

Roux-en-Y gastric bypass pouch outlet reduction using argon plasma coagulation to treat weight regain: a randomized controlled trial with a sham control group



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ABSTRACT

Background and study aims A comparative study was conducted to evaluate the efficacy of argon plasma coagulation (APC) therapy in treating post Roux-en-Y gastric bypass (RYGB) weight regain and the incidence of complications related to this procedure, using a sham treatment group as a control.

Patients and methods Forty-one patients with a minimum weight regain of 10 kg and a minimum postoperative time of 36 months were randomized into two groups.

Results In the APC group (n = 21), the mean initial weight was 100.4 kg and the mean weight regain was 24.94 kg. In the sham group (n = 20), the mean initial weight was 103.65 kg, and the mean weight regain was 25.18 kg. Anastomotic stenosis occurred only after the first APC session. The results for the comparison of APC with the sham group showed a percentage weight regain loss of 63.95 compared to -6.5, and weight loss of 15.02 and -0.57, percentage total weight loss of 14.46 and -0.62, excess weight loss of 54.32% and -2.34%, and BMI reduction of 5.38 and -0.21, with $P < 0.0001$ for all the comparisons. In the APC group, there was a significant reduction in HbA1c (5.66% to 4.96%) and triglycerides (153.20 mg/dL to 132.20 mg/dL).

Conclusions This study indicates that APC outlet pouch reduction outperforms sham treatment in terms of weight loss for patients presenting weight regain after RYGB.

Introduction

Obesity is a serious emerging disease with negative consequences for public health [1]. There are currently more than 2.0 billion overweight and obese people in the world and Brazil ranks fifth worldwide, with 18.0 million Brazilians estimated as falling into this category [2]. Numerous studies of Roux-en-Y gastric bypass (RYGB) have shown significant results, including increased survival, reduced cardiovascular mortality, and control of metabolic diseases [3–6].

The most common late complication of this procedure is the recurrence of obesity and the main factors associated with this are poor diet and bad habits associated with a sedentary lifestyle [7–9], both of which may lead to an increase in the size of the gastric reservoir and dilation of the diameter of the gastro-jejunal anastomosis (GJA), among other consequences [10, 11]. A GJA of more than 15.0 mm in diameter has thus been associated with recurrence of obesity, especially when in combination with complaints of decreased satiety or early hunger due to rapid gastric emptying [11–13].

Major published studies therefore suggest that narrowing a dilated GJA using argon plasma coagulation (APC) would appear to be an effective and safe alternative in cases of the recurrence of obesity in patients who have undergone RYGB [14–18]. Abnormal anatomical findings caused by weight gain after RYGB are found in 71.2% of patients, with 58.9% presenting GJA dilation [18]. APC is technically feasible, reproducible, and relatively inexpensive, and possesses numerous advantages over the usual procedure involving electrocoagulation [14–17]. The incidence of complications is low and the tissue penetration limit of 2.0 to 3.0 mm associated with adequate coagulation makes it possible to apply this procedure in critical areas such as the duodenum and the colon [18, 19, 21].

The present study thus assessed the efficacy of APC and examined the incidence of complications associated with this procedure for treatment of post-RYGB weight regain compared to a sham treatment control group.

Patients and methods

Trial design

The prospective randomized study included 41 patients of the 132 who underwent eligibility analysis. All patients selected completed the follow-up, with no exclusions during the study period. The study was conducted in accordance with the clinical research rules established by CONSORT [20].

Sample size

The sample size was estimated as a total of 41 participants for further randomization into two groups. Based on previous studies, a standard deviation of 18.5 was hypothesized for the change in weight after the APC procedure, along with a 95% confidence interval (CI) and a 5% patient dropout rate [18, 22].

Ethical approval and informed consent

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

Participants

The inclusion criteria were: patients who had undergone RYGB surgery, with a minimum weight regain of 10 kg and a minimum postoperative time of 36 months, loss of satiety, pouch size between 4.0 and 7.0 cm, diameter <5.0 cm, and GJA >15.0 mm. The exclusion criteria were having undergone another type of surgery or having a normal stomach, lack of consent, consumption of candies, taking anticoagulant drugs, alcoholism, depression, and compulsive disorders.

Three APC sessions were conducted at intervals of 8 weeks. Each patient's weight was assessed at the beginning of treatment and 2, 4, and 6 months later. Both groups received standard nutritional guidance immediately after each session of APC or upper digestive endoscopy. Both groups were placed on a liquid diet.

Randomization

The random sequence was generated using the Minitab 18 statistics program (version 18, LLC, State College, Pennsylvania, United States) by a researcher not involved in the allocation of participants. Block randomization was used without stratification and was implemented by an administrative assistant using sequential numbering and sealed envelopes. Individuals in the argon group underwent three APC sessions, at intervals of 8 weeks. Endoscopic evaluation has performed every 2 months until a period of 6 months had elapsed. Individuals in the control group underwent initial diagnostic endoscopy followed by clinical consultation every 2 months until the end of a 6-month period. 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)

This group included patients who underwent APC therapy performed in a 2.0-cm halo around the GJA. This group underwent multidisciplinary monitoring, by way of consultations with a bariatric surgeon, psychologist, physical education instructor, and nutritionist. Follow-up sessions were conducted every 2 months until completion of a 6-month period.

