# Safety and efficacy of endoscopic sleeve gastroplasty for obesity management in new bariatric endoscopy programs: a multicenter international study

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## Abstract

**Background:** Endoscopic sleeve gastroplasty (ESG) is an incisionless procedure that reduces the size of the gastric cavity. In prior studies, it has been proven to be a safe and effective treatment for obesity. In this study, we performed a collaborative study to evaluate the effectiveness of ESG among new endobariatric programs.

**Methods:** This was an international, multicenter study reviewing the outcomes of ESG in centers starting ESG programs. Total body weight loss, change of body mass index (BMI), excess body weight loss (EBWL), technical success, duration of hospitalization, and immediate and delayed adverse events and complications at 24 h, 1 week, and 1, 3, and 6 months post-procedure were evaluated.

**Results:** A total of 91 patients (35 males) from six centers were included. The patients' mean BMI before the procedure was 38.7 kg/m<sup>2</sup>. BMI reduction at 3 months was 7.3 (p < 0.000), at 6 months 9.3 (p < 0.000), and at 12 months 8.6 (p < 0.000) from baseline. EBWL was 17.3% at 1 month (p < 0.000), 29.2% at 3 months (p < 0.000), and 35.6% at 6 months (p < 0.000). The mean procedure duration was 85.1 min. The mean length of hospital stay post-procedure was 27 h. **Conclusion:** ESG provides EBWL percentage sustained up to 12 months. These results are equivalent among the new ESG centers compared to previous studies by expert centers.

## Lay title

Endoscopic sleeve gastroplasty in new bariatric endoscopy programs:

# Plain Language Summary

This article is the result of a collaborative international study on new endoscopic programs offering endoscopic sleeve gastroplasty.

The minimally invasiveness and increasing accessibility of this technique makes it very attractive for patients with obesity while being poor candidate for surgery or refusing surgery.

This study will also provide valuable information regarding this rising technique of endobariatric treatment.

Keywords: bariatric endoscopy, endobariatric, endoscopic sleeve gastroplasty, gastroplasty

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#### Introduction

Obesity has become a global epidemic with sizable socioeconomic and healthcare-associated burden. Combined with the limited effectiveness of diet and behavior modifications,<sup>1</sup> this has created a tremendous interest in surgical and non-surgical weight-loss strategies. Bariatric surgery is a well-studied, proven solution for morbid obesity that provides long-lasting weight loss but has associated comorbidities.<sup>2</sup> Only about 1% of eligible patients undergo bariatric surgery due to potential perceived adverse events, limited access, and preference.<sup>3</sup>

In recent years, endobariatric procedures have been developed for obese patients who are not eligible for, or do not desire bariatric surgery.<sup>4</sup> Endoscopic sleeve gastroplasty (ESG) is an incisionless, minimally invasive weight-loss procedure that utilizes a full-thickness endoscopic suturing system to reduce the gastric volume by approximately 70%.<sup>5,6</sup> In prior studies, it has been proven to be a safe and effective treatment for obesity in select patients.<sup>7-9</sup> There have been many studies from experienced centers demonstrating the safety and efficacy of ESG.<sup>10-12</sup> In this study, we performed a retrospective analysis to evaluate the effects of ESG on weight loss and obesity-related comorbidities in new centers performing the procedure.

#### Methods

This was an international, multicenter, retrospective study reviewing the outcomes of ESG in six centers starting ESG programs, including 91 eligible patients, undergoing ESG over 4 years. None of these patients were included in previous studies. All patients included had a body mass index (BMI) greater than 30 kg/m<sup>2</sup> and had failed noninvasive weight-loss measures or had a BMI greater than 40 kg/m<sup>2</sup> and were not considered as surgical candidates or refused surgery. They did not have any contraindication to ESG, including previous gastric surgery, gastroesophageal varices, acute gastric pathology, hiatal hernia larger than 5 cm, and pregnancy.

This study was conducted under a Western Institutional Review Board (IRB)–approved retrospective study (Pro2020002798). On 17 February 2021, Western IRB approved a request for a waiver of authorization for use and disclosure of protected health information (PHI) for this study. Patients were consented for the procedures as per standard of care.

#### Data collection and primary outcomes

Patient information, including age, sex, medical history of obesity-related chronic diseases/conditions (ORCD), previous bariatric procedures, and baseline height, weight, and BMI, was collected at baseline.

Patients' excess weight (EW) was calculated as the difference between their baseline weight and ideal body weight (using a BMI of 24.9 kg/m<sup>2</sup>).

