Endoscopic Sleeve Gastroplasty Significantly Reduces Body Mass Index and Metabolic Complications in Obese Patients

Reem Z. Sharaiha,[*] Nikhil A. Kumta,[*] Monica Saumoy,[*] Amit P. Desai,[*] Alex M. Sarkisian,[*] Andrea Benevenuto,[*] Amy Tyberg,[*] Rekha Kumar,[‡] Leon Igel,[‡] Elizabeth C. Verna,[§] Robert Schwartz,[*] Christina Frissora,[*] Alpana Shukla,[‡] Louis J. Aronne,[‡] and Michel Kahaleh[*]

[*]*Department of Gastroenterology and* [‡]*Department of Endocrinology, Weill Cornell Medicine, New York, New York; and* [§]*Department of Gastroenterology, Columbia University Medical Center, New York, New York*

BACKGROUND & AIMS: **Endoscopic sleeve gastroplasty (ESG) is an incisionless, minimally invasive bariatric procedure that reduces the length and width of the gastric cavity to facilitate weight loss. We performed a prospective study to evaluate the effects of ESG on total body weight loss and obesity-related comorbidities.**

METHODS: **We collected data from 91 consecutive patients (mean age, 43.86 ± 11.26 years; 68% female) undergoing ESG from August 2013 through March 2016. All patients had a body mass index (BMI) greater than 30 kg/m^2 and had failed noninvasive weight-loss measures or had a BMI greater than 40 kg/m^2 and were not considered as surgical candidates or refused surgery. All procedures were performed with a cap-based flexible endoscopic suturing system to facilitate a triangular pattern of sutures to imbricate the greater curvature of the stomach. Patients were evaluated after 6 months (n = 73), 12 months (n = 53), and 24 months (n = 12) for anthropometric features (BMI, weight, waist circumference, blood pressure) and underwent serologic (hemoglobin A1c), lipid panel, serum triglycerides, and liver function tests. The primary outcomes were total body weight loss at 6, 12, and 24 months. Secondary outcomes were the effects of ESG on metabolic factors (blood pressure, diabetes, hyperlipidemia, steatohepatitis) and safety.**

RESULTS: **The patients' mean BMI before the procedure was 40.7 ± 7.0 kg/m^2. Patients had lost 14.4% of their total body weight at 6 months (80% follow-up rate), 17.6% at 12 months (76% follow-up rate), and 20.9% at 24 months (66% follow-up rate) after ESG. At 12 months after ESG, patients had statistically significant reductions in levels of hemoglobin A1c (P = .01), systolic blood pressure (P = .02), waist circumference (P < .001), alanine aminotransferase (P < .001), and serum triglycerides (P = .02). However, there was no significant change in low-density lipoprotein after vs before ESG (P = .79). There was one serious adverse event (1.1%) (perigastric leak) that occurred that was managed non-operatively.**

CONCLUSIONS: **ESG is a minimally invasive and effective endoscopic weight loss intervention. In addition to sustained total body weight loss up to 24 months, ESG reduced markers of hypertension, diabetes, and hypertriglyceridemia.**

Keywords: Bariatric Surgery; Stomach; Metabolic Disorder; ALT.

Obesity is a central public health concern. It impacts more than one-third of adults in the United States[1] and is strongly associated with an increase in mortality in both men and women, in all racial and ethnic groups, and at all ages.[2] Noninvasive weight loss strategies, which focus on lifestyle modifications and pharmacologic approaches, rarely lead to sustained weight loss.[3,4] Bariatric surgery is superior to therapeutic lifestyle changes, resulting in significant weight loss along with the resolution of metabolic comorbidities in up to

Abbreviations used in this paper: **ALT, alanine aminotransferase; BMI, body mass index; ESG, endoscopic sleeve gastroplasty; EWL, excess weight loss; GE, gastroesophageal; HbA1c, hemoglobin A1c; HDL, high-density lipoprotein; LDL, low-density lipoprotein; %TBWL, percentage total body weight loss; SBP, systolic blood pressure; SD, standard deviation; TBWL, total body weight loss; TG, serum triglycerides.**

Most current article

1542-3565/$36.00
http://dx.doi.org/10.1016/j.cgh.2016.12.012

80% of patients.[5] However, despite its effectiveness, only 1% of eligible patients undergo bariatric surgery because of risks, limited access, cost, and patient preference.[6] Thus, effective but less invasive approaches to treat obesity and its complications are urgently needed.