Group II (sham treatment)

This group included patients who underwent only upper digestive endoscopy with sedation. This group were also given multidisciplinary follow-up, by way of consultations with a bariatric surgeon, psychologist, physical education instructor, and nutri-

tionist. Follow-up sessions were likewise conducted every 2 months up to the end of the 6-month period.

Setting

All endoscopic procedures, APC sessions, and data collection took place at the EndogastroRio Clinic, Rio de Janeiro-RJ, Brazil. Recruitment of participants began in May 2019 and monitoring was concluded in December 2019.

Outcomes

Primary outcomes

Loss of regained weight was expected to be significantly greater in the treatment group compared to the control group at 2, 4, and 6 months. The following parameters were evaluated: weight loss in kg, reduction in body mass index (BMI), percentage loss of regained weight (%RWL), percentage total body weight loss (% TWL), and percentage excess weight loss (% EWL).

Secondary outcomes

The incidence of adverse events such as bleeding and strictures, along with improvements in laboratory metabolic parameters (glycosylated hemoglobin–HbA1c, total cholesterol, low-density lipoprotein, HDL triglycerides) and eating behavior, were also observed.

The study also investigated the incidence of possible complications of APC, such as gastric pain or discomfort, nausea, vomiting, and stenosis of the GJA, which may require dilation by endoscopy.

Interventions

APC session and examinations

APC has been approved by the National Health Surveillance Agency (ANVISA) in Brazil. All examinations were performed after a minimum fasting period of 8 hours. The patient was placed in the left lateral position and 10.0% xylocaine spray followed by intravenous propofol was administered under the supervision of an assistant physician (anesthesiologist), with appropriate cardiopulmonary monitoring for the duration of the examination using a Pentax EG-2970K endoscope (Pentax, Tokyo, Japan). The GJA was measured using an endoscopic ruler with 5.0-mm gradations developed from an endovascular laser surgery catheter. The images obtained were transferred to a Pentax EPK-1000 processor attached to a computer with the ZScan 7 program (Goiânia, GO/Brazil) installed. An argon plasma coagulator device (Argon 2-WEM, Ribeirão Preto, SP) with a disposable endoscopic catheter was then applied to the entire circumference of the GJA, forming a 2-cm-thick halo, at a power of 90W, with a flow of 2.5 L/min.

After completion of the procedure and recovery from the anesthetic, all patients were released in the presence of a companion. A 60 mg per day dexlansoprazole proton pump inhibitor was prescribed for up to 90 days after the final session, in addition to 2 g of sucralfate 12/12 hours for 10 days. All patients were provided with guidance and remained in contact with a

physician in case of the occurrence of adverse events. All patients remained on a liquid diet for 10 days.

Anthropometric and laboratory data

For each patient registered, data relating to weight loss (kg), measured using a calibrated digital scale, BMI, height and weight were recorded twice during each visit, as a way of ensuring the greatest possible accuracy and reliability. In addition to this, pouches ranging in size between 4.0 to 7.0 cm, with diameter <5.0 cm, were measured using a graduated endoscope. All pouches in which it was possible to obtain a retro-view with the device were deemed to be wide. All outcome variables, with the exception of blood tests (total plasma cholesterol, high-density lipoprotein cholesterol-HDL, and HbA1c) were determined on randomization and in months 2, 4, and 6 after randomization.

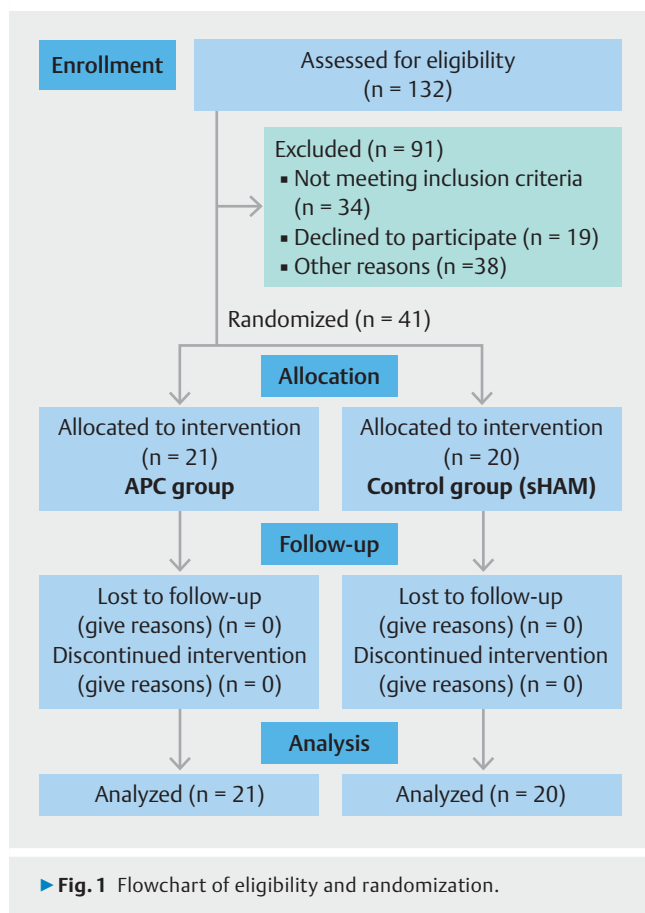
Statistical analysis

For the purposes of data analysis, a database was created using a Microsoft Excel spreadsheet exported to the Minitab 18 statistical program (version 18, LLC, State College, Pennsylvania, United States) [23] and OriginPro 9 (DPR Group, Inc., Northampton, Massachusetts, United States) [24]. The descriptive statistics produced included the number of individuals in the sample (n), mean and standard deviation, CI, and percentages for all the variables. A normality test was performed for all variables. A one-way ANOVA test was applied, adopting an α of 0.05 and a CI of 95% for statistical significance. R^2 was also calculated.

