

# Long-term repercussions of Roux-en-Y gastric bypass in a low-income population: assessment ten years after surgery.

## *Repercussões em longo prazo da derivação gástrica em Y de Roux em população de baixa renda: avaliação após dez anos de cirurgia.*

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### ABSTRACT

**Objective:** to evaluate the weight, nutritional and quality of life of low-income patients after ten years of Roux-en-Y gastric bypass (RYGB). **Methods:** we conducted a longitudinal, retrospective and descriptive study evaluating the excess weight loss, weight regain, arterial hypertension, type 2 diabetes *mellitus*, anemia and hypoalbuminemia in 42 patients of social classes D and E submitted to RYGB. We assessed quality of life through the Bariatric Analysis and Reporting Outcome System (BAROS). **Results:** of the 42 patients, 68.3% defined themselves as doing non-regular physical activity, and only 44.4% and 11.9% had regular medical and nutritional follow-up, respectively. We found a mean excess weight loss of  $75.6\% \pm 12$  (CI=71.9-79.4), and in only one patient there was insufficient weight loss. The mean weight loss was  $22.3\% \pm 16.2$  (CI=17.2-27.3) with 64.04% of the sample presenting regain greater than 15% of the minimum weight; 52.3% of the sample presented anemia after ten years of surgery and 47.6%, iron deficiency. We found hypoalbuminemia in 16.6% of the sample. There was remission of hypertension in 66%, and of type 2 diabetes *mellitus*, in 50%. BAROS showed an improvement in the quality of life of 85.8% of the patients. **Conclusion:** in a population with different socioeconomic limitations, RYGB maintained satisfactory results regarding weight loss, but inefficient follow-up may compromise the final result, especially with regard to nutritional deficiencies.

**Keywords:** *Obesity. Bariatric Surgery. Gastric Bypass. Quality of Life.*

### INTRODUCTION

There is a pandemic of overweight, obesity and metabolic syndrome throughout the world<sup>1</sup>. According to the World Health Organization (WHO), the prevalence of obese people reaches 600 million, which affects about 2% to 7% of health budgets in developed countries<sup>2</sup>. Studies have shown that 50.8% of Brazilians are overweight and, of these, 17.5% are obese, with a growth of 255% in morbid obesity in the last 30 years<sup>3,4</sup>.

Obesity is a chronic disease, of difficult to control, with failure in clinical treatments around 98% in the long term. The consequences are worrying and imply higher economic and social costs, as well as impairment of the quality of life of these patients<sup>5</sup>. Surgical treatment of obesity is the main alternative for weight control, with Roux-en-Y gastric bypass (RYGB)

being one of the most widespread techniques, with a 61.6% average loss of excess weight<sup>6</sup>. It is classically indicated for patients with a body mass index above 40 kg/m<sup>2</sup> independent of comorbidities, and for those above 35 kg/m<sup>2</sup> with comorbidities<sup>7</sup>.

Although bariatric surgery is related to favorable results, it is necessary to have continuous multidisciplinary follow-up so that it is possible to accurately determine the success or failure of the procedure in the long term, especially with regard to weight control and remission of comorbidities<sup>8</sup>. In Brazil, about 150 million people are dependent on the Unified Health System (SUS), which, in turn, is inefficient in the care of patients in need of bariatric surgery. The national average waiting time for surgery reached 2.9 years in 2006, with a mortality rate of 0.6% during the waiting period<sup>2</sup>.

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Even with a nearly 800% increase in the number of bariatric surgeries performed by the SUS between 2001 and 2010, the growth of obesity considerably outstrips the increase in the capacity of referral services in the treatment of this disease<sup>2</sup>. Parallel to this scenario, other problems are present, late postoperative conduction being one of the main ones, since there is a tendency of patients in the postoperative period of bariatric surgery to abandon long-term follow-up<sup>9</sup>. The long-term evolution after bariatric surgery demonstrates, independently of the population, a tendency to hematological and nutritional alterations. Management of these conditions becomes imperative for a satisfactory postoperative period<sup>10</sup>. Nutrient replacement may be hampered by the lower adherence to follow-up of the low-income population, as well as by the high financial cost related to treatment, which requires deep knowledge of the long-term repercussions and the institution of support measures for these patients<sup>11</sup>.

The objective of the present study was to evaluate the weight and nutritional evolution, and the quality of life of low-income patients after ten years of RYGB performed at a public hospital of Recife.

