Dose response for argon plasma coagulation in the treatment of weight regain after Roux-en-Y gastric bypass

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Background and Aims: Argon plasma coagulation (APC) of gastrojejunal anastomosis (GJA) is effective in treating weight regain after Roux-en-Y gastric bypass (RYGB). This study aims to compare the efficacy of different APC settings for treating weight regain.

Methods: This was a single-center retrospective study of patients who had undergone RYGB and then underwent APC from 2014 to 2018 for weight regain. Patients receiving only low-dose APC (45-55 W) or high-dose APC (70-80 W) were compared. The primary outcome was the difference in percentage total weight loss (% TWL) between the groups at 6 and 12 months after the last treatment. Secondary outcomes were technical success, adverse events (AEs), and predictors of weight loss at 12 months.

Results: Two hundred seventeen patients met the inclusion criteria and underwent 411 APC sessions. Of these, 116 (53.5%) patients underwent 267 low-dose APC sessions (2.4 ± 1.5 sessions/patient) and 101 (46.5%) patients underwent 144 high-dose APC sessions (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 experienced 7.3% ± 6.6% and 8.1% ± 7.4% TWL, respectively ($P = .41$). At 12 months, the low- and high-dose groups experienced 5.1% ± 8.5% and 9.7% ± 10.0% TWL, respectively ($P = .008$). Technical success was 100%. The overall AE rate was 8.0%; the most common AE was GJA stenosis (4.6%). The GJA stenosis rate was similar for the low- and high-dose groups (3.0% vs 7.6%, $P = .06$). High-dose APC remained a significant predictor of greater weight loss at 1 year after controlling for confounders.

Conclusion: APC is effective at treating weight regain after RYGB, and higher-watt APC was associated with greater weight loss. (Gastrointest Endosc 2020;91:1078-84.)

Abbreviations: AE, adverse event; APC, argon plasma coagulation; ASGE, American Society for Gastrointestinal Endoscopy; AWL, absolute weight loss; BMI, body mass index; GJA, gastrojejunal anastomosis; LAMS, lumen-apposing metal stent; OR, odds ratio; PPI, proton pump inhibitor; RYGB, Roux-en-Y gastric bypass; TORe, transoral outlet reduction; TWL, total weight loss.

DISCLOSURE: *Dr Jirapinyo has received research support from Apollo Endosurgery, Fractyl, and GI Dynamics, and has served as a consultant to Endogastric Solutions and GI Dynamics. Dr Thompson has served as a consultant for Boston Scientific, Apollo Endosurgery, Fractyl, USGI Medical, Medtronic/Covidien, Olympus/Spiration, and GI Dynamics, has served as an advisory boards member for USGI Medical and Fractyl, has received a research grant and support from USGI Medical, Apollo Endosurgery, Olympus/Spiration, Aspire Bariatrics, Spatz, and GI Dynamics, has served as a general partner for Blueframe Healthcare, and holds stock and royalties for GI Windows. All other authors disclosed no financial relationships.*

0016-5107/$36.00
https://doi.org/10.1016/j.gie.2019.12.036

Received August 17, 2019. Accepted December 15, 2019.

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INTRODUCTION

Roux-en-Y gastric bypass (RYGB) is a common bariatric surgery performed for the treatment of obesity and metabolic diseases. Despite its efficacy, weight regain is not uncommon; most patients start to gain weight after 1 to 2 years. At 10 years, it is estimated that most patients who have undergone RYGB will regain 20% to 30% of the weight they initially lost, and a third of patients will regain almost all of their lost weight.[1,2]

Causes of weight regain are multifactorial. Possible contributing factors include behavioral, psychologic, medical, and anatomic factors. From an anatomic standpoint, gastrogastric fistula and dilation of the gastrojejunal anastomosis (GJA) are associated with weight regain.[3-6] Therefore, correction of these anatomic abnormalities has been a principle of endoscopic and surgical revisional procedures for the treatment of weight regain.

