ORIGINAL ARTICLE



Endoscopic Sleeve Gastroplasty, Laparoscopic Sleeve Gastrectomy, and Laparoscopic Band for Weight Loss: How Do They Compare?

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Abstract

Background Endoscopic sleeve gastroplasty (ESG) is a novel endobariatric procedure. Initial studies demonstrated an association of ESG with weight loss and improvement of obesity-related comorbidities. Our aim was to compare ESG to laparoscopic sleeve gastrectomy (LSG) and laparoscopic adjustable gastric banding (LAGB).

Methods We included 278 obese (BMI > 30) patients who underwent ESG (n = 91), LSG (n = 120), or LAGB (n = 67) at our tertiary care academic center. Primary outcome was percent total body weight loss (%TBWL) at 3, 6, 9, and 12 months. Secondary outcome measures included adverse events (AE), length of stay (LOS), and readmission rate.

Results At 12-month follow-up, LSG achieved the greatest %TBWL compared to LAGB and ESG (29.28 vs 13.30 vs 17.57%, respectively; p < 0.001). However, ESG had a significantly lower rate of morbidity when compared to LSG or LAGB (p = 0.01). The LOS was significantly less for ESG compared to LSG or LAGB (0.34 ± 0.73 vs 3.09 ± 1.47 vs 1.66 ± 3.07 days, respectively; p < 0.01). Readmission rates were not significantly different between the groups (p = 0.72).

Conclusion Although LSG is the most effective option for weight loss, ESG is a safe and feasible endobariatric option associated with low morbidity and short LOS in select patients.

Keywords Endoscopic sleeve gastroplasty · Laparoscopic sleeve gastrectomy · Laparoscopic adjustable gastric band · Weight loss

Abbreviations

ESG	Endoscopic sleeve gastroplasty
LSG	Laparoscopic sleeve gastrectomy

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LAGB	Laparoscopic gastric band
DM	Type II diabetes
BMI	Body mass index
LOS	Length of stay
HgbA1c	Hemoglobin A1C
%TWBL	Percent total body weight loss
AE	Adverse events
RZS	Reem Z. Sharaiha
CA	Cheguevara Afaneh
GD	Gregory F. Dakin
AP	Alfons Pomp

Introduction

Obesity constitutes a twenty-first century pandemic and public health concern with serious implications for the health and well-being of the population. In 2014, approximately 37% of the worldwide population was overweight (BMI > 25).¹ In the USA, over one third of the adult

population has a BMI over 30.^{2,3} Because of its increasing prevalence among adults, the impact of obesity on morbidity, mortality, and healthcare costs is profound.

Bariatric surgery is the most effective treatment for obesity. It is associated with successful long-term maintenance of weight loss and reduction in obesity-related morbidities, as well as improvement in quality of life of these patients.^{4–7} The armamentarium of surgical procedures to combat morbid obesity and related comorbidities has expanded. The laparoscopic sleeve gastrectomy (LSG) remains one of the most popular options, while laparoscopic adjustable gastric banding (LAGB) has decreased over time.^{8–12} Nonetheless, in spite of the efficacy of bariatric surgery in achieving weight loss and resolution of related comorbidities, only 1% of the patients eligible for these procedures select bariatric surgery as their treatment of choice.^{9,13,14}

The increase in the number of patients with obesity has led to the development of innovative treatment strategies to address this disease. Endoscopic bariatric therapy represents a novel, minimally invasive approach to weight loss in patients with obesity that involves restrictive techniques.^{15–17} Endoscopic sleeve gastroplasty (ESG) is a trans-oral endoscopic gastric volume reduction technique that was first reported in 2008 and improved upon in 2013 with the ability to perform full-thickness sutures.^{18,19} Endoscopically placed sutures extend from the incisura to the greater curvature of the stomach and reduce the size of the stomach. Published experience demonstrates successful short-term weight loss, decrease biomarkers of diabetes, and improvement in hypertension and hypertriglyceridemia, with a favorable side effect profile.^{20–22}

Despite initial encouraging results, ESG's role in weight management remains unclear. While early studies showed safety and efficacy of ESG, there has been no studies comparing it to other minimally invasive surgical bariatric procedures. In this study, we aim to study the effectiveness of ESG and compare it to both the laparoscopic sleeve gastrectomy and the laparoscopic adjustable gastric banding.

