ORIGINAL CONTRIBUTIONS



Weight Regain 10 Years After Roux-en-Y Gastric Bypass

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Published online: 31 October 2016 © Springer Science+Business Media New York 2016

Abstract

Objective This study aims to investigate weight regain and the associated variables 10 years after Roux-en-Y gastric bypass. *Method* This retrospective study recruited patients submitted to Roux-en-Y gastric bypass (N = 166) for a 10-year follow-up. The following variables were investigated: body mass index (BMI), percentage of excess weight loss (%EWL), weight regain (WR), and percentage of weight regain (%WG). The chi-squared test or Fisher's exact test compared proportions, and the Mann-Whitney test compared numerical measurements between the groups. Analysis of variance (ANOVA) compared the measurements over time. The significance level was set at 5 %.

Results The sample had a mean age of 39.59 ± 11.69 years, and females prevailed (71.7 %). In the long-term follow-up, 41 % of the patients had weight regain. Seventy-two months after surgery, excess weight, preoperative BMI, gender, age, nutritional monitoring, and iron deficiency did not explain weight regain. Younger patients had regained significantly more weight 96 (p = 0.008) and 120 months (p = 0.004) after surgery than older patients. Patients who regained weight had ferritin <15 µg/dL 96 months after surgery (p = 0.019).

Conclusion Patients submitted to Roux-en-Y gastric bypass presented weight regain, which increased over time. Age, iron

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deficiency, and time since surgery were associated with weight regain in the long-term follow-up.

Keywords Weight regain · Bariatric surgery · Gastric bypass

Introduction

The disease obesity evolved in modern society to a pandemic [1] and may be considered a global challenge. In 2013, the World Health Organization (WHO) [2] proposed a plan of strategies with measures to fight obesity globally, part of a proposal to prevent chronic noncommunicable diseases (NCDs). The causes of obesity are multifactorial [3], and the treatment is a challenge for the patients and professional caregivers. Epidemiological data [4] from Brazil and elsewhere show an alarming increase in the rates of overweight and obesity. According to the National Health Survey (PNS) [5] conducted in Brazil in 2013 by the Brazilian Institute of Geography and Statistics (IBGE), roughly 60 % of Brazilians are overweight, especially females (58.2 %).

Bariatric surgery has established itself as an effective treatment for excess weight and improves or cures the comorbidities associated with morbid obesity [6–8]. After investigating the metabolic effects of bariatric surgery, studies have found that surgery success or failure is not only restricted to weight loss [9] but also important to metabolic changes [10–12], which improve quality of life [11, 13].

Patients may present weight regain after bariatric surgery [14–22], which has been classified in multiple ways in patients submitted to Roux-en-Y gastric bypass. Nevertheless, many studies have reported satisfactory percentage of excess weight loss (%EWL) [7, 8, 14, 23, 24] and body mass index (BMI (kg/m²)) [15].

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Given the need of assessing patients submitted to Roux-en-Y gastric bypass in the long run and standardizations to determine the success or failure of bariatric and metabolic surgery, this study aimed to investigate weight regain and the associated variables 10 years after Roux-en-Y gastric bypass.

Cases and Method

Study Characteristics, Type, Location, Sample Size, Approval, and Inclusion and Exclusion Criteria

This retrospective study collected data from the medical and nutritional records of all patients submitted to bariatric surgery from January 2005 to May 2015 at an obesity service from a private clinic in the city of Campinas, SP, Brazil. Of the 312 patients submitted to bariatric surgery in the study period, 166 were included in the present study as they met the following inclusion criterion: adult patients submitted to Roux-en-Y gastric bypass with regular medical and nutritional monitoring. Patients who had been submitted to other types of surgery or who did not attend the medical and nutritional follow-up visits in the first year after the surgery were excluded, totaling 146 exclusions. The study was approved by the Research Ethics Committee of the Pontifical Catholic University of Campinas, SP, Brazil (no. 1.132.168). Of the 166 patients who were assessed in the 10-year follow-up, 95.8 % (n = 159) attended the 12-month follow-up, 89.2 % (n = 148) attended the 24month follow-up, 71.0 % (n = 118) attended the 48-month follow-up, 53.0 % (n = 88) attended the 72-month followup, 37.9 % (n = 63) attended the 96-month follow-up, and 25.5 % (n = 44) attended the 120-month follow-up.

