Title Page

Full title: Endoscopic Sleeve Gastroplasty with Argon Plasma Coagulation: A Novel Technique

Short title: ESG combined with APC

Authors:

Mohamad I. ITANI[1], MD (email: Mitani2@jh.edu)

Jad FARHA[1], MD (Email: Jfarha1@jh.edu)

Adrian SARTORETTO[2], BMedSc, MBBS (Email: adrians@bmiclinic.com.au)

Shahem ABBARH[1], MBBS (Email: dr.shahem94@gmail.com)

Dilhana BADURDEEN[1], MD (Email: dbadurd1@jhmi.edu)

Diogo Turiani Hourneaux DE MOURA[3], MD, PhD (Email: dthmoura@hotmail.com)

Vivek KUMBHARI[1], MD, PhD (Email: vkumbhari@gmail.com)

Affiliations:

1 Department of Medicine, Division of Gastroenterology and Hepatology, The Johns Hopkins Medical Institutions, Baltimore, MD 21287, USA

2 The BMI Clinic, Double Bay, NSW 2028, Australia

3 Endoscopy Unit-Gastroenterology Department - Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo 2250, Brazil.

Corresponding Author:

Vivek Kumbhari, MD, PhD

Associate Professor of Medicine

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Director of Bariatric Endoscopy

Division of Gastroenterology and Hepatology

Johns Hopkins Medical Institutions

Tel: +1 410 292-2077

Fax: +1 410 550-7861

Email: vkumbhari@gmail.com

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ABSTRACT

Aim

The endoscopic sleeve gastroplasty (ESG) is a minimally invasive procedure in which the anterior and posterior aspects of the greater curvature are stitched endoscopically, producing a sleeve-like anatomy mimicking that in sleeve gastrectomy. However, suture dehiscence and enlargement of the stomach within months of the procedure has been observed. Argon plasma coagulation (APC) is widely used in gastrointestinal endoscopy and has the ability to induce scarring and fibrosis. We coupled ESG with APC to evaluate its potentional to improve durability.

Methods

A 46-year-old female with obesity presented for ESG. Pre-procedure weight was 117 kg with a BMI of 41.4 kg/m^2. After each plication was complete, APC (60W, argon flow rate 1.2L/min) was used to ablate the mucosal surface of the exposed plicated mucosa. APC was applied until the mucosal color was a dark brown, indicating sufficient and successful mucosal and submucosal ablation.

Results

The procedure was successful, and the patient recovered without peri or post-operative complications. Procedure time was 47 minutes. A total of 7 sutures were used. At six months follow-up, the patient lost 17 kg (37.5lbs), equivalent to 14.5% total body weight loss (TBWL) and had a BMI of 35.4 km/m^2. Endoscopic follow-up at 6 months revealed enhanced fibrosis along the plications resulting in a superior sleeve-like lumen.

Conclusions

The combination of ESG with APC could act in a synergistic manner to improve weight loss without adding significant procedure time. Further investigation is imperative to determine whether it should be widely recommended.

Key words: Argon plasma coagulation; Endoscopic sleeve gastroplasty; Endoscopic suturing

INTRODUCTION

Obesity is a worldwide public health concern, with more than 39.8% of US adults and 18.5% of youth being obese as of 2015-2016 (1). Obese patients resorting to non-procedural weight loss strategies such as diet, lifestyle modifications, and medical therapy often do not reach the weight loss goal needed to reverse or significantly improve obesity-related comorbidities, such as diabetes mellitus type 2, hypertension, or gastroesophageal reflux disease (2). Moreover, non-procedural weight loss techniques are inferior to procedural weight loss techniques such as endoscopic bariatric techniques and bariatric and metabolic surgery with respect to the incidence of weight recidivism (3, 4).

Endoscopic sleeve gastroplasty (ESG) is a minimally invasive procedure in which the anterior and posterior walls as well as the greater curvature of the stomach are stitched endoscopically using the OverStitch device (Apollo Endosurgery, Austin, TX, USA) to produce a restrictive tubular anatomy mimicking the endoluminal appearances of laparoscopic sleeve gastrectomy (5). The procedure is most suited for obese patients who either do not qualify for bariatric surgery, or do not wish to undergo surgery due to the perceived risks.

Though there is a plethora of uncontrolled data pertaining to the clinical outcomes of ESG, there is a paucity of data with respect to the anatomical configuration of the stomach in the months and years post ESG. Reports suggest that the sutures dehisce, and the stomach enlarges several months post ESG, regardless of the suturing technique, pattern, or number of sutures used (6). A method that would significantly delay and reduce the

expansion of the stomach over time would address a major pitfall of the procedure and likely improve clinical outcomes.

Argon plasma coagulation (APC) is a thermal based technology that is being increasingly used in gastrointestinal endoscopy to intentionally induce tissue injury resulting in fibrosis and more robust luminal reduction. A prime example of that application is the transoral outlet reduction (TORe) using APC in addition to endoscopic suturing (7). In order to induce fibrosis of the stomach and increase the longevity of the sleeve like conformation, we applied APC to the accordioned stomach wall in a patient undergoing ESG.

METHODS

Patient

A 46-year-old female with a history of hypothyroidism who unsuccessfully lost weight through diet, lifestyle modifications as well as two trials of intra-gastric balloon insertions was referred for endoscopic sleeve gastroplasty (ESG). Her pre-procedure weight was 117 kg with a BMI of 41.4 kg/m^2. The procedure was performed under institutional approval during an American Society for Gastrointestinal Endoscopy (ASGE)-sponsored live endoscopy meeting. Informed consent was also obtained from the patient.