Endoscopic sleeve gastroplasty (ESG) is an incisionless, minimally invasive bariatric procedure performed via an endoscopic rather than surgical approach. The goal of ESG is to reduce the length and width of the stomach to facilitate weight loss. Prior endoscopic techniques for ESG have used endoluminal suturing systems that placed partial-thickness sutures.[7,8] The efficacy of the procedure was limited by frequent suture-line dehiscence, resulting in weight regain. To achieve more durable results, a transmural tissue apposition technique was developed by using a full-thickness endoscopic suturing system.[9,10] This approach has now been shown in multiple case series to be safe and technically feasible, resulting in significant reductions in mean weight and body mass index (BMI).[10–15]

Thus, the aim of this study was to evaluate the impact of ESG on total body weight loss (TBWL) as well as obesity-related comorbidities in a prospective cohort of consecutive patients.

Methods

Consecutive patients undergoing ESG between August 2013 and March 2016 were enrolled in this prospective, single center study. The indications for ESG were based on obesity parameters, with BMI >30 kg/m^2 and previous failed attempts at noninvasive weight loss measures, or in patients with BMI >40 kg/m^2 who refused surgery or were deemed not to be surgical candidates. The procedure was contraindicated in patients with gastric lesions, neoplastic findings, or family history of gastric cancer.[12] Individuals with mental health disorders, significant medical comorbidities precluding sedation, or coagulopathies were also excluded. In addition to a pre-procedural consultation with the gastroenterologist, patients were also seen by an endocrinologist, a nutritionist, and a psychologist to provide a multidisciplinary approach.

Anthropometrics including waist circumference and blood pressure as well as serologic testing included hemoglobin A1c (HbA1c), lipid panel including low-density lipoprotein (LDL), serum triglycerides (TG), and liver function tests were performed at baseline and at each interval follow-up visit. Patients were followed up with a telephone call and an upper gastrointestinal study within the first week. Outpatient follow-up visits were scheduled 1, 3, 6, 9, and 12 months after procedure. If patients were unable to make those appointments, then a phone call follow-up was performed instead. All patients were required to have nutritional follow-up, and this was determined at the discretion of the nutritionist. Procedure-related data including procedure time, number of sutures used, and change in gastric length from the gastroesophageal (GE) junction to pylorus after ESG were collected. Post-procedure data included length of hospital stay, pain scores, duration of follow-up, percent total body weight loss (%TBWL), and all adverse events. The study was approved by the institutional review board (IRB Protocol 1510016654).

Endoscopic Sleeve Gastroplasty Procedure

All procedures were performed by a single endoscopist (R.Z.S.), with patients under general anesthesia in an outpatient endoscopy unit by using CO_2 insufflation.

Patients were placed in the left lateral decubitus position unless otherwise specified. An esophagogastroduodenoscopy was performed with a standard upper endoscope (GIF-H190; Olympus, Center Valley, PA). The distance from the GE junction to the pylorus was measured with the endoscope. After placement of an esophageal overtube (Guardus; US Endoscopy, Mentor, OH), 2 parallel anterior and posterior suture placement sites were mapped by using argon plasma coagulation, starting at the incisura and extending proximally to the GE junction.[14]

A double-channel therapeutic upper endoscope (GIF-2TH180; Olympus) was outfitted with a cap-based flexible endoscopic suturing system (OverStitch; Apollo Endosurgery, Austin, TX) to perform the procedure. The suturing device consists of a needle driver, a catheter-based suture anchor, and an actuating handle.[16] Sutures were reloaded without endoscope removal. ESG was then created by using an interrupted Z pattern to invaginate the greater curvature of the stomach for formation of the sleeve.[9,11] The helix device was used to capture the muscularis propria, allowing sequential full-thickness bites. A running stitch was used to oppose the anterior and posterior placement sites. The stitch was then tightened to approximate the opposing gastric walls, creating a full-thickness volume reduction plication. The suture was cut by using a cinch. A second layer of sutures was then placed over the length of the central sleeve in an interrupted stitch pattern to further reduce gastric volume and reinforce the sleeve.[10] The end result of the procedure was a tubular reconfiguration of the gastric lumen. Lavage of the sleeve with topical gentamicin (80 mg in 60 mL normal saline) was performed to reduce risk of infection. Repeat measurement of the distance from the GE junction to the pylorus was recorded.