All patients included in the present study had been submitted to unbanded laparoscopic Roux-en-Y gastric bypass [8].

Data Collection

The following data were collected from the participants' medical and nutritional records: age, gender, surgery date, and biochemical test results. Patients who attended the medical and nutritional follow-up visits were classified as "yes" and those who did not as "no." The biochemical tests included hemoglobin, serum iron, and ferritin. The analyzed data corresponded to the following occasions: preoperative and 3, 6, 12, 24, 48, 72, 96, and 120 months postoperatively.

Study Variables

Anthropometric Data

BMI [15], percentage of excess weight loss (%EWL) [25], weight regain (WR) [26], and percentage of weight regain (%WR) [26].

EW was calculated by subtracting the ideal weight from the preoperative weight [25]. The ideal weight was calculated as recommended by Deitel and Greenstein in 2003 [25].

WL [25] in kilograms was calculated by subtracting the weight 3, 6, 12, 24, 48, 72, 96, and 120 months after surgery from the preoperative weight.

Surgery outcome was assessed as proposed by Christou et al. in 2006 [15] as excellent when BMI <30 kg/m², good when $30 \le BMI \le 35$ kg/m², and a failure when BMI >35 kg/m².

The %EWL [25] was given by the formula $100 \times$ WL divided by EW. This parameter has been considered an indicator of surgery success [7, 8, 23, 26]. Surgery success was defined as %EWL \geq 50 % [23].

WR [26] in kilograms was calculated by subtracting the lowest postoperative weight from the current weight, as suggested by Novais et al. [26]. The %WR was calculated by multiplying WR by 100 and dividing the product by the lowest postoperative weight.

Weight variation over the 10-year period included the preoperative weight, the lowest postoperative weight, and the weights 3, 6, 12, 24, 48, 72, 96, and 120 months after surgery.

Criteria for Weight Regain Classification

Patients were considered to have WR [19] when % WR \ge 15 % of the lowest postoperative weight, as proposed by Odom et al. [19].

The patients were divided into two groups, one with and one without WR, for comparison of the study variables. Only the data of the 72-, 96-, and 120-month follow-ups were compared. In the 72-month follow-up, 17 % (n = 15) of the patients presented WR according to the adopted criterion [19]. The following variables were investigated to determine whether they were associated with weight regain: postoperative time, age, excess weight, preoperative BMI, gender, nutritional follow-up, and biochemical tests, namely, hemoglobin, serum iron, and ferritin.

Biochemical Tests

The laboratory tests were analyzed according to internationally recognized and validated parameters [27, 28]. Anemia was defined as hemoglobin <13.0 g/dL in men and <12.0 g/dL in women [27]. Depletion of iron stores was defined as serum iron <60 μ g/dL in men and <50 μ g/dL in women. Iron deficiency was defined as serum ferritin <15 μ g/dL, regardless of gender [28].

Statistical Analyses

Initially, a descriptive analysis was conducted by tabulating the frequencies of the categorical variables and the measures of position and dispersion of the numerical variables. The chisquared test or Fisher's exact test, when necessary, compared the proportions. The Mann-Whitney test compared the numerical measurements between the two groups. Repeated measures analysis of variance (ANOVA) compared measurements over time, followed by profile contrasts when necessary. The significance level was set at 5 % for all statistical tests [29–32].

Results

The study sample consisted of 166 patients with a mean age of 39.59 ± 11.69 years, and 119 (71.7 %) participants were females. Women and men had mean excess weights of 48.41 ± 14.65 and 65.03 ± 17.62 kg, respectively. Table 1 shows the %WR. Patients began to regain weight 24 months after surgery, and 50 % (n = 83) of the patients regained a mean of 3.98 ± 2.49 kg. After 120 months, 25.3 % (n = 42) of the patients had regained a mean of 14.60 ± 6.98 kg (Table 1).

