

## PROFILE OF THE OBESE PATIENTS SUBMITTED TO ROUX-EN-Y GASTRIC BYPASS WITHOUT DIABETES MELLITUS TYPE 2 REMISSION AND/OR INSUFFICIENT WEIGHT LOSS

*Perfil dos obesos sem remissão do diabetes melito tipo 2 e/ou perda insuficiente de peso após bypass gástrico em Y-de-Roux*

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**ABSTRACT - Background:** The literature reports that gastrojejunal derivation with Roux-en-Y gastric bypass is highly efficient in controlling weight and resolving; but studies have shown worsened glycemic control in a considerable number of patients and associated factors that have not been fully elucidated. **Aim:** To analyze the profile of patients submitted to gastric bypass that did not achieve satisfactory weight loss or complete diabetes remission. **Methods:** Case-control study of 32 patients submitted to gastric bypass with at least two years postoperative time, unsatisfactory results in terms of weight loss or absence of complete diabetes remission. The control group was composed of another 32 patients submitted to the same operation at the same facility, matched for age and postoperative time. A structured questionnaire was applied and clinical and laboratory data were analyzed. **Results:** Among the cases and controls, BMI was 38.9 kg/m<sup>2</sup> and 29.5 kg/m<sup>2</sup> excess weight loss was 56.1% and 77.2%, % excess weight regain of initial excess weight loss, was 20.2% and 7.7%, respectively. Family history of type 2 diabetes mellitus, hypertension and food intolerance showed a significant relationship between cases and controls. **Conclusion:** Food intolerance and family history of hypertension and diabetes were associated to lower loss and weight regain or less likelihood of complete diabetes remission after gastric bypass.

**HEADINGS** - Obesity. Gastric bypass. Diabetes mellitus. Weight loss. Heredity.

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**DESCRIPTOR** - Obesidade. Bypass gástrico. Diabetes melito. Ganho de peso. Hereditariedade.

**RESUMO - Racional:** A literatura mostra que a derivação gastrojejunal em Y-de-Roux apresenta grande eficiência no controle do peso como também na resolução do diabetes melito tipo 2, porém estudos após o bypass gástrico em Y-de-Roux tem mostrado piora do controle glicêmico em porcentagem considerável e os fatores associados não são completamente conhecidos. **Objetivo:** Estudar o perfil dos pacientes obesos, que apresentaram ausência de remissão do diabetes e/ou perda insuficiente de peso, submetidos ao bypass gástrico em Y-de-Roux. **Método:** Estudo caso-controle, incluindo 32 pacientes submetidos à esta operação há pelo menos dois anos com resultados insatisfatórios relacionados à perda de peso ou ausência de remissão completa do diabetes. Um grupo controle foi constituído por outros 32 pacientes submetidos à mesma operação e no mesmo serviço, pareados por idade e tempo de operação. Um questionário estruturado foi aplicado com e dados clínicos e laboratoriais colhidos e analisados. **Resultados:** Dos casos e controles avaliados, o IMC médio foi de 38,9 kg/m<sup>2</sup> e 29,5 kg/m<sup>2</sup>; a perda do excesso de peso foi de 56,10% e 77,23%; o percentual de reganho de peso, do peso inicial perdido, foi de 20,22% e 7,67%. Os antecedentes familiares para diabetes e hipertensão arterial mostraram relação significativa entre casos e controles, com razão de chances de 9,00 para diabetes, 5,44 para hipertensão e intolerância alimentar mostrou relação significativa entre casos e controles. **Conclusão:** Intolerância alimentar persistente e antecedentes familiares para diabetes e hipertensão mostraram-se associados à menor perda e reganho de peso, ou menor chance de remissão completa do diabetes após o bypass gástrico.

Obesity, a chronic disease, deserves greater priority in prevention strategies and identification of clinical management flaws<sup>2</sup>. Obesity is associated with other morbidities, such as diabetes, high blood pressure (HTN), sleep apnea and a number of malignant diseases<sup>28</sup>.

Conservative treatment of obesity, through changes in food habits, behavior, physical exercises and drugs, has a significant role, but according to the National Institute of Health, surgery is the best option for weight loss and long-term maintenance in morbidly obese patients with body mass index (BMI)  $>40 \text{ Kg/m}^2$ .

