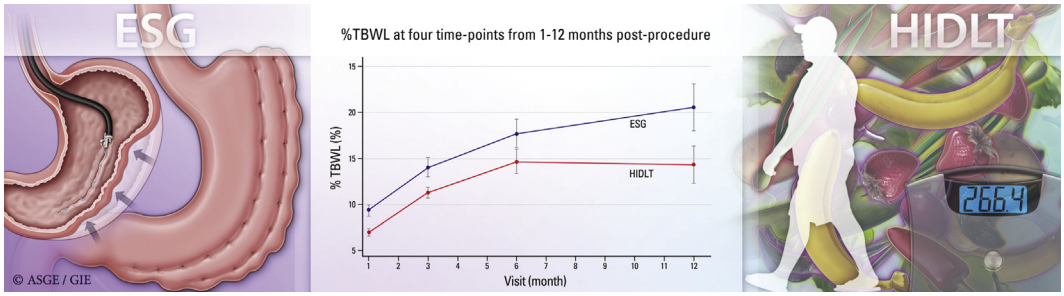
Endoscopic sleeve gastroplasty versus high-intensity diet and lifestyle therapy: a case-matched study CME

Lawrence J. Cheskin, MD,[1,2,7,*] Christine Hill, BS,[1,*] Atif Adam, PhD, MBBS, MPH,[3] Lea Fayad, MD,[3] Margo Dunlap, BSN,[2] Dilhana Badurdeen, MD,[2] Kristen Koller, MSN, CRNP,[2] Linda Bunyard, MS, RD, LDN,[1] Robin Frutchey, MA, LCPC,[1] Haitham Al-Grain, MD, FASA,[4] Scott Kahan, MD, MPH,[5] Abdellah Hedjoudje, MD, MSc,[6] Mouen A. Khashab, MD,[2] Anthony N. Kalloo, MD,[2] Vivek Kumbhari, MD[2]

Baltimore, Maryland; Washington, DC, USA; Besançon, France

GRAPHICAL ABSTRACT



Background and Aims: Endoscopic sleeve gastroplasty (ESG) is a safe and effective minimally invasive bariatric procedure. This study compared weight loss in patients undergoing ESG with that of matched patients undergoing high-intensity diet and lifestyle therapy (HIDLT).

Methods: In this case-matched study, patients were matched 2/3:1 (HIDLT/ESG) by age, sex, and body mass index (BMI). One hundred five patients (30 men) who underwent ESG + low-intensity diet and lifestyle therapy (LIDLT) between 2016 and 2018 were compared with 281 patients (92 men) who underwent HIDLT at the Johns Hopkins Medical Institutions from 2013 to 2014. Weight was evaluated 1, 3, 6, and 12 months after beginning HIDLT or post-ESG to determine the mean percent total body weight loss (%TBWL).

Results: Mean age across both cohorts was 48.0 ± 12.1, and baseline BMI was 40.0 ± 7.7 kg/m^2. In multivariable analysis controlling for age, sex, and baseline BMI, the mean %TBWL at 1, 3, 6, and 12 months was significantly higher in patients undergoing ESG than matched patients undergoing HIDLT. Specifically, at 3 months, the mean %TBWL in the ESG cohort was 14.0% compared with 11.3% in the HIDLT cohort (P <.011), and at 12 months the mean %TBWL in the ESG cohort was 20.6% versus 14.3% in the HIDLT cohort (P < .001). ESG patients with baseline BMI ≤40 kg/m^2 continued to show significantly greater %TBWL than those of the same BMI group in the HIDLT group at 1, 3, 6, and 12 months after intervention (3 months, coefficient = 3.43 [P < .001]; 12 months, coefficient = 8.14 [P < .001]).

Conclusions: Through 12 months of follow-up, patients who underwent ESG achieved significantly greater weight loss than patients enrolled in HIDLT. ESG appears to be a valuable alternative for patients who experience difficulty complying with HIDLT. (Gastrointest Endosc 2020;91:342-9.)