Results

A total of 41 patients were randomly allocated to two groups – an APC and a sham treatment group – containing 21 and 20 patients respectively. The selection and eligibility flowchart, in addition to the randomization process for the allocation of patients to the APC and sham groups, after application of the inclusion and exclusion criteria, is presented in ► **Fig. 1**. In the APC group (four men), the mean age was 46.65 years, the mean initial weight 100.4 (with a range of 72–162) kg, the mean initial BMI 36.12 kg/m², and the mean regained weight 24.94 (range of 15 to 82). In the sham group (seven men), the mean age was 49.53 years, the mean initial weight 103.65 kg (range: 88.70–123.70), the mean baseline BMI 36.67 kg/m² and the mean regained weight 25.18 kg (range: 19.50–32.30). The only complication that occurred was a gastric pouch outlet stenosis after the first APC session. This complication, however, required no treatment, since the patient tolerated a liquid diet, and the patient was therefore able to remain in the study.

The overall results for both groups for regained weight loss, weight loss in kg, %TBWL, %EWL, BMI reduction, serum triglyceride level reduction and glycosylated hemoglobin reduction are shown in ► **Table 1**. ► **Fig. 2** shows the weight reduction for the two groups over time. The APC group had an average initial weight of 100.04 ± 22.27 and, after 6 months, the average weight had fallen to 85.02 ± 16.05 kg, representing a statistically significant weight loss of 15.02 ± 9.63 kg, with $P < 0.0001$ and $R^2 = 45.34\%$ (CI 95%). The sham group did not present any sta-



tistically significant difference in terms of weight loss in kg, with $P > 0.0001$ and $R^2 = 99.85\%$ (CI 95%) and mean initial and final weights of 103.65 ± 10.53 kg and 104.22 ± 10.06 kg respectively, with weight gain of 0.57 ± 2.23 kg. There was also a statistically significant difference between the APC and sham groups in terms of the results for final weight, with $P < 0.0001$. The BMIs for each group exhibited the same statistical pattern as that of the values for weight, as shown in ► **Table 1** and ► **Fig. 3**.

► **Fig. 4** shows the values for %RWL, %TWL, and percentage EWL (%EWL) in the APC group to be 63.95 ± 32.08 , $14.46 \pm 6.16\%$, and $54.32 \pm 28.90\%$, respectively. In the sham group, the figures for the same variables were -2.65 ± 10.24 , -0.62 ± 2.43 , and -2.34 ± 9.03 . There was therefore a statistically significant difference between the groups, with $P < 0.0001$.

The mean diameter of the GJA for the APC group was 34.25 ± 6.13 mm (initial) and 12.65 ± 2.11 mm (final), representing a reduction of 21.60 ± 3.19 mm, with $P < 0.0001$ and $R^2 = 35.43\%$ (CI 95%). The sham group did not present a statistically significant difference, with $P > 0.0001$ and $R^2 = 99.99\%$ (CI 95%) and the initial and final anastomotic diameter remained unchanged at 35.16 ± 4.52 mm (► **Fig. 5**).

A number of biochemical parameters were also analyzed. The mean values for total cholesterol, HDL and LDL before and after, in the sham group, were 186.21 ± 25.36 mg dL⁻¹ and 185.84 ± 24.27 mg dL⁻¹, 48.89 ± 11.26 mg dL⁻¹ and 49.11 ± 10.16 mg dL⁻¹, 122.74 ± 25.36 mg dL⁻¹ and 121.32 ± 27.36 mg

► **Table 1** Overall results for both groups.

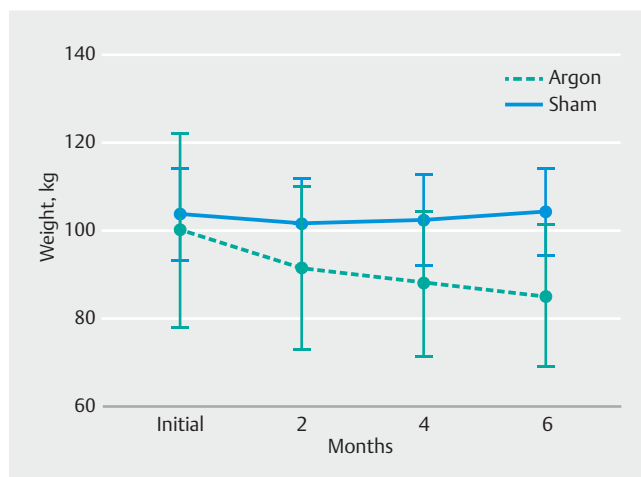
Parameter	APC group	Sham group
Weight (kg)		
Initial	100.04 ± 22.27	103.65 ± 10.53
Final	85.02 ± 16.05^1	104.22 ± 10.06
Reduction	15.02 ± 9.63^2	-0.57 ± 2.23
BMI (kg/m ²)		
Initial	36.13 ± 6.44	36.67 ± 2.23
Final	30.74 ± 4.64^1	36.87 ± 2.09
Reduction	5.38 ± 2.21^3	-0.21 ± 0.39
Anastomosis		
Initial	34.25 ± 6.13	35.16 ± 4.52
Final	12.65 ± 2.11^1	35.16 ± 4.52
Reduction	21.60 ± 3.19^3	0.00
%RWL ¹	-2.65 ± 10.24	63.95 ± 32.08
%TBWL ¹	14.46 ± 6.16	-0.62 ± 2.43
%EWL ¹	54.32 ± 28.90	-2.34 ± 9.03

