

# OUTLET ROUX-Y-GASTRIC BYPASS POUCH REDUCTION USING ARGON PLASMA COAGULATION TO TREAT WEIGHT REGAIN: A Randomized Controlled Trial with SHAM Group

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## Abstract

**Aims:** This study to evaluate the efficacy and complications of Argon Plasma Coagulation (APC) therapy to treat post-RYGB weight regain compared to a sham control group. **Methods:** 41 Patients with minimum regain of 10 kg and minimal postoperative time of 36 months was randomized into two groups. **Results:** In the APC group (n=21), the mean initial weight 100.4 kg, and mean regained weight of 24.94 kg. In the Sham group (n=20), the mean initial weight of 103.65 kg, and mean regained weight of 25.18 kg. Only happened anastomosis stenosis after the first APC session. The comparative results between the APC versus the Sham were percentage recovered weight loss (63.95 x-2.65), weight loss in kg (15.02 x-0.57), percentage total weight loss (14.46 x-0.62), % excess weight loss (54.32 x-2.34), and BMI reduction (5.38 x-0.21), with a p<0.0001 for all the comparisons. There was a significant reduction in the APC group of HbA1c (5.66% to 4.96%) and triglycerides (153.20mg/dL to 132.20mg/dL). **Conclusion:** This study proves that APC outlet pouch reduction is much superior compared to sham in promoting weight loss for patients that presented weight regain after de RYGB.

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## INTRODUCTION

Obesity represents a serious emerging disease with consequent negative public health outcomes.<sup>[1]</sup> There are currently more than 2.0 billion overweight and obese people in the world, and Brazil is in fifth place in the world ranking, with an estimate of more than 18.0 million people.<sup>[2]</sup>

In this scenario, bariatric surgery is more effective in weight loss and control of comorbidities in relation to dietary procedures and drugs.<sup>[3]</sup> Despite the good results and control of the disease in the medium and long term, the Roux-en-Y Gastric Bypass (RYGB) features about 20% of the patients submitted to this surgery do not lose the desired weight in the first year or regain weight after 18 to 24 months.<sup>[3]</sup> The weight regains process can involve several variables, highlighting the size of the gastric pouch (GP), size of the gastrojejunal anastomosis (GJA), BMI prior to surgery, eating habits, psychiatric disorders, problems with self-esteem and socioeconomic conditions.<sup>[4,5]</sup>

According to the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) in its report published in 2015, about 86 thousand bariatric surgeries were performed in Brazil, 70.0% of which was RYGB -type laparoscopic gastroplasty.<sup>[6]</sup> In this sense, several studies regarding RYGB have shown significant results, including increasing survival, reducing cardiovascular mortality, and controlling metabolic diseases.<sup>[7-9]</sup>

In this context, the most common late complication is the recurrence of obesity, in which the main associated factors are food error and bad lifestyle habits associated with a sedentary lifestyle, which can cause an increased gastric reservoir and dilation of the diameter of the GJA and among others.<sup>[10,11]</sup> Thus, GJA above 15.0 mm has been associated with obesity recurrence, especially when associated with complaints of decreased satiety or early hunger due to rapid gastric emptying.<sup>[11-13]</sup>

In this sense, the narrowing of the dilated GJA through argon plasma coagulation (APC) in the recurrence of obesity, in patients undergoing RYGB, presents itself as an effective and safe alternative, according to important published works.<sup>[14-18]</sup> As a consequence of weight gain after RYGB, abnormal anatomical findings are found in 71.2% of patients, with 58.9% presenting with GJA dilation.<sup>[18]</sup> Therefore, APC is technically feasible and reproducible, relatively inexpensive, and with numerous advantages over the usual electrocoagulation.<sup>[14-17]</sup> The complications have a low incidence 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 the colon.<sup>[18]</sup>

Thus, decreasing the diameter of a dilated anastomosis can lead to a 23% reduction in excess weight on average, together with the monitoring of a multidisciplinary team.<sup>[18]</sup> In this sense, the recurrence of obesity is associated with decreased quality of life and recurrence of comorbidities.<sup>[19,20]</sup>

Thus, the present study assessed the efficacy and complications of APC therapy in treating post- RYGB weight recovery compared to a sham control group.

## MATERIALS AND METHODS

### Trial Design

A prospective randomized study that included 41 patients out of 132 submitted to eligibility analysis. All selected patients completed the follow-up, with no exclusion during the study period. The clinical research rules-CONSORT (Available at <http://www.consort-statement.org/>) were used.

### Sample Size

The sample size has estimated at a total of 41 participants for further randomization into two groups. Specifically, a standard deviation of 18.5 has hypothesized for the change in weight after the APC procedure based on previous studies as well as a 95% CI confidence interval and a 5% dropout rate of patients.<sup>[18, 21]</sup>

## **Ethical Considerations**

The study has reviewed and approved by the Clinical Institutional Review Board and has conducted in accordance with the ethical standards laid out in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. Informed consent has obtained from all individual participants included in the study.

## **Participants**

Inclusion criteria were patients who underwent RYGB surgery, with a minimum recovery of 10 kg and a minimum postoperative time of 36 months, loss of feeling full, bag size between 4.0 and 7.0 cm, diameter <5.0 cm and gastrojejunal anastomosis > 15.0 mm. Exclusion criteria were another type of surgery or normal stomach, lack of consent, eating sweets, taking anticoagulant drugs, alcoholism, depression, and compulsive disorders.

Three APC sessions were held, with an 8-week interval between them. Patients' weight has assessed at the beginning of treatment and 2, 4, and 6 months later. Both groups received standard nutritional guidance immediately after each APC session or upper digestive endoscopy. Both groups received a liquid diet.

## **Randomization**

The random sequence has generated using the Minitab 18<sup>®</sup> statistical program (version 18, Minitab, LLC, State College, Pennsylvania, USA) by a researcher not involved in the allocation of participants. Block randomization has used without stratification and has implemented by an administrative assistant using sequential numbering, sealed envelopes. Individuals in the argon arm underwent three APC sessions, with an 8-week interval between them. The endoscopic evaluation has performed every 2 months until completing 6 months. In the control group, the arm underwent an initial diagnostic endoscopy followed by clinical consultation every 2 months until the sixth month. All patients were blinded to the intervention they received. The multidisciplinary team (nutritionist, psychologist, and physical educator) and data analysts were also blinded to the allocation of participants.

