# Interference of wheight loss on cardiovascular risk and type 2 Diabetes 24 months after gastric bypass – cohort retrospective

# Interferência da perda de peso no risco cardiovascular e Diabetes tipo 2 24 meses após bypass gástrico – coorte retrospective

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**ABSTRACT**
Background: Obesity has increased in prevalence and thus has become a public health crisis. The objective of this study was to evaluate the impact of weight loss on the resolution of type 2 diabetes mellitus and cardiovascular risk. Methods: This is a retrospective cohort and descriptive study, involved consulting a database, from March 2018 to March 2019. The subjects were female and male patients, ≥18 years, who had been submitted to bariatric surgery from March 2014 to March 2016. The following data were obtained from their charts: weight, height, age, sex, presence of associated morbidities (type 2 diabetes mellitus, cardiovascular risk), glycated hemoglobina and glucose. The data a presented as the mean and standard deviation, median and interquartile range, or count and percentage. The results were considered statistically significant if p-value ≤0.05. Results: The patients had maintained a substantial percentage of excesso wheight loss (%EWL) during the postoperative period, and the Hb1Ac, glucose, CVR, and metabolic alterations were also reduced. Six months after surgery, group 1 (<70% EWL) and group 2 (≥ 70%) showed reduced Hb1Ac and, glucose and only group 2 showed reduced CVR. From 12 to 18 months after surgery, group 1 showed reduced Hb1Ac. From 18 to 24 months after surgery, group 2 showed reduced CVR and group 1 showed reduced glucose. Conclusion: Bariatric surgery had a positive effect on %EWL and modified the metabolic profile and CVR of patients up to 24 months after gastric bypass, reducing associated comorbidities.

**Keywords:** weight loss, dyslipidemia, obesity, cardiovascular risk.

**RESUMO**
Antecedentes: A obesidade tem aumentado em prevalência e tornou-se assim uma crise de saúde pública. O objectivo deste estudo era avaliar o impacto da perda de peso na resolução da diabetes mellitus tipo 2 e do risco cardiovascular. Métodos: Este é um estudo de coorte retrospectivo e descritivo, envolvendo a consulta de uma base de dados, de Março de 2018 a Março de 2019. Os sujeitos foram pacientes do sexo feminino e masculino, ≥18 anos, que tinham sido submetidos a cirurgia bariátrica, de Março de 2014 a Março de 2016. Os seguintes dados foram obtidos a partir dos seus gráficos: peso, altura, idade, sexo, presença de morbidades associadas (diabetes mellitus tipo 2, risco cardiovascular), hemoglobina glicosilada e glicose. Os dados a apresentados como média e desvio padrão, mediana e intervalo interquartil, ou contagem e percentagem. Os resultados foram considerados estatisticamente significativos se p-valor ≤0.05. Resultados: Os pacientes tinham mantido uma percentagem substancial de perda

de soro excessiva (%EWL) durante o período pós-operatório, e a Hb1Ac, glicose, CVR, e alterações metabólicas também foram reduzidas. Seis meses após a cirurgia, o grupo 1 (<70% EWL) e o grupo 2 (≥ 70%) apresentaram Hb1Ac reduzido e, a glicose e apenas o grupo 2 apresentaram CVR reduzido. De 12 a 18 meses após a cirurgia, o grupo 1 mostrou Hb1Ac reduzido. De 18 a 24 meses após a cirurgia, o grupo 2 mostrou CVR reduzido e, o grupo 1 mostrou glicose reduzida. Conclusão: A cirurgia bariátrica teve um efeito positivo na %EWL e modificou o perfil metabólico e a RVC dos pacientes até 24 meses após o bypass gástrico, reduzindo as comorbilidades associadas.

**Palavras-chave:** perda de peso, dislipidemia, obesidade, risco cardiovascular.

## 1 INTRODUCTION

Obesity has increased in prevalence and thus has become a public health crisis. Moreover obesity increases in frequency of other diseases (BRASI, 2017), contributing to elevated morbidity and mortality in superobese people (WHO, 2017). Cardiovascular risk factors include systemic arterial hypertension (SAH), type 2 diabetes mellitus (T2DM) and dyslipidemia (SBEM, 2018). The treatment of obesity involves drug therapy, nutritional therapy, and physical activity however in severe cases this appoach does not produce satisfactory results, with 95% of individuals returning to their initial weight within 24 months (SANTOS, 2012; BASTOS et al., 2013).