Materials and Methods

We conducted a single-center, retrospective cohort study of obese patients who underwent ESG, LSG, or LABG. Consecutive ESG patients were included who had at least a 1 year follow-up between January 2011 and December 2016. The ESG patients were compared to a cohort of patients undergoing LSG from 2013 to 2014 as well as any patient who underwent a LABG over the period of study. All surgical patients were referred to our academic bariatric center of excellence for management of obesity. Indications for weight loss procedures were based on obesity parameters, with a BMI > 30 kg/m², with previous failed attempts at medical weight loss measures.

Patients were evaluated for candidacy for ESG, LSG, or LABG. The LSG or LAGB was not covered by insurance in patients with a BMI < 40 without comorbidities or a BMI < 35 and comorbidities.²³ ESG was contraindicated in patients with gastric lesions with bleeding potential (ulcers and gastritis), neoplastic findings, or family history of gastric cancer.²⁴ Individuals with mental health disorders, coagulopathies, or other significant medical comorbidities precluding anesthesia were also excluded. Choice of weight loss procedure was ultimately made with the patient after consultation with their gastroenterologist or bariatric surgeon. Additional preprocedural consultations with a primary care physician, cardiologist, endocrinologist, nutritionist, and psychiatrist were provided to ensure multidisciplinary care.

Patient demographics and medical comorbidities were obtained. Variables included age, gender, race, BMI, ASA class,²⁵ diagnosis of hypertension, hyperlipidemia, diabetes, and serologic testing for hemoglobin A1C (HgbA1c). Presence of diabetes was defined as taking diabetes medication (other than metformin prescribed for weight loss) or a HgbA1c $\geq 6.5\%$.²⁶ Hypertension was defined as systolic blood pressure of ≥ 140 mmHg, diastolic blood pressure ≥ 90 mmHg, or taking an anti-hypertensive medication. Hyperlipidemia was defined as currently taking a lipid-lowering medication or an LDL ≥ 160 mg/dL or fasting triglycerides ≥ 200 mg/dL.²⁷ Post procedure data included hospital length of stay, duration of follow-up, and percent total body weight loss (%TBWL). All adverse events and hospital readmission within 90 days of the weight loss procedure were recorded.

Endoscopic and Surgical Techniques

We used a standard technique as previously described.²² A double-channel therapeutic upper endoscope (GIF- 2TH180; Olympus, Center Valley, PA) 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. 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. The helix device was used to capture the muscularis propria, allowing sequential fullthickness 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 fullthickness 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. 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. The ESG was performed by one experienced endoscopist (RZS).

Laparoscopic Sleeve Gastrectomy

Our technique for laparoscopic sleeve gastrectomy has been previously published.^{28,29} The procedures were all performed using the same technique by one of the three surgeons skilled with this procedure (AP, GD, CA).

Briefly, the dissection begins 5 cm from the pylorus. The greater curvature of the stomach is completely mobilized. The hiatus of the esophagus is explored posteriorly and any hiatal hernia is repaired posteriorly if ≥ 3 cm. The sleeve is performed on a 40-fr bougie with sequential firings of the laparoscopic stapler. Buttress material is routinely used except for the first firing which is oversewn. An intraoperative dye leak test is routinely performed.

Laparoscopic Adjustable Gastric Banding

For the adjustable gastric banding, patients are placed in reverse Trendelenburg. The abdomen is accessed and pneumoperitoneum established. The lesser omentum is opened via pars flaccida. The angle of His is mobilized. A retro-gastric dissection is performed. The Lap-Band System (Inamed-Allergan, Santa Barbara-Carpinteria, CA) is introduced in this retrogastric tunnel. The band is plicated in place using gastrogastric sutures. The subcutaneous port is fixed to the anterior fascia of the rectus. All patients had the Lap-Band System placed by one of the two surgeons (AP, GD).