## **Groups**

### **Group I (APC)**

Patients who underwent APC therapy performed around the gastrojejunal anastomosis in a 2.0 cm halo. This group underwent multidisciplinary monitoring, through consultations with a bariatric surgeon, psychologist, physical educator, and nutritionist. The returns were made every 2 months until completing 6 months.

### **Group II (SHAM)**

Patients who underwent only upper digestive endoscopy with sedation. This group also did the multidisciplinary follow-up, through consultations with a bariatric surgeon, psychologist, physical educator, and nutritionist. The returns were made every 2 months until completing 6 months.

## **Setting**

All endoscopic procedures, APC sessions, and data collection took place at the EndogastroRio Clinic, Rio de Janeiro-RJ, Brazil and Angioskope Clinic, São José dos Campos-SP. The recruitment of participants started in May 2019, with the end of the monitoring taking place in December 2019.

## **OUTCOMES**

### **Primary outcomes**

Weight loss recurred at 2, 4, and 6 months more significantly compared to the control group. The following parameters will be evaluated: weight loss in Kg, reduction of the body mass index (BMI), percentage loss of recovered weight (% RWL), percent Total body weight loss (% TWL), and percent EWL (% EWL).

### **Secondary outcomes**

Incidence of adverse events such as bleeding and strictures, improvement of laboratory metabolic parameters (Glycosylated hemoglobin (HbA1c), total cholesterol, LDL, HDL triglycerides) and improvement in the eating behavior.

## INTERVENTIONS

### APC Application and Exams

Argon has approved by the National Health Surveillance Agency (ANVISA) in Brazil and is low-cost. All examinations were performed with a minimum fasting of 8 hours, and the patient was in the left lateral position, with instillation of 10.0% xylocaine spray, followed by intravenous propofol under the supervision of an assistant physician (anesthesiologist) with adequate cardiopulmonary monitoring throughout the period examination using a Pentax EG-2970K endoscope (Pentax, Tokyo, Japan). To measure the gastrojejunal anastomosis, a graduated rule has used every 5.0 mm developed from a catheter for endovascular surgery laser. The images obtained were transferred to a Pentax EPK-1000 processor coupled to a computational unit, containing the ZScan 7 program (Goiânia, GO/Brazil). Then, an argon plasma (Argon 2-WEM, Ribeirão Preto, SP) has applied, with a disposable endoscopic catheter and applied over the entire circumference of the gastrojejunal anastomosis, forming a 2 cm thick halo, using a power of 90 W and flow of 2.5 L/min.

After procedure and anesthetic recovery, all patients were released in the presence of a companion. Proton pump inhibitor Dexlansoprazole 60mg per day for up to 90 days after the last session and sucralfate 2g of 12/12h for 10 days were prescribed. All patients received guidance and maintained contact with a physician in the face of adverse events. All patients were on a liquid diet for 10 days after each team return.

### Anthropometric and Laboratory Data

The data for each registered patient was weight loss (kg), measured using a calibrated digital scale, body mass index (BMI), and height and weight measurements were recorded twice at each visit to increase accuracy and reliability); bag size, measured using the graduation endoscope in relation to length (all bags that allowed the device to be retrovisioned were considered wide).

All outcome variables, except blood tests (total plasma cholesterol, high density lipoprotein cholesterol (HDL) and HbA1c) were determined at randomization and in the second, fourth and sixth months after randomization.

### Statistical analysis

The statistical analysis of the data has performed by an external collaborator (Dr. Idiberto José Zotarelli Filho) and interpreted by the principal investigator (Dr. Ricardo Fittipaldi-Fernandez). For data analysis, a database has built on the Microsoft Excel spreadsheet which has exported to the Minitab 18<sup>®</sup> statistical program (version 18, Minitab, LLC, State College, Pennsylvania, USA) (Minitab<sup>®</sup>)<sup>[22]</sup> and OriginPro<sup>®</sup> 9 (DPR Group, Inc., Northampton, Massachusetts, USA).<sup>[23]</sup> A common descriptive statistical analysis has performed, obtaining the values of total “n”, mean and standard deviation, confidence interval (CI), and percentage for all the variables. Normality test has performed for all variables. One-Way test (ANOVA) has applied, adopting the  $\alpha$ -level less than 0.05 with a statistical difference for 95% CI. The R-sq ( $R^2$ ) value has also analyzed.

## RESULTS

A total of 41 patients were randomized into 2 groups, the APC and Sham group, with each group having 21 and 20 patients respectively. The flowchart of selection and eligibility, as well as the randomization process of the patients selected in their respective APC and Sham groups, after applying the inclusion and exclusion criteria, is shown in Figure 1. In the APC group (4 men), age mean was 46.65 years, mean initial weight of 100.4 (range of 72-162) kg, mean initial BMI of 36.12 kg/m<sup>2</sup> and mean weight recovered of 24.94 (range of 15 to 82). In the Sham group (7 men), the mean age was 49.53 years, the mean initial weight was 103.65 (range: 88.70-123.70) kg, the mean baseline BMI was 36.67 kg/m<sup>2</sup> and the average recovered weight 25.18 (range: 19.50-32.30) Kg.

Only one complication occurred, stenosis after the first APC session, requiring no treatment since the patient tolerated a liquid diet, and remained in the study. The technique was 100% successful.

The overall results of both groups regarding relapsed weight loss, weight loss in kg, total body weight loss (% TBWL), excessive weight loss (% EWL), reduced BMI, reduced serum triglyceride level and glycosylated hemoglobin are shown in Table 1. Figure 2 shows the weight reduction of the two groups over time. The APC group had an average initial weight of  $100.04 \pm 22.27$  and, after 6 months, the average weight was  $85.02 \pm 16.05$  kg, with  $15.02 \pm 9.63$  kg of weight reduction, thus, there was a statistically significant difference with  $p < 0.0001$  and  $R^2 = 45.34\%$  (CI 95%). The sham group did not present statistical difference regarding weight loss, with  $p > 0.0001$  and  $R^2 = 99.85\%$  (CI 95%), with an average of initial and final weight respectively equal to  $103.65 \pm 10.53$  kg and  $104.22 \pm 10.06$  kg, with a weight gain of  $0.57 \pm 2.23$  kg. There was also a significant difference between the APC and Sham groups in relation to the final weight results, with  $p < 0.0001$ . BMI values in each group followed the same statistical results as weight values, as shown in Table 1 and Figure 3.