The frustration of superobese patients with the slow progress of conservative treatment motivates them to seek bariatric surgery (BS), due to its speed and effectiveness in the treatment of obesity. Patients with clinical treatment failure and who have a body mass index (BMI) > 35 kg/m² and associated comorbidities, or patients with a BMI > 40 kg/m², are candidates for BS. The effects of BS on health are satisfactory in terms of quality of life (QoL), in addition to improvements in health conditions related to comorbidities (glycemic levels, hypertension, T2DM, hepatic steatosis, apnea and reflux) (VAN DER BEEK et al., 2014; PIMENTA et al., 2016; BORDALO et al., 2016.

BS has been used as a treatment for the superobese and is an effective and lasting intervention. Indeed, this approach provides a sustained percentage excess weight loss (%EWL), in addition to a substantial improvement in several comorbidities (SANTOS & ARAÚJO, 2012; COSTA et al., 2016). A meta-analysis of 134 studies, involving around 22.000 people whit obesity, showed that, on average, gastric bypass leads to a 61% EWL, a 39.7 kg rediction in body weight, a 13.2 kg/m$^2$ reduction in BMI, and important improvement. or resolution of comorbidities (BUCHWALD et al., 2004). The greatest %EWL and beneficial effects on comorbidities occurs approximately 12 months after surgery, and it lasts in most

patient (SALAMEH, 2006; Sjöström et al., 2004) effects, however, can already be seen in the first 6 months after surgery (SALAMEH, 2006).

Knowing the anthropometric and comorbid profile of patients undergoing BS is essential to assess the risks related to the morbidity and mortality of the surgery and to provide resources, special care and postoperative support (KELLES, DINIZ, BARRETO, 2017). Given the growing number of obesity cases in the world population, and the consequent increase in BS, this study evaluated the impact of weight loss on the resolution of T2DM and on cardiovascular risk (CVR) 24 months after gastric bypass.

## 2 METHODS

This is a retrospective cohort and descriptive study used a quantitative approach and was carried out in an Obesity and Digestive System Surgery Clinic, located in the city of Santa Maria (Rio Grande do Sul, Brazil). The study was developed in accordance with strict ethical precepts and was approved by the Research Ethics Committee of the Franciscan University (UFN) approval number (3.093.324) and CAAE (approval number 04253218.0.0000.5306). The study is in full compliance with STROCSS [32] 2021 www.strocssguideline.com. Data were collected by of analyzing a database of patients at the clinic, from March 2018 to March 2019, who underwent BS from March 2014 to March 2016. The sample consisted of adults of both genders, > 18 years old, who underwent BS at least 24 months prior. The Framinghan Heart Study protocol (2008) was used to establish CVR. This retrospective cohort study started in 1948 and is still active, which makes it possible to estimate the absolute risk of CVR (SAH, smoking, type 2 diabetes mellitus, and dyslipidemia) in the 10 subsequent years, promoting preventive clinical actions. The following data were obtained from the patients' charts: a) weight and height, with which BMI was calculated and classified according to the WHO (2017); b) personal data (age and sex); c) presence of associated morbidities (SAH, T2DM, dyslipidemia and CVR); d) %EWL, calculated using the formula (preoperative weight [kg] - current weight [kg]) / (preoperative weight [kg] - ideal weight to produce BMI {20.8 kg $m^2$ for men and 22 $kg/m^2$} x 100, which was categorized into either group 1 (G1) with < 70% EWL or group 2 (G2) with ≥ 70% EWL according to Deitel & Shikora (2014). The glycated hemoglobin (Hb1Ac) values were classified as follows: for healthy patients, normal level = 4.5% - 5.6%, prediabetes = 5.7% - 6.4%, and diabetes = ≥ 6.5%); the controlled level in patients with diabetes is = 6.5% - 7.0%. The normal glucose levels = were 70 - 125 mg/dL pre-prandial and < 150 mg/dL post-prandial), according to the Brazilian Society of Endocrinology and Metabololism (SBEM, 2018). CVR was determined by evaluating the lipid profile values: total

