Bariatric Surgery in Super-Superobese Patients Maintains Metabolic Improvement Beyond The Failure in Expected Weight Loss.

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Abstract

Background

Extreme obesity leads to increased health risks and perioperative complications. The results of bariatric surgery in patients with super-super obesity (SSO) are presented in this study.

Methods

From April 2008 to August 2019, 60 patients with SSO underwent bariatric surgery. Their weight loss and surgical outcome were analyzed. The mean follow-up time was 7.2 years.

Results

At baseline, the mean age was 41.5 years old, the mean BMI was 63.8 kg/m², 80% of the patients suffered from co-morbidities, and 23.33% were revisional surgeries. Weight loss continued for up to two years after surgery. The percentage of EBW lost at two years was 62.27%, from two to five years: 61.48%, from five to 10 years: 36.82% and after ten years it was 31.89%, the differences in weight change over the time is significant ($P < .001$). The mean BMI at last visit (Mean 7.2 years) was 45.1 kg/m² and 48.33% of the patients failed to lose at least 50% of EBW. Patients with fatty liver, diabetes, sleep apnea and hyperlipidemia had a remission or improvement in more than 70% of the cases. There were 5% perioperative complications, one perioperative death (1.67%) and other patient died in a motor vehicle accident, overall mortality 3.33%.

Conclusion

In the long term, almost half of the patients failed to lose 50% of their EBW. However, the metabolic effects of bariatric surgery were maintained during the follow-up time with a high remission of comorbidities. Revisional bariatric surgery increased the risk of mortality.

Introduction

Obesity is a complex disease of multifaceted etiology with its own associated disabilities, pathophysiology, and co-morbidities¹. The number of obese people is constantly increasing and has almost tripled worldwide in the last five decades². Obesity is a significant risk factor and contributes to increased morbidity and mortality, mainly from cardiovascular diseases and diabetes, but also from cancer, osteoarthritis, liver and kidney diseases, sleep apnea, and depression³. Excess adipose tissue increases the work of the heart and leads to cardiac anatomical changes, alters the lungs, the endocrine system, and immune functions, all with adverse health effects⁴. There is a curvilinear increase in the risk

of mortality as a function of weight; patients with a BMI ≥ 60 have a risk of mortality of more than 275% due to all causes⁵.

Weight loss appears to be the most effective therapy for obesity and obesity-related co-morbidities⁶. Therefore, a 5-10% weight loss provides considerable benefit in reducing health risks⁷.

Conservative treatments, such as diet, physical exercise, medicaments, and behavior modifications revealed a lack of long-term efficacy in patients with extremely high BMI ($\geq 60 \text{ kg/m}^2$)⁸.

With the failure of medical treatment for obesity, patients turn to more aggressive treatments, such as bariatric surgery, to achieve weight loss⁹. Bariatric surgery leads to a substantial improvement in co-morbidities, as well as a reduction in overall mortality by 25-50% during long-term follow-up¹⁰. Bariatric surgical procedures resulted in significant weight loss and an expected and lasting weight loss of approximately 50% of EBW, with improvement or resolution of most of the conditions associated with obesity¹¹. Surgery causes metabolic changes that favor weight loss and associated co-morbidities compared to non-surgical interventions, regardless of the type of procedures used¹². The fundamental basis of bariatric surgery in order to achieve weight loss is the determination that severe obesity is a disease associated with multiple adverse effects on health¹³.

Bariatric surgery has been shown to be feasible and has an acceptable complication rate for SSO¹⁴. That said, the implications for the anesthetic and perioperative care of severely obese patients who undergo weight loss procedures are considerable in SSO¹⁵. Unfortunately, there are very few published data examining and comparing the surgical outcomes in patients with SSO with any of the known bariatric procedures¹⁶.

The long-term results of bariatric surgery in patients with OHS have not been conclusively determined, so the aim of this study is to analyze the results of different types of surgery in patients with BMI $\geq 60 \text{ kg/m}^2$.

Materials & Methods

A retrospective cohort study was performed in patients with BMI $\geq 60 \text{ kg/m}^2$ that underwent bariatric surgery in a private network of medical centers for elective surgery from April 2008 until August 2019. The patient data were collected from the institutional registry and included: age, demographic information, surgery types, and co-morbidities.