(footnotes appear on last page of article)

Obesity is a public health epidemic currently affecting 38% of adults and 17% of children and adolescents in the United States.[1,2] This is particularly problematic because of the comorbidities associated with obesity, including type 2 diabetes mellitus, hypertension, cardiovascular disease, metabolic syndrome, and many forms of cancer. Further, obesity is associated with higher all-cause mortality, morbidity, and depression and with lower health-related quality of life.[3-9]

Treatment for obesity and its associated comorbidities has most recently expanded into the field of bariatric endoscopy, which bridges a gap between diet and lifestyle counseling and pharmaceutical treatment and the most effective treatment for obesity, bariatric surgery[10]. Endoscopic bariatric therapies are a group of minimally invasive procedures designed to treat obesity without irreversibly altering the gastric and/or intestinal anatomy.

Endoscopic sleeve gastroplasty (ESG) is emerging as a safe and particularly effective endoscopic bariatric procedure.[11-16] By using a full-thickness endoscopic suturing system, we found that ESG reduces stomach volume by ~70%, resulting in a tubular gastric cavity along the lesser curvature, with the greater curvature closed off by plications from the gastroesophageal junction to the incisura angularis (Fig. 1).[17-20] Weight loss outcomes after ESG are substantial, with a recent multicenter study (n = 248) reporting percent total body weight loss (%TBWL) of 15.2% and 18.6% at 6 and 24 months, respectively.[13] A multicenter study encompassing clinics in both the United States and Australia reported similar success in adopting ESG for weight control.[16]

Although now gaining traction worldwide, much is left to learn when comparing this procedure with other weight control strategies. Most notably, ESG has not been directly compared with the current first-line treatment for obesity, described by the U.S. Department of Health and Human Services as the combination of low-calorie diet, increased physical activity, and behavioral therapy.[21] Multidisciplinary weight loss centers are best suited for this comparative assessment. High-intensity diet and lifestyle therapy (HIDLT) consists of regular individualized counseling on diet, physical activity, and lifestyle modifications to achieve weight loss in overweight and obese adults. Generally, patients are seen weekly or biweekly for some months before transitioning to monthly visits. In addition, optional resources such as meal replacement products, support groups, and psychotherapy may be offered. Although comprehensive, major limitations of HIDLT are high rates of noncompliance and withdrawal from treatment.[22]

To assess ESG's potential value as a treatment for obesity, this study aimed to compare weight loss outcomes of ESG with those of HIDLT. We hypothesized that patients who underwent ESG would achieve greater %TBWL through 12 months of follow-up compared with patients enrolled in HIDLT.

METHODS

Population

Study participants received elective obesity treatment at a single academic institution, Johns Hopkins Medical Institutions (Baltimore, Md). We compared patients who received HIDLT between 2013 and 2014 with a consecutive series of patients who underwent ESG between 2016 and 2018. Patients undergoing ESG were also provided 12 months of low-intensity diet and lifestyle therapy (LIDLT); however, attendance was not compulsory for inclusion in this study. Both HIDLT and LIDLT were performed at the Johns Hopkins Weight Management Center with the same providers. Patients with eating disorders such as night-eating syndrome, bulimia, and binge eating were excluded from the study.

Patients enrolled in the HIDLT program at Johns Hopkins Weight Management Center were prescribed a low-calorie, high-protein diet (prescribed intake of 800-1200 calories per day); participated in behavioral, nutritional, and exercise counseling; and were offered optional resources including psychotherapy, support groups, and meal replacements. Weight loss medications were not prescribed; however, medications known to induce weight gain were replaced with either weight-neutral or weight-negative alternatives. Patients were generally seen biweekly for some months before progressing to monthly visits.

ESG was performed as an outpatient procedure by a single endoscopist. The ESG technique as well as pre- and postprocedure care has been described elsewhere[16] and remained constant throughout the duration of the study. LIDLT consisted of the option to undertake 12 visits to the Johns Hopkins Weight Management Center over the course of 12 months after ESG. The cost of these visits was included in the single, preprocedure payment for ESG and 1 year of follow-up. In both groups, patients paid out-of-pocket for their therapy because insurance did not cover the costs of treatment in either group. The cost of ESG and LIDLT over the course of 1 year was $16,000. The estimated cost of HIDLT for 1 year was $3200; however, this varied patient-to-patient as patients paid per visit. This study was registered with the internal review board (IRB00122220).