## **METHODS**

We conducted a longitudinal, retrospective and descriptive study of 42 patients classified as low-income, ten years after RYGB, with or without ring, in the General Surgery Service of the Hospital das Clínicas of the Federal University of Pernambuco. Using the criteria established by the Brazilian Institute of Geography and Statistics (IBGE), we included patients of social classes D and E, submitted to RYGB from 2005 to 2008, regardless of sex or age. We excluded patients who died, those who underwent procedures other than RYGB and patients with incomplete medical records.

We collected data on sociodemographic information (age, sex), comorbidities such as arterial hypertension (AH) and type 2 diabetes *mellitus* (DM2), hemoglobin, albumin, serum iron, ferritin, percentage of excess weight lost, quality of life and time of medical and nutritional monitoring.

We used, as a criterion for remission of AH, a systolic blood pressure less than 130mmHg and a diastolic blood pressure less than 85mmHg, in the absence of medication; we considered DM2 controlled in patients with fasting glycemia less than 126mg/dl and HbA1c less than 6.5%, without medication<sup>12,13</sup>. We measured hemoglobin, albumin and serum iron at 10-year post-surgery evaluation. Anemia was characterized as Hemoglobin (Hb) less than 12mg/dl for women and less than 13mg/dl for men. Those with albumin less than 3.5g/dl were considered to have hypoalbuminemia. The lower limit of serum iron considered was 50mcg/dL for women and 65mcg/dL for men.

We used the maximum percentage of excess weight loss to evaluate surgery success. The ideal weight was defined with the Metropolitan Life Foundation (MLF) Table. Calculations were performed using the following formulas: a) Excess Weight (EW) = Current Weight - Ideal Weight (IW); b) Percentage of excess weight = (EW x 100) / IW; c) Men:  $IW = 61.2328 + \{(H - 1.6002) \times 53.5433\}^*$ ; d) Women:  $IW = 53.975 + \{(H - 1.524) \times 53.5433\}^*$ . (\* MLF formulas: IW= Ideal Weight in Kg; H= Height in meters.

We observed the evolution of BMI between the preoperative period, 24 months and ten years postoperatively. The members of the sample underwent an evaluation questionnaire that composes the Bariatric Analysis and Reporting Outcome System (BAROS). This evaluates the individual's self-perception, sexual interest, practice of physical activity, weight evolution and comorbidities.

We performed data collection through the information of the patients' charts and through consultations and examinations performed at the evaluation ten years after surgery. We entered all data in a database created in Microsoft Excel, which we then exported to the SPSS program to analysis. To evaluate the personal profile of the patients, physical activity practice and nutritional post-surgical follow-up, we calculated the percentage frequencies and constructed the respective frequency distributions.

In the evaluation of weight, BMI, hemoglobin, albumin and iron, we computed the following statistics: minimum, maximum, mean, median and standard deviation. We calculated the confidence interval for the estimated mean. We assessed normal weight, BMI and laboratory measures with the Kolmogorov-Smirnov test. For the comparison of the patients' weight, BMI and laboratory measures between the preoperative and 10-year post-operative times, we used the Student's t-test for paired samples. We carried out the comparison of the measurements at the preoperative time, 24 months and ten years after surgery with the Friedman test for paired samples. All conclusions considered a level of significance of 5%.

This research was approved by the Ethics in Research Committee of the Health Sciences Center of the Federal University of Pernambuco (nº 1,295,687/2015) CAAE: 26928314.0.0000.5208.

## RESULTS

We verified that the majority of patients were female (76.2%), with age range between 41 and 50 years (45.2%). Although the prevalence of the described profile was higher, the proportion comparison test was significant only in the gender factor (p-value =0.001), while the age factor was not statistically significant (p-value =0.257).

Table 1 shows the distribution of physical activity practice, nutritional follow-up and postoperative medical follow-up. Most of the patients did not practice physical activity (68.3%), did not have nutritional monitoring (88.1%) and had no medical follow-up (55.6%). The proportion comparison test was significant for physical activity and nutritional monitoring (p-value =0.019 and p-value <0.001, respectively), indicating that the lack of physical activity and nutritional monitoring is a relevant problem in the group of patients under study. Regarding medical follow-up, the proportion comparison test was not significant (p-value =0.564).

