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ORIGINAL CONTRIBUTIONS

Endoscopic Sleeve Gastroplasty for Obesity: a Multicenter Study of 248 Patients with 24 Months Follow-Up

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Abstract

Background Endoscopic sleeve gastroplasty (ESG) is a technique for managing mild to moderately obese patients. We aimed to evaluate the long-term outcomes, reproducibility, and predictors of weight response in a large multicenter cohort.

Methods Patients who underwent ESG between January 2013 and December 2015 in three centers were retrospectively analyzed. All procedures were performed using the Apollo OverStitch device (Apollo Endosurgery, Austin, TX). We performed per protocol (PP) and intention-to-treat (ITT) analyses, where patients lost to follow-up were considered failures. Multivariable linear and logistic regression analyses were performed.

Results We included 248 patients (mean age 44.5 ± 10 years, 73% female). Baseline BMI was 37.8 ± 5.6 kg/m^2. At 6 and 24 months, 33 and 35 patients were lost to follow-up, respectively. At 6 and 24 months, %TBWL was 15.2 [95%CI 14.2–16.3] and 18.6 [15.7–21.5], respectively. Weight loss was similar between centers at both follow-up intervals. At 24 months,

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% of patients achieving ≥10% TBWL was 84.2 and 53% with PP and ITT analyses, respectively. On multivariable linear regression analysis, only %TBWL at 6 months strongly predicted %TBWL at 24 months (adjusted for age, gender, and baseline BMI, $\beta = 1.21$, $p < 0.001$). The odds of achieving ≥10%TBWL at 24 months if a patient achieved <10%TBWL at 6 months is 0.18 [0.034–0.84]. Five (2%) serious adverse events occurred.

Conclusions ESG effectively induces weight loss up to 24 months in moderately obese patients. Failure to achieve adequate weight loss can be predicted early, and patients should be offered adjunctive therapies to augment it.

Keywords Gastric restriction · Stomach · Weight loss procedure · Endoscopic

Introduction

It is now evident that bariatric and metabolic surgical interventions offer a more efficacious and durable weight loss than non-surgical approaches [1]. This efficacy is mediated by multiple anatomic manipulations to the stomach and small intestines, resulting in physiological alterations in GI neuroendocrine signaling, motility, autonomic nervous system signaling, bile acid circulation, and microbiota. These changes lead to a decrease in body adiposity, as well as weight-dependent and -independent improvements in the metabolic and mechanical consequences of obesity [2]. Surgical weight loss interventions, however, are limited by appeal, availability, cost, and short- and long-term risks [3]. Thus, endoscopic bariatric therapies (EBTs) that mimic the anatomical manipulations of surgical procedures offer an intuitive alternative at lower costs, risks, and appeal to more patients with obesity, provided they offer a safe and efficient alternative [4, 5].

Endoscopic sleeve gastroplasty (ESG) is an incisionless, minimally invasive technique, which has been developed for bariatric treatment. ESG reduces gastric capacity by creating a restrictive sleeve through a series of endoluminally placed full-thickness triangular sutures extending from the prepyloric antrum to the gastroesophageal junction. This imbricates the greater curvature of the stomach along its long access and is accomplished using a Food and Drug Administration (FDA)-approved and commercially available endoscopic suturing device (Overstitch; Apollo Endosurgery, Austin, TX) (Fig. 1). Subsequent to a pilot feasibility study [6], multiple groups have further demonstrated the technical feasibility, safety, and short-term efficacy in a variety of clinical settings (academic and private) both in and outside the USA [7–12]. A recent study also demonstrated statistically significant physiologic changes associated with ESG including early satiety, delayed gastric emptying, and a trend toward increased insulin sensitivity [13]. However, the long-term durability and predictors of poor response are yet to be defined. We aim to report the long-term response rate, reproducibility of results, and predictors of poor long-term response in a large multicenter cohort.