Statistical analysis

This study used a retrospective case-matched control subjects design to compare outcomes. Patients who had undergone ESG (cases) were matched in the analysis stage with patients who had gone through HIDLT (control subjects) to balance the key patient characteristics of preprocedure body mass index (BMI), age, and gender between the cases and control subjects (akin to what we would see in a randomized controlled trial). We used kernel matching because it matches members of the control group with cases based on similarity of propensity scores.[23,24] Kernel matching addressed the problem of

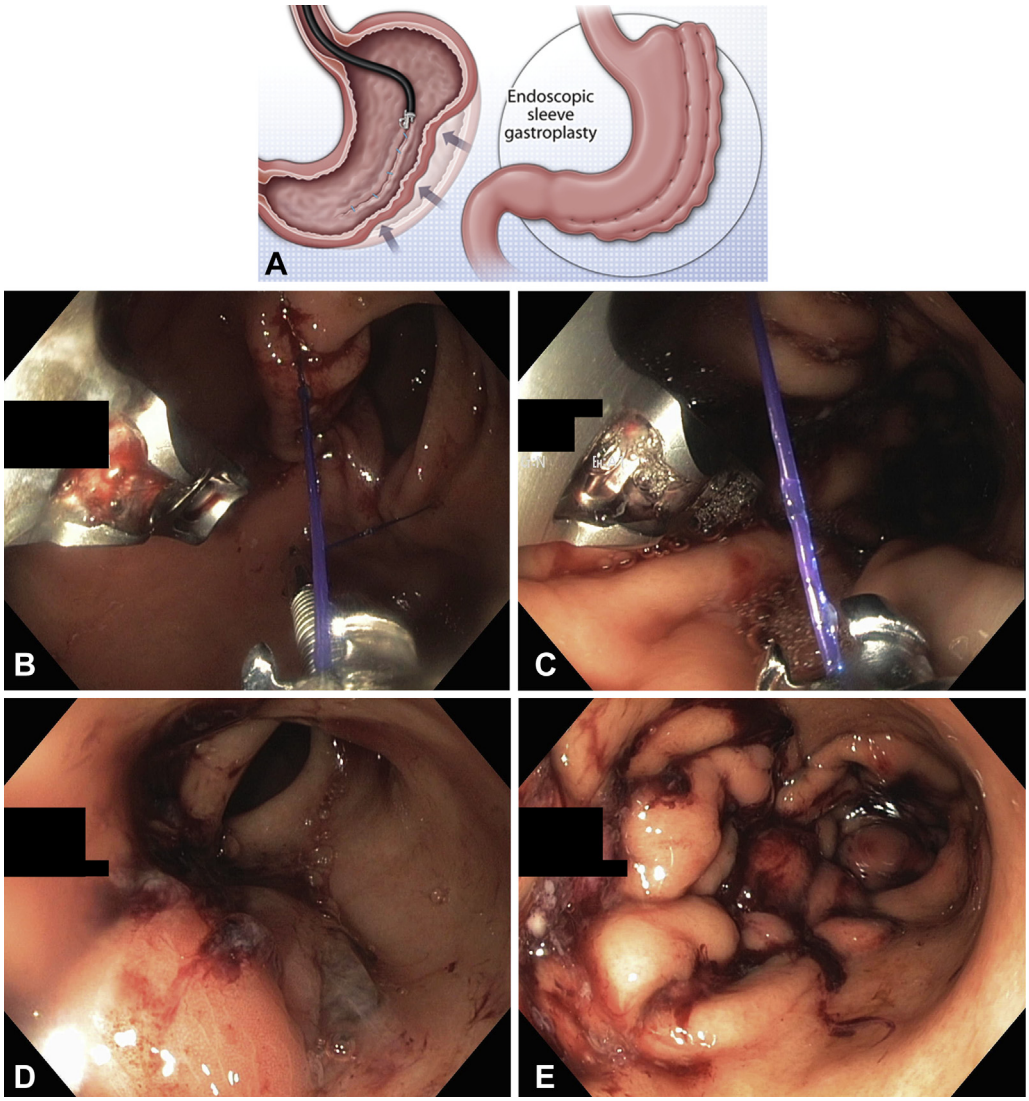


Figure 1. A, Overall effect of endoscopic sleeve gastroplasty on a patient's stomach. **B,** First suture placement, starting on the anterior wall and moving to the posterior wall of the stomach. **C,** Narrowed lumen after 3 plications. Note the reduced volume of the lumen. **D,** Distal aspect of the sleeve created by the sutures. Note the narrowed lumen. **E,** Proximal portion of the sleeve. Note the sleeve-like, noncompliant lumen.