**Table 1.** Distribution of physical activity practice, nutritional monitoring and postoperative medical follow-up.

Assessed factor	N	%	p-value <sup>1</sup>
Physical activity			
Yes	13	31.7	0.019
No	28	68.3	
Nutritional monitoring			
Yes	5	11.9	<0.001
No	37	88.1	
Medical follow-up			
Yes	12	44.4	0.564
No	15	55.6	

<sup>1</sup> Chi-square test for comparison of proportions.

Table 2 shows the descriptive analysis of weight and BMI in the preoperative period, 24 months and ten years after surgery. We observed a reduction in weight and BMI between the preoperative time and 24 months after the procedure. Still, between 24 months and ten years after surgery there was an increase in the mean weight and BMI values. The distribution comparison test was significant for the two factors evaluated (p-value <0.001 for both), indicating that there were significant variations of the mean weight and BMI of the patients assessed between the preoperative time and after 24 months and ten years.

Table 3 shows the analysis of %EWL and weight regain 24 months after surgery. We verified that

on average there was %EWL of 75.6%, while weight regain had an average of 22.3% of the minimum weight. We observed insufficient weight loss, which is the loss of less than 50% of excess weight, in only one (2.38%) patient. We observed pathologic regain (>15% of the minimum weight) in 29 (64.04%) patients.

Table 4 shows the descriptive analysis of laboratory measures. We found that all the measurements decreased, on average, after surgery. The mean comparison test was significant in all the measures evaluated. There was preoperative anemia in 11.9%, which increased to 52.3% after ten years of surgery. We also found 16.6% hypoalbuminemia and 47.6% iron deficiency.

**Table 2.** Descriptive analysis of weight and BMI in the preoperative period and 24 months and ten years after surgery.

	Minimum	Maximum	Mean	Median	Standard deviation	95% CI	p-value <sup>1</sup>
<b>Weight</b>							
Preoperative	98.0	250.0	135.4	127.0	30.3	125.9-144.8	
24 months	54.9	117.0	79.6	77.0	14.3	75.1-84.0	<0.001
10 years	69.0	145.0	97.4	90.8	21.2	90.7-104.0	
<b>BMI</b>							
Preoperative	37.2	114.1	50.8	48.1	12.8	46.8-54.8	
24 months	22.0	44.0	29.7	28.7	4.6	28.2-31.1	<0.001
10 years	25.8	49.6	36.3	34.8	6.9	34.1-38.4	

<sup>1</sup> Friedman test for paired samples.

**Table 3.** Descriptive analysis of %EWL 24 months after surgery and weight regain.

	Minimum	Maximum	Mean	Median	Standard deviation	95% CI
%EWL (24 months)	44.5	101	75.6	73.5	12.0	71.9-79.4
Weight regain	0.0	66.4	22.3	20.0	16.2	17.2-27.3

**Table 4.** Descriptive analysis of hemoglobin, albumin, and iron in the preoperative period and ten years after surgery.

	Minimum	Maximum	Mean	Median	Standard deviation	95% CI	p-value <sup>1</sup>
<b>Hemoglobin</b>							
Preoperative	11.0	15.6	13.3	13.4	1.0	12.9-13.6	
10 years	8.0	16.0	11.9	11.9	1.8	11.4-12.5	<0.001
<b>Albumin</b>							
Preoperative	3.6	4.6	4.2	4.2	0.3	4.1-4.3	
10 years	2.8	4.4	3.8	3.9	0.4	3.7-3.9	<0.001
<b>Iron</b>							
Preoperative	48.6	114.5	76.6	76.4	18.1	71.0-82.3	
10 years	8.9	159.3	63.0	62.6	37.6	51.3-74.7	0.016

<sup>1</sup> Student's t-test for paired samples.

Table 5 shows the prevalence of comorbidities assessed preoperatively and ten years after. We observed a decrease in all comorbidities during this period, but for DM2 the prevalence was not significant (p-value =0.672), indicating that the number of patients with DM2 after ten years postoperatively is smaller, however, similar to the number at the beginning of the research. For the other comorbidities, it was not possible to calculate the p-value of the comparison of the pre and postoperative moments because there was no patient with these comorbidities ten years later.

Table 6 shows the distribution of the BAROS classification. We found that the majority of the patients classified the evolution of quality of life as "Good" (54.8%), followed by those who classified it as "Acceptable" (31%). Only 9.5% of the patients presented a "Very good" evaluation, and 4.8%, "Insufficient". These differences were statistically significant (p-value <0.001), indicating that the most frequent classification in the study group is good to acceptable.