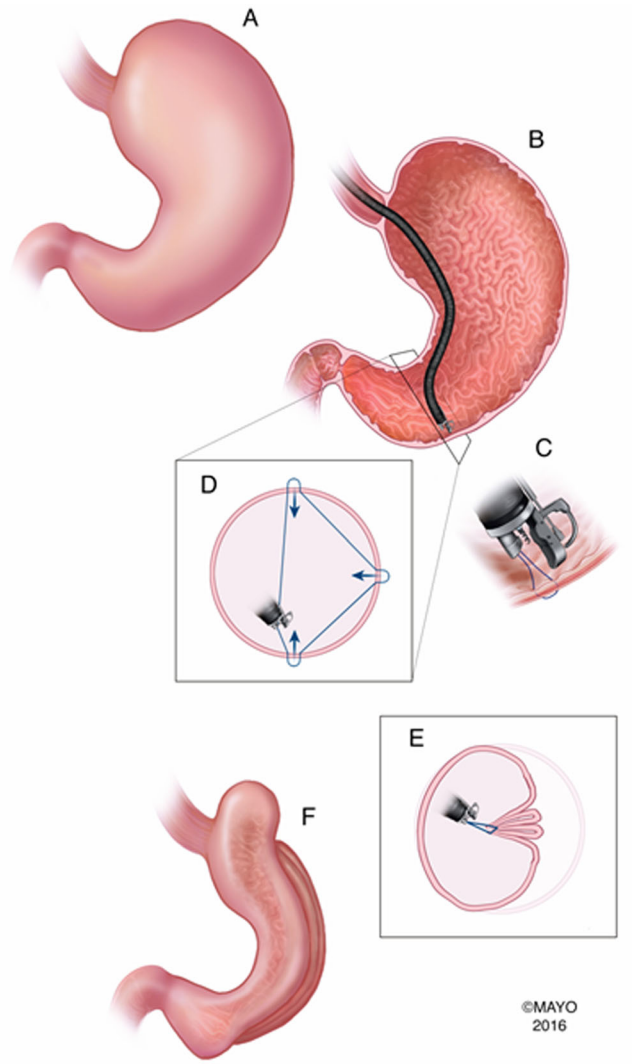

Fig. 1 Schematic representation of ESG procedure steps using over-the-scope full thickness endoscopic suturing device

Methods

Participants

We conducted a three-center (Bariatric Endoscopy Unit, Madrid Sanchinarro University Hospital, Madrid, Spain; Weill Cornell Medical College, Division of Gastroenterology and Hepatology, New York, NY, USA; Mayo Clinic, Division of Gastroenterology and Hepatology, Rochester, MN, USA) retrospective analysis of prospectively maintained databases of patients who underwent ESG between January 2013 and December 2015. All patients were adults with no known

contraindications to ESG, namely, anticoagulation, previous gastric surgery, gastric ulceration, hiatal hernia ≥5 cm, or pregnancy. All patients underwent pre-bariatric procedure evaluation with psychiatry and nutrition. Informed consent was obtained from all individual participants included in the study.

Procedure

All procedures were performed in the endoscopy suite except one patient, who underwent the procedure in the operating room because of the need for a bariatric bed. All procedures were performed under general anesthesia and with the use of carbon dioxide insufflation. The technique was previously described in detail [9, 14]. All procedures were performed in a similar fashion using the Apollo OverStitch device (Apollo Endosurgery, Austin, TX), placing full-thickness sutures to invaginate the greater curvature of the stomach, thus creating a narrow luminal sleeve with a small fundic pouch (Fig. 1). After placement of an esophageal length overtube, the endoscopic suturing device mounted on a double channel gastroscope (GIF2T160 or 180 series, Olympus Optical, Tokyo, Japan) was advanced to the gastric antrum. The tissue helix device was used to ensure that sequential full-thickness bites were taken. Multiple full-thickness running sutures were endoluminally placed from the level of the gastric angular incisure to the gastroesophageal junction to create the ESG. A second layer of sutures was placed over the length of the central sleeve in an interrupted pattern to further reduce the gastric volume and reinforce the sleeve when needed. In Spain, patients post-procedure were hospitalized for observation, symptoms management, and to obtain an upper gastrointestinal series 24 h after the procedure. In the USA, patients were discharged the same day. All patients were given a course of oral antibiotics, oral antiemetics as needed, and daily proton pump inhibitor. Post-procedure, the diet consisted of 2-3 weeks of liquid protein shakes, followed by 2 weeks of puréed diet, and then transitioning to a regular diet. The post-procedural diet was designed to provide 1000–1200 cal/day, delivering 70 g of protein. In addition, subjects were encouraged to drink 56 oz of non-caloric fluids per day and take a daily chewable multivitamin.