Pre-procedure antibiotics were given (levofloxacin 500 mg intravenously). Antiemetics were given before procedure (scopolamine transdermal patch applied the night before, aprepitant 80 mg orally 2 hours before procedure), peri-procedure (dexamethasone 8–10 mg intravenously, ondansetron 4 mg intravenously), and after procedure (prochlorperazine 25 mg rectally).

Initially, patients were admitted overnight for observation. On the basis of pilot studies that demonstrated safety and technical feasibility, our protocol was modified for same day discharge after the first 11 patients.[13,14]

Patients were given a 3-day course of liquid-based antibiotics (levofloxacin or amoxicillin/clavulanic acid), antiemetics, proton pump inhibitors, and pain medications on discharge. All subjects were placed on an immediate postprocedural diet consisting of liquid protein shakes for 2 weeks and advanced as previously described.[14] During this time, an upper gastrointestinal series with oral contrast was performed as an outpatient as part of our protocol to confirm the absence of a suture line leak.[14]

Outcome Measures

Variations in BMI, weight, %TBWL, waist circumference, and serologic tests were measured at baseline and 1, 3, 6, 9, 12, 18, and 24 months after procedure. The primary outcome was TBWL at 6, 12, and 24 months. Clinical success was defined as TBWL of at least 15% in accordance with the Preservation and Incorporation of Valuable Endoscopic Innovations guidelines.[17]

Secondary outcomes included the impact of ESG on metabolic comorbidities, including systolic blood pressure (SBP), diabetes (measured by HbA1c), hyperlipidemia (measured by LDL and serum TG), steatohepatitis (measured by alanine aminotranferase [ALT]), and safety.

Diabetes was defined as currently taking diabetes medication or having HbA1c $\geq$6.5%.[18] Prediabetes was defined as HbA1c between 5.7% and 6.4% without the use of medications. Hypertension was defined as SBP of at least 140 mm Hg or diastolic blood pressure of at least 90 mm Hg from a single measurement or taking an antihypertensive medication when evaluated.[19]

Hyperlipidemia was defined as currently taking a lipid lowering medication or LDL $\geq$160 mg/dL and high triglycerides as fasting level $\geq$200 mg/dL.[19] Abnormal liver enzymes were defined by ALT $>$30 IU/L for men and $>$19 IU/L for women.[20]

In addition, we aimed to identify factors that predicted successful weight loss at 12 months in multivariable analysis. Adverse events were graded according to the American Society for Gastrointestinal Endoscopy lexicon severity grading system.[21,22]

We also attempted to define a learning curve for ESG. Efficiency of the procedure was defined as the point in the learning curve in which the operator starts engaging in performance refinements that lead to gradual decrease in procedure time, with minimal change in mean procedure time observed.[23,24]

Statistical Analysis

Descriptive statistics were calculated for all demographic and clinical variables and reported as mean $\pm$ standard deviation (SD), median with interquartile range, or as a proportion where appropriate. Univariate analysis was performed by using χ^2 test and Fisher exact test for categorical variables and Student t test for continuous variables or Mann-Whitney U test as required. Multivariable analysis was performed by using logistic regression to evaluate the factors influencing the success of ESG. All variables were tested for normality by using the Shapiro-Wilk test, and parametric tests were used as appropriate; otherwise, nonparametric methods were used. Non-linear regression by using a B-spline regression technique was used to analyze the change in procedural times as a function of procedure number. All statistical analysis was conducted by using STATA 13.0 (StataCorp LP, College Station, TX). A P value $<$.05 was considered significant.

Results

Patient Characteristics

Ninety-one patients underwent ESG during the study period. All patients had at least 6 months of follow-up, but we had data on 73 patients (80%). At 12 months 69 patients were eligible, but we had information on 53 patients (76%). Twelve patients had 24 months of follow-up, and we had data on 8 patients (66%). The mean $\pm$ SD age was 43.66 $\pm$ 11.26 years, mean BMI was 38.6 $\pm$ 7.0 kg/m^2 (range, 30.0–68.0), 68% were female, and 34% were white. Mean number of follow-up visits was 4.5 (1–15). Before the procedure 10% of patients were on lorcaserin (Belviq), phentermine-topiramate (Qsymia), or phentermine n = 8; after procedure 1 additional patient received phentermine, with a total of 9 patients; the difference in both groups was not statistically significant ($P > .05$).

Patient demographics are summarized in Table 1.

