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### PARTIAL RESTRICTIVE INTESTINAL BYPASS - A RETROSPECTIVE ANALYSIS OF POST-OPERATIVE PATIENTS WHO UNDERGONELAZZAROTTO SURGERY FOR OBESITY TREATMENT

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#### ABSTRACT

The bariatric surgery procedures that currently exist can provide an improvement in obesity, diabetes, and other comorbidities. However, the anatomical changes inherent to these procedures impose risks that can lead to malnutrition, bone decalcification and other pathologies. This study aimed to evaluate data from patients submitted to partial restrictive intestinal bypass surgery (Lazzarotto surgery). In this study, medical records from 129 patients and data regarding their routine exams collected during a two-year postoperative follow-up to the procedure were included. The Parretti's inclusion and exclusion criteria were used. Measured variables were family history of obesity, age, sex, body mass index (BMI), diabetes, sleep apnea, intestinal rhythm, blood count, serum levels of fasting glucose, albumin, total proteins, aspartate aminotransferase (TGO), alanine aminotransferase (TGP), total cholesterol, and triglycerides. The average initial BMI was 40.58 (SD=5.74). At six months BMI was 32.9 (SD=5.1); at twelve months BMI was 32.1 (SD=5.0); at twenty-four months BMI was 31.2 (SD=5.1). The average initial BMI was statistically different from the average BMI at 6, 12 and 24 months (p<0.0001). After two years, weight loss was statistically higher with improvement of diabetes and dyslipidemia. Albumin levels remained unchanged throughout the period. In conclusion, Lazzarotto surgery showed satisfactory results in decreasing anthropometric measurements and balancing some physiological variables.

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# **INTRODUCTION**

The global obesity epidemic advances continuously, and currently affect about 27% of the world population (WHO, 2020). Genetic characteristics may be associated with obesity (Goodarzi, 2018), however, environmental and social changes in diet and physical activity patterns are its main causes (Caballero, 2019; Nicolaidis, 2019). As a consequence, there is a major impact on public health in the face of an over-increase in non-communicable diseases such as musculoskeletal disorders (Kulkarni et al., 2016), cardiovascular disease (Mandiviwala, 2016), diabetes (Boles et al., 2017) and some cancers (Kolb et al., 2016). Although obesity is a largely preventable condition, the process of weight reversion and stability can be seen as a great challenge to the patient (Meldrum et al., 2017; Ghu et al., 2019). Bariatric surgery (BS) is one of the most effective treatments for controlling and reducing excess weight (Maciejewski et al., 2016), having increased in recent years. In Brazil, according to the Brazilian Society of Bariatric and Metabolic Surgery (SBCBM, 2018), this

number increased by 46.7% between 2012 and 2017. However, its indication involves criteria and assessments related to previous clinical-nutritional failure, time of disease, age, and other comorbidities associated with and resulting from obesity. Currently, it is stated that BS is mainly performed by Roux-en-Y gastric bypass (RYGB) techniques followed by sleeve gastrectomy (SG) (Morales-Maza et al., 2020). The RYGB technique proposes the isolation of up to 97% of the stomach and large portions of the small intestine (Schlottmann and Buxhoeveden, 2018). SG is basically the removal of the large gastric curvature (Chung et al., 2018). Both procedures prove effective in weight loss (Chung et al., 2018; Schlottmann and Buxhoeveden, 2018; Morales-Maza et al., 2020). Nevertheless, after BS, a subset of patients appears to be detrimentally affected by this loss of reward from food and by a lack of alternative strategies for regulating its effects (Scholtz et al., 2015; Kheirvari et al., 2020). On the other hand, the BS performed using the partial restrictive intestinal bypass (PRIB) or Lazzarotto's surgery technique, first described in 2006, aims to significantly reduce the patient's excess weight along with the maintenance of nutritional components (Souza *et al.*, 2011). The technique is based on the reduction of the small intestine by performing an intestinal bypass (Souza *et al.*, 2011). Although performed by a private service for quite some time, studies are important to corroborate with this procedure. Thus, the present work aims to evaluate the BS with PRIB surgical technique, in terms of decreasing anthropometric measurements and balancing physiological variables after six, twelve, and twenty-four months after the procedure in a private service.