Remission of co-morbidity was considered when the signs and symptoms disappear, with no abnormal laboratory tests and without medications, improvements were considered when decrease symptoms and signs of the disease, diminish medications of better labs results. Inclusion criteria included patients 18 years of age or older, complete registry availability, primary and revisional surgeries, and at least one-year post-operative. Follow-up data were obtained from periodical patient visits and reviewing medical

histories from the health insurance database. The study was approved by the Assuta Helsinki review board (Number 2015-073) and registered in Clinicaltrials.gov (number NCT04663425), first posted 11/12/2020. The study is retrospective observational one, so written informed consent was waived by the Helsinki Committee Board Assuta Medical Center.

During the study period, 33,726 bariatric procedures were performed in our Institutions according to the criteria developed by the National Institutes of Health (NIH) Consensus Development Conference Panel in 1991; the recommendations for bariatric surgery are: a BMI ≥ 40 kg/m² or a BMI ≥ 35 kg/m² in combination with high-risk comorbid conditions¹⁷.

Statistical Analysis

Demographic patient data included: age, gender, BMI, weight, and height as well as medical history, previous bariatric surgeries and procedures, chronic treatments, use of medications.

Changes in weight were provided as BMI, EBW, and percent of weight loss. Due to the lack of unanimous criteria for bariatric surgery failure, we elected to use the following two levels of criteria to determine what constituted a failure: a weight loss of 25% or less of the EBW¹⁸⁻¹⁹ or less than 50% loss of weight^{20,21}. Continuous variable summary tables were provided giving frequencies, arithmetic means with standard deviation, and 95% CI (Confidence Interval). Normally distributed variables were compared using an independent samples t-Test and Chi-square test was used to compare counts. Statistical analysis was performed using the SPSS statistical package, Version 21 (SPSS Inc, Chicago, IL, USA). All p-values were 2-sided and p<.05 was considered statistically significant.

Results

Baseline Patient characteristics.

The patients who were identified with BMI ≥ 60 comprised 60 cases, which represented 0.18% of all bariatric surgeries performed at the Medical Center. The mean age of the population was 41.5 years old (range 18 to 69), male to female ratio 1:2, the mean baseline BMI was 63.8 kg/m² (range 60 to 89). Obesity-related diseases were present in 80% of the patients and the remaining 20% did not present a history of obesity-associated diseases (Table 1).

Interventions

All patients underwent a laparoscopic approach for bariatric surgery. Laparoscopic sleeve gastrectomy (LSG) was performed on 40 patients, 15 patients underwent laparoscopic one anastomosis gastric bypass (LOAGB), five patients underwent laparoscopic roux en-y-gastric bypass (LRYGB). For 49 (81.67%) patients it was their first bariatric procedure and for 11 patients (18.33%) it was revisional surgery. In the group of patients that undergone revisional surgery, 10 patients had previously underwent laparoscopic adjustable gastric band (LAGB). Out of those patients, two of them underwent LAGB 3-times, and one

underwent LAGB 2-times. One patient previously had a LSG after LAGB. In five patients (8.33%) the LAGB was removed at the same time. In 4 patients it was converted to LSG, 5 to LRYGBP and 2 to LOGBP.

In two patients (3.33%) cholecystectomies were performed, and in two patients (3.33%) repairs of hiatal hernia were required and one repair of an incisional hernia. The mean operative time was 126.135 (± 63.32) minutes: 121.80 minutes for LSG, 115 minutes for LOAGB, and 194.4 minutes for LRYGB ($p=.004$). The long operative time for LRYGB can be explained since it involves revisional surgeries. The mean operative time for primary surgeries was 121.02 ($SD\pm 69.12$) minutes, and for revisional surgeries 159.21 ($SD\pm 62.73$), without significant statistical difference ($p=.080$).

Follow-up

On the date of analysis (December 31, 2020) the mean follow-up time was 7.2 years ($SD\pm 39.271$). Four (6.66%) of the patients were followed for 2 years, 24 (40%) patients were followed between 2 to 5 years, 25 (41.67%) patients were followed from 5 to 10 years, and seven (11.67%) patients were followed for more than 10 years. During the follow-up period, the percentage of weight loss decreased over time. The mean percentage of weight loss until two years was 62.27%, from two to five years it was 61.48%, from 5 to 10 years it was 36.82%, and after ten years it was 31.89% ($P<.001$), shown in Figure 1.