Eighteen patients (19.8%) had type 2 diabetes mellitus at baseline, of whom 13 patients (14.3%) were on medications. An additional 15 patients (16.5%) were prediabetic at the time of the pre-procedure consultation. Eighteen patients (19.8%) were diagnosed with hypertension and were on antihypertensive medications, and 13 patients (14.3%) had dyslipidemia and were taking cholesterol lowering medications. Twenty-three of 31 men (74%) had elevated ALT at baseline, with a mean ALT of 42.4 IU/L. Forty-two of 60 women (70%) had elevated ALT, with a mean ALT of 28 IU/L.

Procedure Characteristics

All patients underwent successful ESG with general anesthesia. The mean procedure time was 98.3 $\pm$ 39.3 minutes. In B-spline regression the number of procedures that were needed to achieve efficiency was 35 (Figure 1). The mean procedure time for the first 35 cases was 144.9 $\pm$ 39.4 minutes, compared with the mean procedure time of the subsequent cases of 74.32 $\pm$ 18.7 minutes ($P < .001$). The ESG procedure required a median of 6 sutures for the first layer and 3 sutures for the second layer. The mean size of the stomach, defined

Table 1. Patient Demographic Data

Patient characteristic	N (%) N = 91
Age, *y*, mean ± SD (range)	43.86 ± 11.26 (19–66)
BMI, kg/m^2, mean ± SD, (range)	38.6 ± 7.0 (30.0–68.0)
Sex	
Male	29 (31.9)
Female	62 (68.1)
Diabetes	18 (19.8)
Hypertension	18 (19.8)
Dyslipidemia	13 (14.3)
Abnormal liver function tests	65 (71)
Race	
White	31 (34.1)
Hispanic	15 (16.5)
Black	13 (14.3)
Middle Eastern	9 (9.9)
Other	23 (25.1)
Marital status, n (%)	
Single	39 (42.9)
Married	46 (50.5)
Unknown	6 (6.6)

as measurement from the pylorus to the GE junction, before ESG was 34.8 cm and decreased to 20.4 cm after ESG ($P < .001$) (Figure 2). The first 11 patients were admitted to the hospital after ESG for observation, and their mean length of stay was 2.1 days. All subsequent patients (n = 80) were discharged home the same day.

Impact of Endoscopic Sleeve Gastroplasty on Weight Loss

The mean %TBWL was 14.4% at 6 months and increased to 17.6% at 12 months and 20.9% at 24 months (Figure 3). The decrease in weight at each time point compared with baseline was statistically significant (all $P < .001$). The BMI decreased from a mean of 40.7 to 32 kg/m^2 at 12 months ($P < .001$). Seventy percent of patients at 12-month follow-up achieved clinical success as defined by greater than 15% TBWL. In addition, waist circumference significantly decreased from 119.7 ± 14.1 cm to 92.8 ± 5.9 cm ($P = .001$) at 12 months (Table 2).

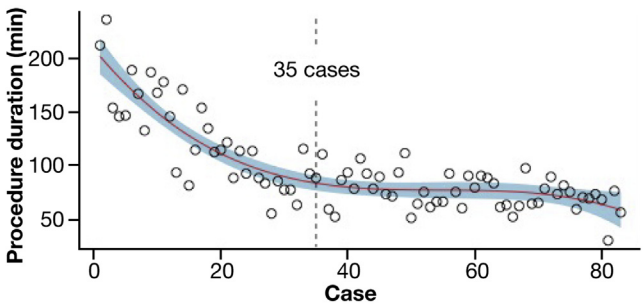

Figure 1. Time of procedure with number of cases on the x-axis. The line represents the number of cases after which the slope of the curve becomes linear.

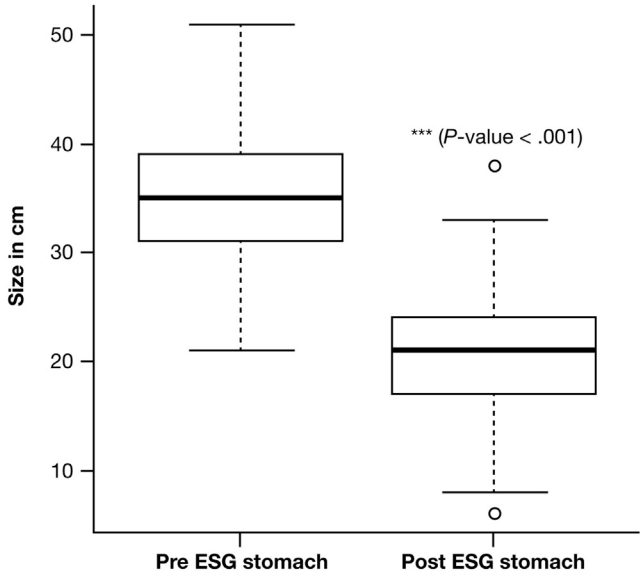

Figure 2. Box plot of reduction in stomach length after ESG.

