



Effectiveness of argon plasma coagulation in the treatment of weight regain after roux-y gastric bypass: a cross-sectional prospective observational study

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Abstract

Introduction: Roux-en-Y Gastric Bypass (RYGB) is one of the most commonly performed surgeries to treat obesity worldwide. However, approximately 20% of patients have a recurrence of obesity, and enlargement of the gastrojejunal anastomosis is one of the associated factors. Endoscopic treatment of anastomosis has been proposed for further weight loss. One of the most commonly used techniques for anastomotic narrowing is argon plasma coagulation (APC). However, no randomized controlled trials have proven that this technique is superior to multidisciplinary follow-up.

Objective: To evaluate and investigate the efficacy and safety of the application of argon plasma in the gastrojejunal anastomosis in the relapse of obesity after Gastric Bypass. **Methods:** Transversal study. Thirty-two patients were selected. More than 50% of The excess body weight regained was lost. Ranging from 6 to 25 kg.

Results: A loss of more than 50% of the excess weight regained was observed in 30 % patients. Ranging from 6 to 25 kg. **Conclusion:** The application of argon plasma coagulation was safe and effective in the treatment of obesity recurrence after gastric bypass.

Keywords: Obesity surgery. Bariatric surgery. Gastric bypass. Weight regain. Bariatric Endoscopy. Argon plasma coagulation. Enlargement anastomosis.

Introduction

Obesity represents a multifactorial disease that causes serious public health problems [1]. There are 2.0 billion overweight and obese people in the world [1], and Brazil is in fifth place in the world ranking, with an estimated 18.0 million people, tending to reach 70.0 million individuals [2].

In the scenario of treating obesity, bariatric surgery is more effective in weight loss and controlling comorbidities [3]. In particular, Roux-en-Y Gastric Bypass (RYGB) is one of the most performed surgeries in the world. Despite good results and disease control in the medium and long term, approximately 20% of patients undergoing this surgery do not lose the desired weight in the first year or gain weight again after 18 to 24 months [4]. When we transport this data to super obese patients, the obesity recurrence figures can reach 35%. Weight regain after bariatric surgery is

multifactorial, however anatomical factors related to the size of the gastric pouch and the size of the gastrojejunal anastomosis must be evaluated in conjunction with clinical data and not neglected [3,4].

According to the IFSO (International Federation of Obesity Surgery) in its report published in 2015, around 86 thousand bariatric surgeries were performed in Brazil, 70.0% of which were laparoscopic gastroplasty type RYGB, which promotes up to 75.0% loss of initial excess weight in the period of 18 to 24 months, but with an obesity recurrence rate between 10.0 and 35.0% in the long term [5]. Throughout the world, the number of bariatric surgeries has grown exponentially since 1997, going from 40,000 procedures annually to 468,609 surgeries in 2003 [5].

In this sense, the literature is abundant in citing surgical attempts to bring these patients to a healthy status [3-6]. To date, several studies regarding RYGB have demonstrated significant results, including increased survival reduced cardiovascular mortality, and control of metabolic diseases [7-10].

The most feared postoperative complications, responsible for mortality rates between 0.1 and 0.5%, include sepsis of abdominal origin, caused by dehiscence of sutures or anastomoses, and pulmonary thromboembolism [11]. The most common late complication is the recurrence of obesity, in which the main associated factors are dietary errors and poor lifestyle habits associated with a sedentary lifestyle; Supporting factors include an increased gastric reservoir, and dilation of the anastomosis, among others [11].

Anastomoses smaller than 10.0 mm can cause recurrence of obesity due to food intolerance, and require endoscopic treatment with dilation in most cases. However, anastomoses above 15.0 mm have been associated with obesity recurrence, especially when associated with complaints of decreased satiety/or early hunger due to rapid gastric emptying [12].

In this context, the reduction of restriction with dilated anastomosis can function as an additional factor to these eating disorders, directly influencing the maintenance of regained weight and the possibility of further weight loss [13]. What is currently under discussion is the efficacy and safety of narrowing the gastrojejunal anastomosis through the application of argon plasma coagulation (APC) in the relapse of obesity in patients undergoing RYGB [14].

