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

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Abstract

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

Methods: This was a single-center retrospective study of RYGB patients who underwent APC from 2014 to 2018 for weight regain. Patients receiving only low-dose APC (45-55 watts) or high-dose APC (70-80 watts) were compared. Primary outcome was the difference in percent total weight loss (%TWL) between 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 inclusion criteria and underwent 411 APC sessions. Of these, 116 (53.5%) patients underwent 267 low-dose APC (2.4±1.5 sessions/patient) and 101 (46.5%) patients underwent 144 high-dose APC (1.4±0.7 sessions/patient). Follow-up

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P.J.: Study design and concept, data collection, statistical analysis, manuscript preparation
D.D.: Study design and concept, data collection
W.D. and G.F.: Data collection
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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=0.41). At 12 months, the low- and high-dose groups experienced 5.1±8.5% and 9.7±10.0% TWL, respectively (p=0.008). Technical success was 100%. The overall AE rate was 8.0%, with the most common one being GJA stenosis (4.6%). The GJA stenosis rate was similar between the low- and high-dose groups (3.0% vs 7.6%, p=0.06). 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, with higher-watt APC being associated with greater weight loss.

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 with most patients starting to gain weight after 1 to 2 years. At 10 years, it is estimated that most RYGB patients will regain 20% to 30% of the weight they initially lost with a third of patients regaining almost all of their lost weight[1,2].

Etiologies of weight regain are multifactorial. Possible contributing factors include behavioral, psychological, medical, and anatomical factors. From an anatomical standpoint, gastrogastric fistula and dilation of the gastrojejunal anastomosis (GJA) are associated with weight regain[3-6]. Therefore, correction of these anatomical 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 that underwent mucosal ablation before suturing experienced more weight loss than those that underwent endoscopic suturing alone. APC in the absence of suturing was subsequently reported by Aly in 2009[8]. Since this case report, there have been 2 series demonstrating safety and efficacy of APC with an average weight loss of between 7.7 kilograms (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 grow. Nevertheless, the optimal techniques and settings are unknown with the current data remaining heterogeneous.

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

METHODS

Study Design

This study was a retrospective study of prospectively collected data. The study was conducted at a single quaternary referral center with the 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

Argon plasma coagulation was performed using the VIO 300D/APC2 electrosurgical system (ERBE USA, Inc, Marietta, Ga, USA), a 7F (2.3 mm outer diameter [OD]) StraightFire APC catheter probe (ERBE USA, Inc, Marietta, Ga, USA), and a standard gastroscope (GIF-HQ190; Olympus America, Central Valley, Pa, USA). The GJA rim was circumferentially ablated and the procedure was repeated every 10 to 12 weeks until target weight was reached or until the GJA size was 10 mm in diameter (Figure 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 percent 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 of this low setting. Therefore, from April 2017 on, the setting has been adjusted to a high-dose APC setting. In this study, low-dose APC setting referred to pulsed APC, flow of 0.8 liters per minute (L/min), effect of 2, and max watts of 45 to 55 watts. High-dose APC setting was forced APC, flow of 0.8 L/min, and max watts of 70 to 80 watts. 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

Primary outcome was a comparison of efficacy for 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 in absolute weight loss (AWL) and %TWL. Secondary outcomes were technical success rate, clinical success rate, adverse event (AE) rate, serious adverse event (SAE) rate, and predictors of %TWL and clinically significant weight loss at 12 months.

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) x 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 formula: weight at the first APC session (kg) – follow-up weight (kg). %TWL was calculated using the formula: (weight at the first APC session – follow-up weight) / weight at first APC session x 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 mean ± standard deviation (SD) to keep it 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 (%). A 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 ratio (OR) were reported for linear and logistic regression analyses, respectively. A significant 2-sided *P* value was set at 0.05 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, a total of 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. Baseline characteristics are shown in Table 1.