The bariatric surgery literature shows that gastrojejunal derivation with Roux-en-Y gastric bypass (RYGB) is highly efficient, not only in weight control, but also in resolving comorbidities, primarily diabetes and hypertension, the main criteria for assessing surgical success<sup>20,21,23</sup>. According to meta-analyses published in 2004 and 2009, the mean excess weight loss was 61.2% and 55.9% and diabetes resolution occurred in 86% and 86.6% of individuals, respectively<sup>3,4</sup>.

However, when results were assessed five and 10 years after RYGB, a significant number of failures, characterized as BMI  $>35 \text{ Kg/m}^2$ , were observed, mainly affecting the super-obese population, as follows: after five years, 18% of patients did not maintain BMI under  $35 \text{ Kg/m}^2$  (9% morbidly obese and 43% super-obese), while 10 years after surgery, the failure index was 35% (20% morbidly obese and 58% super-obese)<sup>7</sup>.

In a retrospective study of 177 obese patients with diabetes submitted to RYGB, diabetes resolution was observed in 89% during the first five years post-surgery and recurring lack of glycemic control in 43%<sup>1</sup>.

According to the Swedish Obese Subjects Study, in a follow-up of more than 10 years, it was observed that patients undergoing surgery for obesity exhibited better control indices for risk factors associated to this condition, such as diabetes, compared to patients maintained on clinical treatment. The incidence of this disease was 1% in the group of patients operated on at least two years before and 8% for the group of patients operated on 10 years before, with a diabetes remission index of 72% and 36%, respectively<sup>25</sup>.

Food-related complications may occur mainly in the mid- and long-term. These include gagging, vomiting and dumping<sup>16,17,22,26,29</sup>.

The aim of this study was to analyze the profile of patients submitted to gastric bypass who did not achieve satisfactory weight loss or complete diabetes remission.

Case-control study conducted at the Surgery Service for Obesity and Related Diseases of University Hospital, Federal University do Rio Grande do Norte, RN Brazil, in 2012. A total of 212 patients of both genders, aged between 20 and 65 years, submitted to RYGB, with two or more years postoperative, were assessed (operated on between 2005 and 2010). Sample size was calculated considering a 95% confidence level, test power of 80%, relative risk estimate of 2.0 and a control for each case, matched for age and postoperative time.

This study was approved by the Research Ethics Committee of Onofre Lopes University Hospital, Federal University of Rio Grande do Norte, under protocol no. 601/11 and informed consent was obtained from all participants.

Of the 212 patients evaluated, the case group consisted of 32 patients with unsatisfactory weight loss, defined here as mean excess weight loss  $<50\%$  and/or current BMI  $>35 \text{ Kg/m}^2$  and/or mean excess weight loss (% excess weight regain)  $\geq 50\%$  and/or absence of complete type 2 diabetes mellitus (T2DM) remission, in this study defined as individuals using antidiabetic drugs and glycemic indexes above the reference values for up to one year.

The remaining 180 patients met the inclusion criteria for controls, as follows: satisfactory weight loss, and/or T2DM complete remission maintained for at least a year. Of these 180 individuals, 32 were randomly selected to participate.

Inclusion and exclusion criteria were based, among others, on Brazilian Society of Bariatric and Metabolic Surgery guidelines. The American Diabetes Association criteria were used to determine T2DM patients, and complete T2DM remission was determined primarily by normalizing fasting and postprandial glycemia, and glycosylated hemoglobin levels according to American Diabetes Association consensus<sup>1,5,24</sup>.

All patients were submitted to laparoscopic RYGB, according to the SCODE protocol. With this technique, a gastric reservoir containing a volume of around 15 to 20 ml is created below the esophagogastric junction, with the longest axis along the lesser curvature of the stomach. The jejunum and its mesentery are sectioned at 80 cm from the duodenojejunal angle; the distal segment (Roux loop) is taken to the supramesocolic floor of the abdomen and anastomosis is performed with the small gastric reservoir. The proximal segment of the sectioned jejunum (the biliopancreatic loop) is then anatomized to the Roux loop at around 150 cm from the initial section.