Impact of Endoscopic Sleeve Gastroplasty on Metabolic Comorbidities at Twelve-month Follow-up

There was a statistically significant change in HbA1c between baseline and at 12 months after ESG in the overall cohort (mean ± SD, 6.1% ± 1.1% vs 5.5% ± 0.48%, respectively; $P = .05$) (Table 2). In patients with diabetes or prediabetes, there was a significant reduction in HgA1c (mean ± SD, 6.6% ± 1.2% vs 5.6% ± 0.51%, respectively; $P = .02$). Furthermore, 5 patients in total were able to stop insulin, and 2 patients stopped all medications.

In addition, there were significant reductions in SBP (129.0 ± 13.4 mm Hg vs 122.2 ± 11.69 mm Hg [$P = .02$]), TG (131.84 ± 83.19 mmol/dL vs 92.36 ± 39.43 mmol/dL [$P = .02$]), and ALT (42.4 vs 22 in men, $P = .05$, and 28 vs 20 in women, $P = .01$) when compared between baseline and 12 months after ESG, respectively.

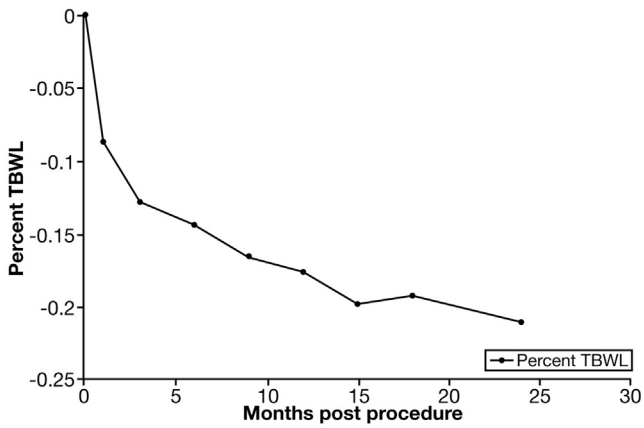

Figure 3. Percentage TBWL after ESG.

Table 2. Post-ESG Improvement in Weight and Medical Comorbidities at 12 Months (N = 53)

	Before ESG, mean (SD)	12 months after ESG, mean (SD)	*P* value
HgbA1c, % (all patients)	6.1 (1.1)	5.5 (0.48)	.05
HgbA1c, % (only diabetes and prediabetes)	6.6 (1.2)	5.6 (0.51)	.02
Waist circumference, *cm*	119.66 (14.05)	92.75 (5.85)	<.001
SBP, *mm Hg*	129.02 (13.44)	122.23 (11.69)	.023
LDL, *mg/dL*	121.62 (38.61)	124.27 (27.82)	.786
TG, *mg/dL*	131.84 (83.19)	92.36 (39.43)	.017
ALT, *mg/dL*	32.28 (16.43)	20.68 (11.44)	<.001

Multivariable Analysis

In univariate analysis, younger age was significantly associated with weight loss at 12 months. In addition, there was a statistically significant difference in achieving %TBWL before and after the 34 cases (odds ratio, 10.3; confidence interval, 1.23–87.53; $P = .031$).

There was no statistically significant effect of the suture number (in both the first and second layers), change in stomach size, total number of sutures, and diabetic status on %TBWL at 12 months ($P > .05$). In the multivariable logistic model, only younger age and case number (>34) were predictive of successful weight loss (Table 3), even after adjusting for initial BMI and gender.

Adverse Events

Thirty-five patients (38.4%) experienced self-limited nausea that lasted <48 hours, and 25 patients (27.4%) experienced mild to moderate abdominal pain that was cramping in nature, again lasting <48 hours. Both the pain and nausea were managed with medications. There was one (1.1%) serious adverse event that occurred with a patient who developed a peri-gastric leak, which was managed non-operatively with placement of a percutaneous drain. The patient presented 8 days after procedure with pain after an episode of dietary indiscretion. He was empirically put on antibiotics until resolution of collection, which was confirmed on repeat imaging 3 weeks later. Antibiotics were continued for 10 days. The leak resolved on subsequent imaging without any additional intervention.