According to Figure 4, the values of %RWL, percent Total body weight loss (%TWL), and percent EWL (%EWL) in relation to the APC group were  $63.95 \pm 32.08\%$ ,  $14.46 \pm 6.16\%$ , and  $54.32 \pm 28.90\%$ , respectively. Regarding the Sham group, they were respectively  $-2.65 \pm 10.24$ ,  $-0.62 \pm 2.43$ , and  $-2.34 \pm 9.03$ . The statistical comparison between groups was significant, with  $p < 0.0001$ .

The GJA diameter values in relation to the APC group were  $34.25 \pm 6.13$  mm (initial),  $12.65 \pm 2.11$  mm (final), with a reduction of  $21.60 \pm 3.19$  mm, with  $p < 0.0001$  and  $R^2 = 35.43\%$  (CI 95%). The sham group did not present statistical difference, with  $p > 0.0001$  and  $R^2 = 99.99\%$  (CI 95%), with the same value of the initial and final anastomotic diameter equal to  $35.16 \pm 4.52$  mm (Figure 5).

Several biochemical parameters were also analyzed. The mean values for total cholesterol, HDL and LDL before and after the SHAM group were  $186.21 \pm 25.36$  mg/dL and  $185.84 \pm 24.27$  mg/dL,  $48.89 \pm 11.26$  mg/dL and  $49.11 \pm 10.16$  mg/dL,  $122.74 \pm 25.36$  mg/dL and  $121.32 \pm 27.36$  mg/dL, respectively, with  $p > 0.0001$ . In the APC group, these values were  $187.25 \pm 23.36$  mg/dL and  $186.50 \pm 22.23$  mg/dL,  $48.40 \pm 8.26$  mg/dL and  $48.85 \pm 8.18$  mg/dL,  $122.5 \pm 24.34$  mg/dL and  $121.0 \pm 25.14$  mg/dL, respectively, with  $p > 0.0001$ . The detainees in the reduction of the average values were in relation to the APC group in relation to HbA1c, with an initial average of  $5.66 \pm 0.61\%$  versus the final average of  $4.96 \pm 0.39\%$  ( $p < 0.0001$ ), and triglycerides with an initial mean of  $153.20 \pm 25.13$  mg/dL versus the final average of  $132.20 \pm 31.46$  mg/dL ( $p < 0.0001$ ) (Figure 6).

There was a significant difference between the groups regarding the anastomotic diameter, with  $p < 0.0001$ . Figure 7 represents the GJA diameter images at 2, 4, and 6 months after the application of the APC.

## DISCUSSION

The GJA review by APC is known to be a relatively safe and effective strategy to manage weight recovery after RYGB. Bleeding at the anastomotic site is an uncommon complication associated with this therapy. Another possible complication is the stenosis of the anastomosis. Endoscopic treatment is the first-line therapy for both situations<sup>[13]</sup>.

In the present study, the endoscopic APC has used with the objective of reducing the diameter of GJA and, therefore, promoting weight loss after RYGB that was relapsed. The results obtained were similar to the literature. Figures 2 and 3 show the results of weight loss in both groups, with the average weight reduction in the APC group being  $15.02 \pm 9.63$  in relation to the Sham control group after 6 months. Thus, the present study confirms the literary findings, showing that this reduction in weight that has relapsed after RYGB is closely related to the reduction of the anastomotic diameter from  $34.25 \pm 6.13$  mm (initial) to  $12.65 \pm 2.11$  mm (final), with a reduction of  $21.60 \pm 3.19$  mm, considering that the liquid diet and nutritional counselling were applied in both groups.

Another important fact that the present study confirmed has in relation to the safety and efficacy of the APC outlet reduction procedure, given that there has only one complication due to stenosis after the first

session of the APC, not requiring treatment. In addition, the technique has 100% successful.

According to the results of the present study, authors studied 30 patients undergoing treatment with an argon plasma, after gastric bypass, and observed after 3 endoscopic sessions of APC spaced between each other by 8 weeks, with an average weight loss of 15.0 kg. In addition, a prospective controlled longitudinal study with APC showed a success rate of 90.0% for weight loss using APC and a reduction of up to 41.0% in the relapsed weight.<sup>[19]</sup> Another study retrospective with 37 participants, the use of APC had a success rate of 50.0% for weight loss using APC and a 24.0% reduction in relapsed weight.<sup>[21]</sup>

Further, a study analyzed APC with a 3 and 6-month follow-up as anastomotic reduction therapy after RYGB and showed that in 53 patients (age 49.0  $\pm$  1.3 years, BMI mean was 52.1  $\pm$  10.7 kg m<sup>-2</sup>. The postoperative period, BMI mean was 29.6  $\pm$  1.1 kg m<sup>-2</sup>. The argon plasma has performed 8.6  $\pm$  3.4 years after RYGB, with weight recovery resulting in a BMI of 35.4  $\pm$  1.1 kg m<sup>-2</sup>. The reduction in anastomosis was 16.1  $\pm$  3.7 mm to 13.5. The average number of sessions was 1.3.<sup>[24]</sup> An anastomotic diameter size over 15.0 mm in the weight regain scenario may be subject to endoscopic review.<sup>[18,32,33]</sup>

Also, authors published retrospective analysis data obtained from 558 patient records with regained weight in eight bariatric centers in the USA and Brazil, who underwent APC between July 31, 2009, and March 29, 2017. The mean weight was 94.5  $\pm$  18.6 kg and the mean BMI was 34.0 kg/m<sup>2</sup> in the APC. When data were available, the mean of the lowest weight was 67.0  $\pm$  23.0 kg and the mean of the lowest BMI was 24.1 kg/m<sup>2</sup> after RYGB. The average weight loss was 6.5, 7.7 and 8.3 kg at 6, 12, and 24 months, respectively, and the changes in weight over time were statistically significant.<sup>[11]</sup>