Weight loss

The mean weight at the last follow-up after the operation was 121.84 kg, the mean BMI was 45.11 kg/m^2 , and the mean percentage of excess body weight (EBW) lost was 48.66%. Eleven (18.33%) patients lost less than 25% of EBW and 29 (48.33%) patients lost less than 50% of EBW (Figure 2). According to the type of bariatric surgery, the mean weight loss of the 15 patients who underwent LOAGB was 61.2% of EBW ($SD\pm 23.77$, 95%CI: 40.214-88.266), the 40 patients who underwent a LSG lost 45.27% of EBW ($SD\pm 22.75$, 95%CI: 37.240-56.080) of the original weight, and the five patients who underwent a LRYGB lost 35.28% of EBW ($SD\pm 19.087$, 95%CI: 28.866-99.426), LOAGB procedure showed higher weight loss but, without statistical significance ($p=.054$).

Patients that underwent primary bariatric surgery lost an average of 48.54% ($SD\pm 23.03$, 95% CI: 45.347-59.973) of their EBW while patients that underwent revisional surgeries lost 36.38% ($SD\pm 22.61$, 95%CI: 15.634-67.886) of their EBW ($p=.118$) (Figure 3). In the patients that failed to lose at least 50% of EBW, 24 (60%) patients had LSG surgery, 3 (20%) patients had LOAGB, and 3 (60%) patients had LRYGB, however, the difference was not statistically significant ($p=.245$).

Co-morbidities

A total of 48 (80%) patients presented with morbidities associated to obesity. The most common co-morbidities were fatty liver, diabetes Type II, hypertension, hyperlipidemia, and sleep apnea (Table 2). The fatty liver, sleep apnea, reflux disease, and diabetes had a high proportion of remission or improvement. Conversely, hypertension had a low rate of improvement, and hyperlipidemia had low rate of remission.

It is noteworthy, that despite the fact that weight loss has not been sufficient in almost half of the patients; the metabolic changes induced by bariatric surgery persist during follow-up. Fatty liver had a remission or improved in 73.91% of patients, and the remaining 26.09% of unchanged patients were among those who did not lose weight. Patients with diabetes mellitus type II, 77.78% remission or improved, while 38.89% were able to maintain normal levels of plasma glucose and hemoglobin A1C, the 22.22% of the patients who continued with the same medication regiment were among those who failed to lose weight. Sleep apnea was in remission in 71.43% of the patients and improve in 14.29% and there was only one patient without who remained unchanged. All the patients who reported reflux before the operation were asymptomatic at the end of the follow-up. Hyperlipidemia had improved or been in remission in 70% of the patients and hypertension improved in 29.1% of the patients.

Perioperative complications

There was one perioperative death (1.67%) due to a post-operative leak after LOAGB and the same patient had previously undergone LAGB and LSG. The second death was due to a motor vehicle accident two years after surgery. The overall perioperative mortality of patients who underwent bariatric surgery for any BMI, in our institution, was 0.04%. One death (10%) occurred in the group of revisional bariatric surgery (11 patients) and one (2.08 %) in the primary bariatric surgery group (49 patients), the risk ratio is 7.92 and the Odds ratio 4.8. When compared with the mortality of patients with $BMI \geq 60 \text{ m/kg}^2$, the difference is statistically significant ($p < .001$). There were three (5%) patients with perioperative complications, one with an anastomotic leak, one patient presented with supraventricular tachycardia, and one patient with a superficial site infection. No blood products were needed and there was no need for re-admissions.

Discussion

Extreme obesity carries risks of severe co-morbidities, psychological disorders, social isolation, and many other disadvantages, as well as increased mortality²². A difficult question to answer is whether obesity in patients with $BMI \geq 60$ is due to the same pathophysiology as patients with $BMI \geq 40$, or if there are other associated factors. The loss of the sense of satiety is a decisive factor in the development of extreme obesity²³. There is a growing interest in the identification of satiety phenotypes that operate in parallel with metabolic phenotypes²⁴.