Argon plasma coagulation (APC) around the GJA was first reported as part of transoral outlet reduction (TORe) in 2006 by Thompson et al.[7] In this series, patients who underwent mucosal ablation before suturing experienced more weight loss than those who underwent endoscopic suturing alone. APC in the absence of suturing was subsequently reported by Aly in 2009.[8] Since this case report, 2 series have demonstrated the safety and efficacy of APC with an average weight loss of between 7.7 kg at 12 months and 15.5 kg at 18 months after the procedure.[9,10] Given its relative simplicity and efficacy, the use of APC for the treatment of weight regain will likely increase. Nevertheless, the optimal techniques and settings are unknown, and the current data remain heterogeneous.

This study aims to assess and compare the efficacy of different electrocautery settings of APC for the treatment of weight regain. In addition, predictors of weight loss are determined.

METHODS

Study design

This was a retrospective study of prospectively collected data. The study was conducted at a single quaternary referral center with a bariatric center of excellence from 2014 to 2018. The study was approved by the Institutional Review Board. Patients who underwent APC for weight regain or inadequate weight loss after RYGB were included in the study. For patients who underwent TORe before APC, weight at the time of the first APC session was used as the initial preprocedural weight. For patients who underwent TORe after APC sessions, last weight before TORe was used as the follow-up postprocedural weight in the analysis. Patients who underwent APC with settings other than those stipulated below were excluded.

Procedure

APC was performed using the VIO 300D/APC2 electrosurgical system (ERBE USA, Inc, Marietta, Ga, USA), a 7F (2.3 mm outer diameter) StraightFire APC catheter probe (ERBE USA), and a standard gastroscope (GIF-HQ190; Olympus America, Central Valley, Pa, USA). The GJA rim was ablated circumferentially, and the procedure was repeated every 10 to 12 weeks until the target weight was reached or until the GJA size was 10 mm in diameter (Fig. 1). In this study, the target weight was defined as the weight that corresponded to a body mass index (BMI) of 30 kg/m^2 or percentage total weight loss (% TWL) of 5%.

From 2014 to April 2017, a low-dose APC setting was used. An interim analysis was conducted in April 2017, which revealed a relatively safe profile for this low setting. Therefore, from April 2017, the setting has been adjusted to a high-dose APC setting. In this study, the low-dose APC setting referred to pulsed APC, a flow of 0.8 L/min, effect of 2, and maximum 45 to 55 W. The high-dose APC setting was forced APC, flow of 0.8 L/min, and maximum 70 to 80 W. Only patients who underwent either low-dose or high-dose APC for all treatment sessions were included in the study. Those who underwent a combination of low- and high-dose APC or APC with other settings were excluded.

Outcomes

The primary outcome was a comparison of the efficacy of low- and high-dose APC at treating weight regain or inadequate weight loss at 6 and 12 months after the last APC session, as reported as the absolute weight loss (AWL) and % TWL. Secondary outcomes were technical success rate, clinical success rate, adverse event (AE)

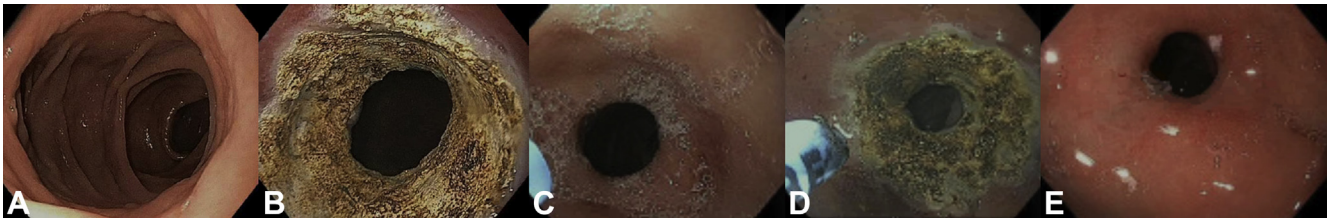

Figure 1. Gastrojejunal anastomosis. **A**, Before APC. **B**, Immediately after argon plasma coagulation (APC). **C**, At a subsequent APC session performed at 3 months. **D**, Immediately after the subsequent APC. **E**, At follow-up.