selection bias by assuming unrelated outcome variables at start; for matched patients the untreated outcomes should be the same regardless of being a case or a control subject.[24,25] To optimize precision and minimize bias because of lower quality matches, we used a variable ratio matching technique (1 ESG case subject to 2-3 HIDLT control subjects "simultaneously").[26,27]

Comparative analyses were run using data at baseline and 1-, 3-, 6-, and 12-month follow-ups. The primary outcome was %TBWL at each time point. This is calculated as total body weight lost at each time point/baseline weight. %TBWL metrics were also assessed by baseline BMI categories: less than or equal to 40 kg/m^2 versus greater than 40 kg/m^2.

All statistical analyses were conducted using STATA 13.0 (College Station, Tex, USA). Descriptive statistics are reported as mean ± standard deviation (SD) or proportion where appropriate. Univariate analysis and multivariate regression analysis were performed to identify factors impacting % TBWL. The χ^2 and Fisher exact tests were performed for all categorical analysis, and Student *t* test or Mann-Whitney U test was used for continuous variables. Because BMI >40 kg/m^2 is often used as a cutoff for insurance coverage, we performed a subgroup analysis at 1, 3, 6, and 12 months comparing patients based on their preoperative BMI status: BMI <40 kg/m^2 and BMI >40 kg/m^2. $P <$ .05 were considered significant. Sensitivity analyses were also run to account for differential follow-up.

RESULTS

Patients

One hundred five patients (30 men) underwent ESG between March 2016 and November 2018. Two hundred

TABLE 1. Descriptive statistics of baseline characteristics in each cohort

	ESG (n = 105)	HIDLT (n = 281)	*P* value
Age, y	47.58 ± 11.97	48.17 ± 12.18	.665
Male	30 (28.57)	92 (32.74)	Reference
Female	75 (71.42)	189 (67.26)	.434
Body mass index, kg/m^2	40.50 ± 7.89	39.85 ± 7.62	.467

Values are mean ± standard deviation or n (%).
ESG, Endoscopic sleeve gastroplasty; *HIDLT*, high-intensity diet and lifestyle therapy.

eighty-one patients (92 men) who underwent HIDLT between 2013 and 2014 were matched as control subjects. The mean age across both cohorts was 48.0 years (SD, 12.1), and the mean preoperative BMI was 40.0 kg/m^2 (SD, 7.7). Age is further broken down into categories in Supplementary Table 1 (available online at www.giejournal.org). There was no significant difference in mean BMI, mean age, or the ratio of male-to-female patients between the 2 groups (Table 1).

Some subjects in this study have been included in previously published research. Specifically, a learning curve study has been published that includes the first 21 of the ESG patients included in this study.[17] A multicenter study by Sartoretto et al[16] includes the first 42 of the consecutive ESG cohort of patients. Further, the first 54 patients in the consecutive ESG cohort were included in a study comparing ESG with laparoscopic sleeve gastroplasty (LSG).[28] Finally, the first 58 patients from the ESG cohort were included in a study comparing ESG with intragastric balloon placement.[29] Within these 58 patients were the entirety of patients included in the previously published literature. Thus, 47 patients are included in this cohort whose data have not been published or presented elsewhere.

Weight loss

Both cohorts achieved significant weight loss throughout follow-up. The mean %TBWL at 1, 3, 6, and 12 months post-ESG was 9.3% (SD, 2.8; n = 96), 14.0% (SD, 4.5; n = 73), 17.7% (SD, 6.4; n = 63), and 20.6% (SD, 8.3; n = 43), respectively. The %TBWL at 1, 3, 6, and 12 months after initiation of HIDLT was 7.0% (SD, 3.2; n = 281), 11.3% (SD, 4.6; n = 237), 14.7% (SD, 8.2; n = 155), and 14.3% (SD, 10.2; n = 101), respectively. Supplementary Table 2 (available online at www.giejournal.org) further details the percentage of patients lost to follow-up at each time point.

In multivariable analysis, controlling for age, sex, and baseline BMI, mean %TBWL was significantly greater in patients who underwent ESG versus HIDLT at 1, 3, 6, and 12 months ($P < .001$, $P < .001$, $P = .011$, and $P < .001$, respectively) (Fig. 2). Similarly, the percentage of patients in each cohort that reached 5%, 10%, and 20% TBWL at 12 months was significantly greater in the ESG group (Table 2). Of note, no patients underwent weight loss pharmacotherapy, subsequent resuturing, or bariatric surgery during the study period.