Patients were evaluated after 1, 3, 6, and 12 months for anthropometric features (BMI, weight) and serologic parameters (hemoglobin A1c, lipid panel, serum triglycerides, and liver function tests). Primary outcomes included total body weight loss (TBWL; weight, in kg), change of BMI ( $\Delta$ BMI, in kg/m<sup>2</sup>), % TBWL, EW loss, % EW loss, and immediate and delayed adverse events and complications at 24 h, 1 week, and 1, 3, and 6 months post-procedure.

Secondary outcomes were the effects of ESG on metabolic factors (diabetes, hyperlipidemia, and steatohepatitis), technical success of the procedure, complication rate, procedure duration, and length of post-procedure recovery duration in post-anesthesia recovery unit (PACU).

Subjects who had a minimum of 1-year follow-up were included in this study.

#### Statistics

Repeated measures ANOVA and *t*-test for dependent means were conducted for comparing continuous variables, while chi-square and Fisher's exact tests were used for categorical variables. Twosided *p*-values less than 0.05 were considered statistically significant. All descriptive and statistical analyses were conducted using MedCalc V18.9 (MedCalc Software, Ostend, Belgium).

#### Procedure

All ESGs were performed similar to that described by Lopez-Nava *et al.*,<sup>13–15</sup> Sharaiha *et al.*,<sup>16</sup> Hill *et al.*,<sup>17</sup> and Barola *et al.*<sup>18</sup> All procedures were performed using general anesthesia and CO<sub>2</sub> insufflation, and all patients were administered prophylactic antibiotics (levofloxacin 500 mg daily on the day of procedure and the following 2 days) and Deep vein thrombosis (DVT) prophylaxis (sequential compression device during procedure) in line with local protocols. The patient was placed in either the left lateral or the supine position. A diagnostic esophagogastroduodenoscopy (EGD) was performed to confirm the absence of exclusion criteria. An esophageal overtube was inserted to safeguard the esophagus and prevent decompression of the insufflated stomach in all subjects. A double-channel therapeutic gastroscope (GIF-2TH180, OLYMPUS, Tokyo, Japan) was then inserted. In most instances, argon plasma coagulation (APC, Forced coagulation, Effect 2, 50 W) (VIO 300D/APC2-HFgenerator; ERBE Elektromedizin, Tubingen, Germany) was used to mark suture placement sites along the anterior and posterior walls of the gastric body. The preference of using overtube or APC was left at the discretion of the endoscopists at each site. APC was used at all centers except at the Fondazione Policlinico A. Gemelli site in Italy (N=33).

Using the OverStitch system (Apollo Endosurgery, Austin, Texas, USA), a 2/0 polypropylene suture was applied, beginning at the anterior wall at the level of the incisura angularis, with further bites taken on the greater curvature and then the posterior wall. Running suture placement was then continued in a retrograde fashion within 1 cm proximal to the initial row, from posterior wall to anterior wall (U-pattern) or anterior wall to posterior wall (Z-pattern), through the greater curvature. Importantly, full-thickness bites of the proximal row were staggered in relation to the distal row so as to avoid the formation of longitudinal gastric pockets. Generally, 6 to 10 bites per suture were performed. On completion of the suture pattern, the needle was released, anchoring the leading end of the suture. Using the cinching device, the suture was pulled tight so as to approximate the tissue together, and the trailing end of the suture was anchored by deploying the cinch.

Sutures were placed serially using this approach until within 1 cm of the gastroesophageal junction, as measured along the lesser curvature. Usually, the fundus was sutured until the endoscope began to retroflex and only one suture was used in this area. Therefore, a fundal pouch remained at the end of each procedure. Typically, a total of 6–10 sutures were used per patient. On completion of the procedure, an endoscopy without the OverStitch attachment was performed to ensure optimal appearance and absence of bleeding. The luminal diameter on completion of the procedure was 13–16 mm.

Key technical elements common to all centers included using the tissue helix for every bite,

attaining a 'pink out' with each bite to ensure a transmural bite, doubling back with each suture (using each suture to form two rows) to ensure foreshortening of the stomach, and leaving a small residual fundal pouch. The decision to perform a reinforcing inner row of sutures ('reinforcing layer') was left to the discretion of the endoscopist during the individual case. More than half of the patients were discharged on the same day (55/91).

Three centers hospitalized patients for 12 h (Juarez Hospital, Mexico; Santander Hospital, Mexico; and La Policia Hospital, Colombia) and one center hospitalized patients for 48 h (Fondazione Policlinico A. Gemelli, Italy) as per their clinical protocol.