Outcome Measures

Percent total body weight loss (%TBWL) was reported at 6 and 24 months. Long-term clinical success was defined as achieving ≥10% TBWL at 24 months. Since not all patients who reached the end of the study presented exactly at 24 months post-procedure, we considered that any follow-up visit occurring between 18 and 24 months to represent the 24 months follow-up visit.

Statistical Analysis

Per protocol (PP) analysis reported result on patients with available data only. Intention-to-treat (ITT) analyses considered patients lost to follow-up as failing to achieve durable weight loss at 24 months.

ANOVA analysis was used to compare %TBWL between the three centers. Multivariable linear and logistic regression analyses were performed to identify predictors of long-term weight loss after ESG. Analyses were performed using SAS version 9.3 software (SAS Institute, Cary, NC) and JMP Pro 10.0 (SAS Institute, Cary, NC). Data in the manuscript are presented as mean ± standard deviation (SD) or 95% confidence interval (CI). For the linear regression model, data was present as β coefficients. For the logistic regression model, odds ratio (OR) was presented. Statistical significance was determined a priori at $p < 0.05$.

Results

Patient Demographics and Weight Loss Outcomes

Consecutive patients (n = 248), who underwent ESG and reached at least 6 months follow-up, were eligible for the study. The mean age was 44.5 ± 10 years, 73% were females, and mean baseline BMI was 37.8 ± 5.6 kg/m^2. Of the 248 patients, 13% (33/248) were lost to follow-up at 6 months. Percent TBWL at 6 months was 15.17% [95% CI 14.2–16.25] and similar between the three centers (p = 0.25) (Table 1). Ninety-two patients reached the 24 months follow-up, and 38% (35/92) were lost to follow-up at 24 months. The 24 months follow-up visit intervals ranged between 18 and 24 months and had a median of 24 months, and the percent TBWL was 18.6% [95% CI 15.7–21.5], without differing significantly between the three centers (p = 0.7) (Table 1). Eighty-four and 56% of the cohort achieved ≥10 and 15% TBWL at 24 months on per protocol analysis (lost to follow-up patients' data amputated). In an ITT analyses, where patients lost to follow-up were considered failures, 53 and 35% reached ≥10 and 15% TBWL at 24 months, respectively (Fig. 2). Table 2 shows weight loss outcomes in patient with BMI ≤35 vs. >35 kg/m^2.

Predictors of Long-Term Response

In linear regression analysis (Table 3), weight loss at 6 months highly predicted weight maintenance as well as predicting weight loss achieved at 24 months both on univariable (β = 1.17, $p < 0.001$) and multivariable (β = 1.21, $p < 0.001$) analysis, after adjusting for age, gender, and baseline BMI (Fig. 3).

In a logistic regression model, the odds of achieving >10% TBWL at 24 months if a patient achieved ≤10%TBWL at 6 months is 0.18 [0.034–0.84]. In other words, failing to

Table 1 Comparison of %TBWL between the three centers in the study at 6 and 24 months

N total	*N* lost to follow-up	%TBWL Madrid	%TBWL Rochester	%TBWL New York	%TBWL All	*p* value
6 months						
248	33	15.8 [14.6–17]	14 [11.5–16.3]	14.2 [12.2–16.25]	15.17 [14.2–16.25]	0.25
24 months [18–24]						
92	35	19.3 [15.1–23.5]	16.8 [11.5–22.1]	19.5 [13.5–25.6]	18.6 [15.7–21.5]	0.7

Ninety-five percent confidence intervals shown

achieve ≥10%TBWL at 6 months is an early-on treatment predictor of poor long-term results and should necessitate adjunctive therapy to enhance the weight loss in those patients.

Adverse Events

Mild adverse events such as per procedural abdominal pain, nausea, or vomiting not requiring further medical attention were not systematically recorded. Five (2%) serious procedural related adverse events occurred: two perigastric inflammatory fluid collections (adjacent to the fundus) that resolved with percutaneous drainage and antibiotics, one self-limited extra-gastric hemorrhage that required blood transfusion, one pulmonary embolism 72 h after the procedure, and one pneumoperitoneum and pneumothorax requiring chest tube placement. All five patients recovered fully without surgical intervention.

Discussion

This study of 248 consecutive patients who underwent endoscopic sleeve gastroplasty for the primary treatment of obesity demonstrates that ESG can safely achieve greater than 10% TBWL in over 75% of patients with mild to moderate obesity with durable weight loss. Thus, ESG is an effective EBT, potentially bridging the gap in obesity care between medical and surgical interventions by offering a viable minimally invasive and less costly option.