TABLE 1. Baseline characteristics of 217 patients who had undergone Roux-en-Y gastric bypass at the first argon plasma coagulation session

Characteristic	All (N = 217)	Low-dose APC (n = 116)	High-dose APC (n = 101)	*P* value
Age (years)	48 ± 10	50 ± 10	46 ± 11	.01
Sex (female, %)	192 (89)	102 (89)	90 (88)	.79
Time since RYGB (years)	10.8 ± 5.4	10.8 ± 5.9	10.8 ± 4.9	.96
BMI (kg/m^2)	36.5 ± 7.9	35.2 ± 6.6	38.1 ± 9.1	.01
Amount of weight regain (%)	41.4 ± 29.8	34.7 ± 23.3	49.0 ± 34.4	.0005
Pretreatment GJA size (mm)	18.7 ± 6.2	17.0 ± 4.2	20.8 ± 7.4	.0001
Number of APC sessions	1.9 ± 1.3	2.4 ± 1.5	1.4 ± 0.7	.0001

Data are presented as means ± standard deviation or number (%).
APC, Argon plasma coagulation; *RYGB*, Roux-en-Y gastric bypass; *BMI*, body mass index; *GJA*, gastrojejunal anastomosis.

rate, serious AE rate, predictors of % TWL, and clinically significant weight loss at 12 months.

The amount of weight regain was calculated using the following formula: (weight at the first APC session − nadir weight after RYGB)/(pre-RYGB weight − nadir weight after RYGB) × 100%. Technical success was defined as completion of at least a circumferential coagulation ring. Clinical success was defined as reaching a GJA size of 10 mm or less or reaching the target weight, defined as a BMI ≤30 kg/m^2 or a loss of ≥5% TWL. AWL was calculated using the following formula: weight at the first APC session (kg) − follow-up weight (kg). % TWL was calculated using this formula: (weight at the first APC session − follow-up weight)/weight at first APC session × 100. Clinically significant weight loss referred to at least 5% TWL. Severity of AEs was graded using the American Society for Gastrointestinal Endoscopy (ASGE) grading system.[11]

Statistical analysis

All continuous variables were expressed as means ± standard deviation to be consistent with other bariatric literature. A Shapiro-Wilk test was used to ensure that the data were of normal distribution. Categorical variables were expressed as proportions (%). The Student t test was used to compare continuous variables. A chi-squared test was used to compare categorical variables. Univariable and multivariable regression analyses were used to determine predictors of % TWL and clinically significant weight loss at 12 months after APC. Possible predictors were defined a priori to include only clinically relevant parameters that were not collinear. Standardized β coefficients and odds ratios (ORs) were reported for linear and logistic regression analyses, respectively. A significant 2-sided *P* value was set at .05 or less. All statistical modeling was performed using SAS version 9.4 software (Cary, NC, USA). This study was approved by the Institutional Review Board.

RESULTS

From 2014 to 2018, 217 patients met the inclusion criteria. Of these, 116 (53.5%) and 101 (46.5%) patients underwent only low- or high-dose APC for all sessions, respectively. Thirty-one percent of the patients underwent TORe before APC. The baseline characteristics are shown in Table 1.

Primary outcome

Clinical success. All of the 217 patients were eligible for 6-month follow-up, and 182 were eligible for 12-month follow-up. Of these, data were available for 180 patients at 6 months (82.9% follow-up rate) and 137 patients at 12 months (75.3% follow-up rate).