Procedural Technique

An initial endoscopic evaluation was performed to exclude contraindications to performing ESG such as the presence of a hiatal hernia greater than 3cm and potentially malignant lesions. The procedure was executed using general anesthesia and CO_2

insufflation with the patient in the supine position. A standard dual-channel GIF-2TH180 gastroscope (Olympus Co., Tokyo, Japan) was used during the procedure.

Using APC (60W, argon gas flow rate 1.2L/min) with a 2.3mm circumferential probe (ERBE Elektromedizin GmbH, Tübingen, Germany), the borders of the plications were marked along the anterior and posterior walls of the stomach from the incisura angularis to the gastroesophageal junction (Video 1). The endoscopic suturing system, OverStitch (Apollo Endosurgery Inc., Austin, TX, USA), was loaded with a 2-0 polypropylene suture and then advanced to the incisura angularis where the first suture was placed on the anterior wall. A tissue retraction screw Helix (Apollo Endosurgery Inc., Austin, Tx, USA) was used to ensure full-thickness stitch placement. Four helix turns were employed to ensure the muscularis propria was reached. Sutures were applied in a 'U shaped' pattern ending 2-3cm proximal to the first bite. The suture was then cinched, creating a plication. Subsequently, APC (60W, flow rate 1.2L/min) was used in order to ablate the mucosal surface of the completed plication and promote fibrosis. APC was applied until the mucosal color was a dark brown, indicating sufficient effect and successful mucosal and submucosal ablation **(Figure 1 and Video 1)**. The APC process was repeated after each plication until the gastroesophageal junction was reached, resulting in a tubular shaped lumen. The sleeve diameter measured approximately 15mm on completion of the procedure **(Figure 2)**.

RESULTS

The prospect of inducing early fibrosis is thought to contribute to a longer lasting effect on the final anatomy of the newly created sleeve appearing lumen. Fibrotic bridges have been shown to develop after ESG (6, 8). The reason for these changes may be due to the serosal-to-serosal approximation achieved by full-thickness bites. A recent study published by our group has shown that fibrosis indeed does occur post-ESG; but also, there is a significant amount of suture dehiscence. It is not yet known whether the stomach reverts to its original configuration on long-term follow-up after the full-thickness sutures dehisce. Thus, it is imperative to work towards ascertaining the most optimal ESG methodology which will ensure luminal restriction for the longest period of time.

The patient underwent ESG with APC ablation successfully without intra- and post-operative complications and was discharged home on the same day. Procedure time from scope-in to scope-out was 47 minutes. Total APC time was 12 minutes. A total of 7 sutures were deployed. From a subjective standpoint, the patient did not endure increased pain as a result of the addition of APC. At six months post-ESG, the patient lost 17 kg (37.5 lbs), equating to 14.5% TBWL, and had a BMI of 35.4 kg/m^2. On endoscopic follow-up, enhanced fibrosis was observed along the greater curvature **(Figure 3)**. The suture line was intact the the appearance of a sleeve-like lumen.

DISCUSSION

APC is commonly used in procedures such as the TORe and is vital in causing luminal narrowing to treat weight regain after bariatric surgery (9). The technique uses thermal

energy from the ionized argon gas to ablate the gastrointestinal tissue to promote scarring. A systematic review and meta-analysis has shown that TORe with full-thickness suturing and APC results in superior weight loss at ≥1-year when compared to TORe with suturing alone (10.64kg ± 4.52, 207 patients, versus 5.66kg ± 2.96, 315 patients, $p<0.0001$, respectively) (10). In an attempt to explain these findings, the authors related the increase in weight loss to deeper submucosal-to-submucosal tissue apposition which was achieved by APC, leading to a more effective and durable weight outcome.

Furthermore, APC ablation has been used as a standalone obesity therapy in both a rat and porcine model (11, 12). Results have been promising so far, with improvement of obesity-related comorbidities, such as hypertension and diabetes mellitus, along with a decrease in body weight as well as visceral adiposity. Additionally, gastric mucosal ablation successfully ablated the ghrelin-releasing cells in the mucosa. By eight weeks of follow up, though histology showed that the mucosal layer had regenerated, ghrelin-producing cells recovered much more slowly, which adds a hormonal component promoting weight loss. Therefore, the combination of ESG with APC could possibly act in a synergistic manner, above and beyond the effect of scarring, to augment weight loss. On the other hand, the slight additional time needed when adding APC, potential increase in adverse events, and the long-term implications of APC to the stomach are important future considerations. There is theoretic potential for suture damage due to the high energy of APC used. However, as the suture after being cinched is short in length and hidden, the tissue bunches up essentially covering and protecting the suture. Another option would be to perform the APC prior to suturing, but this would add additional time

due to the need of ablating a wider surface area. Integrating APC into ESG seems to be safe and is technically comparable to TORe. Further investigation comparing endoscopic suturing alone to combined endoscopic suturing with APC is imperative to determine whether it should be widely recommended.

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Figure and Video Legends:

Figure 1: Endoscopic view of showing argon plasma coagulation probe firing through OverStitch system on the mucosal surface after a gastric plication.

Figure 2: Endoscopic view after completion of endoscopic sleeve gastroplasty with argon plasma coagulation showing a 15mm sleeve diameter.

Figure 3: Endoscopic view at 6 months post-endoscopic sleeve gastroplasty showing enhanced fibrotic bridges.

Video 1: Video recording showcasing the technique of endoscopic sleeve gastroplasty with argon plasma coagulation