cholesterol < 190 mg/dL; high-density lipoprotein cholesterol (HDLc) ≥ 40 mg/dL; low-density lipoprotein cholesterol (LDLc), low < 130mg/dL, intermediate < 100mg/dL, high < 70mg/dL and very high − < 50mg/dL); triglycerides < 150mg/dL (SBC, 2015). These data should be interpreted according to the patients chacaracteristics and clinical evolution (age, hereditary factors, weight, smoking, blood pressure and imaging tests).

### 2.1 STATISTICAL ANALYSIS

Data were collected in Microsoft Excel 2010® , checked and transferred to IBM SPSS® Statistics version 20.0 for statistical analysis. The results were considered statistically significant if p-value ≤0.05. Quantitative data are presented as the mean and standard deviation. When the data were not normally distributed, they are presented as the median and interquartile range. Categoricaly data are presented as the counts and percentages. Analysis of the longitudinal variability of quantitative medians (Hb1Ac, glucose, CVR and %EWL) was evaluated by fusing generalized estimating equations considered as interaction model between the G1 and G2.

## 3 RESULTS

From March 2014 to March 2016, there were 351 patients who underwent gastric bypass. The sample comprised 284 women (80.9%) and 67 men (19.1%), with a mean ± standard deviation (SD) age of 42.5 ± 11.3 years and 40.4 ± 11.8 years. The mean ± SD pre-surgical weight of women was 110.4 ± 17.2 kg, with a BMI of 41.8 ± 6.4 kg/m$^2$, and the mean ± SD pre-surgical weight of males was 128.4 ± 22.8 kg, with a BMI 42.0 ± 7.1 kg/m$^2$. Most patients were married (58.1%). The %EWL was greater in men 74.1% ± 19.4%, than woman 72.4% ± 15.9%. Twenty-four months BS, all female and male patients had a reduced weight (69.4 ± 11.7 kg and 82.8 ± 14.0 kg, respectively) and BMI (26.7 ± 4.5 kg/m$^2$ and 27.0 ± 4.6 kg/m$^2$, respectively) (Table A.1).

Table A.1. Demographic and anthropometric data of patients undergoing OAGB.

| **Characteristic** | **n= 351** |
|---|---|
| **Age (years) – mean ± SD** | 42.1 ±11.2 |
| **Gender – n (%)** | |
| Female | 284 (80.9) |
| Male | 67 (19.1) |
| **Weight (kg)** | |
| Pre-surgical – mean ± SD | 115.8 ± 19.3 |
| Final (24 months) – mean ± SD | 55.9 ± 7.2 |
| **BMI (kg/m$^2$)** | |

| | |
|---|---|
| Pre-surgical – mean ± SD | 42.6 ± 4.6 |
| Final (24 months) – mean ± SD | 26.7 ± 4.5 |
| **%EWL** – mean ± SD | 73.3 ± 0.8 |

SD – Standard Deviation; BMI – Body Mass Index.

The pre-surgical comorbidities presented by the patients were higher among women (SAH, 43.2%; T2DM, 18.23% and dyslipidemia, 47.29%). All patients were indicated for BS according to the criteria established by the Ministry of Health in Brazil[1] (Table A.2).

Table A.2. Description of morbidities associated with obesity in the preoperative period of BS.

| **Morbidities** | **Male (n = 67)** | | **Female (n = 284)** | |
|---|---|---|---|---|
| | **Yes** | **No** | **Yes** | **No** |
| **SAH** | 12,25% | 6,84% | 43,02% | 37,89% |
| **T2DM** | 6,27% | 12,82% | 18,23% | 62,68% |
| **Dyslipidemia** | 11,11% | 7,98% | 47,29% | 33,62% |

SAH (\systemic arterial hypertension); T2DM (Type2 diabetes mellitus)

All patients howed a rediction in wheght, Hb1Ac and glucose, changes that minimize CVR and dyslipidemic risk. In the analysis of Hb1Ac (Figure A.1), in the preoperative period (T1), all patients were overweight and had altered Hb1Ac (5.7%–7.0%).

