Preoperative weight loss in super-obese patients: study of the rate of weight loss and its effects on surgical morbidity

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OBJECTIVES: The incidence of obesity and particularly super obesity, has increased tremendously. At our institution, super obesity represents 30.1% of all severely obese individuals in the bariatric surgery program. In super obesity, surgical morbidity is higher and the results are worse compared with morbid obesity, independent of the surgical technique. The primary strategy for minimizing complications in these patients is to decrease the body mass index before surgery. Preoperative weight reduction can be achieved by a hypocaloric diet, drug therapy, an intragastric balloon, or hospitalization. The objective of this study was to analyze the results of a period of hospitalization for preoperative weight loss in a group of super-obese patients.

METHODS: Twenty super-obese patients were submitted to a weight loss program between 2006 and 2010. The mean patient age was 46 years (range 21-59). The mean BMI was 66 kg/m² (range 51-98) and 12 were women. The average hospital stay was 19.9 weeks and the average weight loss was 19% of the initial weight (7-37%). The average caloric intake was 5 kcal/kg/day. After the weight loss program, the patients underwent gastric bypass surgery.

RESULTS: The statistical analysis revealed that after 14 weeks of treatment (15% loss of initial weight), the weight loss was not significant. All patients had satisfactory surgical recovery and were discharged after an average of 4.6 days.

CONCLUSION: In super obesity, preoperative weight loss is an important method for reducing surgical risks. Hospitalization and a hypocaloric diet are safe and effective. After 14 weeks, the weight loss rate stabilized, signaling the time of surgical intervention in our study.

KEYWORDS: Severe Obesity; Very-Low-Energy Diet; Weight Loss; Bariatric Surgery.

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INTRODUCTION

The incidence of obesity is growing worldwide (1). In the last decade, the Brazilian population with morbid obesity has increased by more than 400% (2). Obesity is now a pandemic and it is directly related to the Westernization of lifestyles and the development of obesogenic environments (3).

Surgical treatment using the various available bariatric techniques has yielded good results. The Roux-en-Y gastric bypass (GBP) has become the most commonly performed weight loss operation. More than 75% of patients undergoing GBP experience good long-term results, with low morbidity and mortality rates (4,5). The eligibility criteria for weight loss surgery were established in 1991; however, there are currently no consensus criteria for the preparation of patients eligible for surgical treatment (6). With the increase in these bariatric procedures, it is essential to standardize the preoperative preparation, especially with regard to selecting the best time to perform the procedure to optimize the safety and efficacy of the treatment, especially in higher risk groups (7).

The population with super obesity (body mass index [BMI] ≥50 kg/m²) increased by 500% in the last decade and accounts for 30 to 50% of the morbidly obese. The increasing demand of...
these patients in bariatric surgery centers is quite clear (8). In the unit of metabolic and bariatric surgery at our university hospital, the super obese (SO) represent approximately 40% of all patients followed in the bariatric surgery program.

This group of obese patients has been under investigation because of the perception of increased risk of complications and higher rates of treatment failure associated with increased BMI (9). Super obesity is related to higher incidences of comorbidities, major technical difficulties, increased risks of surgical and anesthetic complications and higher incidences of peri- and postoperative adversities (10-16). Weight loss before surgery resulted in decreases in morbidity associated with being overweight.

In a retrospective analysis of the data from patients operated on five years prior to the start of the preoperative weight loss program, we found that the incidence of complications in SO patients was approximately 4-fold higher compared with morbidly obese group (BMI <50 kg/m²), and that 80% of the deaths occurred in super obese (17).

Factors related to increased morbidity and mortality in morbidly obese patients undergoing surgical treatment include the following: age, gender, presence of comorbidities, risk factors for pulmonary embolism (PE) and BMI, mainly BMI >55 kg/m², which is the main risk factor for mortality (18-20).

The most common strategies for preoperative weight loss are a hypocaloric diet, drug treatment, an intragastric balloon and hospitalization. The implementation of a household diet has poor outcomes, with low adherence and high dropout rates (21). The options for drug treatment of obesity are limited; additionally, such treatment has poor outcomes and is contraindicated in high-risk patients, such as those with hypertension and heart disease. Most anti-obesity medications have been withdrawn from the market due to their side effects and risks. Today, Brazil is the only country that still sells sibutramine and in Europe, the only anti-obesity drug currently in use is orlistat (22). The use of an intragastric balloon is restricted due to the high cost of the intervention. This treatment also requires close nutritional monitoring, has a recommended duration of six months and has a non-negligible morbidity rate (23).