APC, Argon plasma coagulation; RWL, regained weight loss; TBWL, total body weight loss; EWL, excess weight loss.

¹ $P < 0.0001$ final versus initial.

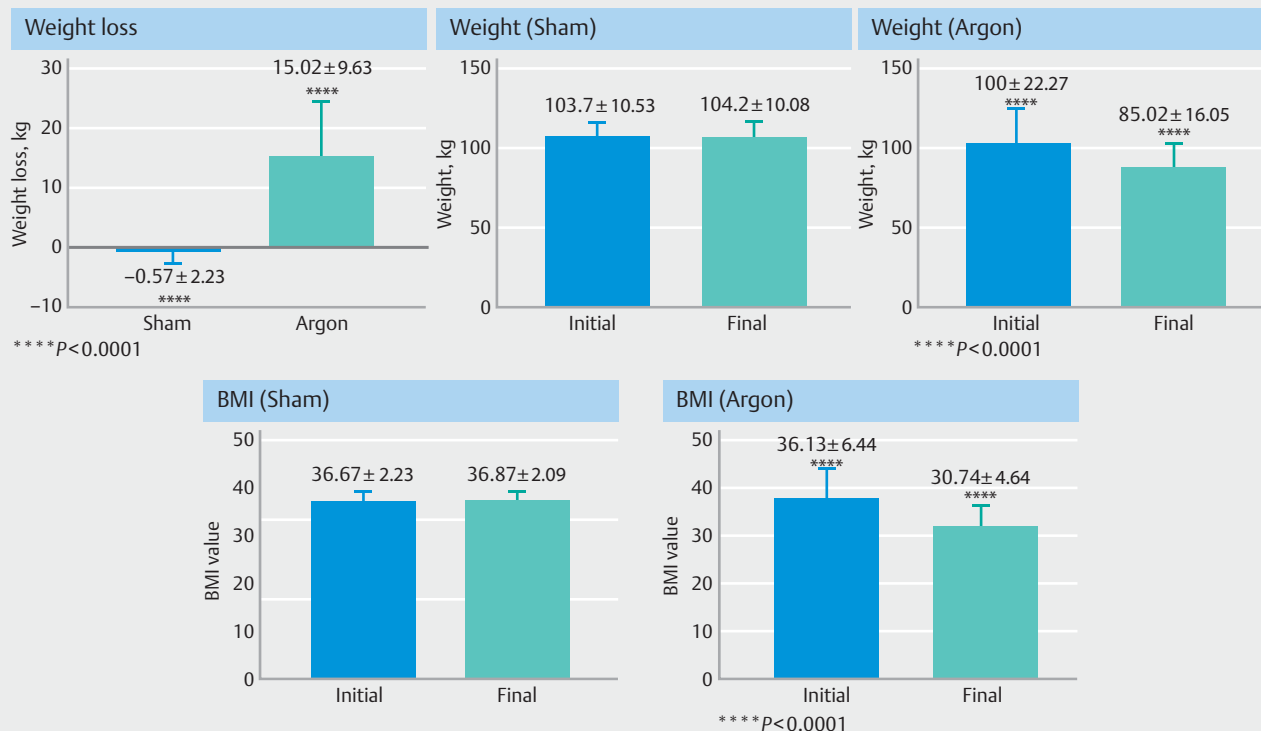
² $P < 0.0001$ between groups.

³ $P < 0.0001$ between groups.

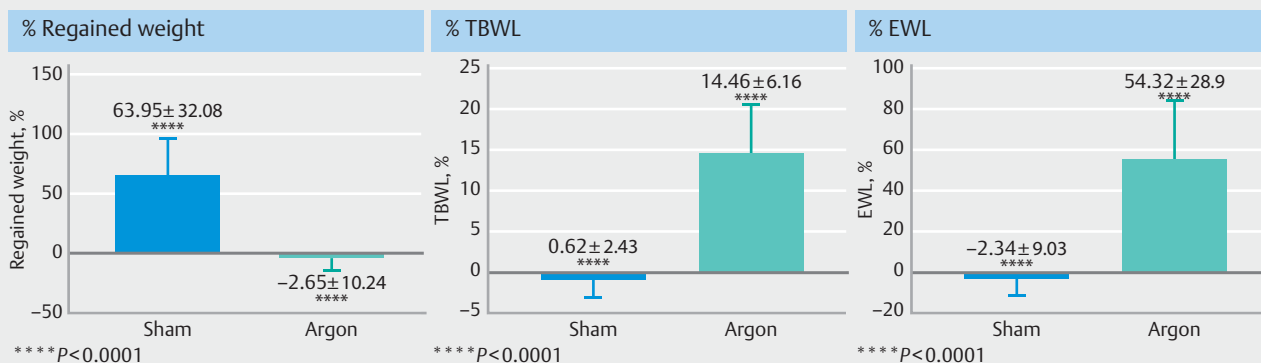


► **Fig. 2** Graph showing weight reduction (kg) over 6 months for APC and sham control groups, with 95% CI.