In all centers, patients were given daily proton pump inhibitors and a regimen of antiemetics, analgesics, and antispasmodics on discharge. All patients commenced a low-calorie liquid diet for at least 2 weeks, progressing through puree to a solid diet by 4 weeks post-procedure. All centers provided patients with a comprehensive ancillary program involving intensive consultation and follow-up visits with the endoscopists and allied health professionals (registered dietitians, behavioral psychologists, exercise physiologists, and obesity medicine specialists). The programs, lasting a minimum of 6 months post-ESG, aimed to help patients establish positive dietary and lifestyle changes.

#### Results

Overall, 91 patients (mean age 39.7 years, SD 11.6 years) underwent ESG from December 2016 through March 2020 at six tertiary care centers (Table 1).

In total, 35 of the patients were males (38%) while 56 were females (62%).

The patients' mean BMI at baseline was 38.7 (range 31.2-57.6) kg/m<sup>2</sup>.

ESG was technically successful in all patients.

The mean procedure duration was 85.1 (SD 31.5) min. Suture pattern was Z-pattern in 81 cases and U-pattern in 10 cases. Average number of sutures was 6.1 (range 3–11 sutures). The number of sutures for each procedure varied widely based on several factors, including the operator(s) and body habitus. Each procedure was performed by an attending advanced endoscopist and some included

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Characteristics	<i>N</i> = 91	
Age, years (average)	39.7 (SD 11.6)	
Gender	35 males (38%), 56 females (62%)	
Pre-ESG BMI (average)	38.7 (31.2–57.6)	
BMI Post-ESG at 1 month	34.5 (25.9–56.6)	
BMI Post-ESG at 3 months	31.3 (25–54.6)	
BMI Post-ESG at 6 months	29.4 (23–54.6)	
BMI Post-ESG at 12 months	30.1 (20.4–53.9)	
Comorbidities		
DM	46 (50.5%)	
HTN	46 (50.5%)	
GERD	22 (24%)	
OSA	21 (23%)	
Procedure duration (min)	85.1 (SD 31.5)	
Length of stay (hours)	27 (SD 17)	
Suture pattern	Z-Pattern – 81, <i>U</i> -Pattern – 10	
Average number of sutures	6.1 (SD 1.6)	
Adverse events	N=9 (10%)	
Nausea/vomiting	2	
Bleeding	6	
Stenosis	1	
Repeat therapy	2	
Length of follow-up (months)	27.2 (SD 12.2)	
BMI, body mass index; ESG, endoscopic sleeve		

Table 1. Demographics and clinical characteristics. .

BMI, body mass index; ESG, endoscopic sleeve gastroplasty; SD, standard deviation ; DM, diabetes mellitus, Gastroesophageal reflux disease (GERD); HTN, Hypertension; OSA, obstructive sleep apnea.

the assistance of an advanced endoscopy fellow. Every fellow received extensive training on the OverStitch suturing system before performing ESG. Furthermore, the body habitus of each patient differs and affects the technique of the procedure.

Therefore, 37 out of 91 (41%) procedures were performed with involvement from at least one Gastroenterology fellow in training. The mean length of recovery time before discharge was 27 (range 4–50) h.

BMI reduction at 1 month was 4.2 (p < 0.000), at 3 months was 7.3 (p < 0.000), at 6 months was 9.3 (p < 0.000), and at 12 months was 8.6 (p < 0.000) from baseline (Figure 1).

EBWL was 17.3% at 1 month (p < 0.000), 29.2% at 3 months (p < 0.000), and 35.6% at 6 months (p < 0.000) (Figure 2). Patients had lost 7.2% of their total body weight at 1 month, 11.2% at 3 months, and 17.4% at 6 months post-ESG

However, 2/91 patients underwent repeat procedures. One case required suture reinforcement and stent through the sleeve due to stenosis, while the other case had sleeve gastroplasty breakdown due to loss of suture integrity.

Immediate adverse events included nausea or vomiting (n=2, 2%) and bleeding (n=6, 7%). Extended adverse event included stenosis (n=1).