Besides, authors evaluated the efficacy and safety of endoscopic treatment of increased GJA with APC. A randomized controlled study was performed comparing APC to exclusive multidisciplinary management after regaining weight. Forty-two patients were divided into two groups: APC (n=22) and control (n=20). After 14 months of follow-up with a crossover in 6 months, significant improvement in satiety and greater weight loss has found in the APC group and after crossing. APC has associated with significant weight loss (9.73 vs. + 1.38), reduction in anastomosis diameter, early satiety (0.77 vs. 0.59),  $p < 0.001$ , and increased quality of life. Considering the average total weight loss during the entire follow-up, weight loss was similar in both groups (13.02 kg in the APC and 11.52 kg in the control).<sup>[12]</sup>

Also, another study published in 2020<sup>[14]</sup>, reported ablation with argon plasma coagulation (APC) plus full-thickness endoscopic suture (FTS-APC) and ablation alone for the treatment of weight recovery. A randomized, single-pilot study with forty patients, comparing the efficacy and safety of APC alone versus FTS-APC for transoral outlet reduction. Patients weighing at least 20% recover from the nadir and GJA [?] 15 mm were considered eligible. The primary endpoint was the percentage of total weight loss (% TWL) in 12 months. Secondary outcomes were the incidence of adverse events, improvement in laboratory metabolic parameters and improvement in the quality of life, and eating behavior. At 12 months, the mean %TWL was 8.3%  $\pm$  5.5% in the APC group alone versus 7.5%  $\pm$  7.7% in the STF-APC group. The percentage of solid pre-revision gastric retention in 1 hour was positively correlated with the probability of reaching [?]10% TWL in 12 months. Both groups experienced significant reductions in levels of low-density lipoprotein and triglycerides at 12 months.

A recent retrospective study of two hundred and seventeen patients compared the effectiveness of different APC configurations in the treatment of weight recovery. Patients who received low-dose (45-55 W) and high-dose (70-80 W) APC were compared. Of the selected patients, 116 (53.5%) patients underwent low-dose APC sessions (2.4 sessions/patient) and 101 (46.5%) patients underwent 144 APC sessions. in high doses (1.4  $\pm$  0.7 sessions / patient). Follow-up rates were 82.9% and 75.3% at 6 and 12 months. At 6 months, the low and high dose groups showed 7.3% and 8.1% TWL, respectively. At 12 months, the low and high dose groups experienced 5.1% and 9.7% TWL, respectively. Technical success was 100%. The overall rate of AE was 8.0%, with stenosis being 4.6%. Therefore, the higher watt APC has associated with greater weight loss.<sup>[15]</sup>

In this context, the authors Heneghan et al. (2012)<sup>[25]</sup> concluded that patients with normal post-surgical

anatomy regain less weight than patients with altered proximal surgical anatomy, especially in the increase in the diameter of the gastrojejunal anastomosis. In addition, the authors Abu et al<sup>[26]</sup> and Ramos et al. (2017)<sup>[27]</sup> evaluated the size of GJA and its influence on weight loss, where an anastomosis calibrated to 15.0 mm shows better results when compared to the anastomosis of 45.0 mm in a 2-year follow-up. Therefore, values between 10 and 15.0 mm are the desired GJA diameter.

Thus, several methods such as endoluminal reduction of GJA such as surgery<sup>[28]</sup>, suturing<sup>[29,30]</sup>, and APC in gastrojejunal anastomosis have been proposed to reduce the recovered weight in patients undergoing RYGB.<sup>[12]</sup> In this scenario, surgical treatments are the most performed, however, they are associated with a higher incidence of complications and morbidity and mortality when compared to the other treatments proposed above.<sup>[28]</sup>

Besides, transoral outlet reduction (TORe) performed using a traditional suture pattern is effective in inducing short and medium-term weight loss in patients with weight recovery after RYGB.<sup>[30]</sup> In this sense, a study analyzed the technical feasibility and safety of TORe in stock markets were determined and its impact on weight and metabolic profiles has assessed. Patients with RYGB who underwent pouch TORe were included. The GJA has ablated by coagulation with argon plasma or dissected by endoscopic submucosal dissection. A suture has used to place stitches around the GJA in a continuous ring. The suture has attached to a balloon (8-12 mm). The primary endpoint was technical feasibility. Secondary outcomes were the percentage of total body weight lost (% TWL), adverse events, impact on comorbidities, and predictors of weight loss. Thus, 252 patients with RYGB were submitted to 260 TORe. They recovered 52.6 +- 46.4% of the weight lost and weighed 107.6 +- 24.6 kg. The technical success rate was 100%. At 6 and 12 months, the % TWL was 9.6 +- 6.3 and 8.4 +- 8.2. At 12 months, blood pressure, hemoglobin A1c and ALT had improved.<sup>[31]</sup>

A systematic review and meta-analysis study evaluated the effectiveness of endoscopic therapies for recovered weight after RYGB. The primary endpoints were absolute weight loss (AWL), excess weight loss (EWL), and total body weight loss (TBWL). Thirty-two studies were included in the qualitative analysis. Twenty-six full-thickness (FT) endoscopic sutures described and AWL, EWL, and TBWL combined in 3 months were 8.5 kg, 21.6 kg and 7.3 kg, respectively. At 6 months, they were 8.6 kg, 23.7 kg and 8.0 kg, respectively. At 12 months, they were 7.63 kg, 16.9 kg and 6.6 kg, respectively. Subgroup analysis showed that all results were significantly greater in the group with suture with TF combined with APC. Two articles described APC alone with an average AWL of 15.4 +- 2.0 and 15.4 +- 9.1 kg at 3 and 6 months, respectively. When performing APC before the suture, it seems to result in greater weight loss.<sup>[32]</sup>

Since the loss of gastric restriction in the bypass can be one of the main causes of obesity recurrence. Therefore, the present study showed that the use of argon plasma in reducing the gastrojejunal anastomosis diameter promoted greater weight loss compared to the control group that underwent only to upper digestive endoscopy with sedation and liquid diet.

## **CONFLICT OF INTEREST**

The authors declare they have no conflict of interest.

## **INFORMED CONSENT**

Informed consent has obtained from all individual participants included in the study.