At 6 months, the low- and high-dose APC groups lost 7.2 ± 7.1 kg and 8.5 ± 8.0 kg, which corresponded to 7.3% ± 6.6% and 8.1% ±7.4% TWL, respectively (*P* = .41). At 12 months, the low- and high-dose APC groups lost 5.3 ± 9.4 kg and 9.3 ± 10.7 kg, which corresponded to 5.1% ± 8.5% and 9.7% ± 10.0% TWL, respectively (*P* = .008) (Fig. 2). At 6 months, 59% and 63% of the low- and high-dose APC groups achieved at least 5% TWL (*P* = .59), respectively. At 12 months, 42% and 60% of the low- and high-dose APC groups achieved at least 5% TWL (*P* = .04), respectively. At the time of follow-up, 71.3% and 62.1% of the low- and high-dose APC groups reached the target weight or a GJA size of 10 mm or smaller (*P* = .22), respectively.

Secondary outcomes

Technical success. A total of 217 patients underwent 411 APC sessions. Specifically, 116 (53.5%) patients underwent 267 low-dose APC procedures (2.4 ± 1.5 procedures/patient), and the remaining 101 (46.5%) patients underwent 144 high-dose APC procedures (1.4 ± 0.7 procedures/patient). The technical success rate was 100%. Of the 411 sessions, 84%, 14%, and 2% were performed with the patient under intravenous conscious sedation, monitored anesthesia care, and general anesthesia, respectively. Fellows participated in 92% of the sessions. All sessions (100%) were performed as an outpatient procedure. All patients (100%) were prescribed a proton pump inhibitor (PPI) and liquid sucralfate and were placed on a liquid diet for 45 days after the procedure.[12] PPIs were prescribed in open capsule form rather than an intact

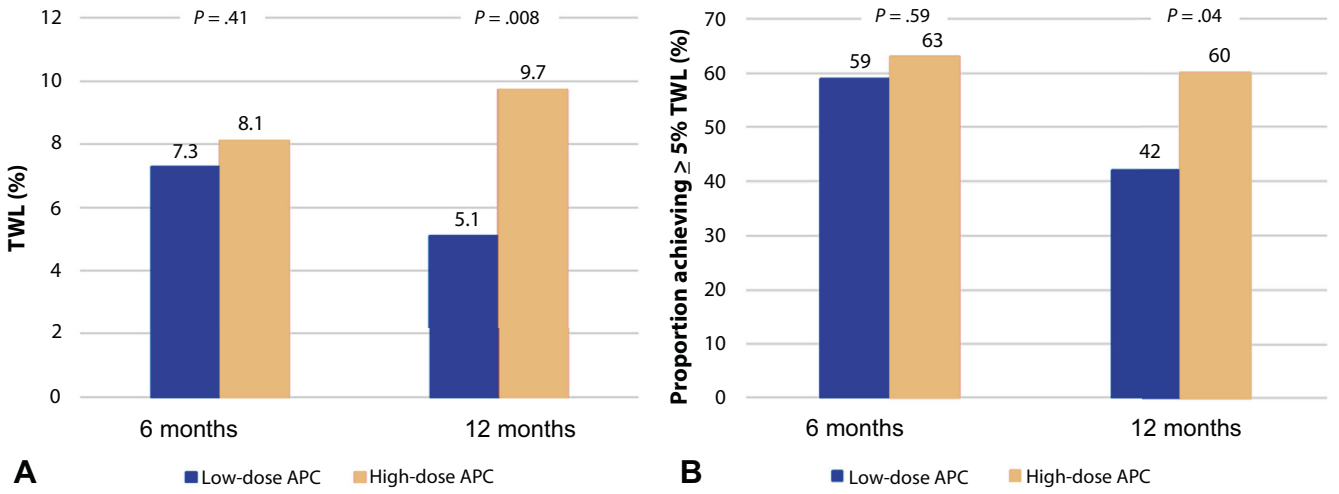

Figure 2. Efficacy of low- and high-dose argon plasma coagulation (APC) for the treatment of weight regain after Roux-en-Y gastric bypass. **A**, Percent total weight loss (TWL) at 6 and 12 months. **B**, Proportion of patients who achieved at least 5% TWL at 6 and 12 months.

capsule form to increase absorption, given the faster transit time after gastric bypass.[13] After 45 days, all patients (100%) underwent maintenance nutritional counseling, which counseled a 1200-kcal solid diet daily. In addition, all patients were counseled to participate in at least 150 minutes per week of physical activity, which must include resistance training. Patients who reported difficulty adhering to this lifestyle intervention were referred to the center's behavioral psychologist for further evaluation and treatment.