There was a 67% (52/91) follow-up rate for metabolic outcomes, while 39 subjects were lost to follow-up (43%). Reasons for loss to follow-up included (but not limited to) several barriers, such as insurance coverage, poor compliance, and relocation of few subjects. We were able to collect complete data on 52 patients for diabetes, hypertriglyceridemia, and steatohepatitis at baseline, 6 and 12 months post-ESG. Significant reductions were noted in HbA1c by 0.3% (p < 0.000) at 6 months post-ESG and by 0.35% at 12 months post-ESG (p < 0.000). Significant reduction was noted in ALT by 12.25 U/L (p < 0.000) at 6 months and by 13.27 U/L at 12 months (p < 0.000). Significant reduction was noted in AST by 8.7 U/L (p < 0.000) at 6 months and by 10.4 U/L at 12 months (p < 0.000). Significant reduction was noted in LDL by 13.8 mg/dL (p < 0.000) at 6 months and by 13.1 mg/dL at 12 months (p < 0.000). Significant reduction was noted in triglycerides by 99.9 mg/dL (p < 0.000) at 6 months and by 108.8 mg/dL at 12 months (p < 0.000) from baseline (Table 2).

#### Discussion

This study of 91 patients demonstrates that ESG can safely provide sustained clinically significant weight loss and improvement of comorbidities. In this study, the patients' mean BMI before the procedure was  $38.7 \pm 7.3$  kg/m<sup>2.19</sup> We did see an



Figure 1. BMI reduction post-ESG.



Figure 2. EBWL reduction post-ESG.

impressive improvement in BMI with a reduction of BMI by 9.3 kg/m<sup>2</sup> at 6 months from baseline. This is similar than prior studies which have shown reductions in BMI of  $4.9^{19}$  and  $5.6 \text{ kg/m}^2$ at 6 months.<sup>20</sup> In a meta-analysis, the mean BMI reduction at 6 months was  $5.65 \text{ kg/m}^{2.21}$  In addition, we observed improvement in markers of diabetes, hypertriglyceridemia, and steatohepatitis in all patients in whom the variables were collected after ESG. Among the 52 patients in which metabolic variables were collected, there

were significant reductions in HbA1c, ALT, AST, LDL, and triglycerides at both 6 and 12 months post-ESG (Table 2). Other studies have looked at similar metabolic variables.<sup>22</sup> In a single-center study with 91 patients undergoing ESG, there were reductions between baseline and 12 months after ESG in HbA1c (mean  $\pm$  SD, 6.1%  $\pm$  1.1% versus 5.5%  $\pm$  0.48%, respectively; p = 0.05), Systolic Blood Pressure (SBP) (129.0  $\pm$  13.4 versus 122.2  $\pm$  11.69 mmHg; p = 0.02), triglycerides (TG) (131.84  $\pm$  83.19

Outcome (N=52)	Pre-ESG ( <i>N</i> = 52)	Post-ESG 6 months ( <i>N</i> = 52)	Post-ESG 12 months ( <i>N</i> = 52)	
Mean HbA1C	5.73	5.43 ( <i>p</i> < 0.000)	5.43 ( <i>p</i> < 0.000)	
Mean ALT	56.9	44.70 ( <i>p</i> < 0.00001)	43.7 ( <i>p</i> < 0.000)	
Mean AST	49.9	41.19 ( <i>p</i> < 0.000)	39.45 ( <i>p</i> < 0.000)	
Mean LDL	127.2	113.5 ( <i>p</i> < 0.000)	114.1 ( <i>p</i> < 0.000)	
Mean triglycerides	357.6	257.65 ( <i>p</i> < 0.000)	248.8 ( <i>p</i> < 0.000)	
ALT, Alanine transaminase; AST, Aspartate Transaminase; LDL, low-density lipoprotein.				

Table 2. Comparison of primary and secondary characteristics pre- and post-ESG 6 and 12 months.

*versus* 92.36  $\pm$  39.43 mmol/dL; p=0.02), and ALT (42.4 *versus* 22 in men, p=0.05, and 28 *versus* 20 in women, p=0.01).<sup>11</sup> In another single-center study evaluating 1000 patients, 13/17 patients with diabetes, 28/28 patients with hypertension, and 18/32 patients with dyslipidemia had complete remission of disease at 12-to 18-month follow-up.<sup>23</sup>

Durability of weight loss is the most important concern when choosing ESG as a weight-loss procedure. Evidence on long-term weight loss after ESG is lacking. Due to this, medical insurance companies are hesitant to cover the cost of the procedure, and thus, few patients are offered ESG, unless they agree to pay out of pocket costs. This is an important barrier in many countries. Apart from the lack of reimbursement issues, barriers also include lack of referrals due to local physicians referring to surgery (even for BMI 30-35) due to pre-established referral patterns and lack of awareness of ESG conducting centers. New bariatric programs must take this into consideration when establishing a new program to recruit new patients. To increase awareness, we suggest reaching out to local physicians and potential patients.