Outcome Measures

Changes in BMI and %TBWL were measured during scheduled follow-up at 3, 6, 9, and 12 months post

Table 1	Patient demographic
data	

procedure. The primary outcome was change in BMI and %TBWL at 12 months post procedure. Secondary outcomes included post procedure hospital length of stay and post procedure adverse events, as well as hospital readmission within 90 days. Adverse events were classified according to modified Clavien-Dindo classification of surgical complications.³⁰

Statistical Analysis

Descriptive statistics were calculated for all demographic and clinical variables and reported as median (range), mean \pm standard deviation, or proportion where appropriate. Univariate analysis was performed using the χ^2 test and Fisher exact test for categorical variables and the Student *t* test, Wilcoxon test, or Mann-Whitney *U* test as required for continuous variables. All variables were tested for normality using the Shapiro-Wilk test. All statistical analysis was conducted using STATA 13.0 (StataCorp LP, College Station, TX). A *p* value of < 0.05 was considered significant.

Results

Patient Characteristics

We evaluated consecutive patients who have had bariatric procedures at our institution (n = 278) during a 1-year time period. Of those 278 patients, 120 patients had a LSG, 91 had an ESG, and 67 had a LAGB. All patients reached at least 6 months follow-up and were eligible for the study. The mean age was 42 ± 12 years (range 18-77), 76% were female, and the mean baseline BMI was 43.82 ± 0.50 kg/m². On average, patients who had LSG had higher BMI than LAGB, and patients who had ESG had lower BMI (47.22 ± 7.84 for LSG, 38.61 ± 6.98 for ESG, and 44.98 ± 6.45 for LAGB;

Mean \pm SD	LSG $(n = 120)$	ESG $(n = 91)$	LAGB $(n = 67)$	p value
Age in years	40.71 ± 11.95	43.86 ± 11.26	41.94 ± 13.31	0.173
Male	26 (21.67%)	29 (31.87%)	13 (19.40%)	0.126
Female	94 (78.33%)	62 (68.13%)	54 (80.60%)	< 0.001
BMI kg/m ²	47.22 ± 7.84	38.61 ± 6.98	44.98 ± 6.45	< 0.001
ASA class	3 (2–4)	2 (2-3)	2 (2–3)	0.786
Diabetes	31 (25.83%)	20 (21.98%)	15 (22.73%)	0.020
HgbA1c	6.30 ± 1.25	5.82 ± 0.98	6.04 ± 1.00	< 0.001
Hypertension	61 (50.83%)	18 (19.78%)	33 (50.00%)	< 0.001
Hyperlipidemia	47 (39.17%)	13 (14.29%)	25 (37.88%)	< 0.001
Obstructive sleep apnea	52 (43.33%)	15 (16.67%)	14 (21.21%)	< 0.001

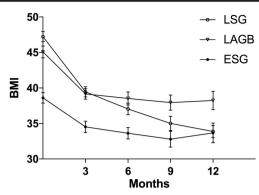


Fig. 1 Weight loss at 12 months—BMI. This is a XY plot depicting average BMI \pm standard error of measurement at the time of surgery, 3, 6, 9, and 12 months after LSG, ESG, or LAGB

p < 0.001). Incidence of hypertension and hyperlipidemia were also higher in the surgical groups compared to the ESG group (p < 0.01) (Table 1).

Impact on Weight Loss

At 6-month follow-up, LSG achieved the greatest %TBWL compared to ESG and LABG (23.48 vs 14.37 vs 12.68%, respectively). At 12-month follow-up, the LSG achieved the greatest BMI decrease (Fig. 1) and %TBWL at 12 months compared to ESG and LABG (29.28 vs 17.57 vs 13.30%, respectively; p < 0.001) (Fig. 2).

In multivariable analysis when controlling for age, gender, and ASA class, LSG was the procedure associated with the most significant weight loss (p value < 0.001). This remained significant when we stratified with BMI > 40 kg/m². However, when we stratified by BMI < 40 kg/m², even after adjusting for age, gender, and ASA, there was no significant difference in %TBWL at 12 months when comparing the three different techniques: LSG with ESG or LAGB (p value = 0.21) (Table 2).