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#### DATA AVAILABILITY

The authors declare that data supporting the findings of this study are available within the article.

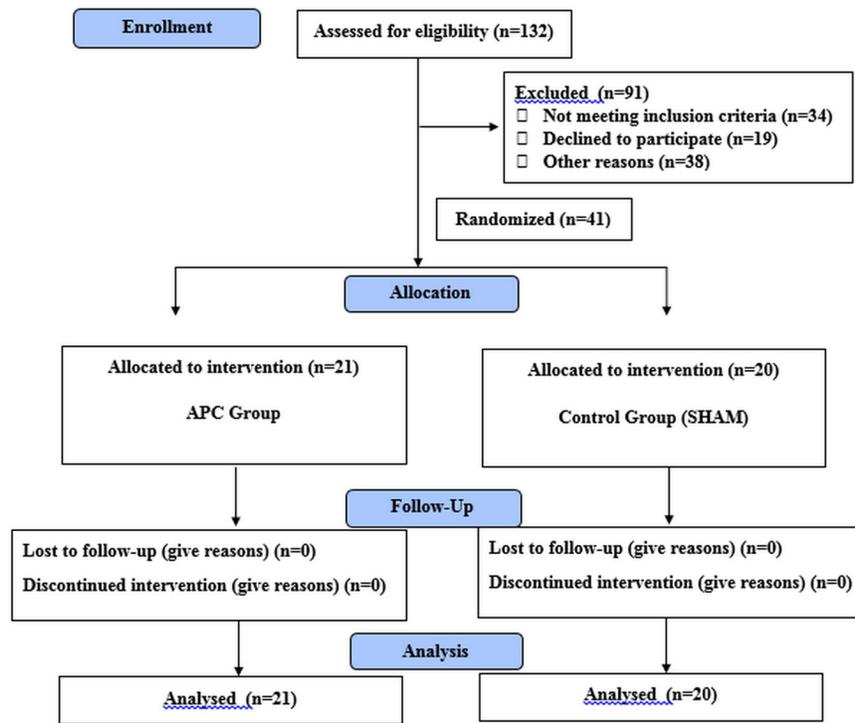
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**Figure 1.** Flow chart – Eligibility and Randomization.



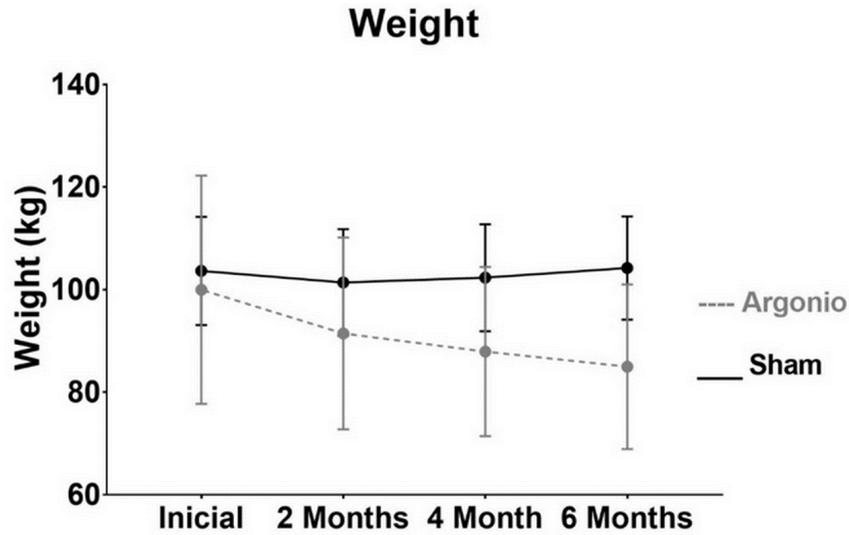
**Table 1.** General clinical data of weight (kg), BMI (kg/m<sup>2</sup>), anastomotic diameter (mm), of both APC and SHAM groups, and results of statistical comparison, with p <0.0001 as significant (CI 95%).

PARAMETER	APC GROUP	SHAM GROUP
<b>WEIGHT (kg)</b>		
Initial	100.04 ± 22.27	103.65 ± 10.53
Final	85.02 ± 16.05*	104.22 ± 10.06
Reduction	15.02 ± 9.63 <sup>+</sup>	-0.57 ± 2.23
<b>BMI (kg/m<sup>2</sup>)</b>		
Initial	36.13 ± 6.44	36.67 ± 2.23