dL⁻¹, respectively, with $p > 0.0001$. In the APC group, the equivalent figures were 187.25 ± 23.36 mg dL⁻¹ and 186.50 ± 22.23 mg dL⁻¹, 48.40 ± 8.26 mg dL⁻¹ and 48.85 ± 8.18 mg dL⁻¹, 122.5 ± 24.34 mg dL⁻¹ and 121.0 ± 25.14 mg dL⁻¹, respectively, with $P > 0.0001$. A statistically significant reduction was found in two of the parameters under analysis: HbA1c, with an initial average of $5.66 \pm 0.61\%$ compared to a final average of $4.96 \pm 0.39\%$ ($P < 0.0001$), and triglycerides with an initial mean of



► **Fig. 3** Boxplot model graphs showing weight, weight loss (kg), and BMI (kg/m²) for the APC and sham control groups, with a level of significance of $P < 0.0001$ (CI 95%).



► **Fig. 4** Boxplots showing percentages of regained weight loss, total body weight loss and excess weight loss for the APC and sham control groups, with a level of significance of $P < 0.0001$ (CI 95%).

153.20 ± 25.13 mg dL⁻¹ compared to a final average of 132.20 ± 31.46 mg dL⁻¹ ($P < 0.0001$) (► **Fig. 6**).

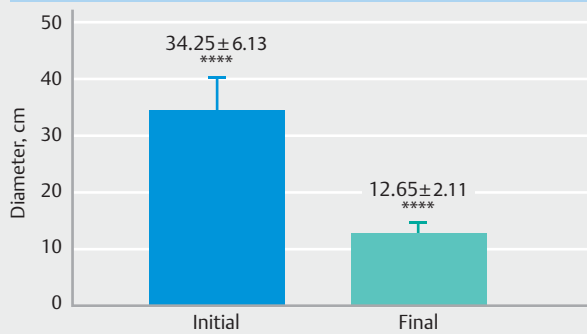
There was also a statistically significant difference between groups regarding the diameter of the anastomosis, with $P < 0.0001$. ► **Fig. 7** shows GJA diameter images for 2, 4, and 6 months after the APC.

Discussion

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

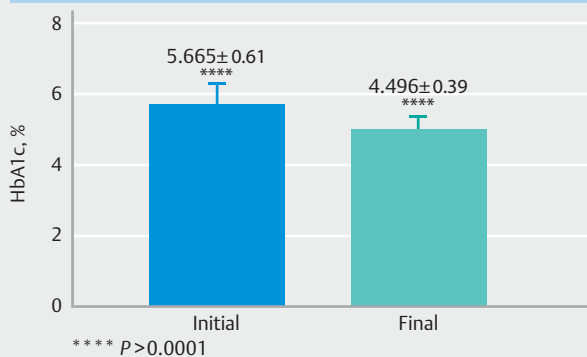
In the present study, endoscopic APC was used to reduce the diameter of the GJA and thereby produce weight loss after

Anastomosis (Argon)

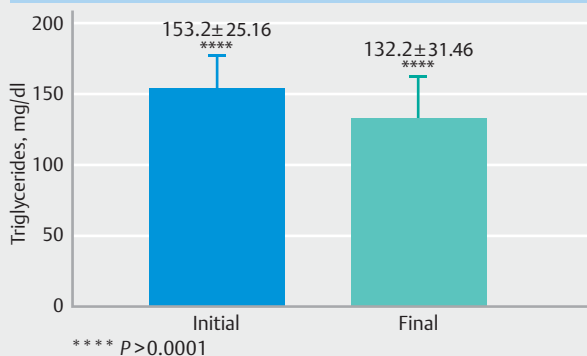


► **Fig. 5** Boxplots showing reduction in diameter of gastro-jejunal anastomosis in the APC group, with a significance of $P < 0.0001$ (CI 95 %).

HbA1c (Argon)



Triglycerides (Argon)



► **Fig. 6** Boxplots showing percentages of glycosylated hemoglobin (HbA1c) and triglycerides (mg dL⁻¹) for the APC groups, with a level of significance of $P < 0.0001$ (CI 95 %).

RYGB weight regain. The results obtained were similar to those found in the literature. ► **Fig. 2** and ► **Fig. 3** show the weight loss results for both groups, with the average weight reduction in the APC group being 15.02 ± 9.63 , which is higher than that of the sham control group after six months. The present study

Argon Application – 2 months



Result – 2 months



Argon Application – 4 months



Result – 4 months



Argon Application – 6 months



Result – 6 months



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

thus confirms the findings reported in the literature to the effect that reduction in weight regained after RYGB is closely related to reduction of the diameter of the anastomosis 21.60 ± 3.19 mm from 34.25 ± 6.13 mm (initial) to 12.65 ± 2.11 mm (final), given that a liquid diet and nutritional counseling were common to both groups.