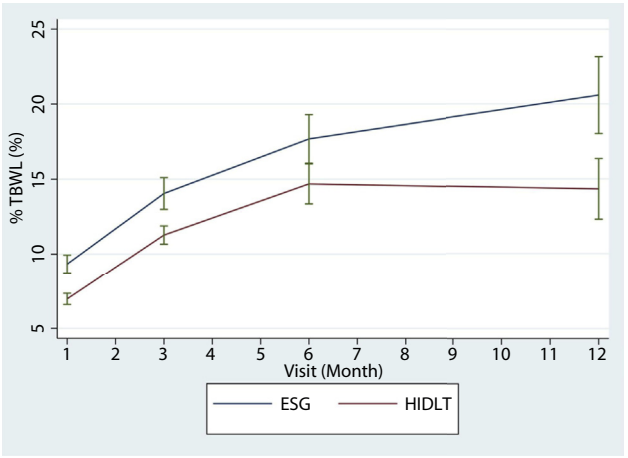


Figure 2. %TBWL at 4 time points from 1 to 12 months postprocedure in the ESG cohort and after initiation of therapy in the HIDLT cohort. *ESG*, Endoscopic sleeve gastroplasty; *HIDLT*, high-intensity diet and lifestyle therapy; *%TBWL*, percent total body weight loss.

Sensitivity analyses (Supplementary Table 2, available online at www.giejournal.org) show that significantly more patients in the ESG group achieved 5%, 10%, and 20% TBWL as compared with HIDLT patients in 2 of 3 scenarios (scenarios 2 and 3), whereas in scenario 1 significantly more patients in the ESG group achieved 5% TBWL only. In each scenario, those not followed through 12 months were assumed to have not lost any more weight since their last visit, so last known weight was brought forward to the 12-month visit. In scenario 1, all ESG patients (n = 105) were included, whereas in scenario 2 all HIDLT patients were included (n = 281), and in scenario 3 all ESG (n = 105) and HIDLT (n = 281) patients were included.

Subgroup analysis

In the subgroup analysis, %TBWL in patients with baseline BMI ≤40 kg/m^2 and BMI >40 kg/m^2 were examined separately. After adjusting for age at intervention and gender, at 1 month and 3 months after intervention, patients in both BMI subgroups had superior %TBWL with ESG compared with HIDLT (Table 3). In detail, ESG patients with baseline BMI ≤40 kg/m^2 and BMI >40 kg/

TABLE 2. Patients in each cohort who achieved 5, 10, and 20% TBWL at 12 months of follow-up

	ESG (n)	ESG patients* (%)	HIDLT (n)	HIDLT patients* (%)	*P* value
>5% TBWL at 12 mo	41	95.35	79	79.0	.045
>10% TBWL at 12 mo	39	90.70	60	60.0	.002
>20% TBWL at 12 mo	24	55.81	27	27.0	<.001

ESG, Endoscopic sleeve gastroplasty; *HIDLT*, high-intensity diet and lifestyle therapy; *TBWL*, total body weight loss.
*Forty-three of 105 ESG and 100 of 281 HIDLT patients presented at 12 months for follow-up.

m^2 showed an identically superior %TBWL at 2.4% ($P <$ .001) than matched HIDLT patients at 1 month after intervention. At 3 months after intervention, ESG patients with baseline BMI $\leq$40 kg/m^2 had a 3.3% greater %TBWL than those in the corresponding HIDLT group, whereas ESG patients with baseline BMI >40 kg/m^2 had a 2.1% greater %TBWL than those in the corresponding HIDLT group. ESG patients with BMI $\leq$40 kg/m^2 continued to show significantly greater %TBWL than those in the BMI-matched HIDLT cohort at 6 and 12 months after intervention. Specifically, those undergoing ESG saw 4.1% greater TBWL at 6 months and 8.2% TBWL at 12 months. This difference was not seen in patients with baseline BMI >40 kg/m^2. Instead, there was no significant difference in %TBWL with ESG at 6 months and 12 months after intervention compared with those in the corresponding HIDLT group (Table 3).