Figure A.1: Link between glycated hemoglobin, time of surgery and percentage of weight loss.

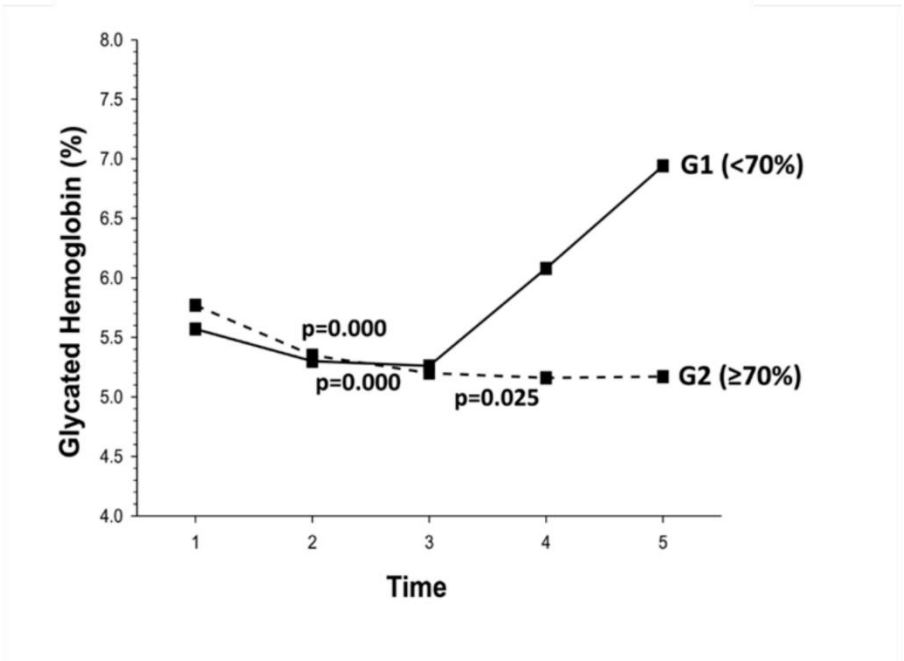


Figure 1:Glycated hemoglobin (Hb1Ac), ), time of surgery and percentage weight loss (%).

Six months after surgery, there was a reduction in weight and Hb1Ac in both G1 and G2 (p=0.000). However, 12 months after gastric bypass, only G1 (<70% EWL) showed a

reduction in Hb1Ac (p=0.025) that lasted up to 24 months. In the analysis of glucose (Figure A.2), in the preoperative period (T1) all patients were overweight and had altered glucose levels (> 100 mg/dL). After the procedure (6 months), in both groups there was a reduction in weight and glucose (p=0.000), changes that lasted up to 18 months. However, in the 18 months after gastric bypass, G2 showed a reduction in glucose and greater stability that lasted up to 24 months. Although patients in G1 showed less weight reduction, the presented a significant drop in glucose (p=0.036), and the patients may had become hypoglycemic, which is not desirable.

Figure A.2: Link between cardiovascular risk, time of surgery and percentage weight loss (%) − CVR/ Time/%EWL.