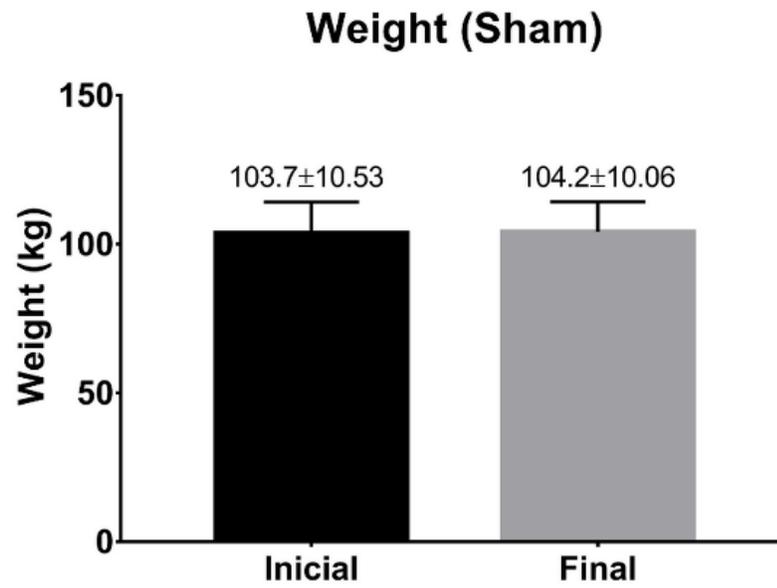
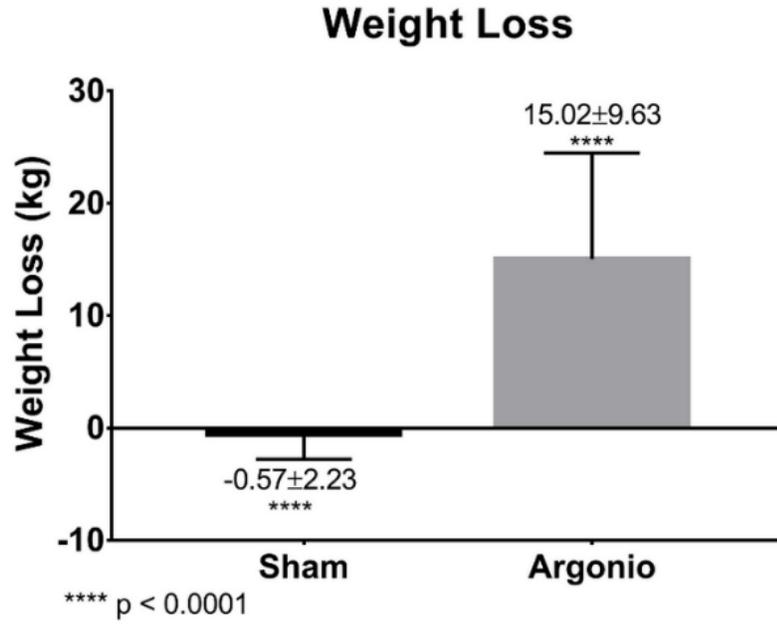
PARAMETER	APC GROUP	SHAM GROUP
Final	30.74 ± 4.64*	36.87 ± 2.09
Reduction	5.38 ± 2.21 <sup>+</sup>	-0.21 ± 0.39
<b>ANASTOMOSIS</b>		
Initial	34.25 ± 6.13	35.16 ± 4.52
Final	12.65 ± 2.11*	35.16 ± 4.52
Reduction	21.60 ± 3.19 <sup>+</sup>	0.00
%RWL <sup>+</sup>	63.95 ± 32.08	-2.65 ± 10.24
%TBWL <sup>+</sup>	14.46 ± 6.16	-0.62 ± 2.43
%EWL <sup>+</sup>	54.32 ± 28.90	-2.34 ± 9.03

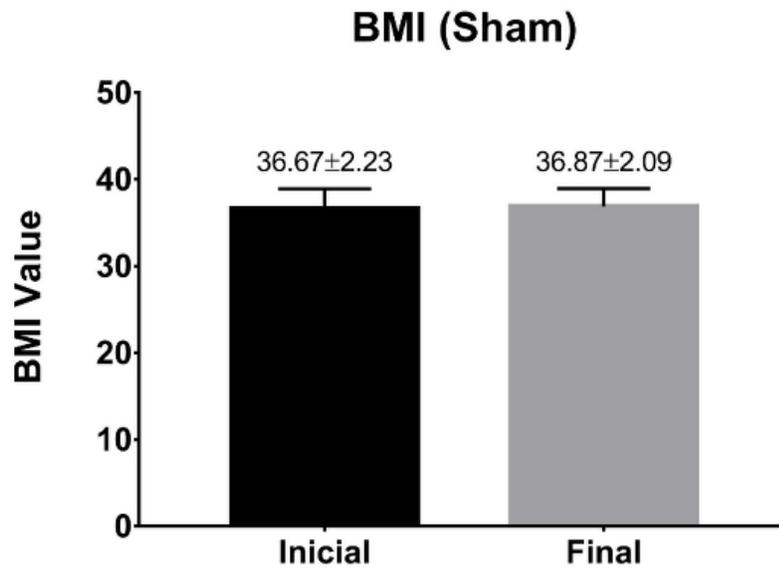
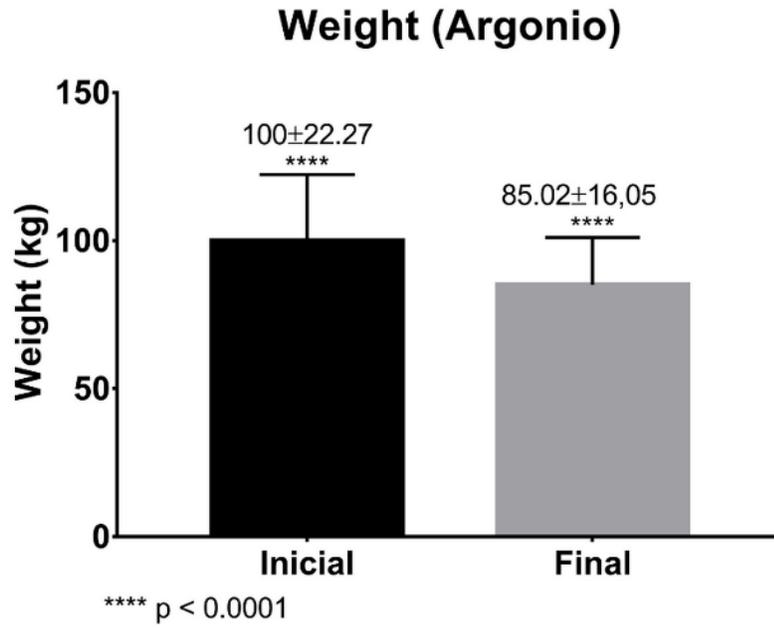
+p<0.0001 between groups; \*p<0.0001 final versus initial.

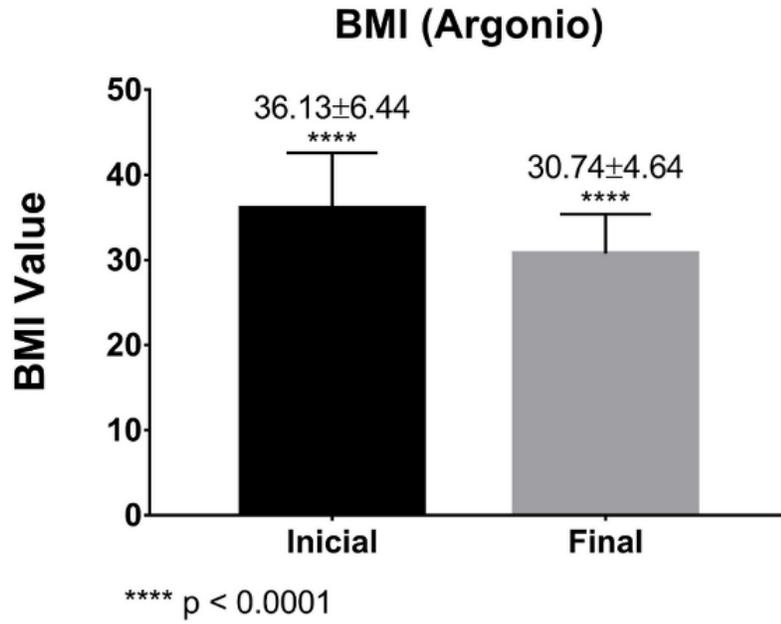
**Figure 2.** Dot-Plot model chart showing the weight reduction (kg) over six months, for the APC and SHAM groups, with 95% CI.