For a subset of patients who underwent follow-up endoscopy, post-treatment GJA size was 15.8 ± 7.1 mm (average 6.1% reduction) and 14.9 ± 6.3 mm (average 18.8% reduction) for the low- and high-dose APC groups, respectively.

Adverse events. AEs occurred in 33 of 411 sessions (8.0% AE rate). Of these, 18 were from the low-dose APC group (18 of 267; 6.7% AE rate) and 15 were from the high-dose APC group (15 of 144; 10.4% AE rate) (P = .19). These AEs included GJA stenosis (3.0% in the low-dose group vs 7.6% in the high-dose group, P = .06), GI bleeding (2.6% in the low-dose group vs 2.8% in the high-dose group, P = .93), superficial mucosal coagulation of the Roux limb treated with prophylactic clipping (0.7% in the low-dose group), and esophagitis treated with PPI (0.4% in the low-dose group). All cases of GJA stenoses were treated successfully with hydrostatic balloon dilation alone (11 cases) or hydrostatic balloon followed by a lumen-apposing metal stent (LAMS) in a subsequent session (6 cases). One patient remained symptomatic from GJA stenosis despite hydrostatic balloon and LAMS, and therefore underwent incisional therapy, which resolved the symptom. All cases of GI bleeding were treated successfully either endoscopically with epinephrine injection and clipping (4 cases), clipping alone (2 cases), hemospray (1 case), hot biopsy forceps (1 case), and removal of the irritating suture (1 case), or conservatively with PPI alone (2 cases). None of the AEs met the criteria for a severe AE according to the ASGE lexicon (serious AE rate of 0%).

Predictors of weight loss. Results from the univariable and multivariable regression analyses are shown in Tables 2 and 3. On multivariable regression, high-dose APC was a significant predictor of both % TWL and the likelihood of achieving ≥5% TWL at 12 months (β = 4.9, P = .01; OR, 2.8; 95% confidence interval [CI], 1.1, 7.2; P = .03, respectively) after controlling for age, sex, BMI, weight regain, time since RYGB, GJA size, and number of APC sessions. In addition, the number of APC treatment sessions was also associated with both % TWL and the likelihood of achieving ≥5% TWL at 12 months (β = 1.3, P = .03; OR, 1.5; 95% CI, 1.1, 2.0; P = .01, respectively) after controlling for age, sex, BMI, weight regain, time since RYGB, GJA size, and APC watts.

DISCUSSION

This study demonstrates that APC appears safe and effective at treating weight regain aft RYGB. In addition, using APC settings with a higher frequency output (ie, wattage) is associated with greater weight loss with a similar risk profile.

As far as we know, this is the first study to address optimal APC settings for the treatment of weight regain. Although there have been a few studies evaluating the application of APC for the treatment of weight regain, they used different settings and there have been no comparisons to date. In 2015, Baretta et al[9] reported their experience from Brazil using APC with a flow of 2 L/min and output of 90 W to treat weight regain in 30 patients. However, the mode of APC was not reported. In this study, a total of 3 treatment sessions were performed over an 8-week

TABLE 2. Predictors of % total weight loss at 12 months after argon plasma coagulation treatment sessions for weight regain in patients with Roux-en-Y gastric bypass

	Univariable			Multivariable		
Variable	**β**	**SE**	***P* value**	**β**	**SE**	***P* value**
Age	−0.01	0.08	.91	0.10	0.09	.24
Male sex	−6.18	2.87	.03	−4.57	2.96	.12
BMI	0.38	0.12	.003	0.28	0.14	.05
Weight regain	0.11	0.04	.004	0.08	0.04	.06
Duration from RYGB	−0.06	0.14	.68	−0.18	0.14	.20
Pre-GJA size	0.25	0.14	.07	0.09	0.14	.52
High-dose APC	4.51	1.68	.008	4.88	1.87	.01
No. of APC sessions	0.49	0.55	.37	1.28	0.56	.03

P values <.05 are statistically significant.
SE, Standard error; *BMI*, body mass index; *RYGB*, Roux-en-Y gastric bypass; *GJA*, gastrojejunal anastomosis; *APC*, argon plasma coagulation.