## **MATERIAL AND METHODS**

*Ethical Aspects and Type of Study and Sampling:* This study was submitted to and approved by the Ethics Committee of Positivo University (# 81280-330). The STROBE guideline was followed to perform this article. This is a cross-sectional study that included 129 records of patients who undergoneBS with PRIB surgical techniquebetween 2006 and 2018. The patients signed an informed consent. Medical records of patients who were diagnosed with grade II and III obesity, with follow up of 24 months postsurgerywere included.

**Primary data:** Data regarding family history of obesity, age, sex, body mass index (BMI), diabetes, sleep apnea, intestinal rhythm, blood count, serum levels of fasting glucose, albumin, total proteins, aspartate aminotransferase, alanine aminotransferase, total cholesterol, and triglycerides. The average BMI was correlated to serum levels of fasting glucose, albumin, total proteins, aspartate aminotransferase (TGO), alanine aminotransferase (TGP), total cholesterol, and triglycerides, prior to BS and after six, twelve, and twenty four months.

**Statistical Analyses:** Data were analyzed using Epi Info 7 (CDC, Atlanta, US) and Graph Pad Prism 8.0 (Graph-Pad Software Inc., San Diego, CA, USA). The Shapiro–Wilk's test was used to verify the normality of the data. A one-way ANOVA and Tukey's post-test were used for a comparison of means among the periods, "initial", "six months", "twelve months" and "twenty-four months". The comparison of BMI means between periods was made using the *t-test*. Pearson's correlation test was used to evaluate serological factors correlated with BMI. Linear logistic regression analysis was also used to evaluate factors associated with BMI at 24 months. The established alpha was 5%.

Table 1. Sample characteristics

Variables	Values		
Age (years)			
Mean (SD)	38.33 (11.49)		
Min-Max	15-67		
Body Weight			
Mean (SD)	113.35 (19.56)		
Min-Max	84-190		
Height			
Mean (SD)	1.66 (0.08)		
Min-Max	1.50-1.98		
$BMI (kg/m^2)$			
Mean (SD)	40.58 (5.74)		
Min-Max	30.8-58.3		
Intestinal rhythm			
Mean (SD)	1.35 (0.59)		
Min-Max	1-3		
Gender n (%)			
Female	94 (72.9)		
Male	35 (27.1)		
Chronic diseases n (%)			
Diabetes Yes	34 (26.4)		
No	95 (73.6)		
Sleep apnea Yes	18 (14)		
No	111 (86)		
Family history of obesity n (%)			
Yes	114 (88.3)		
No	15 (11.7)		

## RESULTS

A total of 5222 patients' records from a private service were initially screened, and 129 were selected according to the inclusion and exclusion criteria. In the initial exam of the patients, the mean age was 38.33 (SD=11.49). The body weight in kilograms and height in centimeters were 113.35 (SD=19.56) and 1.66 (SD=0.08), respectively. The mean functioning of the intestinal rhythm was 1.35 (SD=0.59) per day. The characteristics of the sample are presented in Table 1. There was no correlation between the mean of initial BMI and the mean of serum levels of fasting glucose, albumin, total protein, indicators of liver damage (TGO and TGP), total cholesterol and triglycerides (Figure 1) (p>0.05). After six, twelve, and twenty-four months of BS, patients had a BMI mean of, respectively, 32.9 (SD=5.1), 32.1 (SD=5.0), and 31.2 (SD=5.1). The mean initial BMI was significantly higher than the mean BMI after 6, 12, and 24 months of BS (p<0.0001) (Figure 2).