The present study also confirmed the safety and efficacy of the APC outlet reduction procedure, since only one complication occurred in one patient, who experienced an outlet pouch stenosis after the first session of APC. This stenosis did not, however, require treatment.

The results of the present study corroborate the findings of Baretta et al. (2015) [18], who studied 30 patients undergoing treatment with argon plasma after gastric bypass and observed an average weight loss of 15.0 kg after three sessions of endoscopic APC at regular intervals of 8 weeks. Another prospective controlled longitudinal study involving APC showed a success rate of 90.0% for weight loss using APC and a reduction of up to 41.0% in regained weight [19]. Another retrospective study, with 37 participants, by De Souza et al. (2015) [22] showed that the use of APC had a success rate of 50.0% for weight loss using APC and a 24.0% reduction in regained weight.

A reduction in the diameter of a dilated anastomosis, in combination with monitoring by a multidisciplinary team, therefore, can lead to a 23% reduction in excess weight on aver-

age [18]. Recurrence of obesity is associated with decreased quality of life and the recurrence of comorbidities [19,21].

A prospective controlled study carried out by Schulman et al. analyzed the application of APC with follow-up at 3 and 6 months of anastomosis reduction therapy after RYGB. These authors showed that, in 53 patients, (mean age 49.0 ± 1.3 years) the mean BMI was $52.1 \pm 10.7 \text{ kg/m}^2$, while the mean BMI was 29.6 postoperatively $\pm 1.1 \text{ kg/m}^2$. After 8.6 years of RYGB surgery, APC was used to treat weight regain, resulting in a BMI of $35.4 \pm 1.1 \text{ kg/m}^2$. The reduction in the diameter of the anastomosis was from 16.1 mm to 13.5 mm and the mean number of APC sessions was 1.3 [25]. An anastomosis with a diameter of over 15.0 mm may therefore, in cases of weight regain, be subjected to endoscopic review [11, 12, 18].

Likewise, Moon et al. (2018) [11] published retrospective data obtained from the records of 558 patients with weight regain, all of whom had undergone APC between July 31, 2009, and March 29, 2017 at one of eight bariatric centers in the USA and Brazil. The mean weight of the patients on APC was $94.5 \pm 18.6 \text{ kg}$ and the mean BMI 34.0 kg/m^2 . When data were available, the mean lowest weight was $67.0 \pm 23.0 \text{ kg}$ and the mean lowest BMI was 24.1 kg/m^2 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 [11].

De Quadros et al. (2020) [12] also evaluated the efficacy and safety of endoscopic treatment of increased GJA using APC. A randomized controlled study was carried out to compare APC to exclusive multidisciplinary management after weight regain. Forty-two patients were divided into two groups: APC ($n=22$) and control ($n=20$). After 14 months of follow-up with a crossover at 6 months, significant improvements in satiety and greater weight loss were found in the APC group and after the crossover. APC was found to be associated with significant weight loss of 9.73 vs. $+1.38$, reduction in the diameter of the anastomosis, early satiety (0.77 vs. 0.59 , $P<0.001$), and increased quality of life. Mean total weight loss during the entire follow-up period was similar in both groups, 13.02 kg in the APC group and 11.52 kg in the control.

A prospective randomized trial study conducted by Brunaldi et al. [14] likewise reported on ablation with APC plus full-thickness endoscopic suturing (FTS-APC) and APC alone for the treatment of weight regain. In this randomized, single-pilot study with forty patients, comparing the efficacy and safety of APC alone versus FTS-APC for transoral outlet reduction, patients presenting at least 20% weight regain from the lowest point and GJA $\geq 15 \text{ mm}$ were considered eligible. The primary outcome was the percentage of total weight loss (%TWL) in 12 months. Secondary outcomes were the incidence of adverse events, improvements in metabolic laboratory parameters and improvements in quality of life and eating habits. At 12 months, the mean %TWL was 8.3 ± 5.5 in the APC group alone versus 7.5 ± 7.7 in the STF-APC group. The percentage of solid pre-review gastric retention within 1 hour was found to be positively associated with the probability of achieving $\geq 10\%$ TWL within 12 months. Both groups experienced significant reduc-

tions in levels of low-density lipoprotein and triglycerides at 12 months.

A recent retrospective study of 217 patients conducted by Jirapinyo et al. compared the effectiveness of different APC configurations in the treatment of weight regain. Patients who received low-dose ($45\text{--}55 \text{ W}$) and high-dose ($70\text{--}80 \text{ W}$) APC were compared. Of the selected patients, 116 (53.5%) underwent low-dose APC sessions (2.4 sessions/patient) and 101 (46.5%) underwent 144 APC sessions at high doses (1.4 ± 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 presented 7.3% and 8.1% TWL, respectively. At 12 months, the low- and high-dose groups experienced 5.1% and 9.7% TWL, respectively. The technical success rate was 100%. The overall rate of AE was 8.0%, with that of stenosis being 4.6%. Higher-watt APC has thus been shown to be associated with greater weight loss [15].