Table 3. Predictors of TWBL >15% at 12 Months

Variable	Univariate odds ratio	*P* value	Multivariable odds ratio	*P* value
Age	0.88 (0.8–0.96)	.007	0.85 (0.77–0.96)	.006
Race				
White	Reference		—	
Black	0.18 (0.03–1.2)	.76		—
Hispanic	0.22 (0.03–2.5)			
Other	0.55 (0.04–6.8)			
Gender (female)	0.21 (0.03–1.7)	.15	0.47 (0.03–6.6)	.57
Initial BMI	1.01 (0.92–1.1)	.78	1.1 (0.93–1.25)	.31
Case number				
<35	Reference	.03		.02
>35	10.3 (1.2–87.5)		18.6 (1.6–219.6)	

Discussion

With the rising prevalence of obesity and an increasing population of non-responders to noninvasive measures including diet, exercise, and medications, there is a growing need for effective minimally invasive interventions. ESG represents a minimally invasive restrictive-type of weight loss option to meet this growing need.[16]

Here we report the largest series of patients to date who underwent ESG and achieved very significant weight loss with 17.6% TBWL at 6 months, progressive TBWL at 24 months to 20.9%. Importantly, in addition to weight loss, we found significant improvements in almost all measures of obesity-associated comorbidities.

Prior published studies have demonstrated that ESG can achieve up to 18%–20% TBWL at 12 and 24 months.[11,12,14] Our TBWL findings in this present study are consistent with the published literature.[11,12,14] We also demonstrate restriction and a decrease of stomach volume after ESG by measuring stomach length, where patients have a significant reduction in stomach size.

Our study is an ESG study that examines metabolic profiles, demonstrating a reduction in medical comorbidities with statistically significant decreases in SBP, HbA1c, serum TG, and ALT. This is similar to what has been published in the surgical literature.[25–31] Reduction in comorbidities is an important result and highlights the fact that this procedure may have an impact on long-term outcomes including morbidity and mortality.

We also found that age and increasing case number were predictive of %TBWL. We believe younger age was predictive because of the social impact of obesity at a younger age and the ability to change eating habits in a younger patient. These suggest both motivation and the ability to change eating habits in obese patients. These findings suggest older patients may need further dedicated close follow-up nutritional programs and that

post-procedure care should be tailored to the individual patient. Moreover, >34 cases were also predictive of % TBWL, suggesting that the learning curve is also important.

A study of 50 patients found nutritional and psychological contacts were predictive of %TBWL when controlling for BMI.[12,32] There was no difference in number of follow-up visits and outcome in our study, $P = .13$, but our follow-up, although encouraged, was not mandatory; therefore any significant difference may not be seen.

Overall, ESG was well-tolerated. Less severe adverse events including nausea and abdominal pain are expected after procedure and were managed conservatively. Our serious adverse event rate was low (1.1%), with 1 perigastric infected collection. Accordingly, we modified our clinical protocol to include a 3-day course of antibiotics after the procedure. This is low compared with surgical bariatric procedures, which have been reported to be as high as 18%, and less than 5%, which is the threshold set by the Preservation and Incorporation of Valuable Endoscopic Innovations guidelines.[17,33,34]

Durability of sutures is an important point that we did not study in great detail. Twelve patients underwent repeat endoscopy for various reasons. The majority had bridging fibrosis, indicating that this procedure may alter the anatomy of the stomach. One to 2 sutures were noted to be loose, and those were mostly placed in the fundal area. The durability of suturing is likely related to the full-thickness nature of this procedure.[35–37]

We recognize there are some limitations to our present study. Our study was performed by a single bariatric endoscopist, limiting generalization of our findings. Before performing the ESG, the endoscopist had performed many procedures with the endoscopic suturing device. These included >50 stent fixations and >20 fistula and perforation closures. Continuous suture pattern was also practiced in an animal model setting before clinical use. However, with sufficient training and experience, similar results should be achievable. We demonstrate a significant decrease in mean procedure time with the increasing number of cases. There was a statistically significant decrease in procedure time from the first 35 cases to the subsequent cases. After 35 cases, the B-spline regression showed that after 35 procedures, an achievement of a plateau phase in procedure time was seen, and that the expected times to complete an ESG were fairly equal, suggesting achievement of efficiency. This suggests there is a learning curve to performing the procedure. Our study also lacks a surgical or medical control group. Last, we had limited long-term patient follow-up. Further follow-up studies will be needed to assess long-term durability and efficacy.