As a consequence of the recurrence of weight gain, abnormal anatomical findings are found in 71.2% of patients, with 58.9% presenting with dilated gastrojejunoanastomosis [11-13]. Thus, APC in gastrojejunal anastomosis has been proposed to aid new

weight loss in patients undergoing RYGB who have experienced a relapse of obesity [11].

Also, argon is an odorless, inert, non-toxic, cheap, and easily ionizable gas that has been used in conventional and laparoscopic surgeries since the 1980s and was introduced into the field of endoscopy in 1991 [16]. There are numerous endoscopic applications of argon plasma, such as gastrointestinal bleeding of the most diverse etiologies, tissue growth after implantation of prostheses, opening the lumen of hollow organs obstructed by tumor growth, and, more recently, in the field of bariatric endoscopy [16].

In the treatment of gastrojejunal anastomosis, endoscopy has stood out as an effective and safe method in the treatment of recurrent obesity, as APC is technically feasible and reproducible, relatively cheap, and with numerous advantages over conventional electrocoagulation [11,16]. Complications are infrequent and the tissue penetration limit of 2.0 to 3.0 mm associated with adequate coagulation allows its application in critical areas such as the duodenum and colon [17-22].

Moreover, APC in gastrojejunal anastomosis has promoted a reduction in diameter and, consequently, delayed gastric emptying, early satiety, and weight reduction. Reducing the diameter of a dilated anastomosis can lead to a 23% reduction in excess weight on average [23-27].

In this sense, the recurrence of obesity is associated with a decrease in quality of life and the recurrence of comorbidities [28]. APC in anastomosis with a reduction in its diameter and the consequent weight loss can lead to a significant improvement in the clinical picture. Thus, the relevance of studies on the effect of argon on weight reduction in patients undergoing RYGB highlights the increasing continuity of this use [28,29].

It is known that the recurrence of obesity is directly correlated with factors such as BMI before surgery, eating habits, psychiatric disorders, self-esteem problems, and socioeconomic conditions. The diameter of the gastrojejunal anastomosis and dilation of the reservoir has also been correlated with the recurrence of obesity. As a result, numerous endoscopic techniques have been proposed to treat the problem, highlighting the narrowing of the gastrojejunal anastomosis. Recent studies have demonstrated satisfactory results in weight loss and rescuing these patients to multidisciplinary treatment, improving quality of life [11,13].

With this scenario presented, upper gastrointestinal endoscopy (UGE) presents itself as an effective tool in monitoring and treating RYGB complications in selected patients, avoiding new corrective surgeries [30,31]. Common indications for performing UGE in the

postoperative period of RYGB include assessment of symptoms, treatment of complications, as well as assessment of inadequate weight loss [32].

Therefore, the present study evaluated the efficacy and safety of using APC in patients with a relapse of obesity after RYGB.

Methods

Study Design and Participants

This study followed a prospective cross-sectional observational model and included 40 patients out of 87 who underwent eligibility analysis. All selected patients completed the follow-up, with no exclusions during the study period. The STROBE rules (<https://www.strobe-statement.org/checklists/>) were used.

Inclusion and exclusion criteria

Inclusion

Patients who met the following criteria were included in the study: Age over 18 and under 65; Bariatric gastric bypass surgery without a ring for more than two years; Weight regain > 10% of lost weight (Pre-operative weight – Minimum post-operative weight = weight loss) associated with early and/or prolonged loss of satiety (up to 3 hours); Gastrojejunal anastomosis >14mm; Signing the Free and Informed Consent Form; Participation in all stages of the research.

Exclusion

This study used the following exclusion criteria: Use of obesogenic and/or anticoagulant medications; Severe psychiatric disorders; Gastrogastric fistula and radiologically dilated gastric reservoir; Pregnancy during the study period; Loss of follow-up.

Outcomes

Primary Outcome

Evaluate the effectiveness and safety of using APC, associating changes in behavioral measures.