Adverse events

Five moderate-to-severe adverse events (4.8%) occurred in the ESG cohort, compared with zero in the HIDLT group. Three events consisted of upper GI bleeding because of gastric ulceration. In 1 case, the patient underwent diagnostic endoscopy, admission, and monitoring for 48 hours. The other cases were resolved successfully with medical management and did not require admission. One patient developed perigastric fluid collection, which was successfully managed medically, as described by Barola et al.[30] Further, 1 patient experienced dehydration that required readmission for intravenous hydration. No adverse events required surgical intervention, and no mortality occurred as a result of ESG.

DISCUSSION

Results of this analysis indicate that through 12 months after intervention, patients who underwent ESG achieved greater weight loss than patients who underwent HIDLT. Although currently limited, the literature on ESG is growing rapidly. Recently, multicenter studies have illustrated its safety, feasibility, and reproducible weight loss outcomes.[13,16] Further, reports of the learning curve for ESG demonstrate its ability to be learned and incorporated into practice by trained endoscopists.[17,31] As ESG continues to gain traction worldwide, a comprehensive understanding of its outcomes and relative place among the battery of weight loss treatments is important.

Because ESG is a relatively novel procedure, only 2 studies have compared the results of ESG directly with that of another weight loss therapy. In the first, ESG was compared with LSG and laparoscopic adjustable gastric banding. Of the 3 procedures compared, as an outpatient procedure, ESG was found to have the lowest rate of morbidity (P = .01) and the shortest hospital stay. Regarding relative efficacy at 6- and 12-month follow-up, weight loss after ESG was greater than that after laparoscopic adjustable gastric banding but less than after LSG.[32] More recently, our group compared ESG with LSG in a case-matched cohort and found greater weight loss in the LSG group, but with a greater rate of adverse events and new-onset gastroesophageal reflux postprocedure.[28] However, no studies have yet compared ESG directly with diet and lifestyle therapy, the first-line treatment of obesity. Currently, a large multicenter randomized clinical (the Multicenter ESG Trial [MERIT Trial, NCT03406975]) is underway comparing ESG with diet and lifestyle therapy. Our study is the first to compare ESG with diet and lifestyle therapy using a retrospective, case-control analysis.

In interpreting these results, it is essential to consider the notoriously high rates of noncompliance and withdrawal from treatment in HIDLT programs.[23,33] A meta-analysis of weight loss interventions found compliance rates of 63.1% in registered clinical trials and 59.6% in observational studies.[33] A previous meta-analysis on only weight loss interventions containing a control group reported a mean attrition rate of 31%.[34] In our sample, 53% remained engaged after 6 months of therapy and 36% remained at 1 year. Therefore, ESG may be a valuable alternative for patients who have had trouble complying with HIDLT.

In contemplating the results of any weight loss treatment, it is important to consider the multifactorial nature of obesity. Environmental, genetic, psychological, social, and cultural factors may contribute to an individual's weight to varying degrees.[21] Further, personality traits have been linked to weight loss outcomes. Disinhibition, restraint, low novelty-seeking, internal locus of control, and secure attachment style have all been associated with increased compliance in weight loss programs and thus more positive outcomes. Patients with opposite traits (eg, external locus of control) have shown diminished levels of compliance and thus less-substantial weight loss.[35-39] Thus, certain weight loss strategies may be more effective in individuals with particular characteristics. Along the same lines, many obese patients do not respond

TABLE 3. Subgroup analysis examining %TBWL in patients with baseline BMI ≤40 kg/m^2 and >40 kg/m^2 separately