Hospitalization for weight loss offers the possibility of keeping the patient in a controlled environment with a controlled diet of very low caloric value. A very-low-energy diet can be safely followed in a hospital environment, providing a greater probability of achieving effective weight loss. By having access to an auxiliary hospital, where patients can be hospitalized for a longer period at lower cost, this option was chosen for preoperative weight loss in SO high-risk patients in our bariatric surgery program.

We initiated a protocol for preoperative weight loss in SO patients consisting of the hospitalization of these patients for biometric monitoring and controlled nutrition. The aim of this study was to evaluate, in the period of preoperative preparation, the effect of the length of hospital stay on the rate of weight loss in SO patients maintained on a very-low-energy diet to identify a predictor for the optimal time for surgical intervention following weight loss. A secondary objective was to analyze the efficacy of weight loss with respect to postoperative outcome improvement.

**MATERIALS AND METHODS**

We studied 20 high-risk, morbidly obese patients with BMIs ≥50 kg/m² who were consecutively included in the schedule for bariatric surgery at the Hospital das Clínicas, University of São Paulo Medical School, which is a university hospital that is part of Brazil’s public health system program and is a major hospital complex in Latin America. The patients were admitted preoperatively to the Hospital Auxiliary of Suzano for the purpose of losing weight before surgery. This was a retrospective study performed by collecting information from patients’ records. Table 1 shows the demographics of the study group.

The Hospital Auxiliary of Suzano is a 150-bed country institution located in the city of Suzano, 32 miles from the city of São Paulo, in southeastern Brazil. All the patients remained on an inpatient basis throughout the period of stay and were restricted to the diet administered by the dietitians. Water was provided *ad libitum*, except in patients with certain clinical conditions that require fluid restriction. Patients who were fit for activity were encouraged to participate in outdoor and indoor physical activities, which consisted of walks around the hospital in a flat and wooded area or jogging in a sports court and handcraft workshops monitored by occupational therapists.

The daily caloric load during hospitalization was offered in the form of five balanced meals, which were low in carbohydrates and prioritized vegetables, fruits and lean proteins. The caloric content varied from 1,500 to 600 cal/day, which was calculated based on the patient’s initial weight and was revised as the weight loss progressed during the period of hospitalization. All patients were followed by dietitians and medical staff to avoid ketosis, dehydration and acute malnutrition. Once a month, the subjects were referred to our main institution for surgical staff evaluation, analysis of the treatment progress and decision-making regarding surgery scheduling.

The assessment during the preoperative examination consisted of the following parameters: composition of the caloric load of the diet, physical activity capacity level, length of stay and evolution of the weight curve (Figure 1), which involved weight measurements during the hospitalization. Table 1 presents the comorbidities of the patients at the beginning of treatment and the results in terms of percentages of initial weight loss, BMI and absolute weight after the final pre-operative medical treatment.

During the preoperative period, all patients underwent upper endoscopy, abdominal sonography, thorax radiography, echocardiography, spirometry and blood and urine tests. In cases of clinical suspicion of obstructive sleep apnea syndrome, polysomnography was also performed.

For the statistical analysis of the results, the nonparametric analysis of variance (ANOVA) test and multiple comparison tests were applied (24,25).

After the preoperative weight loss, all the patients were submitted to open Roux-en-Y gastric bypass. The technical aspects of the surgical technique were standardized and involved a 15- to 20-cm median longitudinal laparotomy, 5-cm gastric pouch, 50- to 70-cm biliopancreatic limb, 100- to 120-cm Roux limb and retrocolic-nutrogastric anastomosis. All patients received a gastrostomy and drainage with a silastic drain. The mesenteric defect and the Petersen’s space were closed. All patients received prophylactic antibiotics for 48 hours and low-molecular-weight heparin until the 21st postoperative day, which was suspended in cases of bleeding. The oral intake was started in most cases on postoperative day 1.

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The incidences of early complications were retrospectively analyzed and compared with the results of our series at the end of the preoperative treatment period (CAF: chronic atrial fibrillation; DLP: dyslipidemia; DM2: diabetes mellitus type 2; HPB: high blood pressure; OCPD: obsessive-compulsive personality disorder; OSAS: obstructive sleep apnea syndrome).