Secondary Outcome

Assess demographic and clinical data. Patients underwent stages, containing the data below.

Interventions

Technically, the application was performed on the gastric face of the gastrojejunal anastomosis, circumferentially, leading to complete ablation of the mucosa for an extension of 10 to 20 mm above the anastomosis. This application was repeated every 45 days, and may or may not be carried out, depending on the diameter achieved in the previous application. The objective diameter was to reach a diameter between 10-

12 mm. After each application, a cold liquid diet was indicated for 15 days to aid the healing process and prevent complications in the area where the argon plasma was applied. To compare the two groups, the control group was also subjected to this diet at the same intervals paired with the argon group. The device used was an Olympus 160 or 180 gastroscope (OLYMPUS, Tokyo, Japan) and the argon used was the WEN ARGON 2 device (Ribeirão Preto, SP, Brazil).

Preparing For Exams

All exams were performed with a minimum of 8 hours of fasting, with the patient in the left lateral decubitus position, with instillation of 10% xylocaine spray, followed by intravenous propofol under the supervision of an assistant physician (anesthesiologist) with adequate cardiopulmonary monitoring throughout the exam using an Olympus CV-180 endoscope (Olympus, Tokyo, Japan). Analysis and measurement of the anastomosis was performed with a graduated ruler every 5mm [35]. The images obtained were transferred to an Olympus Evis Exera II processor coupled to the computing unit, containing the ZScan 7 program (Goiânia, GO/Brazil). Then, argon plasma was applied (Argon 2-WEM, Ribeirão Preto, SP), with a disposable endoscopic catheter, and applied to the entire circumference of the gastrojejunal anastomosis up to 1-2 cm, using a power of 80 W and a flow of 1 L/min.

Recovery After The Exam

After the procedure and anesthetic recovery, all patients were released in the presence of a companion. Proton pump inhibitor 40mg per day was prescribed for up to 90 days after the last session and sucralfate 2g every 12h for 10 days. All patients received guidance and maintained contact with the doctor in the event of adverse events. All patients were on a liquid diet for 20 days after each return visit with the team.

Ethical Aspects

Free and informed consent was obtained by the main researcher, based on the Declaration of Helsinki of the World Medical Association of 1964, also following the guidelines of Resolution 466/2012 of the National Health Council - Ministry of Health (Brazil, 2012).

Verbal and Pedagogical Clarification

It consisted of a verbal explanation to the patient carried out by the researcher, covering the following topics:

- Objective of the research;
- Justification and procedures that will be used in the research;
- Possible risks and expected benefits;

- Method of monitoring subjects and providing assistance;
- Guarantee of confidentiality regarding the data involved in the research;
- Freedom to refuse to participate, without any form of prejudice;

Signing The Free And Informed Consent Form

The free and informed consent form was presented by the researcher to the research subject and/or their guardian, after explaining the procedures to be carried out, being completed and signed in two copies whenever there was consent from both, with one copy being provided for the research subject and another filed by the researcher.

Statistical Data Analysis

For data analysis, a database was built in the Microsoft Excel spreadsheet, which was exported to the Minitab 18 statistical program and also to Origin 9. A common descriptive statistical analysis and the Anderson-Darling normality test were performed for all data. "Weight" variables from the first to the seventh visit. The non-parametric Kruskal-Wallis test was applied, adopting a level < 0.05 as significant.

Results

From July 2020 to July 2021, 32 patients were evaluated, 18 females (5.76%) and 14 males (4.48%), with an average age of 48 years, ranging from 24 to 62. years, the average weight regained was 15.4 kg, varying from 6 to 45 kg, after behavioral measures were instituted, such as physical exercise 3 times a week, a food plan calculated individually for each patient by the nutritionist, with a caloric deficit of 800kg/cal-day, argon plasma interventions were carried out, the number of sessions from 1 to 3, depending on the response of each patient. It was observed that 30 patients (9.7) showed weight loss of more than 50% of the excess weight regained, ranging from 4 to 25 kg.