		Change in TBWL (%)	95% Confidence interval		Change in TBWL (%)	95% Confidence interval	
1-month follow-up		*BMI <40 (n = 215)*			*BMI >40 (n = 162)*		
Procedure	HIDLT	Reference			Reference		
	ESG	2.431	1.456	3.406	2.500	1.365	3.634
Age	<40 y	.120	−.975	1.214	1.737	.374	3.100
	41-55	.269	−.728	1.266	1.268	.107	2.429
	>55 y	Reference			Reference		
Sex	Male	Reference			Reference		
	Female	1.505	.543	2.466	.350	−.675	1.375
3-month follow-up		*BMI <40 (n = 166)*			*BMI >40 (n = 132)*		
Procedure	HIDLT	Reference			Reference		
	ESG	3.271	1.641	4.901	2.201	.372	4.030
Age	<40 y	Reference			Reference		
	41-55	1.712	−.099	3.524	3.195	.919	5.471
	>55 y	1.303	−.279	2.885	2.113	.271	3.955
Sex	Male	Reference			Reference		
	Female	1.823	.259	3.387	.768	−.885	2.421
6-month follow-up		*BMI <40 (n = 110)*			*BMI >40 (n = 102)*		
Procedure	HIDLT	Reference			Reference		
	ESG	4.036	.877	7.196	1.804	−1.528	5.136
Age	<40 y	1.852	−1.912	5.616	5.983	1.535	10.432
	41-55	2.250	−1.041	5.541	4.805	1.262	8.348
	>55 y	Reference			Reference		
Sex	Male	Reference			Reference		
	Female	−.234	−3.784	3.317	.136	−3.024	3.296
12-month follow-up		*BMI <40 (n = 71)*			*BMI >40 (n = 72)*		
Procedure	HIDLT	Reference			Reference		
	ESG	8.155	4.009	12.301	4.739	−.558	10.035
Age	<40 y	Reference			Reference		
	41-55	2.896	−1.551	7.342	10.451	2.922	17.981
	>55 y	3.530	−.681	7.740	5.504	−.722	11.729
Sex	Male	Reference			Reference		
	Female	−1.519	−5.625	2.586	12.951	6.869	19.034

ESG, Endoscopic sleeve gastroplasty; *HIDLT*, high-intensity diet and lifestyle therapy; *TBWL*, total body weight loss.

to traditional strategies for weight loss. Given the diversity of the obese population, ESG may begin to fill some gaps in the obesity treatment arsenal.

Based on subgroup analyses, ESG resulted in superior weight loss at 1 year as compared with HIDLT in patients with a BMI <40 kg/m^2. However, no significant difference in weight loss was seen between patients undergoing ESG or enrolling in HIDLT at 1 year for patients whose initial BMI was >40 kg/m^2. This suggests that ESG is more effective in patients with a BMI between 30 and 40 kg/m^2. The logic for this observation is unknown. We hypothesize that the effect of sleeve gastroplasty is less profound in patients with a higher BMI because the restrictive effect is tempered by the counteracting neurohormonal effects that are altered with bariatric surgery. This is worth exploring in future randomized control trials because it will give us insight into which patients are superior candidates for endoscopic bariatric therapy. Currently, for patients with a BMI >40 kg/m^2, bariatric surgery remains the criterion standard for treatment.[40,41]

The primary limitations of this study relate to the recent adoption of ESG as a treatment modality. For instance, the short duration of follow-up reported in this study is a limitation, because this procedure was first performed at the reporting academic center 3 years before the date of the analysis. The moderate sample of patients who have

undergone ESG is thus also related to its recent adoption as a treatment modality. This is also reflected throughout follow-up as the number of patients at each successive time point decreases. The ESG cohort consists of the first 105 patients to undergo ESG at Johns Hopkins by a single endoscopist. To our knowledge, however, no data support the difference in weight loss outcomes based on procedural experience of the practitioner. The single-center nature of this study provides value and limitation. It is valuable in that it provides consistency between HIDLT and the LIDLT included with ESG. However, it limits the generalizability of the results. Further, this study is limited by the lack of data and thus analyses of the possible effects of race, ethnicity, and comorbidities on weight loss outcomes in each cohort. These represent interesting variables to consider in future research. Future research should also aim to evaluate the costs of each treatment cohort in an analytical manner. It is worth noting again that because treatment in both cohorts was limited to private payment methods, we infer that both cohorts are of predominantly middle to high socioeconomic status. Future research into the effects of socioeconomic status on outcomes would be beneficial.

ESG with LIDLT results in statistically and clinically superior weight loss to HIDLT. The patient population that appears to derive the most benefit from ESG are those with a BMI <40 kg/m^2. The adverse event rate associated with ESG may be acceptable to many patients in light of the superior weight loss as compared with HIDLT. Future work is needed to assess ESG outcomes in a larger, prospective, multicenter study, with longer follow-up (NCT03406975).

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Abbreviations: BMI, body mass index; ESG, endoscopic sleeve gastroplasty; HIDLT, high-intensity diet and lifestyle therapy; LIDLT, low-intensity diet and lifestyle therapy; LSG, laparoscopic sleeve gastrectomy; %TBWL, percent total body weight loss.