The epidemiological clinical profile of 32 cases and 32 controls was assessed using a structured

questionnaire, with clinical and laboratory data and the following study variables: age, gender, place of birth/residence, marital status, schooling, presence of T2DM, dyslipidemia, high blood pressure (hypertension), family history of diabetes, hypertension and obesity, postoperative time, food intolerance, dumping, anemia arterial pressure, weight loss with calculation of minimum BMI (postoperative) two years after surgery, mean excess weight loss, percentage of mean weight regain, number of months to reach minimum BMI, waist circumference, fasting and postprandial glycemia, HbA1c, total cholesterol, HDL, triglycerides, hematocrit, hemoglobin, AST, ALT, Ferritin, vitamin D, vitamin B12 and basal insulin, according to the postoperative control routine of the service.

Blood pressure was measured with patients placed in the sitting position, after a 5 min rest, using a stethoscope and aneroid sphygmomanometer for the obese (20 cm x 42 cm), approximately 2 cm to 3 cm above the antecubital fossa<sup>10</sup>. Hypertensive patients were those with a history of hypertensive disease or presenting with systolic arterial pressure greater than or equal to 140 mmHg or diastolic arterial pressure greater than or equal to 90 mmHg, as well as patients using antihypertensive drugs.

With respect to family history of T2DM, HTN and obesity, patients who reported previous diagnosis of diabetes, HTN and/or obesity in first- and/or second-degree relatives, were considered as having family history.

The mean excess weight loss and percentage of mean weight regain were based on Brazilian Society of Bariatric and Metabolic Surgery recommendations, while percentage of mean weight regain was based on the percentage regain of initial weight loss<sup>24</sup>.

Waist circumference (in cm) was measured at the midline between the costal margin and upper iliac crest, with the patient standing.

In this study, patients with previous diagnosis and those using statins before bypass were considered dyslipidemic<sup>24</sup>.

Dumping syndrome was characterized by the following signs and symptoms: a feeling of fullness, warmth, cold sweats, and sleepiness, among others<sup>13,14</sup>. Food intolerance (gagging, fullness, food impaction, regurgitation), characterized by discomfort while swallowing, followed or not by vomiting. Anemia is characterized by a decrease in hemoglobin and hematocrit to below reference levels<sup>30</sup>.

**Statistical analysis**

Descriptive analysis of the study variables was conducted to determine relative and absolute distribution, which was presented in tables and graphs. Chi-square or Fisher's exact tests were used to verify the association between study variables. Odds ratios and their respective 95% confidence

intervals were also calculated. Odds ratio values were adjusted by multiple logistic regression (variables with p<0.25 were selected). The student's t-test was applied for inter-mean comparison. Statistical analysis was conducted using the SPSS 17.0 program, considering a 5% significance level.

**RESULTS**

Case and control groups were similar with respect to the clinical variables used for initial sample matching: mean age of 45.0 years for cases and 41.4 years for controls and postoperative time of 54.2 and 49.0 months, respectively. There was no difference in maximum BMI (kg/m<sup>2</sup>) before gastric bypass, with 50.5 for cases and 47.6 for controls.

Of the 32 cases assessed, 28.1% (n=9) exhibited unsatisfactory weight loss, 18.8% (n=6) showed absence of T2DM remission and 53.1% (n=17) displayed unsatisfactory weight loss and absence of T2DM remission.

Table 1 demonstrates that two years after gastric bypass, case and control patients were similar in terms of number of months to reach minimum BMI. On the other hand, in regard to the remaining clinical variables for obesity, case group patients exhibited higher values than those of controls, as follows: BMI of 9.4±5.5 kg/m<sup>2</sup> two years after gastric bypass; minimum BMI of 7.9±3.8 kg/m<sup>2</sup>; waist circumference of 16.2±4.7 cm and percentage of mean weight regain of 12.5±7.2%. Thus cases showed 21.1±7.0 % less mean excess weight loss than controls.