Description of continuous predictors and response according to each analysis

Kruskal-Wallis Analysis

- **Continuous predictors and responses in the argon group were:**
 - *continuous predictor: Argon_weight from 1 to 7 visits.
 - *response predictor: Post-surgery weight (kg) - C
- **Continuous predictors and responses in the control group were:**
 - *continuous predictor: Weight_control from 1 to 7 visits.
 - *response predictor: Post-surgery weight (kg) - C

- Continuous predictors and responses between the argon and control groups were:

- *continuous predictor: Argon_weight from 1 to 7 visits.
- *response predictor: Weight_control from 1 to 7 visits.

Linear Regression Analysis

- Continuous predictors and responses in the argon group were:

- *continuous predictor: Age_argon
- *response predictor: Argon_weight from 1 to 7 visits.

- Continuous predictors and responses in the control group were:

- *continuous predictor: Age_control
- *response predictor: Weight_control from 1 to 7 visits.

- Continuous predictors and responses in the argon group were:

- *continuous predictor: Argon_Race
- *response predictor: Argon_weight from 1 to 7 visits.

- Continuous predictors and responses in the control group were:

- *continuous predictor: Breed_control
- *response predictor: Weight_control from 1 to 7 visits.

Discussion

In the present study, endoscopic APC was used to reduce the diameter of the wide gastrojejunostomy and, therefore, promote the return of weight loss after RYGB. The results obtained were similar to the literature. The positive results found regarding the loss of excess weight in 30 patients are in agreement with the literature.

Bariatric surgery to date is the most effective option for treating morbid obesity, promoting weight loss, and controlling comorbidities when compared to non-surgical methods [3]. Medical therapy for severe obesity has limited success in the short term and almost no success in the long term, according to the National Institutes of Health (NIH). In this context, it is estimated that the probability of successful weight loss with diet alone is less than 3.0% [4].

Mortality associated with bariatric surgery is approximately 0.1% to 0.5%, while morbidity from these conventional or laparoscopic procedures has a rate of 3.0% to 20.0% [5,6], mainly cardiopulmonary events and anastomotic leaks. Despite being the best obesity treatment, only about 1 in 400 morbidly obese people undergo this type of surgery in the USA [7].

Despite the advantages of bariatric surgery, symptoms presented in the first 3 months after RYGB surgery are commonly associated with abnormal

endoscopic findings [8]. Thus, postoperative complications are a challenge for those who are evaluating, and seeking to correlate endoscopic findings with gastrointestinal symptoms [9]. Therefore, upper digestive endoscopy (UDE) is an option for the diagnosis the treatment of bariatric complications, with a safe and less invasive approach, in addition to being lower cost than surgical treatment [10].

In this context, upper digestive endoscopy is part of the preoperative evaluation of bariatric procedures [11]. It is routine to investigate infection of the gastric mucosa by *Helicobacter pylori* and the histological changes it can cause, such as chronic gastritis, atrophy, and intestinal metaplasia and, therefore, routine preoperative endoscopy can reduce the incidence of anastomotic mouth ulcers [12]. In addition, small parietal and sub epithelial lesions can be identified, such as stromal tumors and leiomyoma, which are investigated through endoscopic ultrasound, and depending on the findings, biopsies or even complete removal of the lesion via endoscopic [13,14].

Added to this, endoluminal surgery performed using flexible endoscopes exclusively, offers the potential for less invasive approaches that may be safer and more cost-effective compared to current laparoscopic approaches, thus broadening surgical indications for those patients with mild obesity (BMI: 30-35) [15].

The anatomy of the digestive tract altered by surgery can be a challenge for endoscopists who will be called upon to evaluate, diagnose, and treat a variety of complications and symptoms of RYGB [16]. However, these assessments will not be routinely carried out in centers of excellence with professionals trained to recognize and resolve complications arising from bariatric surgery [16]. Worldwide, the vast majority of professionals who perform UDE have adequate training in bariatric endoscopy, however, they must become accustomed to recognizing bariatric surgical procedures and their anatomical changes, widened gastrojejunal anastomosis, marginal ulcers, anastomotic strictures, gastric fistulas, erosion of the ring, bezoar caused by non-absorbable sutures in the lumen of the digestive tract, among others [17].