## DISCUSSION

Regarding the regular practice of physical activity, we found that 31.7% of the sample declared themselves to be regular practitioners of exercises, a number smaller than that found in the study by Boscatto *et al.*, who demonstrated a total of 40% physically active within a sample where only 53.6% belonged to social classes D or E<sup>14</sup>. This strengthens the association between low family income, sedentary lifestyle and obesity, since the present study was performed exclusively with individuals belonging to classes D or E.

A trend of irregularity in both nutritional and medical follow-up has already been identified in the postoperative period of bariatric surgery. Some studies have demonstrated, mainly in patients with weight regain, 100% absence of follow-up<sup>9,15</sup>. In this study, were observed regular nutritional and medical follow-up only in 11.9% and 44.4% of the sample, respectively. This may represent a sample selection bias since part of it was composed of patients who,

**Table 5.** Prevalence of comorbidities evaluated preoperatively and ten years after surgery.

Assessed factor	Evaluation time		p-value <sup>1</sup>
	Preoperative	10 years after	
AH	25 (59.5%)	11 (26.2%)	0.002
DM2	4 (9.5%)	2 (4.8%)	0.672
Other Comorbidities	7 (16.6%)	0 (0.0%)	-

<sup>1</sup> Chi-square test for comparison of proportion.

**Table 6.** Distribution of the BAROS classification.

BAROS Classification	N	%	p-value <sup>1</sup>
Very good	4	9.5	<0.001
Good	23	54.8	
Acceptable	13	31.0	
Insufficient	2	4.8	

<sup>1</sup> Chi-square test for comparison of proportion.

through the follow-up protocol, sought the Service for the annual consultation. Those without follow-up may be theoretically more difficult to reach due to outdated medical record information.

The excess weight loss of an average of 75.6% follows the standards of established studies such as that of Fobi, with the finding of %EWL of 72% in ten years, and Capella, with 77% in five years<sup>9,16</sup>. Studies from poorer countries show considerable variation in %EWL, with a tendency towards lower average losses. This can be seen in the Indian study of Lakdawala *et al.*, who observed a %EWL of 62.2%, or that of Valezi *et al.*, of 66.8%<sup>17,18</sup>. The study carried out in Venezuela by Leyba *et al.* showed a 69.8% of excess weight loss. By evaluating these studies, it is possible to notice a lower mean BMI in those who had a higher mean %EWL<sup>19</sup>.

The possible association between poorer populations and more severe patients, as having a higher BMI, could explain the higher %EWL in the samples with lower mean BMI. This was observed in the study idealized by Csendes *et al.*, which showed that those with BMI between 35 and 39 had %EWL of 76%, while in those with more than 50 the loss was 64%<sup>20</sup>. Although in the present study the mean BMI was 50.8 kg/m<sup>2</sup>, there was an excess weight loss over that observed in these other studies. This may be related to the fact that almost two-thirds of the sample was composed of patients with BMI < 50.

A concern similar to insufficient weight loss, though much more common, is weight regain. This problem has a strong association with wrong eating habits, sedentary lifestyle, alcohol intake, among other problems. The low income population, as evaluated in this study, tends to be more impaired, since predisposing factors to weight regain are more present in this group<sup>21</sup>. In our study, we observed pathological regurgitation in 64.04% of the patients. Bastos *et al.* found significant weight regain (>15%) in 28.1% of their sample<sup>22</sup>.

The superiority of their results may be related to the fact that 43% of the study sample belonged to classes A and B, associated with the follow-up of, on average, 54 months.

When evaluating comorbidities, we observed a remission of 66% of AH, a number equal to that found by Leyba *et al.* in a study with five years of follow-up after gastric RYGB, and also similar to the 73.1% found by Silveira Jr *et al.* at six months postoperatively<sup>19,23</sup>. These findings suggest a long-lasting effect of RYGB and little dependence on weight variations, since at six months (early phase in relation to final weight loss in most patients) we had a remission rate similar to that found after ten years, even with significant weight regain.

Type 2 diabetes *mellitus* classically shows remission around 76% after bariatric procedures<sup>24</sup>. Csendes *et al.* obtained remission in 95% of patients in a 10-year follow-up<sup>20</sup>. This finding is well above the 50% found in the present study. Once again, the socioeconomic question, which is very relevant in this study, may justify a lower rate of success because it is evaluating patients with more severe DM2 or with a longer time of disease, and with more difficult access to optimal comorbidity treatment.