Primary Outcome

Clinical Success—Out of 217 patients, all 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=0.41). 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=0.008) (Figure 2). At 6 months, 59% and 63% of the low- and high-dose APC groups achieved at least 5% TWL (p=0.59), respectively. At 12 months, 42% and 60% of the low- and high-dose APC groups achieved at least 5% TWL (p=0.04), 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=0.22), 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). Technical success rate was 100%. Of the 411 cases, 84%, 14%, and 2% were performed with the patient under intravenous conscious sedation (IVCS), monitored anesthesia care (MAC), and general anesthesia (GA), respectively. Fellows participated in 92% of the cases. All cases (100%) were performed as an outpatient procedure. All patients (100%) were prescribed proton pump inhibitor and liquid sucralfate and were placed on a liquid diet for 45 days after the procedure[12]. Of note, a PPI was

prescribed as an open capsule form rather than an intact capsule form to increase absorption given a faster transit time postgastric bypass[13].

After 45 days, all patients (100%) underwent maintenance nutritional counseling, which included 1,200 kcal solid diet daily. Additionally, 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 of 6.1% reduction) and 14.9 ± 6.3 mm (average of 18.8% reduction) for the low- and high-dose APC groups, respectively.

Adverse Events—Adverse events occurred in 33 out of 411 cases (8.0% AE rate). Of these, 18 were from low-dose APC (18/267; 6.7% AE rate) and 15 were from high-dose APC (15/144; 10.4% AE rate) (p=0.19). These AEs included GJA stenosis (3.0% in low-dose versus 7.6% in high-dose groups, p=0.06), GI bleeding (2.6% in low-dose versus 2.8% in high-dose groups, p=0.93), superficial mucosal coagulation of the Roux limb treated with prophylactic clipping (0.7% in low-dose group), and esophagitis treated with PPI (0.4% in low-dose group). All GJA stenoses were treated successfully with hydrostatic balloon dilation alone (11) or hydrostatic balloon followed by lumen-apposing metal stent (LAMS) on a subsequent session (6). One patient remained symptomatic from GJA stenosis despite hydrostatic balloon and LAMS, and therefore underwent incisional therapy, which resolved the symptom. All GI bleeding cases were successfully treated either endoscopically with epinephrine injection and clipping (4), clipping alone (2), hemospray (1), hot biopsy forceps (1), and removal of the irritating suture (1), or conservatively with PPI alone (2). None of the AEs met criteria for being severe according to the ASGE lexicon (SAE rate of 0%).

Predictors of Weight Loss—Results from 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=0.01 and OR of 2.8 [1.1,7.2], p=0.03, respectively) after controlling for age, sex, BMI, weight regain, duration from RYGB, GJA size and number of APC sessions. Additionally, 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=0.03 and OR of 1.5 [1.1,2.0], p=0.01, respectively) after controlling for age, sex, BMI, weight regain, duration from RYGB, GJA size, and APC watts.

DISCUSSION

This study demonstrates that APC appears safe and effective at treating weight regain aft RYGB. Additionally, 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 watts to treat weight regain in 30 patients. However, mode of APC was not reported. In this study, a total of 3 treatment sessions were performed at an 8-week interval. 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 in Brazil (7) and the U.S. (1). In this study, the APC settings were pulsed APC, flow of 2 L/min, and output of 70 watts. At 12 months, the average weight loss was 7.7 kg. The AE rate was 5.4% with the most common one being 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 precisely control. Mode, or waveform, can also affect the depth of penetration, however, this was collinear with power in our study and could not be evaluated. Goulet et al. previously demonstrated in an in vivo porcine colon model that higher watt APC was associated with deeper tissue effect. Specifically, muscularis propria injury occurred in 22% of lesions with 10 watts, 62% of lesions with 20 watts, and 86% of lesions with 40 watts holding other variables constant[15]. This finding however 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 adverse event after APC. Specifically, the overall GJA stenosis rate was 4.6%, with 3.0% in the low-dose and 7.6% in the high-dose APC groups, respectively. Although these rates (3.0% versus 7.6%) were not statistically significant (p=0.06), 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 higher wattage. All stenoses in our cohort were treated successfully via an endoscopic approach using hydrostatic balloon dilation, LAMS placement or incisional therapy. No surgical revision was required.

Of note, 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 yet incompetent GJA[16]. In some circumstances, when the pouch is markedly enlarged and the GJA is only modestly dilated, endoscopic plication may be used (Figure 3). This algorithm is currently being validated by our group.