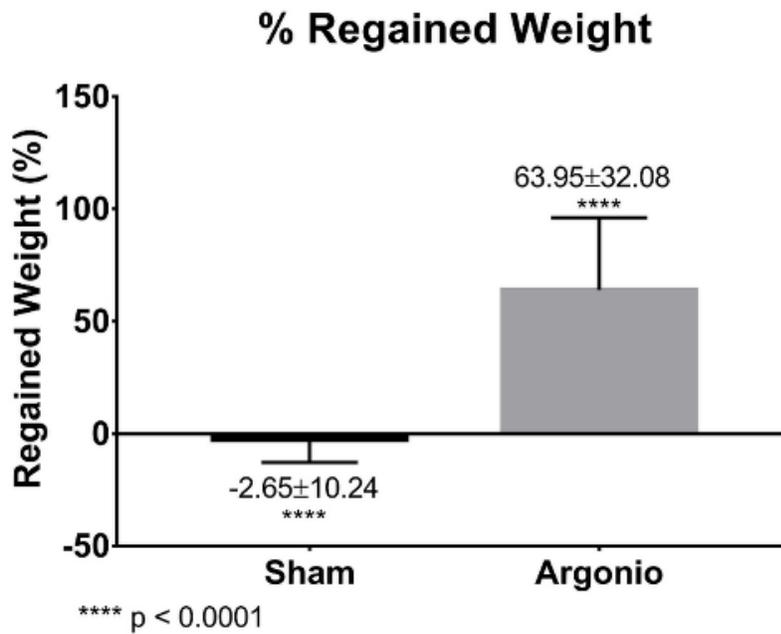
**Figure 3.** Box-Plot model graphs showing the values of weight and weight loss (kg), as well as BMI (kg/m<sup>2</sup>) in relation to the APC and SHAM groups, with p <0.0001 as significant (CI 95%).