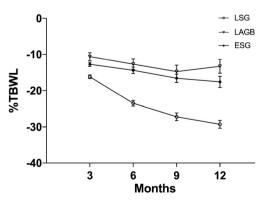


Fig. 2 Weight loss at 12 months—TBWL. This is a XY plot depicting average %TBWL \pm standard error of measurement at 3, 6, 9, and 12 months after LSG, ESG, or LAGB

 Table 2
 Multivariable analysis comparing bariatric procedure type with %TBWL at 12 months

	Coefficient	95% confidence	p value
Stratified by Bl	MI < 40		
Procedure type	2:		
LSG	Ref		
ESG	- 0.053	- 0.139, 0.032	0.210
LAGB	-0.117	- 0.246, 0.013	0.075
Age	0.000	- 0.003, 0.004	0.927
Gender:			
Female	Ref		
Male	0.004	- 0.100, 0.108	0.939
ASA class	0.071	- 0.215, 0.357	0.118
Stratified by Bl	MI > 40		
Procedure type	2:		
LSG	Ref		
ESG	- 0.121	-0.171, -0.070	< 0.001
LAGB	-0.148	- 0.190, - 0.105	< 0.001
Age	-0.001	- 0.003, 0.001	0.053
Gender:			
Female	Ref		
Male	- 0.056	- 0.102, - 0.010	0.018
ASA class	- 0.010	- 0.049, 0.027	0.572

Length of Stay

Post-procedure length of stay was significantly less for ESG compared to LSG or LAGB (0.34 ± 0.73 vs 3.09 ± 1.47 vs 1.66 ± 3.07 days, respectively; p < 0.01) (Table 3).

Adverse Events

We noted a statistically significant difference in adverse event rates for ESG compared to LSG or LAGB (2.20 vs 9.17 vs 8.96%, p value < 0.05) (Table 3). In the ESG group, the patient developed a peri-gastric leak 11 days post procedure after eating a solid meal (despite being instructed to maintain a liquid diet for 2 weeks). The patient was managed non-operatively with a percutaneous drain. Another patient was re-admitted with a migraine and was discharged later.

In the LSG group, one patient developed a peri-gastric leak and was taken back to the operating room for drainage of an intra-abdominal abscess and later was readmitted for a gastroesophageal stricture requiring a stent. Another patient demonstrated a peri-gastric leak on upper GI series and was brought back to the operating room; however, no leak was identified. Another patient developed wound dehiscence with herniated viscera requiring reoperation for closure and later developed a serous leakage from the same wound necessitating its opening. One patient developed a pulmonary embolism requiring

Table 3 Procedure-related outcomes

Mean \pm SD (range)	LSG $(n = 120)$	ESG $(n = 91)$	LAGB $(n = 67)$	p value
Hospital length of stay (days)	3.09 ± 1.47 (2–11)	0.34 ± 0.73 (0-3)	1.66 ± 3.07 (0–19)	< 0.001
Re-admissions at 90 days (%)	5 (4.17%)	2 (2.20%)	2 (2.99%)	0.72
Total post procedure morbidity (%)	11 (9.17%)	2 (2.20%)	6 (8.97%)	< 0.05
Events required no procedure (%)	6 (5.00%)	1 (1.10%)	4 (5.97%)	
Events required surgery or endoscopy (%)	5 (4.17%)	0 (0.00%)	2 (3.00%)	
Events required interventional radiology (%)	0 (0.00%)	1 (1.10%)	0 (0.00%)	

anticoagulation. One patient developed hypercarbic respiratory failure after a successful LSG, requiring re-intubation. One patient developed a prolonged post-operative ileus. One other patient developed a wound infection requiring antibiotics. One patient developed a urinary tract infection requiring antibiotics. Two patients had to be re-admitted for fluid resuscitation, and one patient was re-admitted to the hospital after 28 days with nausea and vomiting, had an EGD that showed bile reflux.

In the LAGB group, two patients had failure of contrast to pass during upper GI series, requiring re-operation for removal of the band. Two patients developed a pulmonary embolism after discharge, one required readmission for anticoagulation. One patient developed a wound infection requiring antibiotics, and one patient had to be admitted with abdominal pain, but was discharged after a negative workup (Table 4).