There are a few limitations to this study. Due to its retrospective nature, there are some patients who were lost to follow up, which may have introduced bias. In the study, the follow-up rate of 82.9% and 75.3% at 6 and 12 months, which is comparable to those of most retrospective studies. Additionally, baseline characteristics of the low- and high-dose

APC groups are relatively different with the high-dose group being younger and having 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 to TORe because this is typically performed in larger anastomoses. Last, 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 watts 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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Acronyms and Abbreviations

APC	argon plasma coagulation
GJA	gastrojejunal anastomosis
RYGB	Roux-en-Y gastric bypass
TWL	total weight loss
AE	adverse event
TORe	transoral outlet reduction
OD	outer diameter
AWL	absolute weight loss
SAE	serious adverse event
Kg	kilogram
S.D.	standard deviation
O.R.	odds ratio

BMI	body mass index
IVCS	intravenous conscious sedation
MAC	monitored anesthesia care
GA	general anesthesia
GI	gastrointestinal
PPI	proton pump inhibitor
LAMS	lumen-apposing metal stent
ASGE	American Society of Gastrointestinal Endoscopy
C.I.	confidence interval
TX	Texas
IOP	Incisionless Operating Platform
CA	California

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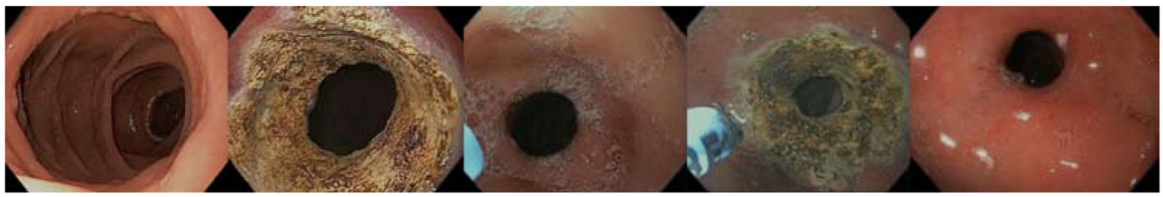

Figure 1.
Gastrojejunal anastomosis. A, Before APC. B, Immediately after APC. C, At a subsequent APC session performed at 3 months. D, Immediately after the subsequent APC. E, At follow-up.

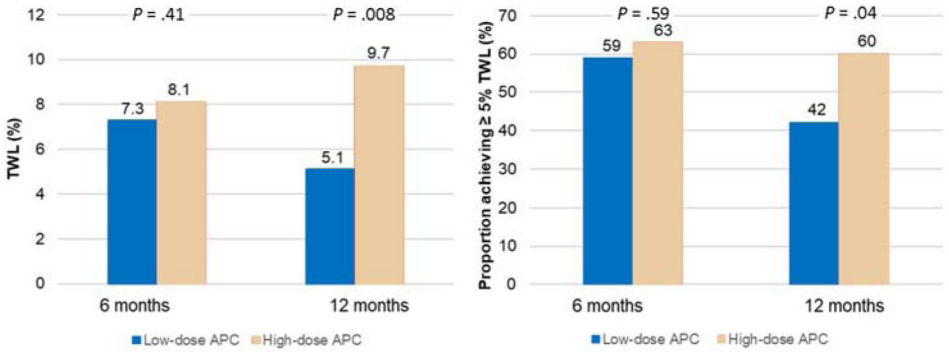

Figure 2.

Efficacy of low- and high-dose argon plasma coagulation (APC) for the treatment of weight regain after RYGB. 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.