Heneghan et al. (2012) [26] similarly concluded that patients with normal post-surgical anatomy regain less weight than patients with altered proximal surgical anatomy, especially an increase in the diameter of the GJA. Likewise, Abu-Dayeh et al. [27] and Ramos et al. (2017) [28] evaluated the size of GJA and its influence on weight loss and demonstrated that an anastomosis calibrated to 15.0 mm produces better results compared to an anastomosis of 45.0 mm in a 2-year follow-up. They therefore recommend a GJA diameter of between 10 and 15.0 mm .

Numerous methods for endoluminal reduction of GJA, including surgery [29], suturing [30,31], and APC in the GJA, therefore, have been proposed as ways of achieving loss of regained weight in patients undergoing RYGB [12]. In such cases, surgical treatment is the most common, although this is associated with a higher incidence of complications, morbidity and mortality compared to the other treatments proposed above [29].

Transoral outlet reduction (TORe) performed using a traditional suture pattern has also been shown to be effective in affecting short- to medium-term weight loss in patients with weight regain after RYGB [31]. One study examined the technical feasibility and safety of TORe and assessed its impact on weight and metabolic profiles. Patients with RYGB who underwent TORe were included. The GJA was ablated by coagulation with argon plasma or subjected to endoscopic submucosal dissection. A suture was used to place stitches around the GJA in a continuous ring and the suturing was subsequently attached to a balloon ($8\text{--}12 \text{ mm}$). The primary outcome was technical feasibility. Secondary outcomes were the %TWL, adverse events, impact on comorbidities, and predictors of weight loss. Two hundred and fifty-two patients with RYGB underwent 260 TORes. These patients regained $52.6 \pm 46.4\%$ of the weight lost and weighed $107.6 \pm 24.6 \text{ kg}$. The technical success rate was 100%. At 6 and 12 months, the %TWL was 9.6 ± 6.3 and 8.4 ± 8.2 respectively. At 12 months, blood pressure, hemoglobin A1c and alanine aminotransferase had all improved [32].

One systematic review and meta-analysis evaluated the effectiveness of endoscopic therapies for regained weight after RYGB. The primary outcomes were absolute weight loss (AWL),

EWL, and TBWL. Thirty-two studies were included in the qualitative analysis. Twenty-six full-thickness (FT) endoscopic suturing procedures were described and AWL, EWL, and TBWL at 3 months were 8.5 kg, 21.6 kg, and 7.3 kg, at 6 months, 8.6 kg, 23.7 kg, and 8.0 kg, and, at 12 months, 7.63 kg, 16.9 kg, and 6.6 kg, respectively. Subgroup analysis showed that all results were significantly improved in the group with FT suturing combined with APC. Two articles described APC alone as producing an average AWL of 15.4 ± 2.0 and 15.4 ± 9.1 kg at 3 and 6 months, respectively. When performed prior to the suturing, APC would seem to result in greater weight loss [33].

Conclusions

The present study thus has shown that the use of argon plasma to reduce the diameter of the GJA produced greater weight loss compared to a control group that underwent only upper digestive endoscopy with sedation and a liquid diet. The present study also confirmed the safety and efficacy of the APC outlet reduction procedure.

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Competing interests

The authors declare that they have no conflict of interest.

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EndogastroRio Clinic, Rio de Janeiro-RJ, Brazil

Clinical trial

Brazilian Clinical Trials Registry
ENDOG2356

TRIAL REGISTRATION: Prospective, Randomized ENDOG2356 at Brazilian Clinical Trials Registry

