bypass are far more commonly performed. Other studies have presented promising results and feasibility of sleeve gastrectomy in a similar cohort group [40]. However, LAGB may be still worthy of consideration in higher risk patients due to its peri-operative safety profile and demonstrated efficacy in this setting.

There is a need to distinguish the pathophysiological mechanism of weight loss and improvement in cardiac function in order to accurately predict potential responders. Moreover, further large-scale randomized clinical studies with a longer duration of follow-up are necessitated.

Conclusion

Bariatric surgery is safe and highly effective in obese patients with severe heart failure with significant weight loss and substantial improvements in cardiac function and clinical symptoms. It is associated with longer length of stay and higher morbidity rates but not an increased mortality risk. A threshold pre-operative BMI of 49 kg/m^2 or less and absence of atrial fibrillation may be significant predictors for improvement in cardiac function. There is a potential role for bariatric surgery to act as a bridge-to-transplantation or even ameliorate this requirement altogether. In the future, increased focus on bariatric surgery in patients with severe heart failure is warranted.

Compliance with Ethical Standards

Conflict of Interest Professor Brown received grants from Johnson and Johnson, grants from Medtronic, grants from GORE, personal fees from GORE, grants from Applied Medical, grants from Apollo Endosurgery, grants and personal fees from Novo Nordisc and personal fees from Merck Sharpe and Dohme, outside the submitted work. The rest of the authors declare that they have no conflict of interest.

Ethical Approval The Alfred Health Ethics Committee approved the prospective collection of data from the Upper Gastrointestinal and General Surgery database (Project ref. no. 544/18).

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

For this type of study, formal consent is not required.

Informed consent does not apply.

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