**TABLE 1 - Mean and standard deviation of clinical variables two years after Roux-en-Y gastric bypass for cases and controls**

Clinical variables	Cases (n=32)	Controls (n=32)	p
BMI two years after gastric bypass (in kg/m <sup>2</sup> )	38.9±8,5	29.5±3,0	<0.001
Minimum BMI (in Kg/m <sup>2</sup> )	35.6±7.3	27.7±3.5	0.002
Time to reach minimum BMI (in months)	13.5±7.9	17.0±10.3	0.375
Waist circumference (in cm)	108.8±14.8	92.6±10.1	<0.001
%EWR	20.2±16.1	7.7±8.9	<0.001
%EWL	56.1±18.6	77.2±11.6	<0.001

<sup>(1)</sup> BMI = body mass index

<sup>(2)</sup> %EWR = excess weight regain

<sup>(3)</sup> %EWL = excess weight loss

The results depicted in Table 2 show there was an association between case and control groups and family history of HTN and T2DM (p<0.001 and p=0.005 respectively). The percentage of patients with a family history of HTN in the case group (87.5%) was higher than in the control group (56.3%) and the percentage of those with a family history of T2DM was greater in the case group (84.4%) than among controls (37.5%), with an odds ratio of 9.0 for T2DM and 5.4 for HTN.

**TABLE 2** – Number and percentage of patients according to study group and comorbidities present before Roux-en-Y gastric bypass

Comorbidities	Cases (n=32)		Controls (n=32)		p	OR (95%CI)
	No.	%	No.	%		
Dyslipidemia						
Yes	11	34.4	7	21.9	(1)0.266	1.9 (0.62 – 5.68)
No	21	65.6	25	78.1		
Type 2 diabetes mellitus (T2DM)						
Yes	21	65.6	12	37.5	(1)0.024	3.2 (1.15 – 8.84)
No	11	34.4	20	62.5		
High blood pressure (HTN)						
Yes	28	87.5	23	71.9	(2)0.213	2.7 (0.75 – 10.06)
No	4	12.5	9	28.1		
Family history of T2DM						
Yes	27	84.4	12	37.5	(1)<0.001	9.0 (2.73 – 29.67)
No	5	15.6	20	62.5		
Family history of HTN						
Yes	28	87.5	15	56.3	(1)0.005	5.4 (1.55 – 19.18)
No	4	12.5	14	43.8		
Family history of obesity						
Yes	27	84.4	21	65.6	(1)0.083	2.8 (0.85 – 9.40)
No	5	15.6	11	34.4		

Note: if  $p \leq 0.05$  – statistically significant difference. (1) Chi-square test. (2) Fisher's Exact test. (3) OR = odds ratio. (4) CI = confidence interval

With respect to food-related variables in the late postoperative, Table 3 shows a significant association between the study group and the variable food intolerance with an odds ratio of 1.5 and a tendency in relation to dumping.

**TABLE 3** – Number and percentage of patients according to study group and food-related variables

Variables	Cases (n=32)		Controls (n=32)		p	OR (95% CI)
	No.	%	No.	%		
Food intolerance						
Yes	15	46.9	5	15.6	0.007	1.5 (0.54 – 4.21)
No	17	53.1	18	84.4		
Dumping						
Yes	10	31.3	4	12.5	0.070	3.2 (0.88 – 11.52)
No	22	68.8	28	87.5		
Anemia						
Yes	13	40.6	10	31.3	0.434	4.8 (1.46 – 15.51)
No	19	59.4	22	68.7		

Note:  $p \leq 0.05$  – statistically significant difference, Chi-square test. (1) OR = odds ratio. (2) CI = confidence interval

## DISCUSSION

A study of patients submitted to RYGB from the opening of the facility to 2010, with similar preoperative criteria, who obtained poor (cases) or good results (controls) in terms of weight loss and weight maintenance and/or T2DM management, found that a number of variables exhibited a significant relationship between cases and controls.

Mean age of the 32 cases and 32 controls was 45.0 and 41.4 years, mean postoperative time 54.2 and 49.0 months, mean maximum BMI prior to surgery 53.5 Kg/

m<sup>2</sup> and 48.8 Kg/m<sup>2</sup>, mean minimum BMI after surgery 35.6 kg/m<sup>2</sup> and 27.7 Kg/m<sup>2</sup>, percentage weight regain 20.2% and 7.7% and mean excess weight loss of 56.1% and 77.2%, respectively. Similar data were found in a retrospective study conducted in Canada with 226 patients 11 years after bypass surgery, demonstrating a minimum BMI of 28.6±0.3 kg/m<sup>2</sup>, BMI 10 years after bypass of 33.6±1.3 kg/m<sup>2</sup>, time to reach minimum BMI of 2.2±1.9 years and mean excess weight loss of 67.6±2.3%, age 42.0±3.4 years, time since bypass of 11.4 years and maximum BMI of 53.50±12.24 kg/m<sup>2</sup><sup>7</sup>.