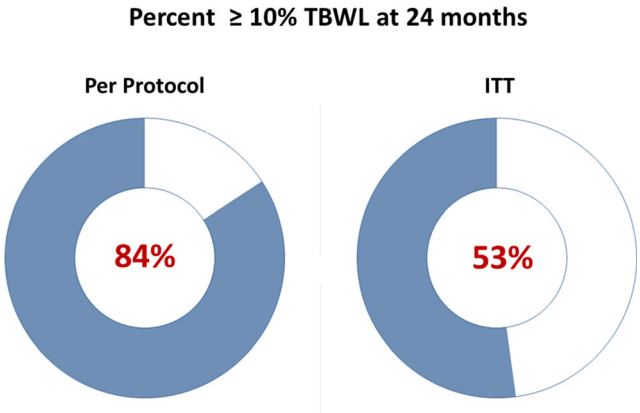

Fig. 2 Percent of patient achieving ≥10% TBWL at 24 months on per-protocol and intention-to-treat analysis

The US National Institutes of Health (NIH), the World Health Organization, and numerous other scientific organizations including the American Medical Association (AMA) recognize obesity as a chronic disease requiring primary therapy. The obesity epidemic continues to be pervasive with over 2 billion overweight adults across the globe and is linked to many of the top ten causes for death. Therefore, effective and readily available therapies are needed in our armamentarium against obesity.

The scientific literature is clear in showing that the magnitude of weight loss is strongly associated with improvements in obesity-related co-morbidities and long-term weight maintenance [15]. The odds of clinically significant improvements in obesity related co-morbidities are much higher when %TBWL exceeds 10% [16, 17]. Standard lifestyle interventions typically result in 3–5% TBWL only, and the addition of pharmacotherapies results in moderate increases in those achieving at least 5%TBWL [18]. Bariatric surgery has historically been the most effective at producing sustained weight loss, ranging between 20 and 30% TBWL [19, 20]. Moreover, weight maintenance has proven to be difficult with lifestyle interventions alone, and weight recidivism is common after cessation of pharmacotherapies [15, 21]. Therefore, >10% TBWL is rarely achieved with these noninvasive interventions, and bariatric surgery, although effective, is of limited appeal to the vast majority of obese patients considering costs, patient preference, access to care, and the potential surgical morbidity and mortality [15–17, 22].

Other endoscopic bariatric therapies (EBTs), such as intragastric balloons (IGBs), are currently in use worldwide and recently been approved in the USA [23]. In a

Table 2 Comparison of %TBWL between BMI groups

BMI	6 months	*N*	24 months [18–24]	*N*
≤35	12.6 [10.8–14.2]	65	13.6 [11–16]	20
>35	16.3 [15.2–17.4]	150	21 [17–25]	37

Ninety-five percent confidence intervals shown

Table 3 Multivariable linear regression model predicting %TBWL at 24 months

	Univariable β	p value	Multivariable β	p value
Age	−0.22	0.11	0.105	0.25
Gender	0.16	0.44	0.07	0.59
BMI	1.5	0.66	0.2	0.93
%TBWL at 6 months	1.17	<0.001	1.21	<0.001

step-up, personalized-medicine approach to obesity, the availability of these interventions is pivotal in crafting multi-faceted therapy plans, suitable for each individual patient. ESG, being a step above other less-invasive EBTs, provides a superior option in terms of weight loss magnitude, durability, and cost-effectiveness, which may be more appropriate to specific groups of patients, who, albeit not being amenable to surgery, are in need of a more intense approach compared with intraluminal space occupying devices. Currently, available IGBs result in about 10% TBWL at 6 months, and only about two-thirds of the weight loss is preserved at 1 year (6 months after balloon removal). This weight recidivism is in contrast to the initial 15%TBWL observed with ESG at 6 months, which is preserved in a significant proportion of patients at 24 months [24, 25]. Furthermore, unlike other EBTs that require two or more endoscopy sessions for placement, adjustment, and removal, ESG requires a single session and is performed using standard commercially available endoscopic tools and equipment. Finally, ESG has been shown to result in physiological perturbations in gastric physiology and appetite that may be instrumental in overcoming the compensatory body counter-regulatory responses that lead to weight recidivism [13]. Whether ESG will prove to be similar or more effective to sequential IGB therapy (i.e. balloon-after-balloon approach) is yet to be elucidated.