Table 1Descriptive analysis of the study variables and percentage ofweight regain (%WR) by postoperative time in patients submitted toRoux-en-Y gastric bypass with long-term follow-up (10 years)

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Variables	Number	$X \pm SD$	Median
Age (years)			
Female	119	39.59 ± 11.69	38.00
Male	47	39.47 ± 12.40	37.00
Height (m)			
Female	119	1.63 ± 0.06	1.63
Male	47	1.76 ± 0.07	1.76
Ideal weight (kg)			
Female	119	59.72 ± 3.39	59.65
Male	47	70.03 ± 3.90	69.79
Excess weight (kg)			
Female	119	48.41 ± 14.65	45.32
Male	47	65.03 ± 17.62	64.21
%WR 12 months	1	1.70	1.70
%WR 24 months	83	3.98 ± 2.49	3.72
%WR 48 months	94	6.98 ± 4.24	6.96
%WR 72 months	82	9.74 ± 5.74	9.20
%WR 96 months	59	12.59 ± 6.31	12.83
%WR 120 months	42	14.60 ± 6.98	13.77

SD standard deviation, %WR percentage of weight regain in kilograms by postoperative time in months

Four years after surgery, the recovered weight is called weight regain. According to the established criterion [19], patients are considered to have weight regain when they regain at least 15 % of the lowest postoperative weight. In the long-term follow-up, 41 % [19] of the study patients had weight regain (Fig. 1).

Figure 1 shows the anthropometric data collected in the 10year follow-up. The mean preoperative BMI and weight were $41.43 \pm 5.44 \text{ kg/m}^2$ and $115.81 \pm 20.69 \text{ kg}$, respectively. The lowest BMI was reached 1 year after surgery $(27.72 \pm 4.70 \text{ kg/m}^2)$ and did not change 2 years after surgery $(27.78 \pm 4.70 \text{ kg/m}^2)$. In the long-term follow-up, the mean BMI was $32.53 \pm 4.83 \text{ kg/m}^2$, classified as grade I overweight by the WHO [33] and considered a good surgery outcome based on BMI [15]. The %EWLs were greater in the first and second years after surgery ($75.15 \pm 18.27 \text{ and } 74.49 \pm 19.16$, respectively), and 10 years after surgery, %EWL reached 51.64 ± 18.03 , which is also considered a successful surgery outcome [23].

Figure 2 shows the variables related to weight regain after dividing the sample into two groups, one with and one without weight regain. Seventy-two months after surgery, excess weight, preoperative BMI, gender, age, nutritional followup, and iron deficiency did not explain weight regain. In the long-term follow-up, the age of the two groups differed: younger patients had regained more weight 96 (p = 0.008) and 120 months (p = 0.004) after surgery than older patients. Ninety-six months after surgery, the group with weight regain had a mean ferritin of <15 µg/dL (p = 0.019).

Discussion

The %EWL is the most commonly used parameter by studies that investigate bariatric surgery outcomes [6–8, 14, 23, 24, 26]; thus, it is an important parameter for classifying surgery outcome. BMI \leq 35 kg/m² [15] for morbidly obese individuals is also considered a successful outcome in the long-term follow-up. However, the literature does not yet agree on the definitions for surgery success and failure [15, 23, 34].

Divergences in the literature regarding weight regain are even greater. A standard for classifying weight regain does not exist, hindering comparison between studies. Studies [14–22] have used different criteria to report weight regain in patients submitted to Roux-en-Y gastric bypass.

In the 10-year follow-up, the study sample had a mean %EWL of 51.64 ± 18.03 %, which is similar to the percentage reported by Higa et al. [23] in a long-term follow-up study. In a recent review and meta-analysis on the midterm results of gastric bypass, the %EWL was 70 % in 10 years but with limited follow-up rates [7].