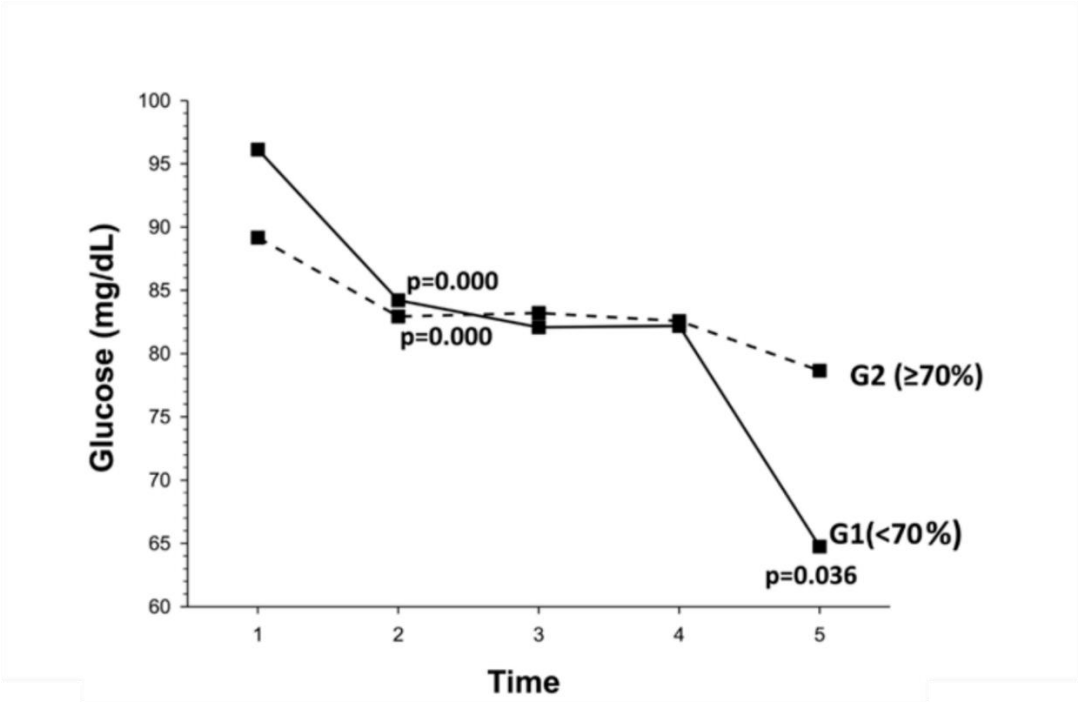


Figure 2: Glucose, time of surgery and percentage weight loss (%).

Figure (A.3) shows details of CVR , in the preoperative period (T1), all patients were predicted to have a high rate (31%) of cardiovascular complications in the subsequente 10 years. Six months after gastric bypass, there was a reduction in cardiovascular complications in both groups, due to the loss of excess weight and a reduction in Hb1Ac and glucose. However, compared with G1, G2 showed a significant difference regarding the reduction of CVR at 6 months (p=0.045) and 12 months (p=0.001) after surgery.

Figure A.3: Link between cardiovascular risk, time of surgery and percentage weight loss.