Readmissions

There was no statistically significant difference between all readmission events within 90 days between the three groups (LSG 4.17%, ESG 2.20%, and LAGB 2.99%, p value = 0.72) (Table 3).

Discussion

This study highlights the safety and efficacy of ESG in improving weight loss up to 12 months post-procedure. The ESG cohort had a 17.57% decrease in TBWL with a lower rate of post-procedural morbidity as compared to the LSG and LAGB. These results are consistent with previously published studies of ESG with 13–18% TBWL at 12 months.²⁴ There has been increasing literature and experience supporting ESG as an effective nonsurgical approach to gastric remodeling by promoting satiety and impairing gastric emptying, altering potential gut metabolic and neurohormonal signaling vital in regulating weight loss.

Since the first study on ESG demonstrated the feasibility of creating an ESG in 2013, there has been much interest in obtaining long-term outcome data. However, despite the clinical experiences that have been published, the adverse events with ESG have been sparse. In contrast, and in large part attributable to the plethora of data on the surgical techniques for weight loss, the existing surgical literature describes various peri- and post-operative complications of bariatric surgery, ranging from wound infections to death. Our study found that ESG patients had significantly fewer adverse events as compared to those who underwent a LAGB or a

 Table 4
 Adverse events as a fraction of overall procedure number all within 90 days

Grade	LSG $(n = 120)$		ESG $(n = 91)$		LAGB $(n = 67)$	
Ι	Post op ileus Dehydration ^{&} Dehydration ^{&}	3 (2.50%)	Migraine ^{&}	1 (1.1%)	Abdominal pain ^{&}	1 (1.5%)
Π	PE Wound infection UTI treated with antibiotics	3 (2.50%)	-	0	Wound infection PE ^{&} PE	3 (4.5%)
III	N/V had EGD ^{&} Wound complication ^{&} Suspected leak needing surgery	3 (2.50%)	Leak ^{&}	1 (1.1%)	Band removal Band removal	2 (3.0%)
IV	Leak ^{&} Hypercarbic respiratory failure in ICU	2 (1.67%)	-	0	-	0
V	_	0	_	0	_	0

This is based on Clavien-Dindo classification of surgical complications³⁰

& This denotes patients who were re-admitted to the hospital

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LSG. There was only one endoluminal leak readmission out of the 91 patients who underwent an ESG. Not surprisingly, our study found that the average LOS with ESG is significantly less than that of LSG or LAGB groups, with the vast majority of patients going home the same day.

Similar to an algorithmic or stepwise approach to weight loss through promotion of diet and lifestyle modification, we propose that endoscopic therapies be considered in the "bariatric treatment gap" or a body mass index between 30 and 40. Patients with a BMI greater than 40 should be assessed for surgical options such as a LSG, given extensive data to support the greatest weight loss and decrease in weight-related comorbidities from surgery as compared to other therapies. However, for those patients with a BMI less than 40 who have failed an adequate trial of dietary changes, lifestyle modification, and pharmacologic therapy, endoscopic therapies, including intragastric balloon placement should be considered as part of the approach to weight loss. While engaging and activating patients to become active participants in their own care is vital, the advent of weight loss centers can help facilitate a multidisciplinary approach to obesity, individualizing treatment options to each and every patient.

Our study carries several inherent limitations. First, there is an obvious limitation related to the retrospective nature of the study. Second, the follow-up is limited to 12 months. While our study was strengthened by the three arms, there was no control group or randomization among the different cohorts. We found that weight loss in the ESG group was comparable to that from the LAGB cohort with fewer post-operated complications and a shorter inpatient length of stay.

Endoscopic sleeve gastroplasty is a viable and safe weight loss approach for those between a BMI of 30 to 40. Further prospective studies demonstrating long-term weight loss durability and effectiveness are needed.

Author Contributions Study conception and design: Drs. Sharaiha, Novikov, Afaneh

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Critical revision: Drs. Novikov, Afaneh, Saumoy, Shukla, Dakin, Pomp, Dawod, Shah, Aronne, and Sharaiha

Compliance with Ethical Standards

Conflict of Interest Drs. Novikov, Afaneh, Saumoy, Parra, Shukla, Dakin, Pomp, Dawod, Shah, and Aronne have nothing to disclose.

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