References

- [1] World Health Organization; <https://www.sbcbrm.org.br/endoscopia-e-obesidade/>
- [2] IBGE- Instituto Brasileiro de Geografia e Estatística; <http://www.ibge.gov.br>
- [3] Almby K, Edholm D. Anastomotic strictures after Roux-en-Y gastric bypass: a cohort study from the Scandinavian Obesity Surgery Registry. *Obes Surg* 2019; 29: 172–177
- [4] Keren D, Rainis T. Intra-gastric balloons for overweight populations-1 year post removal. *Obes Surg* 2018; 28: 2368–2373
- [5] Falcão de Santana M, Menezes Marques L, Lopes Gibara V et al. Ectopic spleen mimicking hepatocellular carcinoma in the late post-operative period of bariatric surgery. *Cell Mol Biol (Noisy-le-grand)* 2018; 64: 113–115
- [6] Docimo S Jr, Svestka M. Endoscopic evaluation and treatment of postoperative bariatric surgery complications. *Surg Innov* 2017; 24: 616–624
- [7] Schlosser T, Feisthammel J, Moessner J et al. Endoscopic treatment of obesity and complications after bariatric surgery. *Minerva Chir* 2017; 72: 530–537
- [8] Schulman AR, Thompson CC. Complications of bariatric surgery: what you can expect to see in your GI practice. *Am J Gastroenterol* 2017; 112: 1640–1655
- [9] Montoya-Ramírez J, Aguilar-Espinosa F, Gutiérrez-Salinas J et al. Robot-assisted surgery and endoscopic management of gastrocolic fistula: A rare complication of acute pancreatitis in a patient who had undergone sleeve gastrectomy. *Asian J Endosc Surg* 2019; 12: 465–468
- [10] Turcu F, Balahura C, Doras I et al. Symptomatic stenosis after laparoscopic sleeve gastrectomy - incidence and management in a high-volume bariatric surgery center. *Chirurgia (Bucur)* 2018; 113: 826–836
- [11] Moon RC, Teixeira AF, Neto MG et al. Efficacy of utilizing argon plasma coagulation for weight regain in Roux-en-Y gastric bypass patients: a multi-center study. *Obes Surg* 2018; 28: 2737–2744
- [12] de Quadros LG, Neto MG, Marchesini JC et al. Endoscopic argon plasma coagulation vs. multidisciplinary evaluation in the management of weight regain after gastric bypass surgery: a randomized controlled trial with sham group. *Obes Surg* 2020; 30: 1904–1916
- [13] De Moura DTH, Sachdev AH, Lu PW et al. Acute bleeding after argon plasma coagulation for weight regain after gastric bypass: A case report. *World J Clin Cases* 2019; 7: 2038–2043
- [14] Brunaldi VO, Farias GFA, de Rezende DT et al. Argon plasma coagulation alone versus argon plasma coagulation plus full-thickness endoscopic suturing to treat weight regain after Roux-en-Y gastric bypass: a prospective randomized trial (with videos). *Gastrointest Endosc* 2020; 92: 97–107.e5
- [15] Jirapinyo P, de Moura DTH, Dong WY et al. Dose response for argon plasma coagulation in the treatment of weight regain after Roux-en-Y gastric bypass. *Gastrointest Endosc* 2020; 91: 1078–1084
- [16] Nguyen D, Dip F, Huaco JA et al. Outcomes of revisional treatment modalities in non-complicated Roux-en-Y gastric bypass patients with weight regain. *Obes Surg* 2015; 25: 928–934
- [17] Malik VS, Willett WC, Hu FB. Global obesity: trends, risk factors and policy implications. *Nat Rev Endocrinol* 2013; 9: 13–27
- [18] Baretta GA, Alhinho HC, Matias JE et al. Argon plasma coagulation of gastrojejunal anastomosis for weight regain after gastric bypass. *Obes Surg* 2015; 25: 72–79
- [19] Cambi MP, Marchesini SD, Baretta GA. Post-bariatric surgery weight regain: evaluation of nutritional profile of candidate patients for endoscopic argon plasma coagulation. *Arq Bras Cir Dig* 2015; 28: 40–43
- [20] CONSORT; 2023: <http://www.consort-statement.org>
- [21] Thompson CC, Jacobsen GR, Schroder GL et al. Stoma size critical to 12-month outcomes in endoscopic suturing for gastric bypass repair. *Surg Obes Relat Dis* 2012; 8: 282–287
- [22] De Souza LM, de Quadros LG, Kaiser RL et al. Argon plasma effect about anastomosis was significant to inhibit the weight regained in patients undergoing gastric bypass. *J Obes Weight Loss Ther* 2015; 5: 264
- [23] Minitab Quality Analysis. <https://www.minitab.com>
- [24] Moberly JG, Bernards MT, Waynant KV. Key features and updates for origin 2018. *J Cheminform* 2018; 10: 5
- [25] Schulman A, Abidi WM, Thompson CC. Plication versus argon plasma coagulation in the treatment of weight regain after gastric bypass: a

- matched controlled cohort study. *Obes Surg* 2013; 30: 1904–1916 doi:10.1007/s11695-020-04414-6
- [26] Heneghan HM, Yimcharoen P, Brethauer SA et al. Influence of pouch and stoma size on weight loss after gastric bypass. *Surg Obes Relat Dis* 2012; 8: 408–415
- [27] Abu Dayyeh BK, Acosta A, Camilleri M et al. Endoscopic sleeve gastroplasty alters gastric physiology and induces loss of body weight in obese individuals. *Clin Gastroenterol Hepatol* 2017; 1: P37–P43.e1 doi:10.1016/j.cgh.2015.12.030
- [28] Ramos AC, Marchesini JC, de Souza Bastos EL et al. The role of gastrojejunostomy size on gastric bypass weight loss. *Obes Surg* 2017; 27: 2317–2323
- [29] Galvao Neto M, Marins Campos J. Therapeutic flexible endoscopy after bariatric surgery: a solution for complex clinical scenarios. *Cir Esp* 2015; 93: 1–3
- [30] Schulman A, Chan WW, Thompson CC. Endoscopic suturing for failed gastric by-pass: predictors of success. *AGA*; 2013, abstracts S-827 Mo1958
- [31] Jirapinyo P, Slattey J, Ryan MB et al. Evaluation of an endoscopic suturing device for transoral outlet reduction in patients with weight regain following Roux-en-Y gastric bypass. *Endoscopy* 2013; 45: 532–536
- [32] Jirapinyo P, Kröner PT, Thompson CC. Purse-string transoral outlet reduction (TORe) is effective at inducing weight loss and improvement in metabolic comorbidities after Roux-en-Y gastric bypass. *Endoscopy* 2018; 50: 371–377
- [33] Brunaldi VO, Jirapinyo P, de Moura DTH et al. Endoscopic treatment of weight regain following Roux-en-Y gastric bypass: a systematic review and meta-analysis. *Obes Surg* 2018; 28: 266–276