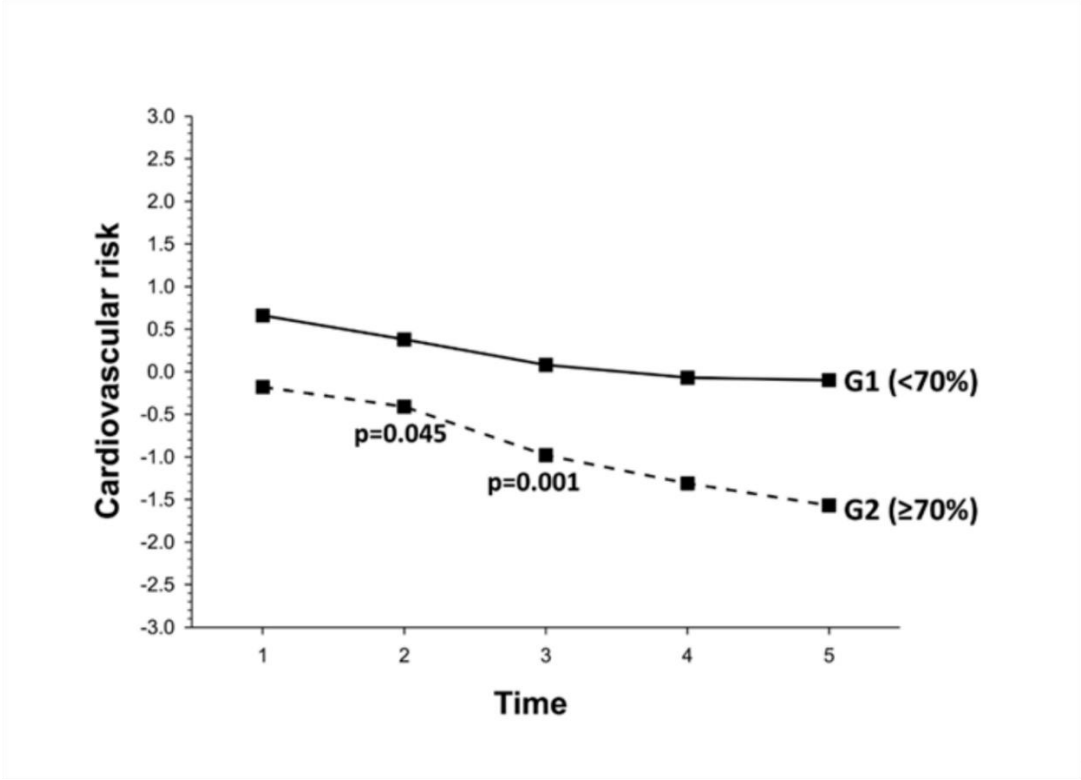


Figure 3: Cardiovascular risk (CVR), time of surgery and percentage weight loss (%).

## 4 DISCUSSION

In this study, the majority of patients who had BS were female (80.9%), which corroborates the results of other studies carried out in different regions of the country (SBEM, 2017; SALAMEH, 2006; OLIVEIRA et al., 2014). Unlike women, men tend to seek BS only when their daily physical activities are compromised (CARVALHO et al., 2013). According to Sandoval (2011), in super-obese patients, clinical treatment (behavioral changes and pharmacological treatment) results in a reduction of only 5% - 10% of body weight (rarely maintained), while in gastric bypass (generally indicated for obese patients with a BMI > 40 kg/m$^2$) there is a 50% reduction that is maintained in the long term.

BS is quite effective at producing long-term weight loss, as show in this study and previous study (COSTA et al., 2014; BARROS et al., 2015). The BMI was reduced by ~ 70%, which implies a significant reduction in cardiovascular mortality and mortality for all causes associated with excess weight. Costa et al. (2014) reported similar data: >50%EWL in 94.7% of the patients investigated.

In the evaluation of preoperative comorbidities, the 284 women had greater morbidity, demonstrating that obesity is a clinical condition that works as a risk factor for the emergence of other diseases. The most common comorbidities in females were hypertension (43.0%),

T2DM (18.2%), and dyslipidemia (47.2%). These data are similar to other reports (BARROS et al., 2015; PUZZIFERRI et al., 2006; SANCHEZ-SANTOS et al., 2006). Barros et al. (2015) found an even higher prevalence of hypertension (50%) in the preoperative period. Sanchez-Santos et al. (2006) showed that in 50 patients, 5 years after Roux-en-Y gastric bypass, 85.7% had an improvement in the comorbidities associated with obesity. Dyslipidemia, present in most women in this study, had a significant reduction in both groups evaluated (G1 and G2), with a reduction in excess weight, Hb1Ac, and glucose. According to Silva Neto et al. (2014), the anatomical and hormonal changes resulting from BS help to reduce weight and improve or even resolve type 2 DM.

Hb1Ac was reduced in G1 12 months after BS and was then stable until 24 months. Patients who lost more weight (G2, ≥ 70% EWL) showed similar changes in Hb1Ac until 12 months. After 18 months, they showed a significant increase until 24 months, which may be explained by the behavior of fasting glucose, although we cannot say that fasting glucose is directly related to Hb1Ac. Schauer et al. (2014) found a reduction in Hb1Ac (2.9% ± 1.6%) 12 months BS. Other authors (MINGRONE et al., 2012; KASHYAP et al., 2013) have observed that 24 months after the intervention of studies with similar populations, they also found similar values and, finally, the study by Hsu et al. (2015), with an even longer follow-up (5 years), obtained a result similar to the present study.