Among the subjects studied, there were 12 females and 8 males, with a mean age of 45.6 years. The youngest patient was 21 years old and the oldest was 59 years old. The average initial body weight was 180 kg and the average BMI at the beginning of the hospitalization was 67 kg/m² (range 51 to 98 kg/m²). Eighteen patients had arterial hypertension that was previously diagnosed and for which they were undergoing treatment, 8 patients had type 2 diabetes mellitus that was being monitored, 5 patients had dyslipidemia and 9 patients had obstructive sleep apnea. One patient had a diagnosis of congestive heart failure, with grade III diastolic dysfunction. Another patient had chronic atrial fibrillation. Only 2 of the 20 patients had no diseases associated with obesity (Table 1).

The daily caloric load during hospitalization ranged from 600 to 1,500 kcal/24 h, averaging 917 kcal/24 h (5 cal/kg/24 h). The mean length of stay at the Auxiliary Hospital of Suzano was 19.8 weeks (range 7 to 45 weeks). The mean percentage of the initial body weight loss was 19.7% (range 7 to 37%). The average BMI after admission to the surgical unit was 55 kg/m² (range 45 to 78 kg/m²). Figure 1 shows the weight curves of the patients over time.

To maintain the representativeness of the sample, we chose to perform the statistical analysis only until the 24th week, as the monitoring was performed in only 80% of the patients at that time point. We used the nonparametric ANOVA test for ordinal data to determine whether there was a change in weight over time. After determining the time point at which the change in weight over the hospitalization became non-significant, we applied multiple

| Gender | Age (years) | Initial body weight (kg) | Initial BMI (kg/m²) | Comorbidities | % Loss of initial body weight | Final weight (kg) | Final BMI (kg/m²) |
|--------|-------------|--------------------------|---------------------|---------------|-------------------------------|------------------|------------------|
| FEM    | 46          | 136                      | 59                  | OSAS HBP knee arthrosis | 20               | 108.8            | 56               |
| MALE   | 54          | 207                      | 70                  | HBP            | 27.7                         | 149.6            | 48               |
| MALE   | 24          | 213.4                    | 78                  | HBP DM2        | 20.6                         | 169.4            | 60               |
| MALE   | 43          | 269                      | 98                  | HBP DM2 congestive heart failure | 53.5             | 124.9            | 54               |
| MALE   | 46          | 191                      | 68                  | HBP DLP OSAS arthrosis | 20.5             | 151.9            | 54               |
| FEM    | 48          | 208.7                    | 85                  | HBP DM2 OSAS   | 14.1                         | 179.3            | 73               |
| FEM    | 45          | 152.2                    | 70                  | HBP OCPD arthrosis | 30.2                         | 106.1            | 48               |
| FEM    | 46          | 130                      | 55                  | HBP DM2 DLP    | 15.4                         | 110              | 47               |
| FEM    | 47          | 170                      | 62                  | HBP DLP poliomyelitis sequelae | 37               | 107              | 39               |
| MALE   | 47          | 220                      | 78                  | HBP OSAS CAF  | 28.6                         | 157              | 57               |
| FEM    | 53          | 168.8                    | 51                  | HBP DM2 OSAS   | 19.4                         | 136              | 41               |
| FEM    | 48          | 182.4                    | 57                  | HBP DLP        | 21.6                         | 143              | 45               |
| MALE   | 52          | 142.1                    | 64                  | HBP DM2 OSAS   | 7                            | 132.1            | 59               |
| MALE   | 50          | 217                      | 68                  | HBP DM2 OSAS   | 26.7                         | 159              | 50               |
| FEM    | 59          | 130                      | 51                  | HBP OSAS       | 8.3                          | 119.2            | 50               |
| FEM    | 43          | 175                      | 58                  | HBP OSAS       | 14                           | 150.6            | 50               |
| FEM    | 56          | 158.6                    | 72                  | HBP knee arthrosis | 24.5                         | 119.7            | 55               |
| MALE   | 21          | 234                      | 68                  | HBP DM2 OSAS knee arthrosis | 22.5             | 181.4            | 53               |
| FEM    | 51          | 149                      | 64                  | HBP DM2 OSAS knee arthrosis | 16.6             | 123.4            | 53               |
| MALE   | 47          | 173.6                    | 83                  | DM2 DLP        | 19.3                         | 140              | 67               |