In conclusion, ESG is a minimally invasive and effective endoscopic weight loss intervention. Because of the growing obesity epidemic and the rising cost of health care in the United States, there is increased demand for less invasive bariatric therapies. ESG has evolved into a same day, outpatient endoscopic procedure with a significant impact on weight loss and a low rate of adverse events. This study demonstrates that ESG can reduce measures of obesity-associated medical comorbidities in addition to successful weight loss. Although long-term data are still needed, ESG has established its foothold in the armamentarium of bariatric therapy.

References

1. Ogden CL, Carroll MD, Kit BK, et al. Prevalence of childhood and adult obesity in the United States, 2011-2012. JAMA 2014; 311:806–814.
2. Adams KF, Schatzkin A, Harris TB, et al. Overweight, obesity, and mortality in a large prospective cohort of persons 50 to 71 years old. N Engl J Med 2006;355:763–778.
3. Look ARG. Eight-year weight losses with an intensive lifestyle intervention: the look AHEAD study. Obesity (Silver Spring) 2014;22:5–13.
4. Yanovski SZ, Yanovski JA. Long-term drug treatment for obesity: a systematic and clinical review. JAMA 2014;311:74–86.
5. De Palma GD, Forestieri P. Role of endoscopy in the bariatric surgery of patients. World J Gastroenterol 2014;20:7777–7784.
6. Mechanick JI, Youdim A, Jones DB, et al. Clinical practice guidelines for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient: 2013 update—cosponsored by American Association of Clinical Endocrinologists, the Obesity Society, and American Society for Metabolic & Bariatric Surgery. Surg Obes Relat Dis 2013; 9:159–191.
7. Kumar N, Thompson CC. Endoscopic solutions for weight loss. Curr Opin Gastroenterol 2011;27:407–411.
8. Brethauer SA, Chand B, Schauer PR, et al. Transoral gastric volume reduction as intervention for weight management: 12-month follow-up of TRIM trial. Surg Obes Relat Dis 2012; 8:296–303.
9. Kumar N, Sahdala NH, Shaikh S, et al. Endoscopic sleeve gastroplasty for primary therapy of obesity: initial human cases. Gastroenterology 2014;146:S571–S572.
10. Abu Dayyeh BK, Rajan E, Gostout CJ. Endoscopic sleeve gastroplasty: a potential endoscopic alternative to surgical sleeve gastrectomy for treatment of obesity. Gastrointest Endosc 2013; 78:530–535.
11. 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 2015.
12. Lopez-Nava G, Galvao M, Bautista-Castano I, et al. Endoscopic sleeve gastroplasty with 1-year follow-up: factors predictive of success. Endosc Int Open 2016;4:E222–E227.
13. Lopez-Nava G, Galvao MP, da Bautista-Castano I, et al. Endoscopic sleeve gastroplasty for the treatment of obesity. Endoscopy 2015;47:449–452.
14. Sharaiha RZ, Kedia P, Kumta N, et al. Initial experience with endoscopic sleeve gastroplasty: technical success and reproducibility in the bariatric population. Endoscopy 2015; 47:164–166.
15. Lopez-Nava Breviere G, Bautista-Castano I, Fernandez-Corbelle JP, et al. Endoscopic sleeve gastroplasty (the Apollo method): a new approach to obesity management. Rev Esp Enferm Dig 2016;108:201–206.