Six months after BS, glucose was reduced in both groups (G1 and G2), with a similar global behavior up to 18 months. After 18 months, G2 showed a reduction in glucose and greater stability up to 24 months. However, G1 had a significant drop in glucose (p=0.036), and the patients may have become hypoglycemia. According to Santos and Araújo (2012), hypoglycemia can be explained by the endocrine effect that this procedure produces, even in the early postoperative period. From these data, it is possible to suggest that glycemic control occurs quickly after the intervention and is maintained in the long term. The results of our study are consistente with what has been reported by other authors (SALAMEH, 2006; CARVALHO et al., 2013; COSTA et al., 2014; PARIKH et al., 2014). Corroborating other studies (WHO, 2017; VAN DER BEEK et al., 2014; KELLES et al., 2017; SANDOVAL, 2011), patients who underwent BS had a significant reduction in anthropometric and laboratory parameters from 6 to 12 months after the surgical procedure.

Studies with longer follow-ups showed a higher percentage of patients with normal blood glucose levels. At 6 months of follow-up, Parikh et al. [30] found 65% of patients with HbA1c <6%. At 12 months Shauer et al. (2014) observed that 42% of their patients had Hb1Ac < 6%, and at 18 months Kashyap et al. (2013 found a diabetes remission rate of 80%. Finally,

after 5 years Hsu et al. (2015) reported that 53% of individuals normal glycemic control after, which is considered prolonged remission. Carvalho et al. (2007) evaluated patients at the pre and postoperative moments of BS: 15 with a diagnosis of DM2 and 5 with altered fasting glucose. At the post-surgical time, the 20 patients had normal glucose and Hb1Ac levels, and they no longer required medication. This result can be explained by the reduction in the path between the stomach and the intestine. Hence, food contacts the final part of the intestine, which results in an increase in the production of incretins, substances that stimulate the production of insulin, and regulate glucose metabolism. This improvement in glucose and Hb1Ac levels observed in this study may be justified by the glycemic process.

Studies have shown that a reduction in dyslipidemia reduces the risk of cardiovascular diseases (BRASIL, 2017). Due tothe important reduction in body weight, BS already has a positive short-term impact on the control/resolution of comorbidities associated with obesity, including DM2, dyslipidemia, SAH and CVR. Within this period, the following changes are anticipated: a 20 - 50 Kg reduction in body weight; a 35% decrease in BMI; and resolution of SAH, DM2, and dyslipidemia in, respectively, 62%, 76% and 70% of individuals (BUCHWALD et al., 2004; HSU et al., 2015; PARIKH et al., 2014). Theis beneficial effects are maintained in the long term, as has been reported in other studies in patients followed for 10 years after the procedure (WHO, 2017; SILVA-NETO et al., 2014), and translate into a reduction in cardiovascular mortality, making BS the current treatment of choice for obese patients whom drug and behavioral therapy has failed to control weight and comorbidities (WHO, 2017; SBEM, 2018). In the present study, 6 months after BS, the expected results described above were already observed and were sustained, 24 months after BS. We suggest that, in the evaluated patients, there was a significant improvement in T2DM and dyslipidemia and, consequently, an important reduction in the CVR.

### 4.1 LIMITATIONS

However, a possible limitation of the study is the sample size, as it is a database with a small quantitative number of patients. This fact confirms the need to establish well-designed and long-term clinical trials, with an extensive database for a better understanding of the benefits of bariatric surgery in controlling the lipid profile and associated morbidities.

## 5 CONCLUSION

In the present study, BS by the Roux-in-Y method is an important factor in weight loss, with a reduction around (±70%) of the %EWL, reducing metabolic (T2DM and CVR) and lipid

(glucose, Hb1Ac ) and in the reduction of associated morbidities, improving the quality of life and health conditions related to obesity, in the 24 months after the surgical intervention. More research is needed to clarify the impact of %EWL on metabolic indicators and lipid profile two years after BS.

## ETHICAL APPROVAL

The study was approved by ethical committee of Universidade Franciscana (UFN approval number 3.093.324) and CAAE (approval number 04253218.0.0000.5306).

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## DECLARATION OF COMPETING INTEREST

The authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article.

## DISCLOSURE

There are no external sources of funding to support this study.

## INFORMED CONSENT

Informed consent was obtained from the physician in charge of the Obesity and Digestive Surgery Clinic, where data from all participating subjects were collected and included in this study.

## PROVENANCE AND PEER REVIEW

Not commissioned, externally peer reviewed.

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