Current reports suggest that weight loss is maintained between the first and second year, and recently 5-year durability results were published.<sup>20,24</sup> The 5-year follow-up study reported an average weight loss of 18.7 kg with 14.5% TBWL 5 years from initial ESG.<sup>25</sup>

In our study, there was a reduction of %EBWL of 35.6% at 6 months. In Li *et al.*,<sup>26</sup> %EWL at 1, 3, 6, and 12 months was 31.16% (p=0.000), 43.61% (p=0.000), 53.14% (p=0.000), and 59.08% (p=0.015), respectively. Patients who

underwent ESG had minimal adverse events, including abdominal pain, nausea/vomiting, and heartburn, which resolved after a few days. Most patients were discharged home after the procedure, and none required readmission or ER visits for these mild symptoms. Concerns are raised as to whether the sutures may cause vascular compromise or trapping of food particles within the plications. None of our patients demonstrated issues related to those concerns. Among the 91 patients who underwent primary ESG, all were able to tolerate the post-procedure abdominal pain; none requested procedure reversal due to this. In our study, only two patients reported nausea and six patients had bleeding post-ESG. Overall, it appears that post-procedure bleeding and nausea are common complaints that can be managed conservatively on an outpatient basis. Previous studies on ESG concluded that postprocedure bleeding and nausea are common, short-term, and self-limiting.<sup>27</sup>

We did have two patients who required revision of ESG. One patient had persistent nausea and vomiting and on upper gastrointestinal (GI) series, it was noted to have retained contrast in the fundus without passage into the small bowel. On delayed imaging, minimal contrast was noted to have passed into the small bowel and was suggestive of delayed gastric emptying. EGD was performed 15 days after ESG and revealed a 12-mm luminal diameter with difficulty passing the therapeutic endoscope due to an angulated or 'twisted' sleeve requiring placement of an  $18 \times 80 \text{ mm}^2$  through the scope stent across the length of the sleeve gastroplasty. Patient's symptoms resolved and she returned for stent removal in 1 month, and after removal, certain parts of the sleeve appeared open due to the stent. This is the first reported case of a

patient with ESG requiring luminal stent placement. She returned again in 1 month for ESG revision and placement of six additional sutures to 'tighten' the sleeve and at 6-month follow-up had lost 43 pounds and reduced BMI from 40 to 33 kg/ m<sup>2</sup>. The second patient lost 20 pounds and reduced BMI by 3 kg/m<sup>2</sup> but plateaued after 3 months without further weight loss. She underwent revision of ESG 5 months after the index procedure and was noted to have intact mucosal fibrotic bridges in the distal portion of the sleeve gastroplasty but had opening or dehiscence of the proximal body. Six additional sutures were placed to reform the gastric sleeve. At 1-month follow-up from revision ESG (6-month post index ESG), the patient had lost 10 additional pounds but again plateaued and went on to have laparoscopic sleeve gastrectomy.

The study period precludes us from drawing any conclusions on long-term expectations, as we assessed patients for weight loss at 1, 3, 6, and 12 months post-ESG. It is possible that some patients showed better results after this period. We were able to collect complete data on 52 patients for diabetes, hypertriglyceridemia, and steatohepatitis at 6 and 12 months post-ESG.

In conclusion, ESG is a minimally invasive and effective bariatric endoscopic intervention. It appears to be well-tolerated, safe, and effective. In addition to significant weight loss, ESG reduced markers of diabetes, hypertriglyceridemia, and steatohepatitis. Our study of new centers performing ESG showed similar outcomes to prior studies with experienced centers.

Significant weight loss occurred during the first 6 months without mortality or major morbidity. Mild-to-moderate self-limiting bleeding and/or nausea during the first week post-ESG was common but did not require hospitalization. In essence, this procedure bridges a major gap between surgical weight loss and medical intervention. Refining and developing the tools used might result in better control of bleeding and nausea after ESG. Longer studies are awaited to shed light on durability of outcomes and long-term safety.

#### Author contribution(s)

Avik Sarkar: Conceptualization; Data curation; Investigation; Methodology; Project administration; Resources; Supervision; Writing – review & editing. **Augustine Tawadros:** Data curation; Resources; Writing – original draft; Writing – review & editing.

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**Michel Kahaleh:** Data curation; Formal analysis; Investigation; Methodology; Project administration; Resources; Software; Supervision; Validation; Visualization; Writing – review & editing.

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