Bariatric surgery in patients with SSO could be a risky procedure from the point of view of anesthesiology and postoperative management in relation to systemic diseases. Aggressive preoperative optimization can avert the effects of BMI on anesthetic outcomes²⁵. The proportion of patients with SSO in our Institution was 0.18% of the total bariatric patients and was far less than that reported by Courcoulas, which was 12% of 2559 patients²⁶. In this group, patients with LAGB failed in weight loss and quality of life improvement and had to remove the band and convert it into another type of operation. In a comparison of procedures in super-morbid obesity patients reported by Bettencourt-Silva, they showed that LAGB was the metabolic surgery with the least effective results, with only 21.7% of EBW loss²⁷.

Although, there are authors, who promote the use of LAGB^{28,29}, our results in SSO patients show that LAGB should not be offered to these patients. Our results were in line with Cho who reported a high percentage of band removal in more than 37% of his patients, generally due to intolerance, slippage, or erosion³⁰. Langer reported that the resection of the gastric fundus, the predominant area of human ghrelin production, significantly reduced ghrelin after LSG but not after LAGB³¹. This reduction remains stable at follow-up 6 months postoperatively, which may contribute to the superior weight loss when compared with LAGB.

LSG and LRYGB offer good results in weight loss for SSO patients. LSG has demonstrated effective and satisfactory long-term results without the need for conversion to another type of metabolic surgery in patients with risks and extreme obesity³². Patients that underwent LSG had a mean loss of 46.66% EBW, with a mean BMI of 64 kg/m² before surgery and 46.44 kg/m² after surgery. These results are acceptable and did not have higher complications, coinciding with Villamere that LSG is safe without increased risk³³. Gonzalez-Heredia's study reported poor weight loss after LSG³⁴, however, in our study, the weight loss for patients who underwent LSG was acceptable, even in the long-term follow-up, as demonstrated by Arapis³⁵.

We agree with Nesser that LRYGB offers the best results among restrictive surgeries³⁶. In our group of patients, the results were altered by the fact that all the patients who underwent a LRYGB were revisional. None of our patients underwent malabsorptive surgery, which can be explained by the lack of compliance in this group of patients. Marek asserts in his study, that patients with a BMI ≥ 60 had greater psychosocial sequelae, as demonstrated by more binge-eating episodes, and higher prevalence of major depressive disorders³⁷.

The results of this study show more optimal results in terms of weight loss after LOAGB, coinciding with the results of Madhoc that reported EBW loss of 70.4%³⁸.

In this study, the results reveal a high index of failure to lose weight in more than 48% of the patients. Preoperative factors that can predict inadequate weight loss include higher BMI, diabetes, and older age³⁹. Preoperative excessive BMI, especially, ≥ 60 , implies a lower percentage of weight loss will occur. Comparatively, while less obese (BMI ≤ 50) individuals continued losing weight, heavier individuals (BMI ≥ 50) regained significant weight⁴⁰. Although the weight loss may be insufficient, it does not imply loss of the metabolic effect of bariatric surgery⁴¹. The results of the present study demonstrate metabolic changes through a high rate of remission or improvement in fatty liver, diabetes Type II, sleep apnea, asthma, and knee and back pain. Although diabetes has a high rate of remission or improvement, Runkel explains that this depends on the severity and duration of diabetes⁴².

Revisional surgery is an important factor to discuss since in SSO there are other uncontrollable factors that influence weight regain. We accept the criteria set forth by Lunel, which indicates that candidates for

a third revision surgery should be considered cautiously⁴³. In this group of patients, the only perioperative death occurred after third bariatric surgery.

There was no higher complication index in surgeries for patients with a BMI $\geq$ 60, coinciding with the report by Kushnir⁴⁴. Bennet, in a study of mortality in bariatric surgery, found that mortality is related to age, and male sex, not finding a relationship with the increase in BMI as in our study⁴⁵. We suggest considering revisional surgery cases as a risk factor in addition to age, gender, and health conditions.

The limitations of the study were the low number of patients and the completion of follow-up beyond 10 years in few patients.

The strengths of the study are that it provides long-term results of weight loss and metabolic changes from restrictive procedures as treatment in patients suffering from SSO.