TABLE 3. Predictors of the likelihood of achieving at least 5% total weight loss at 12 months after argon plasma coagulation treatment sessions for weight regain in patients with Roux-en-Y gastric bypass

	Univariable		Multivariable	
Variable	**Odds ratio [95% CI]**	***P* value**	**Odds ratio [95% CI]**	***P* value**
Age	0.99 [0.95-1.02]	.51	1.01 [0.97-1.05]	.68
Male sex	4.58 [0.95-22.1]	.06	2.54 [0.47-13.70]	.28
BMI	1.09 [1.02-1.15]	.006	1.09 [1.01-1.17]	.03
Weight regain	1.02 [1.00-1.03]	.07	1.01 [0.99-1.03]	.39
Duration from RYGB	0.99 [0.94-1.05]	.82	0.97 [0.90-1.04]	.39
Pre-GJA size	1.05 [0.99-1.12]	.11	1.04 [0.96-1.13]	.29
High-dose APC	2.15 [1.02-4.52]	.04	2.80 [1.10-7.16]	.03
No. of APC sessions	1.21 [0.95-1.54]	.12	1.50 [1.11-2.02]	.01

P values <.05 are statistically significant.
CI, Confidence interval; *BMI*, body mass index; *RYGB*, Roux-en-Y gastric bypass; *GJA*, gastrojejunal anastomosis; *APC*, argon plasma coagulation.

period. After 3 sessions, patients lost 15.5 kg with a decrease in GJA size of 17 mm (66.9%). The AE rate was 6.7%, all of which were GJA stenosis. In 2018, Moon et al[10] published a case series on 558 patients from 8 bariatric centers, 7 in Brazil and 1 in the United States. In this study, the APC settings were pulsed APC, flow of 2 L/min, and output of 70 W. At 12 months, the average weight loss was 7.7 kg. The AE rate was 5.4%; the most common AE was GJA stenosis (2.7%). Neither study reported sufficient data to calculate % TWL, and the data are inadequate for formal comparison.

It has been demonstrated that a higher-power APC setting is associated with a deeper tissue effect. Specifically, duration of APC application, power setting, and distance between the probe and target tissue all contribute to coagulation depth in order of decreasing importance.[12-14] Other than power, these variables are difficult to control precisely. The mode, or waveform, can also affect the depth of penetration; however, this was collinear with the power in our study and could not be evaluated. Goulet et al[15] previously demonstrated in an in vivo porcine colon model that higher-watt APC was associated with a deeper tissue effect. Specifically, muscularis propria injury occurred in 22% of lesions with 10 W, 62% of lesions with 20 W, and 86% of lesions with 40 W, with all other variables remaining constant. However, this finding has yet to be clinically proven. In our study, it is likely that higher wattage is also associated with deeper tissue injury around the GJA. This may then lead to more-effective tissue scarring, and thus greater reduction in GJA aperture and greater weight loss. In our series, GJA stenosis was the most-common AE after APC. Specifically, the overall GJA stenosis rate was 4.6%, 3.0% in the low-dose APC group and 7.6% in the high-dose APC group. Although these rates (3.0% versus 7.6%) were not statistically significant (P = .06), it appeared that there was a trend toward a higher stenotic rate with the higher wattage. This was likely due to more tissue injury at the muscularis propria associated with the higher wattage. All stenoses in our cohort were treated successfully via an endoscopic approach using