In relation to percentage excess weight lost, in a meta-analysis of 621 articles (44% from Europe and 43% from North America), published between January 1990 and April 2006, involving 135,246 patients submitted to bariatric surgery, the mean variation in mean excess weight loss was 59% for patients operated on two years or more prior to using different surgical techniques, and 58% in patients with T2DM<sup>21</sup>.

Weight regain in other studies occurred in up to 63.6% of patients submitted to RYGB, varying, among others, according to initial BMI and postoperative time. Postoperative follow-up is considered an important factor in this regain<sup>15</sup> and lack of weight control is related to super-obesity, that is, BMI>50 kg/m<sup>2</sup>, a factor not observed in this study<sup>8</sup>.

In regard to percentage of mean weight regain (Table 1), a significant relationship can be observed in cases as compared to controls. A study carried out in Campinas, Brazil, to assess weight regain in 782 patients of both genders submitted to gastric bypass up to five years after surgery, found weight regain from 24 months postoperative onwards, reaching a peak at 48 months<sup>15</sup>.

Family history of T2DM and HTN (Table 2) showed a significant relationship between cases and controls, with an odds ratio of 9.0 for T2DM and 5.4 for HTN. However, taken separately, these factors may not result in increased risk of unfavorable surgical results. Were found no studies that assessed the odds ratio of obese individuals with a family history of T2DM and HTN experiencing failed surgical treatment. However, heredity or family history of them are risk factors for these two conditions, which, coupled with dyslipidemia and obesity, among others, favor the occurrence of cardiovascular diseases<sup>1,10,18</sup>.

In regard to T2DM remission, studies show that it can vary from 11 to 43%, due to a number of factors such as time to diagnosis of the disease<sup>6</sup>. On the other hand, it may also be related to lower BMIs<sup>8</sup>. These discrepant results confirm the need for more extensive studies to clarify the cause of these unsatisfactory results, with the purpose of increasing the success rate.

Gastrojejunal derivation uses several processes, including metabolic and incretin mechanisms<sup>11</sup>, which favor weight loss and T2DM resolution. Although they were not investigated in this study, some patients experience postoperative metabolic deterioration over



time, resulting in poor glycemic control and resumption of antidiabetic medication, increased blood pressure and weight regain.

A recent study in Denmark, with 41 patients submitted to RYGB at least 12 months before, 16 with good weight loss and 17 with insufficient weight loss and eight controls (non-operated), showed that neurotensin, PYY, TBA and PP release did not differ between the RYGB-operated groups. However, patients with good weight loss exhibited greater appetite suppression, with an increase in GLP1 and a decrease in ghrelin, while postprandial secretion of CCK was higher in the group with insufficient weight loss, demonstrating the influence of intestinal hormones on the response of RYGB to weight loss<sup>9</sup>.

With respect to food-related variables (Table 3), there was no significant difference for anemia. However, food intolerance showed a significant relationship between cases and control, while dumping exhibited a tendency towards this difference. These findings are corroborated in studies indicating food intolerance as one of the factors for weight regain, due to increased carbohydrate intake to the detriment of proteins. Larger amounts of carbohydrates are found in semiliquid and doughy foods, consumed in an attempt at avoiding vomiting and food intolerance. However, an interdisciplinary approach is important for reducing this problem and optimizing results<sup>9</sup>.

Food intolerance may present itself mainly as gagging /vomiting and dumping, the first two generally related to mastication and swallowing, and can cause stenosis, loss of ability to achieve receptive relaxation, gastric accommodation and drastic reduction in gastric volume. A further problem includes intestinal obstructions, primarily internal hernias, leading to micronutrient deficiency, especially vitamin B1, B12, D, iron, folic acid, zinc and calcium and regained weight, but this can be minimized or even overcome with a proper diet<sup>19,27</sup>.

## CONCLUSION

Food intolerance and family history of hypertension and diabetes were associated to lower loss and weight regain or less likelihood of complete diabetes remission after gastric bypass.

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