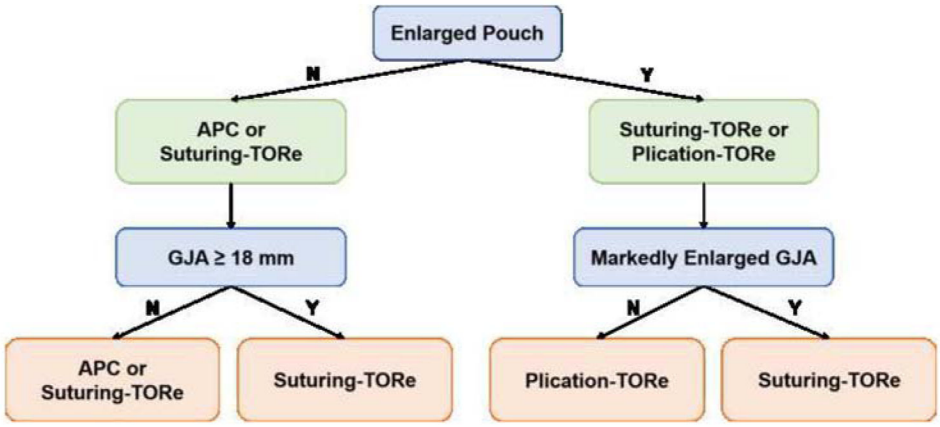

Figure 3.
Algorithm for the endoscopic treatment of weight regain after RYGB.

Table 1.

Baseline characteristics of 217 RYGB patients at the first argon plasma coagulation (APC) session. Data presented as mean ± SD or N (%).

	All N = 217	**Low-dose APC N = 116**	**High-dose APC N = 101**	***P* value**
Age (years)	48 ± 10	50 ± 10	46 ± 11	0.01
Sex (female, %)	192 (89)	102 (89)	90 (88)	0.79
Duration from RYGB (years)	10.8 ± 5.4	10.8 ± 5.9	10.8 ± 4.9	0.96
BMI (kg/m^2)	36.5 ± 7.9	35.2 ± 6.6	38.1 ± 9.1	0.01
Amount of weight regain (%)	41.4 ± 29.8	34.7 ± 23.3	49.0 ± 34.4	0.0005
Pretreatment GJA size (mm)	18.7 ± 6.2	17.0 ± 4.2	20.8 ± 7.4	0.0001
Number of APC sessions	1.9 ± 1.3	2.4 ± 1.5	1.4 ± 0.7	0.0001

Table 2.

Predictors of %TWL at 12 months after APC treatment sessions for weight regain in patients with RYGB

Univariable				Multivariable			
Variables	**β**	**SE**	***P* value**	**Variables**	**β**	**SE**	***P* value**
Age	−0.01	0.08	0.91	Age	0.10	0.09	0.24
Male sex	**−6.18**	**2.87**	**0.03**	Male sex	−4.57	2.96	0.12
BMI	**0.38**	**0.12**	**0.003**	BMI	0.28	0.14	0.05
Weight regain	**0.11**	**0.04**	**0.004**	Weight regain	0.08	0.04	0.06
Duration from RYGB	−0.06	0.14	0.68	Duration from RYGB	−0.18	0.14	0.20
Pre-GJA size	0.25	0.14	0.07	Pre-GJA size	0.09	0.14	0.52
High-dose APC	**4.51**	**1.68**	**0.008**	**High-dose APC**	**4.88**	**1.87**	**0.01**
No. of APC sessions	0.49	0.55	0.37	**# of APC sessions**	**1.28**	**0.56**	**0.03**

Table 3.

Predictors of the likelihood of achieving at least 5% TWL at 12 months after APC treatment sessions for weight regain in patients with RYGB

Univariable			Multivariable		
Variables	**Odds ratio [95% C.I.]**	***P* value**	**Variables**	**Odds ratio [95% C.I.]**	***P* value**
Age	0.99 [0.95,1.02]	0.51	Age	1.01 [0.97,1.05]	0.68
Male sex	4.58 [0.95,22.1]	0.06	Male sex	2.54 [0.47,13.70]	0.28
BMI	**1.09 [1.02,1.15]**	**0.006**	**BMI**	**1.09 [1.01,1.17]**	**0.03**
Weight regain	1.02 [1.00,1.03]	0.07	Weight regain	1.01 [0.99,1.03]	0.39
Duration from RYGB	0.99 [0.94,1.05]	0.82	Duration from RYGB	0.97 [0.90,1.04]	0.39
Pre-GJA size	1.05 [0.99,1.12]	0.11	Pre-GJA size	1.04 [0.96,1.13]	0.29
High-dose APC	**2.15 [1.02,4.52]**	**0.04**	**High-dose APC**	**2.80 [1.10,7.16]**	**0.03**
# of APC sessions	1.21 [0.95,1.54]	0.12	**# of APC sessions**	**1.50 [1.11,2.02]**	**0.01**