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Table 1 - Demographics of the study group. Gender, age, initial weight and BMI, comorbidities, weight loss percentage and weight and BMI at the end of the preoperative treatment period (CAF: chronic atrial fibrillation; DLP: dyslipidemia; DM2: diabetes mellitus type 2; HPB: high blood pressure; OCPD: obsessive-compulsive personality disorder; OSAS: obstructive sleep apnea syndrome).
comparison tests (24,25). Figure 2 represents the results of this analysis in the form of a curve that shows the relative effect of treatment, which reflects the statistical impact of each of the consecutive weekly weight variations on the final treatment result.

We found that the first 14 weeks of the intervention constituted the period during which the weight loss was statistically significant for the study sample. The average rate of weight loss was 2.0 kg/week until week 14, at which time the group had achieved an average weight loss of 15%. Eighteen individuals experienced weight losses of 10% of their initial weight by an average of 8 weeks of hospitalization (Table 2).

After determining that the patients were ready to undergo surgery and after completion of the preoperative preparation, the patients were submitted to open GBP. Only the patient with congestive heart failure developed a major complication, namely, decreasing oxygen saturation and respiratory difficulty that required intubation, assisted ventilation and monitoring in the intensive care unit. Nevertheless, this patient progressed well and was discharged on postoperative day 6. The mean hospital stay was 4.6 days (range 3 to 6 days).

**DISCUSSION**

There have been comparatively few studies analyzing postoperative morbidity and mortality in SO patients, as well as investigation of morbidity predictors and complication prevention protocols in this distinct group of patients. Despite the important information available regarding the benefits of preoperative weight loss, the following questions remain: which patients should be encouraged to lose weight before surgery? Are the benefits of weight loss dependent on the pre-operative BMI, patient demographics, or other factors? How much weight should be lost? What is the best clinical intervention to achieve the intended result and for how long should the intervention be performed? (26). Among the supporters of preoperative weight loss, there is no consensus regarding what percentage of weight the patient undergoing bariatric surgery should lose before surgery.

These important issues need to be addressed. We do not know the point at which the prolongation of hospitalization and treatment and the consequent delay in surgical treatment yield a cost-benefit ratio that is disadvantageous to the patient.

Male gender, hypertension, known risk factors for a PE (prior PE, presence of a vena cava filter, hypoventilation and pulmonary hypertension), age over 40 years, time of morbid obesity, coronary disease, lung disease, dyslipidemia and BMI $\geq 50$ kg/m$^2$ have been identified as risks associated with bariatric surgery. SO is an independent risk factor for intra- and postoperative complications (18-20). BMI is the only risk factor that can be modified by preoperative weight loss.

In this series, a 10% weight loss was achieved in 7.7 weeks (Table 2), 15.2% in 15 weeks and 19.7% in 21.3 weeks of hospitalization. Until week 14 (63% of the average length of stay), 78.3% of patients achieved the intended weight loss. At this point, the weight loss became statistically insignificant.

Most surgical morbidity and mortality derived from SO are associated with the greater technical difficulty of the surgery, the presence and severity of comorbid conditions directly related to the degree of obesity, disease duration, limited mobility and decreased reserve to react and recover from postoperative complications.

**Figure 2** - Curve of relative effects of treatment. The impact of each of the consecutive weekly weight variations on the final treatment result is shown. The abscissa axis shows the time of treatment in weeks and the ordinate axis shows statistical significance of the weight variation. After the 14th week, the weekly weight variation lost statistical significance.
Table 2 - Length of stay necessary to achieve an approximately 10% loss of initial body weight.