16. Kumar N. Endoscopic therapy for weight loss: gastroplasty, duodenal sleeves, intragastric balloons, and aspiration. World J Gastrointest Endosc 2015;7:847–859.
17. Therapy ASGE/ASMBS Task Force on Endoscopic Bariatric Therapy, Ginsberg GG, Chand B, et al. A pathway to endoscopic bariatric therapies. Gastrointest Endosc 2011;74:943–953.
18. Buse JB, Caprio S, Cefalu WT, et al. How do we define cure of diabetes? Diabetes Care 2009;32:2133–2135.
19. Belle SH, Berk PD, Chapman WH, et al. Baseline characteristics of participants in the Longitudinal Assessment of Bariatric Surgery-2 (LABS-2) study. Surg Obes Relat Dis 2013;9:926–935.
20. Prati D, Taioli E, Zanella A, et al. Updated definitions of healthy ranges for serum alanine aminotransferase levels. Ann Intern Med 2002;137:1–10.
21. Romagnuolo J, Cotton PB, Eisen G, et al. Identifying and reporting risk factors for adverse events in endoscopy: part I—cardiopulmonary events. Gastrointest Endosc 2011; 73:579–585.
22. Romagnuolo J, Cotton PB, Eisen G, et al. Identifying and reporting risk factors for adverse events in endoscopy: part II—noncardiopulmonary events. Gastrointest Endosc 2011; 73:586–597.
23. Li X, Wang J, Ferguson MK. Competence versus mastery: the time course for developing proficiency in video-assisted thoracoscopic lobectomy. J Thorac Cardiovasc Surg 2014;147:1150–1154.
24. Patel KS, Calixte R, Modayil RJ, et al. The light at the end of the tunnel: a single-operator learning curve analysis for per oral endoscopic myotomy. Gastrointest Endosc 2015;81:1181–1187.
25. Vanommeslaeghe H, Deylgat B, Van Cauwenberge S, et al. Laparoscopic Roux-en-Y gastric bypass in the elderly: feasibility, short-term safety, and impact on comorbidity and weight in 250 cases. Surg Endosc 2015;29:910–915.
26. Schauer PR, Bhatt DL, Kashyap SR. Bariatric surgery versus intensive medical therapy for diabetes. N Engl J Med 2014;371:682.
27. Lee CJ, Clark JM, Asamoah V, et al. Prevalence and characteristics of individuals without diabetes and hypertension who underwent bariatric surgery: lessons learned about metabolically healthy obese. Surg Obes Relat Dis 2015;11:142–146.
28. Wilhelm SM, Young J, Kale-Pradhan PB. Effect of bariatric surgery on hypertension: a meta-analysis. Ann Pharmacother 2014;48:674–682.
29. Flores L, Vidal J, Canivell S, et al. Hypertension remission 1 year after bariatric surgery: predictive factors. Surg Obes Relat Dis 2014;10:661–665.
30. Ricci C, Gaeta M, Rausa E, et al. Early impact of bariatric surgery on type II diabetes, hypertension, and hyperlipidemia: a systematic review, meta-analysis and meta-regression on 6,587 patients. Obes Surg 2014;24:522–528.
31. Yska JP, van Roon EN, de Boer A, et al. Remission of type 2 diabetes mellitus in patients after different types of bariatric surgery: a population-based cohort study in the United Kingdom. JAMA Surg 2015;150:1126–1133.
32. Lopez-Nava G, Galvao MP, Bautista-Castano I, et al. Endoscopic sleeve gastroplasty: how i do it? Obes Surg 2015; 25:1534–1538.
33. Kolbe N, Carlin AM, Bakey S, et al. Assessing risk of critical care complications and mortality in the elective bariatric surgery population using a modified frailty index. Obes Surg 2015; 25:1401–1407.
34. Morgan DJ, Ho KM, Armstrong J, et al. Long-term clinical outcomes and health care utilization after bariatric surgery: a population-based study. Ann Surg 2015;262:86–92.
35. Kumta NA, Doshi R, Aronne LJ, et al. Trimming the fat: endoscopic suturing for tightening of prior endoscopic sleeve gastroplasty. Gastrointest Endosc 2017;85:253–254.
36. Thompson CC, Chand B, Chen YK, et al. Endoscopic suturing for transoral outlet reduction increases weight loss after Roux-en-Y gastric bypass surgery. Gastroenterology 2013; 145:129–137 e3.
37. Kumar N, Thompson CC. Transoral outlet reduction for weight regain after gastric bypass: long-term follow-up. Gastrointest Endosc 2016;83:776–779.

Reprint requests
Address requests for reprints to: Reem Sharaiha, MD, MSc, Advanced Endoscopy, Division of Gastroenterology and Hepatology, Department of Medicine, Weill Cornell Medical College, 1305 York Avenue, 4th Floor, New York, New York 10021. e-mail: rzs9001@med.cornell.edu; fax: (646) 962-0110.

Conflicts of interest
These authors disclose the following: Reem Sharaiha is a consultant for Apollo. Michel Kahaleh receives grant support from Mauna Kea Technologies and is a consultant for Boston Scientific. The remaining authors disclose no conflicts.