The Swedish Obese Subjects (SOS) [35], a prospective controlled study to collect information about the long-term

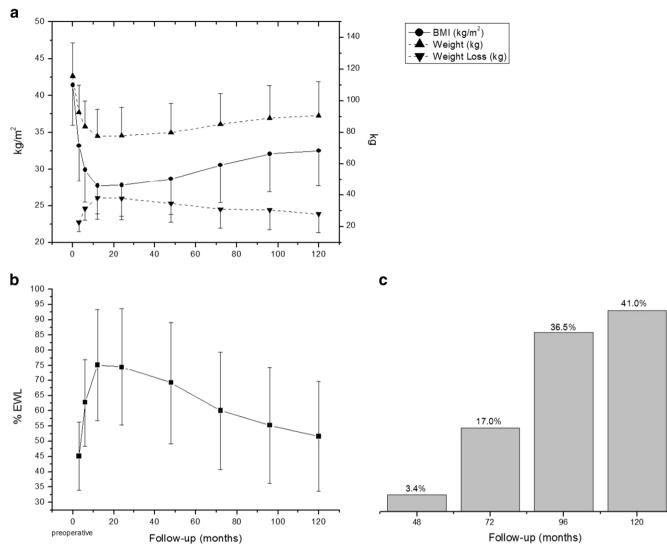


Fig. 1 Nutritional status variables (anthropometric data) over time of patients submitted to Roux-en-Y gastric bypass with long-term followup (10 years). **a** Mean and standard deviation; *BMI* body mass index in kg/m²; **p* value <0.0001 for all variables over time. **b** Mean and standard deviation; %*EWL* percentage of excess weight loss; **p* value

<0.0001 over time. $c \ \% WR$ percentage of weight regain *repeatedmeasures analysis of variance (ANOVA); the statistical analyses included only the patients who had attended all the follow-up visits over the 10-year study period

effects of bariatric surgery, found that after 10 years of gastric bypass, patients had weight losses of 25 ± 11 % and after 15 years, of 27 ± 12 %. Weight changes after 20 years should be assessed judiciously given the small number of participants in such long-term follow-ups [35].

Nearly all patients (n = 159, 95.7%) attended the follow-up visit 1 year after surgery but only 44 (26.5%) attended the follow-up visit 10 years after surgery. Other studies [23, 24] have reported the difficulty of collecting long-term follow-up data in these patients. In a retrospective study, Higa et al. [23] found a %EWL of 57% 10 years after surgery, but only 7% of the patients had attended the 10-year follow-up visit, demonstrating the difficulty of following these patients. In a systematic review, Puzziferi et al. [24] reported a %EWL in excess of 50% and control of the comorbidities, yet few studies

contained long-term follow-up data. A retrospective cohort study with 2070 patients [18] found that 40 % of the patients had %EWL between 50 and 75 % 60 months after surgery, which is considered a good outcome. The prospective SOS [35] study had a 15-year follow-up rate of 32 %.

Studies have suggested different %WRs of the lowest postoperative weight to classify weight regain, as follows: Odom et al. [19], 15 %; Abu Dayyeh et al. [20], 20 %; Freire et al. [17], 10 %; Nicoletti et al. [14], 10 %; and Cooper et al. [21], \geq 25 % as excessive weight regain. The present study defined weight regain as a weight gain of at least 15 % of the lowest postoperative weight, as proposed by Odom et al. [19].

The study criterion used for classifying weight regain was based on the study by Odom et al. published in 2010 [19]. Twenty-eight months after surgery, 79 % of $p=0.49^{3}$

ug/dl

 $p=0.68^{3}$

Serum iron

(pre, kg/m²)

Age

80

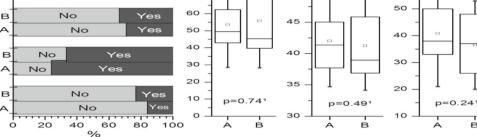
70

60

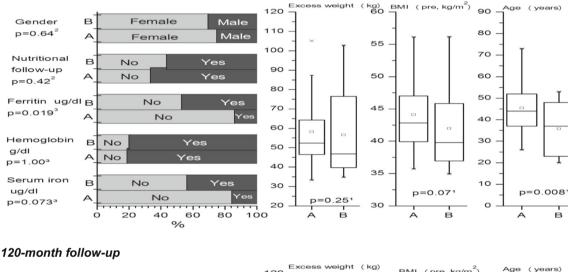
(years)