When analyzing the hemoglobin and serum iron deficiencies of the patients submitted to RYGB, the numbers found in this study were discretely lower than the 63.6% and 54.4% observed in the survey carried out in Mexico by Vargas-Ruiz *et al.* and well above that shown by Karefylakis *et al.*, in Sweden<sup>25,26</sup>. This Swedish study found 27% of anemic patients and 20% with iron deficiency after ten years postoperatively. The difference between the present work and the European one can result from the cultural and socioeconomic differences between the components of the samples. While one has developed into an example of quality of life, the other comes from a developing country, which is conducted in a typically poorer region of this nation and studying people of low socioeconomic status.

Hypoalbuminemia, observed in 16.6% of the sample after ten years of surgery, follows the same line of reasoning as anemia. Studies from developing countries, such as those carried out by Remedios *et al.*, in India, and by Yupanqui *et al.*, in Colombia, showed, respectively, 14.8% and 20% of hypoalbuminemia in the postoperative period of RYGB<sup>27,28</sup>. Skroubis *et al.*, in Greece, followed 65 patients for 12 months and observed only one (1.59%) case of hypoalbuminemia<sup>29</sup>. A Spanish study conducted by Gracia *et al.*, with follow-up of 115 patients, did not find any patients with low albumin levels after four years of follow-up<sup>30</sup>.

BAROS, although questioned, presents itself as a great tool for the assessment of the postoperative quality of life of bariatric patients. In this study, through this evaluation criterion, we observed a consistent improvement in the quality of life of 85.8% of the sample. This was lower than the

96.3% found by Bastos *et al.*, which may reflect the difference in weight regain rates, since there was considerable regain in only 28.1% of their sample to the detriment of 64.04% obtained in the present study, in addition to the worse socioeconomic conditions of our patients<sup>22</sup>.

Our study demonstrated that RYGB successfully caused loss of more than 50% of weight, but it proved to be faulty in long-term maintenance. Associating this finding with the low index of follow-up, both medical and nutritional, we can conclude that, faced with a population with the different socioeconomic limitations presented, the procedure maintains satisfactory results regarding weight loss, but inefficient follow-up may compromise the final result. Even with weight and nutritional evolutions different from optimal, the quality of life tends to improve in the great majority of obese subjects submitted to RYGB.

## R E S U M O

**Objetivo:** avaliar a evolução ponderal, nutricional e a qualidade de vida de pacientes de baixa renda, após dez anos de derivação gástrica em Y de Roux (DGYR). **Métodos:** estudo longitudinal, retrospectivo e descritivo, que avaliou a perda do excesso de peso, o ganho de peso, a evolução da hipertensão arterial, do diabetes mellitus tipo 2, da anemia e da hipoproteinemia em 42 pacientes de classes sociais D e E submetidos à DGYR. A qualidade de vida foi avaliada através do Bariatric Analysis and Reporting Outcome System (BAROS). **Resultados:** dos 42 pacientes, 68,3% se definiram como não praticantes de atividade física regular, e somente 44,4% e 11,9% tinham acompanhamento médico e nutricional regulares, respectivamente. Foi encontrada média da perda do excesso de peso de 75,6%±12 (IC=71,9-79,4) e perda ponderal insuficiente apenas em um paciente. O ganho ponderal médio foi de 22,3%±16,2 (IC=17,2-27,3), com 64,04% da amostra apresentando ganho maior do que 15% do peso mínimo. 52,3% da amostra apresentou anemia após dez anos de cirurgia e 47,6% deficiência de ferro. Hipoproteinemia foi encontrada em 16,6% da amostra. Houve remissão da HAS em 66% e do diabetes mellitus tipo 2 em 50%. O BAROS demonstrou melhora na qualidade de vida em 85,8% dos pacientes. **Conclusão:** pudemos observar, em uma população com diversas limitações socioeconômicas, que a DGYR manteve resultados satisfatórios quanto à perda peso, mas o seguimento ineficiente pode comprometer o resultado final, especialmente no que diz respeito às deficiências nutricionais.

**Descritores:** Obesidade. Cirurgia Bariátrica. Derivação Gástrica. Qualidade de Vida.

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