Obesity is a chronic disease, and as such, no individual medication, device, or surgical intervention will likely offer a cure. In response to significant caloric restriction and loss of body fat stores, there are physiologic counter-regulatory processes that increase hunger, decrease satiety, and increase metabolic efficiency and cost of adherence relative to reward in the weight maintenance phase of therapy, making long-term weight maintenance difficult [26]. Therefore, an NIH working group on weight maintenance recommended an aggressive pharmaceutical and behavioral intervention that counter the physiological and behavioral adaptations, and re-establish the balance between intake and expenditure in the weight maintenance phase after a significant weight loss [27]. Our study demonstrates that the odds of achieving ≥10%TBWL at 24 months if a patient achieved <10%TBWL at 6 months is only 18%. Similar to our findings, weight loss performance in the early period has been shown to be a significant predictor of long-term outcome of Roux-en-Y gastric bypass surgery (RYGB) [28]. This observation provides the rationale for concurrent use of anti-obesity pharmacotherapies and more intensive behavioral programs in ESG patients achieving <10% TBWL at 6 months to augment the weight loss magnitude and durability, thus proposing an algorithmic and cost-effective long-term management strategy for obesity. While ESG is not meant to replace bariatric procedures such as the sleeve gastrectomy or gastric bypass, ESG is proving to be an effective alternative to those who are ineligible (BMI < 40 kg/m^2) or do not wish to undergo surgery.

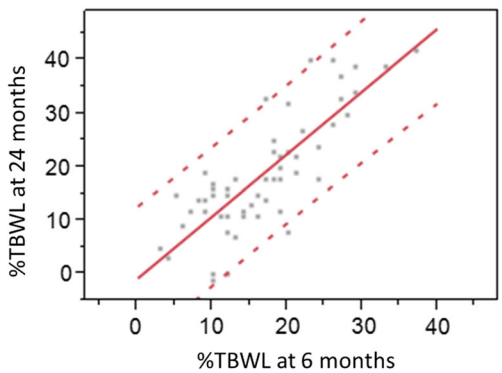

Fig. 3 Linear regression line and 95% confidence intervals showing high correlation between weight loss achieved at 6 and 24 months after ESG

Our study has limitations, such as the lack of a control group, limited long-term follow-up, lack of endoscopic or radiographic evaluation of the plication durability, and significant loss to follow-up rate at 24 months. Furthermore, this study was done in expert centers that have developed high level of proficiency in this technique; thus, generalizing these results to all operators might be premature. However, a recent study examining the learning curve of ESG has demonstrated that efficiency can be reached after 35 cases [29]. Finally, the safety of converting patients who fail ESG to bariatric surgery is not well studied yet. From our clinical experience, conversion to RYGB should be straightforward as the lesser curvature and the cardia of the stomach are anatomically preserved and suture free after ESG. Hypothetically, conversion to laparoscopic sleeve gastrectomy might pose more technical challenge as the surgical stapler might traverse ESG suture locking mechanism while removing the greater curvature of the stomach. However, a pre-operative carful endoscopic

examination with potential removal of ESG sutures can mitigate this issue.

The above limitations are not unique to our study but are inherent limitations to many new interventional weight loss studies. We attempted to compensate for these shortcomings by analyzing reproducibility of the technique among three independent centers in a large cohort, reporting 24 months weight loss outcomes, and performing both per protocol and intention-to-treat analyses to provide granular data to inform clinical decision making and future studies.

In conclusion, ESG is a minimally invasive and cost-effective weight loss intervention that, in conjunction with lifestyle and behavioral intervention programs, may offer a paradigm shift in our management of obesity that targets current gaps in therapy. ESG along with other EBTs in a multidisciplinary approach may allow us to gain ground in our losing battle against obesity.

Compliance with Ethical Standards

Conflict of Interest Authors 1, 2, 5, and 16 are consultants for Apollo Endosurgery (Austin, TX).

Author 15 is the chief medical officer for Apollo Endosurgery (Austin, TX).

All other authors have nothing to disclose.

Statement of Informed Consent Informed consent was obtained from all individuals undergoing all procedures and included in our study. No identifying information is included in our study.

Statement of Ethical Rights and Human Rights (as No Animal Experiments Were Conducted in this Study) All procedures performed in our study were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments.

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