в

72-month follow-up weight (kg) 60 вмі 110 в Female Gender Male 100 $p=0.75^{3}$ Δ Female Male 55 90 Nutritional Yes в No 80 follow-up А No 50 Yes $p = 0.89^{2}$ 70 60 Ferritin ug/dl B No Yes 45 $p=0.74^{3}$ 50 Δ No Yes 40 Hemoglobin в No 40 g/dl



96-month follow-up



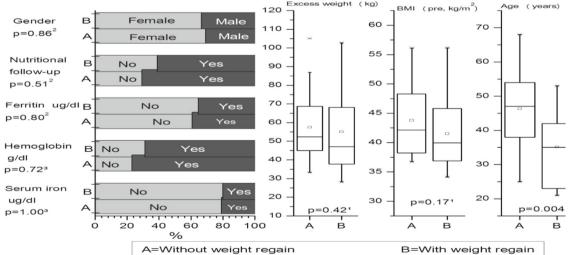


Fig. 2 Variables possibly related to weight regain and comparison between groups of patients submitted to Roux-en-Y gastric bypass with long-term follow-up (10 years). a Based on the Mann-Whitney test; b based on the chi-squared test; c based on the Fisher's exact test with p < 0.05. Weight regain was defined as regain >15 % of the lowest

postoperative weight [19], BMI (pre) was defined as preoperative body mass index, and anemia was defined as hemoglobin <13.0 g/dL in men and <12.0 g/dL in women [27]. Depletion of iron stores was defined as serum iron <60 µg/dL in men and <50 µg/dL in women. Iron deficiency was defined as serum ferritin <15 µg/dL [28]

the patients reported some weight regain, and of these, 15 % were classified as having regained weight based on the definition of weight regain, which is regaining at least 15 % of the lowest postoperative weight [19].

Weight recovery began 24 months after surgery with 83 patients presenting a mean %WR of 3.98 ± 2.49 . However, weight recovery was only considered weight regain 48 months after surgery and in only four (3.4 %) patients. In the 72-, 96-, and 120-month follow-ups, 17, 36.5, and 41 % of the study patients had weight regain, which is confirmed by other studies [15–17, 20].

The mean BMI of the study sample 10 years after surgery was $32.27 \pm 5.12 \text{ kg/m}^2$, which is considered a good outcome for morbidly obese patients according to the BMI-based criteria proposed by Christou et al. [15]. Barhouch et al. [18] found a BMI of >30 kg/m² in roughly 50 % of the patients 60 months after surgery. The study sample presented the lowest BMIs 12 and 24 months after surgery, namely, 27.72 ± 4.55 and $27.78 \pm 4.70 \text{ kg/m}^2$, respectively. In 2014, Still et al. [22] found that BMI is more consistent for the assessment of variables associated with weight regain and also suggested the need of longitudinal studies to assess weight loss.

Since many cutoffs have been suggested for weight regain, study comparisons are difficult. Standardization of the definitions of bariatric surgery's success or failure would be an important step, as proposed by the Brazilian Society of Bariatric and Metabolic Surgery (SBCBM) in 2015 [34]. More studies are necessary to compare the outcomes with the literature.

The variables investigated by this study as possibly associated with weight regain were age, excess weight, preoperative BMI, gender, nutritional follow-up, time since surgery, and the following biochemical variables: hemoglobin, serum iron, and ferritin. The patients were divided into two groups, one with and one without weight regain. In the 72-month followup, none of the study variables explained weight regain. In the 96- and 120-month follow-ups, the younger patients had regained more weight, and in the 120-month follow-up, the patients with iron deficiency presented weight regain.

The studies by Odom et al. [19] and Magro et al. [16] did not find associations of gender and age with weight regain. A similar result was found by the present study as the percentage of weight regained by men and women did not differ but younger patients regained more weight as follow-up time increased.