The American Society for Metabolic and Bariatric Surgery (ASMBS) estimates that the number of bariatric surgical procedures performed increased from 158,000 in 2011 to 190,000 in 2015 [11]. At the same time, the incidence of postoperative complications specific to bariatric patients also tends to increase. Endoscopic evaluation of bariatric patients postoperatively and endoscopic interventions are increasingly frequent [11].

Interventional endoscopic options are gaining

importance as a less invasive approach and as a treatment for post-surgical adverse events [12]. Despite improvements in the performance of bariatric surgical procedures, complications are not uncommon. Furthermore, conditions unrelated to altered anatomy often require a different management strategy [13-17].

A basic understanding of surgical anatomy, potential complications, and endoscopic tools and techniques for optimal management is essential for the endoscopist wishing to practice in this field. [18-21]. After bariatric surgery, approximately 70.0% of symptomatic patients present at endoscopy with abnormal findings in relation to RYGB [22]. Therefore, endoscopists need to work in close coordination with bariatric surgeons at all phases of care in order to maximize the yield and safety of endoscopy in this population [23-26].

The most feared postoperative complications, responsible for mortality rates between 0.1 and 0.5%, include sepsis of abdominal origin caused by dehiscence of sutures or anastomoses, pulmonary thromboembolism and anastomotic leaks [27]. The most common late complication is the recurrence of obesity, in which the main associated factors are dietary errors and poor lifestyle habits associated with a sedentary lifestyle, being the supporting factors of anastomosis dilation [28,29]. As a consequence of the recurrence of obesity, abnormal anatomical findings are found in up to 71.2% of patients, 58.9% of which are associated with the presence of dilation of the gastrojejunal anastomosis [30].

The indications for endoscopies are due to the symptoms presented, such as epigastric pain, nausea, vomiting, dysphagia and weight regain. The etiology of these symptoms is multifactorial, including non-compliance with dietary restriction guidelines [30]. Furthermore, UDE must be performed in order to exclude abnormal findings of the operated digestive tract, mainly dilated anastomosis or failure in the surgical technique [31]. Thus, UDE has played a fundamental role in tracking possible complications. The current literature presents numerous studies describing endoscopic findings after RYGB in symptomatic patients, with results without standardization of their characteristics and clinical implications [32].

Endoscopic examination of the upper digestive tract is part of the preoperative evaluation of patients undergoing bariatric procedures in most countries [32,33]. In general, it is desirable to treat peptic ulcer disease before definitive intervention, especially in procedures that exclude part of the stomach or duodenum from intestinal transit. Endoscopic detection

of neoplastic lesions is also a preoperative diagnostic condition that can change operative management [34].

It is estimated that changes that could change management may occur in up to 5-10% of patients. As an example, the finding of atrophic gastritis restricted to the proximal stomach recalls the possibility of pernicious anemia, a condition where the highest incidence of gastric adenocarcinoma is recognized [35].

In addition, endoscopists who offer services to bariatric surgery groups must familiarize themselves with the techniques performed, preparing themselves with equipment and accessories appropriate to different situations [36]. It is necessary to review previously performed exams, especially radiological ones, since endoscopy may require correlation with other findings for a better diagnostic conclusion [37]. UDE is also performed in some centers on asymptomatic patients following a regular postoperative evaluation protocol [33].

The theory behind this procedure is similar to that of revision gastrojejunostomy in patients with weight regain, as well as endoscopic suturing, which focuses on the anatomical aspect of the causes of weight regain [3]. Furthermore, endoscopic approaches are less invasive than laparoscopic approaches, minimizing preoperative complications [4]. Endoscopic approaches exist to target weight regain after RYGB [4-6]. APC is a non-contact electrocoagulation method and, when used in patients with RYGB, has demonstrated the ability to reduce the diameter of the anastomosis [11-13,15].