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*Dr Cheskin and Ms Hill contributed equally to this article.

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Current affiliations: Johns Hopkins Weight Management Center, Department of Health, Behavior & Society (1), U.S. Department of International Health (3), Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA; Division of Gastroenterology and Hepatology, Department of Medicine, The Johns Hopkins Medical Institutions, Baltimore, Maryland, USA (2), Department of Anesthesiology & Critical Care Medicine, The Johns Hopkins Medical Institutions, Baltimore, Maryland, USA (4), National Center for Weight and Wellness, Washington, DC, USA (5), Faculté de médecine de Franche-Comté CHRU Jean Minjoz, Besançon, France (6), Department of Nutrition and Food Studies, College of Health and Human Services, George Mason University, Fairfax, Virginia, USA (7).

Reprint requests: Vivek Kumbhari, MD, Division of Gastroenterology and Hepatology, Johns Hopkins Medical Institutions, Sheikh Zayed Bld, 1800 Orleans St, Ste 7125G, Baltimore, MD 21287. E-mail: vkumbhari@gmail.com.

SUPPLEMENTARY TABLE 1. Breakdown of patient ages into categories

	ESG (n = 105)	HIDLT (n = 281)	*P* value
Age <40 y	29 (27.62)	73 (25.98)	
Age 41-55 y	48 (45.71)	118 (41.99)	
Age >55 y	28 (26.67)	90 (32.04)	
Male	30 (28.57)	92 (32.74)	Reference.
Female	75 (71.42)	189 (67.26)	.434
Body mass index, kg/m^2	40.50 ± 7.89	39.85 ± 7.62	.467

Values are mean ± standard deviation or n (%).
ESG, Endoscopic sleeve gastroplasty; *HIDLT*, high-intensity diet and lifestyle therapy.

SUPPLEMENTARY TABLE 2. Follow-up at each time point

Endoscopic sleeve gastroplasty			High-intensity diet and lifestyle therapy		
Time point	**Follow-up sample**	**Percentage included**	**Time point**	**Follow-up sample**	**Percentage included**
Baseline	106	100	Baseline	281	100.00
1 mo	96	90.57	1 mo	281	100.00
3 mo	73	68.87	3 mo	225	80.07
6 mo	63	59.43	6 mo	149	53.02
12 mo	43	40.57	12 mo	100	35.59

	ESG (n)	ESG patients* (%)	HIDLT (n)	HIDLT patients* (%)	*P* value
Scenario 1†					
>5% TBWL at 12 mo	94	89.52	79	79.0	.038
>10% TBWL at 12 mo	71	67.62	60	60.0	.202
>20% TBWL at 12 mo	28	26.67	27	27.0	.957
Scenario 2‡					
>5% TBWL at 12 mo	41	95.35	219	77.9	.008
>10% TBWL at 12 mo	39	90.70	143	50.9	<.001
>20% TBWL at 12 mo	24	55.81	31	11.0	<.001
Scenario 3§					
>5% TBWL at 12 mo	94	89.52	219	77.9	.018
>10% TBWL at 12 mo	71	67.62	143	50.9	.002
>20% TBWL at 12 mo	28	26.67	31	11.0	.001

ESG, Endoscopic sleeve gastroplasty; *HIDLT*, high-intensity diet and lifestyle therapy; *TBWL*, total body weight loss.
*43 of the 105 ESG and 100 of the 281 HIDLT patients presented at 12-months for follow-up.
†All ESG patients (n = 105) were included. Those not followed up through 12 months were assumed to have not lost any more weight since last visit, so last known weight was brought forward to the 12-month visit. Significantly more patients in the ESG group achieve 5% TBWL at 12 months.
‡All HIDLT patients (n = 281) were included. Those not followed up through 12 months were assumed to have not lost any more weight since last visit, so last known weight was brought forward to the 12-month visit. Significantly more patients in the ESG group achieved 5%, 10%, and 20% TBWL as compared with HIDLT patients.
§All patients (ESG n = 105 and HIDLT n = 281) were included. Those not followed up through 12 months were assumed to have not lost any more weight since last visit, so last known weight was brought forward to the 12-month visit. Significantly more patients in the ESG group achieved 5%, 10%, and 20% TBWL as compared with HIDLT patients.