| Patient | Initial body weight (IniBW) (kg) | Weight 90% IniBW | Weight near 90%IniBW (kg) achieved during the treatment | Weeks of treatment required to achieve a weight near 90% IniBW |
|---------|----------------------------------|------------------|---------------------------------------------------------|------------------------------------------------------------|
| 1       | 136                              | 122.4            | 122.8                                                   | 6                                                          |
| 2       | 207                              | 186.3            | 186.1                                                   | 6                                                          |
| 3       | 186.3                            | 167.7            | 168.8                                                   | 7                                                          |
| 4       | 269                              | 242.1            | 242.7                                                   | 6                                                          |
| 5       | 191                              | 171.9            | 171                                                     | 10                                                         |
| 6       | 208.7                            | 187.8            | 187                                                     | 10                                                         |
| 7       | 152.2                            | 137              | 136.4                                                   | 5                                                          |
| 8       | 130                              | 117              | 117.8                                                   | 8                                                          |
| 9       | 170                              | 153              | 152                                                     | 4                                                          |
| 10      | 220                              | 198              | 200.2                                                   | 10                                                         |
| 11      | 168.8                            | 151.9            | 152                                                     | 7                                                          |
| 12      | 182.4                            | 164.2            | 165                                                     | 6                                                          |
| 13      | 142.1                            | 127.9            | 132.1 (93%Pi)                                           | 8 (*)                                                      |
| 14      | 217                              | 195.3            | 194.6                                                   | 4                                                          |
| 15      | 130                              | 117              | 119.2 (91.7%Pi)                                         | 17 (**)                                                   |
| 16      | 175                              | 157.5            | 156.6                                                   | 11                                                         |
| 17      | 158.6                            | 142.7            | 142                                                     | 11                                                         |
| 18      | 234                              | 210.6            | 211                                                     | 6                                                          |
| 19      | 149                              | 134.1            | 133.8                                                   | 14                                                         |
| 20      | 173.6                            | 156.2            | 156.8                                                   | 9                                                          |

Average length of stay required to achieve a weight near 90% of the initial body weight (*) 7.7

(*) Average length of stay, excluding patients 13 and 15, who did not reach at least a 10% loss of initial body weight.

Technically, surgeries in the SO are more difficult, mainly due to steatohepatitis, hepatomegaly, the size and weight of the greater omentum, the thickness and shortening of the mesentery, the thickness of the lesser omentum and the increased intra-abdominal pressure. Wound infection, dehiscence and incisional hernias are highly prevalent in open bariatric surgery and are significantly reduced by the minimally invasive method of laparoscopic surgery. In contrast, in laparoscopic surgery, the thicker abdominal wall generates the need for greater torque to mobilize the laparoscopic instruments, consequently lowering the sensitivity and precision of movements.

The advantage of weight loss before surgery is evident by the decrease in the operative time required (27). Alvarado et al. retrospectively assessed 90 patients with an average BMI of 48 kg/m² and a mean preoperative weight loss of 7.25% of initial body weight and they noted significant differences in the surgical time (i.e., a 36-minute reduction in operative time in patients with losses of ≥5% of their initial weight). A relationship was also observed between the initial weight loss and the one-year surgical result; specifically, every preoperative loss of 1% of the initial weight led to a more than 1.8% loss of excess weight 1 year after surgery (28).

In a prospective randomized study, Alami et al. also demonstrated this relationship between weight and operative time; specifically, losses of >5% of the initial body weight were associated with a 37-minute decrease in operative time (29).

In association with technical facilitation, preoperative weight loss also improves the control of related diseases, with a reduction of the risks of anesthesia and surgery. Weight loss of 10% has been shown to lead to positive effects on comorbidities (30). Low-calorie diets are extremely effective in acute weight loss. Two weeks of a low-calorie liquid diet causes a significant decrease in liver volume and changes in body composition, with decreased fat mass (31). The loss of liver volume occurred mainly at the beginning of the diet period, during the time of consumption of liver glycogen and 80% of this decrease occurred within 2 weeks of treatment initiation. The loss of visceral fat occurred evenly over the period studied (32,33).

After 12 weeks of a very low caloric diet (456-680 cal/day in 37 patients with an average BMI of 47 kg/m²), Colles et al. demonstrated a mean loss of 10% of the initial weight of patients and an average BMI decrease of 5 points (31).

Interestingly, in our series, the same weight loss was obtained in an average of 7.7 weeks, i.e., in 36% less time. The fact that almost all of our patients were SO may explain this difference, as the rate of weight loss appears to be greater in individuals with higher BMIs.

Despite the lack of an objective evaluation of this factor, there was consensus in the perception by surgeons in our group that weight loss greatly facilitated the implementation of the procedures, especially the mobilization of the small bowel. When we retrospectively compared the incidence of complications in this series with SO patients operated upon the past 5 years, there were significant differences in the incidences of complications and mortality rates.