Conclusion

In the long term, half of the patients failed to lose 50% of their EBW. However, the metabolic effects of bariatric surgery were maintained during the follow-up time with a high remission of co-morbidities. Bariatric surgery in patients with SSO was feasible with acceptable perioperative complications and higher mortality rate. Revisional bariatric surgery increased the risk of mortality.

Declarations

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Author contributions: SS and AR write the main article, SS and RB prepared figures, SS and IB: collected the data. All the authors reviewed the manuscript.

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<https://clinicaltrials.gov/ct2/show/NCT04663425>

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Tables

Table 1- Demographic patient characteristics.

Characteristic	Average (N60)	SD/95%CI
Age (years)	41.5	11.25/1.45
Weight (Kgs)	171.96	27.12/3.50
Height (Cm)	163.75	12.19/1.57
BMI (Kg/m ²)	63.81	4.77/0.62
Operative Time (min.)	126.15	63.32/8.17
Follow-up (Month)	73.57	39.33/5.08
	N	Percent
Male	20	33.33%
Female	40	66.67%
Healthy	12	20%
Co-morbidities	48	80%
LSG	40	66.67%
LSAGBP	15	25%
LRYBP	5	8.33%
Revision of LAGB	9	15%
Revision of LSG	5	8.33%
Primary Procedure	46	76.67%

Table 2- Co-morbidities and post-bariatric surgery outcomes.

	Preoperative		Postoperative		
			Improvement	Remission	No-changes
Co-morbidity	N	Percent	N (%)	N (%)	N (%)
Fatty Liver	23	38.33%	7 (30.43%)	10 (43.48%)	6 (26.09%)
Diabetes Type II	18	30%	7 (38.89%)	7 (38.89%)	4 (22.22%)
HTN	17	28.33%	5 (29.41%)	0	12 (70.59%)
Hyperlipidemia	10	16.67%	6 (60%)	1 (10%)	3 (30%)
Sleep Apnea	7	11.67%	1 (14.29%)	5 (71.43%)	1 (14.29%)
Asthma	5	8.33%	2 (40%)	3 (60%)	0
Knee Pain	4	6.67%	3 (75%)	0	1 (25%)
Back Pain	2	3.33%	1 (50%)	0	1 (50%)
Depression	2	3.33%	1 (50%)	0	1 (50%)
GERD	3	5%	1 (33.33%)	2 (66.67%)	0
SVT	2	3.33%	0	0	2 (100%)
Infertility	1	1.67%	0	0	1 (100%)
Breast Cancer	1	1.67%	0	0	1 (100%)
Fibromyalgia	1	1.67%	1 (100%)	0	0
Cirrhosis	1	1.67%	0	0	1 (100%)
Hypothyroidism	3	5%	1 (33.33%)	0	2 (66.67%)
Drug Abuse	1	1.67%	0	1 (100%)	0
PTC	1	1.67%	1 (100%)	0	0
No Disease	12	20%	-	-	-

The most common co-morbidities in patients with BMI $\geq$ than 60 are fatty liver, Diabetes type II, HTN and hyperlipidemia. The results show that the metabolic changes induced by bariatric surgery persist despite inadequate weight loss.

Abbreviations: N- Number of patients, HTN- Hypertension, GERD- Gastro-esophageal reflux disease, SVT- Supraventricular tachycardia, and PTC- Pseudo tumor cerebri.

Figures

Figure 1

Percent of excess body weight loss over the time. The weight loss is demonstrated until 2 years follow-up, until 5 years, until 10 years and more than 10 years follow-up, corroborating gradual weight gain the further we get from the surgery.

Figure 2

Wight loss expressed in kilograms. The percentage of excess weight loss is expressed here as well as the corresponding point in each patient has been marked at 25% of the weight lost and 50% of excess weight lost, which shows the high rate of failure of weight loss expected in each patient.

Figure 3

Mean EBW loss per type of bariatric surgery. One anastomosis gastric bypass is the surgery that provided greater weight loss than Sleeve gastrectomy and Roux-en-Y gastric bypass, as well as revisional surgery of previous bariatric procedures provokes less weight loss than primary bariatric surgeries. Abbreviations: EBW- excess body weight.

Supplementary Files

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- [DATA1.xlsx](#)