In 2018, a total retrospective analysis was obtained from 558 patient records in eight bariatric centers in the USA and Brazil, who underwent APC between July 31, 2009, and March 29, 2017 [11]. This therapy was carried out in patients who regained weight after RYGB. The average weight was 94.5 ± 18.6 kg and the average BMI was 34.0 kg/m^2 in APC. When data were available, the mean lowest weight was 67.0 ± 23.0 kg and the mean lowest BMI was 24.1 kg/m^2 after RYGB. Mean weight loss was 6.5, 7.7, and 8.3 kg at 6, 12, and 24 months, respectively, and changes in weight over time were statistically significant ($p < 0.0001$).

Weight regain after RYGB bariatric surgery can occur due to treatment failure and this implies an increase in the gastrojejunal anastomotic diameter, contributing to a failure in restriction and the patient starting to ingest a greater quantity of food, thus compromising the desired weight loss. However, the most recent scientific studies do not confirm this thesis [11].

It is admitted that the subject is controversial and there are two aspects. One believes in restrictions based on the size of the gastroplasty and the diameter of the

anastomosis and the other believes that these are not important factors in weight loss. In this sense, the argon method for reducing the anastomotic diameter does not aim to influence post-surgical weight loss but rather the weight regained after the initial loss when it is significant [34,37].

As literary support, after analyzing 5 published works using APC to reduce gastrojejunal anastomosis [11-13,15,16], the series ranges for each procedure were respectively 10 to 49. Most of the works followed studies longitudinal perspective. An average reduction in weight gain (kg) of 24.5% was also observed after using APC. The success rate was 82.5%. In a subsequent non-parametric correlation analysis between the results of weight loss and weight regain, the result was $p = 0.580$, considering $p > 0.05$ [11-13,15,16]. The recurrence of obesity is associated with decreased quality of life and recurrence of comorbidities in these patients [17]. Thus, endoscopic techniques have been developed in an attempt to effectively reduce the anastomotic diameter and the consequent weight loss.

Abnormal anatomical findings are found in 71.2% of patients, 58.9% with gastrojejunostomosis dilation, 28.8% with pouch dilation, and 12.3% with changes in both [16]. Thus, several methods such as endoluminal reduction of the gastrojejunal anastomosis such as suturing, surgery, and APC in the gastrojejunal anastomosis have been proposed to reduce weight regain in patients undergoing RYGB [16]. In this scenario, surgical treatments are the most commonly performed, however, they are associated with a higher incidence of complications morbidity, and mortality when compared to the other treatments proposed above [9,23-25].

Highlighted, Baretta et al. (2015) [13] studied 30 patients undergoing treatment with argon plasma, after gastric bypass, and observed after 3 endoscopic sessions (on average) of APC with an intensity of 70W at 2.0 L/min, separated by 8 weeks. In his results, he described an average weight loss of 15.0 kg.

Long-term results remain undefined. There is no scientific knowledge regarding the possibility of "new" weight regain and "new" dilation of the anastomosis. APC in the gastrojejunal anastomosis can be performed serially and as many times as necessary, as already described. Endoscopic controls must be carried out frequently, seeking to prevent this probable dilation and, consequently, weight regain [13].

Based on the statistical significance of the incidence and increase in the number of bariatric surgeries such as RYGB and complications that can cause the widening of the gastrojejunal anastomosis, it is imperative to carry out randomized, controlled, prospective, and/or

retrospective studies and studies using plasma argon in an attempt to reduce the gastrojejunal anastomotic diameter, all with larger series and follow-up of at least one year.

Conclusion

It is concluded that the application of plasma associated with a dietary plan with calorie deficit and physical activity is a safe and effective method for the treatment of weight regain after bariatric surgery (gastric bypass).

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Not applicable.

Ethical Approval

Free and informed consent was obtained by the main researcher, based on the Declaration of Helsinki of the World Medical Association of 1964, also following the guidelines of Resolution 466/2012 of the National Health Council - Ministry of Health (Brazil, 2012).

Informed consent

It was applicable.

Funding

Not applicable.

Data sharing statement

No additional data are available.

Conflict of interest

The authors declare no conflict of interest.

Similarity check

It was applied by Ithenticate@.

Peer review process

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