 Table 2. Multivariate analysis of the factors associated with BMI at twenty-four months

Variables	Coefficient	Standard error	F-test	P-value	
Sex	12.12	10.62	0.17	0.680	
Age (years)	0.59	0.43	1.87	0,173	
Family history	-39.63	14.58	7.38	0.007*	
Diabetes	4.63	11.23	1.69	0.680	
Note: Linear logistic regression. * Indicates statistical					
significance.	-				

Figure 3 presents serological variables measurements after the periods of six, twelve and twenty four months of BS.Albumin was the only variable that did not show statistical significant variation over time (p>0.05). The mean intestinal rhythmduring the first six and twelve months was significantly higher than the mean of initial intestinal rhythm (p<0.001 and p<0.001, respectively). The multivariate analysis of the factors associated with BMI at twenty-four months is shown in Table 2. Family history of obesity was the only factor associated with the final BMI (p=0.007). Patients with a family history of obesity had the lowest final BMI.

# DISCUSSION

Obesity is a complex multifactorial disease that negatively affects most of the body's physiological functions, comprising a significant threat to public health services (Chooi et al., 2018; Hruby and Hu, 2018), specially when it is currently agreed that obese people can be at hight risk of mortality or to develop health complications from COVID-19 infection (Hussain et al., 2020; Stefan et al., 2020). In 2016, the World Health Organization (WHO, 2020) stated that 650 million adults were diagnosed as obese. This data indicates that the prevalence of obesity is almost tripling since 1975 (WHO, 2021). Aiming at a strategy that substantially minimizes the deaths and the burden of obese individuals, the WHO adopted in 2004, health promotion focused on physical activity and diet control (WHO, 2004). However, it is accepted that BS, through its various techniques, still is the most effective strategy in the control of severe and morbid obesity (Verdan et al., 2012; Gloy et al., 2013; Chang et al., 2014; Mauro et al., 2019). Given the above, the objective of this study was to evaluate the effectiveness of BS with PRIB surgical technique, in terms of decreasing anthropometric measurements and balancing physiological variables after six, twelve and twenty-four months after the procedure. Herein this study, some initial characteristics of the included patients can be interesting. The mean age of the individuals was similar to the current literature, from 37 to 40 years (Buchwald et al., 2004; Silva et al., 2015; Gallé et al., 2020). According to the National Institute of Health Consensus Development Conference on Gastrointestinal Surgery for Severe Obesity, BS is supposed to be more effective in individuals aged 18 to 60 years (Hubbard and Hall, 1991), withmore recent studies also reporting BS in elderly patients (Smith et al., 2019; Susmallian et al., 2019).

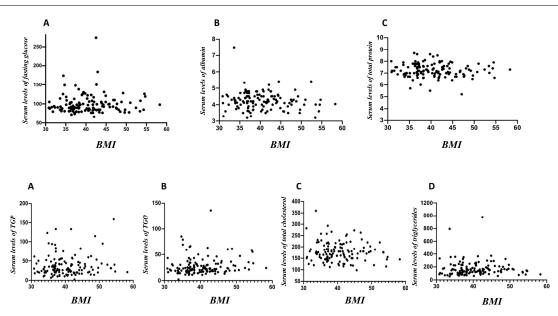


Figure 1. Correlation between the average mean of initial BMI and the mean of serological variables (u/l). None of the variables showed a correlation with the average mean BMI (R=0.06, p=0.43; R=0.02, p=0.23; R=0.06, p=0.43; R=0.08, p=0.32; R=0.11, p=0.20; R=0.05, p=0.88, respectively)

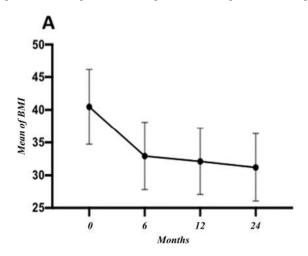


Figure 2. Average mean of BMI after six, twelve and twenty-four months of BS. There was a statistically significant difference between initial average BMI and the average BMI after six, twelve, and twenty-four months (p>0.0001)

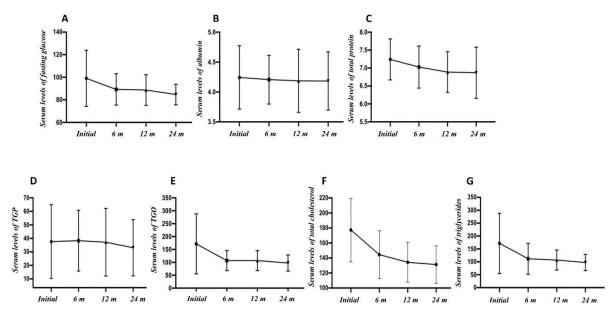


Figure 1. Average mean of serum levels after six, twelve, and twenty-four months of BS