Abu Dayyeh et al. [20], Freire et al. [17], Magro et al. [16], and Sjöström [36] found that time since surgery was associated with weight regain, which confirms the present results where weight regain was first detected at the 48-month follow-up and increased in the 72-, 96-, and 120-month followups. The present study did not find a statistically significant relationship between BMI and weight regain. Similar results were discussed by Freire et al. [17] and Odom et al. [19].

The mechanisms involved in weight regain must be understood to enable teams that treat these patients to develop strategies that help patients and make them aware that obesity is a disease that requires control. In 2015, the SBCBM discussed new nomenclatures to report surgical success and failure, and surgical success was defined as the control of obesity [34].

A study strength was investigating whether surgical success and failure indicators were associated with many parameters and follow-up occasions. In 2014, Still et al. [22] reported that most studies conduct assessments 12 to 24 months after surgery, but ideally, weight loss should be assessed longitudinally, as performed by the present study.

Loss to follow-up also reflects the difficulties associated with the nutritional follow-up of Roux-en-Y gastric bypass patients. Only 26.4 % of the patients attended the study's 10-year follow-up, and nutritional follow-up was not associated with weight regain 72, 96, and 120 months after surgery. In 2008, Magro et al. [16] reported that 60 % of the patients who regained weight never attended the nutritional follow-ups and 80 % never attended the psychological follow-ups.

In the 96- and 120-month follow-ups, weight regain was associated with younger age and in the late follow-up with iron deficiency.

In the 96- and 120-month follow-ups, 69.6 and 66.7 %, respectively, of the patients who presented weight regain according to the established criterion were women of childbearing age. Thus, the relationship found herein between iron-deficiency anemia and weight regain may be very unspecific given the characteristics of the study population. So, other studies that include supplements, dietary assessment, and physical activity, among others, are necessary. These variables were not accessed in the present study because of limitations stemming from the retrospective design.

The groups without weight regain in the 96- and 120month follow-ups had mean ages of 45.5 (75 % women) and 46.3 years (69.2 % women), respectively. These groups were further away from childbearing age and possibly at a lower risk of developing iron-deficiency anemia.

In 2014, Still et al. [22] assessed the relationships between weight regain and clinical factors in Roux-en-Y gastric bypass patients, and they found a positive relationship between iron deficiency and percentage of excess BMI loss.

A recent Brazilian study [37] assessed the weight regain and the nutritional profile of argon plasma candidates and found that patients with weight regain were mostly women, had iron-deficiency anemia and other nutritional deficiencies, and did not attend the multidisciplinary follow-ups.

Despite the limitations associated with retrospective studies that prevented controlling for certain variables (data not available), such as supplementation and other nutritional deficiencies, the study patients had been submitted to the same surgical technique, operated by the same team, and followed for 10 years by the researcher responsible for the study.

Another limitation is loss to follow-up, which is common in the obesity centers that follow these patients. Other variables that may also be associated with weight regain should be assessed, such as dietary, behavioral, and hormonal factors. Hence, more studies in patients submitted to Roux-en-Y gastric bypass are critical to confirm the present results, as is the need of universally accepted definitions for weight regain and surgery outcome.

In conclusion, patients submitted to Roux-en-Y gastric bypass present weight regain, which increased over time. Age, iron deficiency, and time since surgery were associated with weight regain 10 years after bariatric surgery.

Acknowledgments We thank the Pontifical Catholic University of Campinas, SP, Brazil and the Coordination for the Improvement of Higher Education Personnel for the master's scholarship provided to the Master's Program in Health Sciences of PUC-Campinas, SP, Brazil.

Compliance with Ethical Standards

Statement of Authorship DVMF conceived and designed the study, collected and analyzed the data, and wrote the manuscript. VALM helped to conceive the study, supervised the research, and reviewed the manuscript. The authors read and approved the final version of the article.

Sponsor This project was not sponsored.

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

Ethical Approval 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.

Informed Consent Does not apply. For this type of study, formal consent is not required.

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