By retrospectively analyzing major complications (fistula, cavitary abscess, bleeding and deep wound infection) and mortality in the group of patients (n = 538) operated on before the beginning of this protocol (17) and by stratifying this group by BMI, we noted that the BMI >50 kg/m² group had a greater incidence of all major complications and represented the patient group with the majority of complications in our series. The fistula rate was 2.19% for all the patients (non-SO and SO), and the subgroup analysis revealed a 1% fistula rate in the non-SO group (n = 345), representing 30.76% of the total number of fistulas. The SO group (n = 193) had a 4.66% fistula rate, representing 69.24% of all fistulas (Table 3). Similar findings were obtained when we analyzed all the other major complications, as shown in Table 3. In this series of 20 subjects, we observed no complications, highlighting a tendency toward a positive effect of this intervention.
In bariatric surgery, any policy designed to decrease operative morbidity is associated with reduced cost, as the cost of complications, reoperations and prolonged stays in intensive care greatly exceeds the cost of prevention strategies (34). Thus, the option of preoperative hospitalization for a relatively long period, at a low-cost institution, such as the secondary health-care center where this study was conducted, is justified by the very significant decrease in morbidity and absence of mortality in a group of patients with very high operative risk.

From the data obtained, we conclude that hospitalization for diet control and weight loss prior to bariatric surgery is safe and effective, occurring in a predictable manner in the SO population and yielding significant weight loss until the 14th week of caloric restriction. After 14 weeks of treatment, the weight loss stabilizes and loses significance, at which time the patients in our series were submitted to surgery. The main objective was to define the best time for these patients to undergo surgery after the preoperative weight loss. After the evaluation of these initial 20 patients, the SO undergoing preoperative weight loss continued the treatment, preferably for up to 14 weeks. The initial 20 patients stayed longer because the optimal weight loss period was unknown and the decision-making regarding when to operate on the high-risk patients was made on a case by case basis.

The goal of hospitalization is not to lose the highest amount of preoperative weight possible, but rather to lose the amount of weight that is closest to what is considered in the literature as sufficient to reduce risk (between 10 and 20% of the initial weight). This goal was achieved in an average of 14 weeks, which is the standard weight loss period at our institution. SO patients are hospitalized either until a 20% loss of initial weight is achieved or for 14 weeks, whichever comes first, because we have demonstrated that weight loss is insignificant after this period.

In this study, we also demonstrated that preoperative weight loss through a controlled, very-low-energy diet, even in the absence of drug treatment or increased physical activity, is efficient in SO patients. The absence of major surgical and postoperative complications in a group of patients with increased preoperative risk is also indicative of the benefits of the preoperative weight loss protocol in the high-risk, SO population.

### Table 3 - Morbimortality incidence. Major complications included the following: fistula, cavitary abscess, bleeding and deep wound infection. The analysis of 538 patients before the beginning of this protocol, stratified by BMI. The columns show the incidences of each complication in the total historical group, two subgroups (BMI < 50 Kg/m²), and study group (BMI > 50 Kg/m² with preoperative weight loss).

| Fistula | Cavitary Abscess | Bleeding | Wound Infection | Deaths |
|---------|-----------------|----------|-----------------|--------|
| % group | % total          | % group  | % total         | % group|
| BMI < 50 Kg/m² | n = 345 | 1 | 30.76 | 0.75 | 42.85 | 1.25 | 41.66 | 1.5 | 35.29 | 0.25 | 20 |
| BMI > 50 Kg/m² | n = 193 | 4.66 | 69.24 | 2.07 | 57.15 | 3.62 | 58.34 | 5.69 | 64.71 | 2.07 | 80 |
| All BMI | n = 538 | 2.19 | 100 | 1.18 | 100 | 2.6 | 100 | 2.2 | 100 | 0.55 | 100 |
| BMI > 50 Kg/m² with preop Weight Loss | n = 20 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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### AUTHOR CONTRIBUTIONS

Santo MA and Ricciopo D were responsible for the the project design, data collection and assistance (surgical procedures and follow-up), analysis of the results and data review. Pajekci D was responsible for data collection and assistance (surgical procedures and follow-up) and review of the results. de Cleva R was responsible for data collection and assistance (follow-up). Kawamoto F was responsible for data collection and assistance (surgical procedures and follow-up). Cecconello I was responsible for data review.
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