Furthermore, in this present sample, there was female gender prevalence. Silva et al. (2015)suggest that BS is most frequently performedin women due to the perception of self-care and quality of life. It is also important to note that the BMI index was used even though it has low sensitivity and has a large inter-individual variability, partially attributed to age, sex and ethnicity (Caballero, 2019). Nevertheless, the BMI index is commonly used to define overweight and obesity in several epidemiological studies (Gloy et al., 2013; Chooi et al., 2018; Susmallian et al., 2019; Courcoulas et al., 2020; Järvholm et al., 2020). Thus, BMI can be more accurately comparedto other variables. The mean BMI of the patients included in this study was 40.58 (SD=5.74) being classified into grade III obesity, with a very high risk of developing comorbidities (WHO, 2020). This current sample also presented the majority of patients free from chronic diseases such as diabetes and sleep apnea. Another interesting finding in this present study is the report of most patients having a family history of obesity. Currently, there has been much discussion about the genetic and environmental influences of parents and guardians on childhood obesity, suggesting that the child may be predisposed to develop weight accumulation (Hruby and Hu, 2018; Nielsen et al., 2015; López-Contreras, 2020). This study did not approached the moment when obesity was perceived, but it can be assumed that the family habits may have influenced the individual's obesity state, as it was in the aforementioned studies. Subsequently, family history was still correlated with a decrease in BMI at twentyfour months. Again, the family perception of obesity, its complications and associated comorbidities could corroborate for self-awareness of the disease already installed.

After BS by the PRIB surgical technique, the mean BMI was statistically lower than at six, twelve, and twenty-four months. However, the relative decrease in the BMI values (%) of the current work was not higher than what has been demonstrated in the RYGB technique, estimated at 30 to 35% (Cummings et al., 2004), and in the SG technique, estimated at 25 to 30%, during the first post-surgical year (Barros et al., 2019). Furthermore, while in the present work the recorded weight loss (data not shown) was higher than 50%, after 18 to 24 months of BS a systematic review shows means of 61.6% of weight loss for the RYGB surgical technique and 68.2% for the SG surgical technique (Buchwald et al., 2004). Nevertheless, the PRIB surgical BS technique was able to maintain the serum albumin levels even with the increased intestinal rhythm, while decreased levels of triglycerides, cholesterol, fasting glucose, TGP, TGO and total proteins were also noted. It is also important to note that this procedure, which does not perform gastroplasty or isolate parts of the intestine, partially restricts the transit of the chyme in the small intestine, allowing the weight loss by eating normally, as long as the patient ingests water with the food (500 mL right before the meals, 250 mL in the middle and 250 mL right after finish eating; afterwards, a 5 to 10 minutes seating at the toilet is suggested to stimulate the gastrocolic reflex) - this inhibits the occurrence of "hematonutrometabolic" imbalance. A study with a murine model shows a decrease in serum albumin levels when the animals were exposed to BS by the RYGB surgical technique (Medeiros et al., 2011). The same was described in a study with humans who undergone the SG (Caron et al., 2017).

Themain objective of BSshould not be the loss of weight indefinitely, but to facilitate it, decreasing the need for food supplementation and hinder weight gain (Souza *et al.*, 2011; DeWind and Payne, 2014). Recently, a recent systematic review demonstrates, after 18 months of BS, a recovery of weight attributed to psychiatric comorbidities and psychopathologies (Mauro *et al.*, 2019).In contrast, the BSby PRIB surgical techniqueof the present work upholds the premise that the patient can be released to eat any food until is satisfied (DeWind and Payne, 2014), minimizing psychiatric unbalancerelated to the restriction of foods (Kambanis *et al.*, 2020). In conclusion, the BS performed with PRIB surgical technique demonstrated satisfactory results in terms of decreasing anthropometric measurementsand balancing physiological variables after twenty-four months.

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