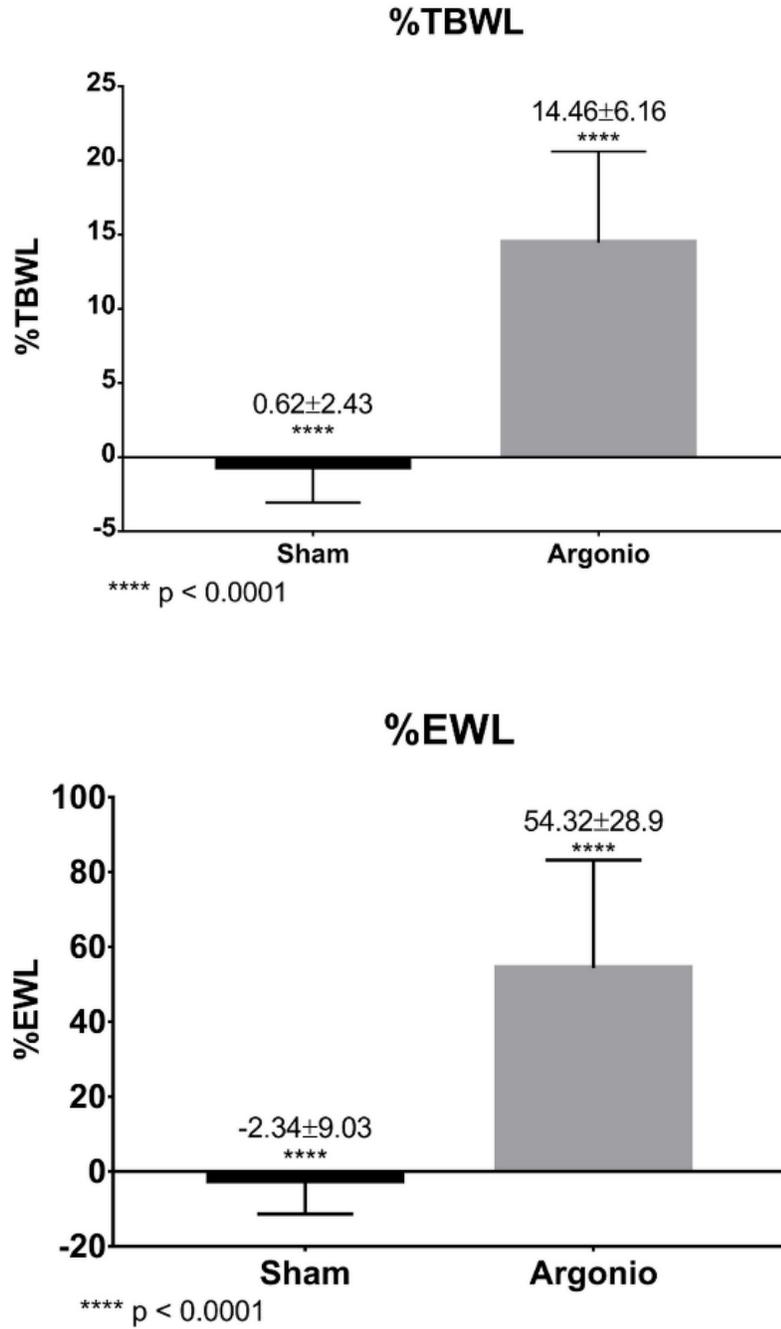




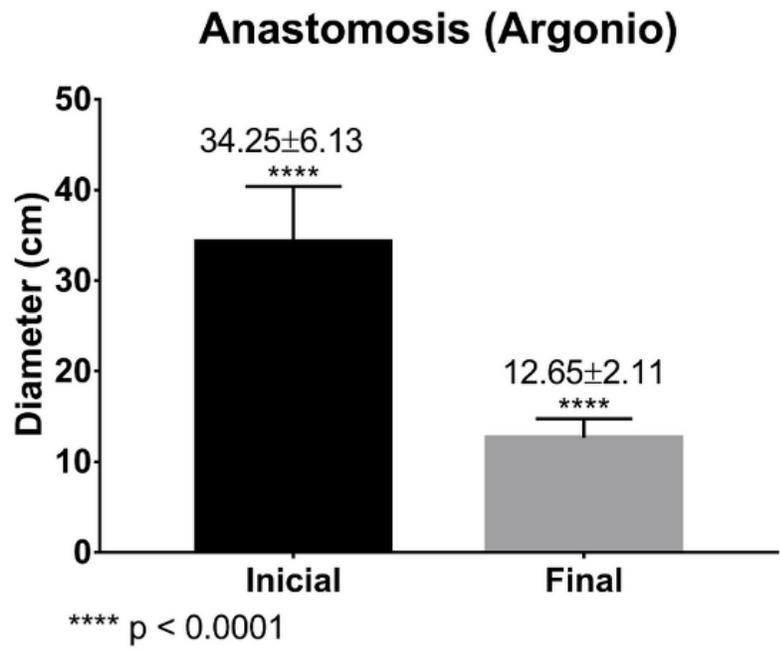


**Figure 4.** Box-Plot model graphics showing the values in percentage of weight regained total body weight loss and excess weight loss in relation to the APC and SHAM groups, with p < 0.0001 as significant (CI 95%).

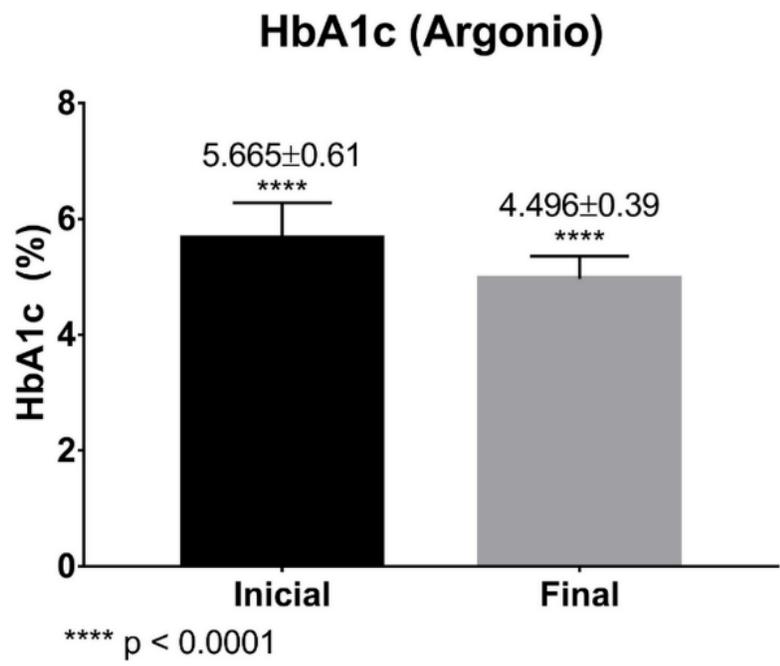


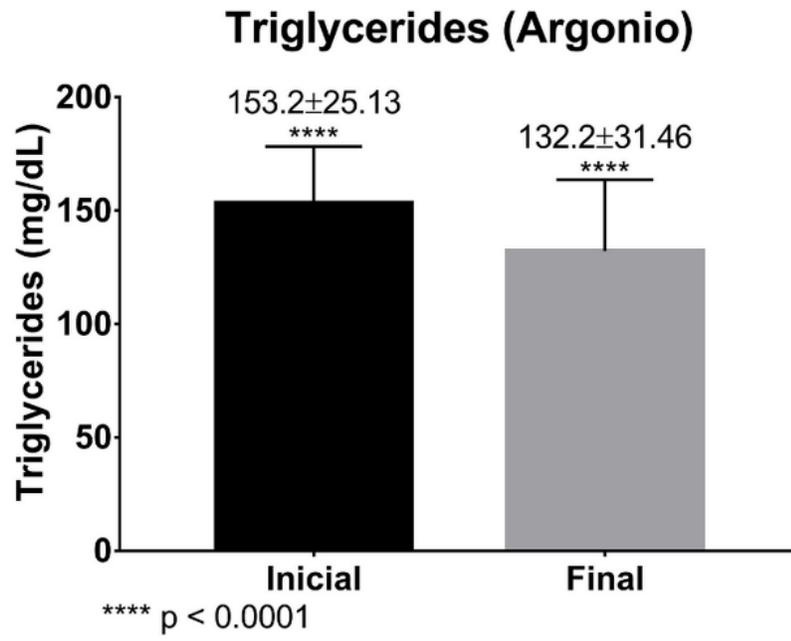


**Figure 5.** Box-Plot model graph showing the values of the decrease in the diameter of the gastrojejunal anastomosis to the APC group, with  $p < 0.0001$  as significant (CI 95%).

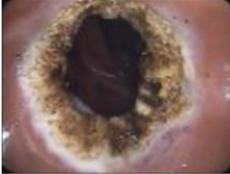


**Figure 6.** Box-Plot model graphs showing the values of glycosylated hemoglobin (HbA1c) in percentage and triglycerides (mg / dL) to the APC groups, with  $p < 0.0001$  as significant (CI 95%).





**Figure 7.** GJA diameter images at 2, 4, and 6 months after APC application.

<b>First APC session (before APC)</b> 	<b>First APC session (after APC)</b> 
<b>Second APC session (before APC)</b> 	<b>Second APC session (after APC)</b> 
<b>Third APC session (before APC)</b> 	<b>Third APC session (after APC)</b> 
<b>Beggining of treatment aspect</b> 	<b>Final of treatment aspect (6 months)</b> 

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**Argon Application - 2 MONTHS    Result - 2 MONTHS**

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**Argon Application - 4 MONTHS    Result - 4 MONTHS**

**Argon Application - 6 MONTHS    Result - 6 MONTHS**

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