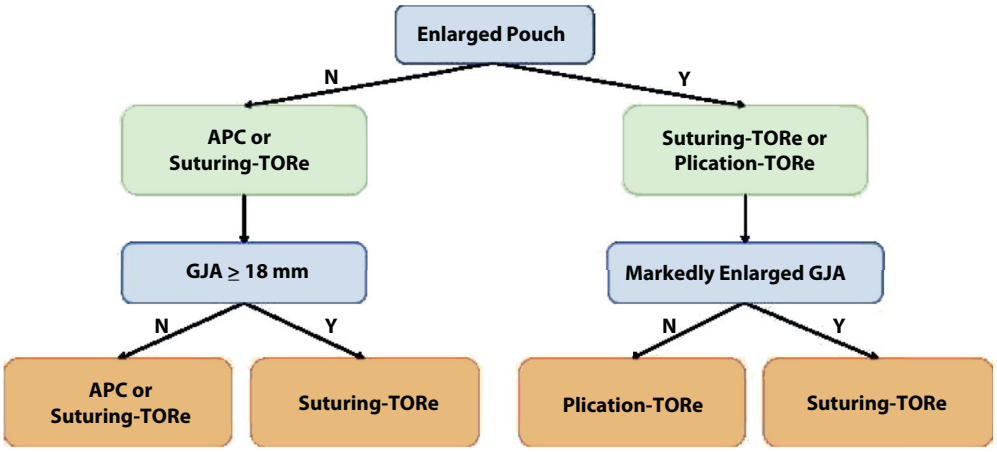

Figure 3. Algorithm for the endoscopic treatment of weight regain after Roux-en-Y gastric bypass. *APC*, Argon plasma coagulation; *GJA*, gastrojejunal anastomosis; *TORe*, transoral outlet reduction.

hydrostatic balloon dilation, LAMS placement, or incisional therapy. No surgical revision was required.

In our practice, we have found that larger GJA apertures respond better to endoscopic suturing than APC and require fewer treatment sessions. Specifically, we have shown that when the GJA is equal to or larger than 18 mm, endoscopic suturing is the preferred approach. On the other hand, when the GJA is smaller than 18 mm, suturing or APC results in similar weight loss. Therefore, either therapy may be applied for a smaller but incompetent GJA.[16] In some circumstances, when the pouch is markedly enlarged and the GJA is only modestly dilated, endoscopic plication may be used (Fig. 3). This algorithm is currently being validated by our group.

There are a few limitations to this study. Due to its retrospective nature, some patients were lost to follow-up, which may have introduced bias. In the study, the follow-up rates of 82.9% and 75.3% at 6 and 12 months, respectively, are comparable to those of most retrospective studies. In addition, the baseline characteristics of the low- and high-dose APC groups are relatively different; the high-dose group members were younger and had higher initial BMI, weight regain, and GJA size. Nevertheless, these factors were adjusted for in the regression models, which demonstrated that high-dose APC remained a significant predictor of weight loss. In this study, the baseline GJA was only modestly dilated, limiting any comparison with TORe because this is typically performed in larger anastomoses. Although attempts were made to keep the duration of APC and the distance between the probe and target tissue constant, exact control of these factors could not be assured. Nevertheless, all cases were supervised by the same expert bariatric endoscopist to minimize heterogeneity. In addition, all of these factors are encountered during real-life endoscopy and likely make the results of the study more representative of the typical usage of APC.

In conclusion, APC of the GJA appears to be safe and effective at reducing the GJA size and at treating weight regain after RYGB. Application of higher power settings of 70 to 80 W appears to be associated with greater weight loss and a comparable rate of GJA stenosis. Given the prevalence of weight regain after RYGB and the availability of APC in most endoscopy units, this technology may offer a solution for this patient population. Nevertheless, in this study, patients had only modestly dilated GJA and repeated sessions were required, limiting the generalizability of these results. Larger studies with longer-term data are now needed to better understand optimal patient selection and durability of the procedure.

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