Endoscopic sleeve gastroplasty, laparoscopic sleeve gastrectomy, and laparoscopic greater curve plication: do they differ at 2 years?

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ABSTRACT

Background Endoscopic sleeve gastroplasty (ESG) is an effective treatment option for obesity. However, data comparing its efficacy to bariatric surgery are scarce. We aimed to compare the effectiveness and safety of ESG with laparoscopic sleeve gastrectomy (LSG) and laparoscopic greater curve plication (LGCP) at 2 years.

Methods We reviewed 353 patient records and identified 296 patients who underwent ESG (n = 199), LSG (n = 61), and LGCP (n = 36) at four centers in Spain between 2014 and 2016. We compared their total body weight loss (% TBWL) and safety over 2 years. A linear mixed model (LMM) was used to analyze repeated measures of weight loss outcomes at 6, 12, 18, and 24 months to compare the three procedures.

Results Among the 296 patients, 210 (ESG 135, LSG 43, LGCP 32) completed 1 year of follow-up and 102 (ESG 46, LSG 34, LGCP 22) reached 2 years. Their mean (standard deviation [SD]) body mass index (BMI) was 39.6 (4.8) kg/m2. There were no differences in age, sex, or BMI between the groups. In LMM analysis, adjusting for age, sex, and initial BMI, we found ESG had a significantly lower TBWL and safety over 2 years. A linear mixed model (LMM) was used to analyze repeated measures of weight loss outcomes at 6, 12, 18, and 24 months to compare the three procedures.

Conclusion All three procedures induced significant weight loss in obese patients. Although the weight loss was lower with ESG compared with other techniques, it displayed a better safety profile and shorter hospital stay.

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Introduction

Obesity is a chronic, treatable disease that has reached epidemic proportions in the last decade [1]. Several treatment options are currently available to effectively manage obesity. Among them, bariatric surgery has been demonstrated to be effective in inducing and sustaining weight loss and improving co-morbid illnesses [2]. Since its earliest description in the 1950s, the technique of bariatric surgery has undergone numerous transformations. From being an initial malabsorptive procedure, there has been a gradual shift towards a restrictive gastric approach [3]. Similarly, there has been a significant move towards performing minimally invasive laparoscopic surgical procedures, such as laparoscopic sleeve gastrectomy (LSG), gastric band placement, and laparoscopic greater curve plication (LGCP) [4].

However, despite its advantages, the number of patients opting for bariatric surgery has remained low [5]. A worldwide survey showed that the number of bariatric surgical procedures performed in 2016 was 634,897, which is just a fraction of the overall obese population [6]. At this rate, it would take approximately 43 years to operate on the currently eligible obese patients, not including any extra new patients added each year by the expanding epidemic [7]. There is a huge need to develop therapies with comparable efficacy and safety profiles, which, at the same time, have the potential to reach the wider obese population.

The endoluminal bariatric approach is a novel alternative treatment option for obesity and has evolved significantly in the last decade [8]. The technique of suturing the stomach from within the lumen and restricting the gastric volume, similarly to existing restrictive bariatric surgical procedures, has brought in new enthusiasm among both surgeons and gastroenterologists. Since its introduction in 2013, multiple studies have demonstrated the safety and efficacy of endoscopic sleeve gastroplasty (ESG) [9, 10]. A meta-analysis showed ESG achieved a total body weight loss (TBWL) of 20% at 1 year, and the overall adverse event rate was 2.26% [11]. ESG has also been shown to result in resolution or improvement of co-morbidities, similarly to LSG [12]. We have demonstrated that the weight loss achieved with ESG improved health-related quality of life and physical activity status in obese patients at 9 months [13].

Recent comparative studies have established the superiority of ESG over intragastric balloons (21.3% vs. 13.9%) and high-intensity diet and lifestyle therapy (20.6% vs. 14.3%) at 12 months [14, 15]. However, data comparing the efficacy of ESG to its surgical counterparts LSG and LGCP are limited [16, 17].

This study’s objective was to compare the weight loss outcomes between ESG, LSG, and LGCP patients over a 2-year follow-up period and analyze the complication rates of the three procedures.
Methods

Trial design

We retrospectively reviewed the records of patients who underwent ESG, LSG, LGCP at four hospitals in Spain between January 2014 to April 2016. The ESG data were obtained from: HM Sanchinarro University Hospital, Madrid, Spain; Dexeus University Hospital, Barcelona, Spain; and Clínica Diagonal, Barcelona, Spain. The LSG/LGCP data were collected from Belvitge University Hospital, Barcelona, Spain (Fig. 1). The institutional review board approved the study. All authors had access to the study data and reviewed and approved the final manuscript. The study was conducted following the ethical principles detailed in the Declaration of Helsinki and was consistent with Good Clinical Practices recommendations.

Participants

We reviewed the records and identified patients who completed 1 and 2 years of follow-up. We excluded patients with missing or incomplete data. Bariatric surgery was offered for: (a) class III obesity (body mass index $\geq 40$ kg/m$^2$); (b) class II obesity ($\geq 35$ kg/m$^2$) with one or more obesity-related comorbidities; and (c) those who had failed prior diet and lifestyle intervention. The surgical team decided on the type of surgery after extensive discussion of the risks and benefits with the patients (Fig. 1).

All the patients referred for ESG had declined surgery and failed diet and lifestyle therapy. The inclusion criteria for ESG were: (a) age $\geq 18$ years; (b) BMI $> 30$ kg/m$^2$; and (c) able to comply with instructions and provide informed consent. We excluded those with: (a) severe systemic illnesses (chronic kidney disease, liver disease, collagen vascular disease, inflammatory bowel disease, viral hepatitis, HIV); (b) substance abuse; (c) uncontrolled eating disorder; (d) psychiatric disorder; (e) pregnancy; and (f) coagulopathy. ESG was offered as a self-pay procedure and was not covered by insurance. All patients paid the cost upfront before the procedure. We collected information on the weight loss outcomes, length of stay, and complication rate.

We acknowledge that some of the patients included in the ESG group have been used in our previous research describing our experience with ESG [9]. This study attempts to provide a different clinical insight and to add to the expanding literature on this novel technique.

Intervention

ESG

All ESG procedures (OverStitch; Apollo Endosurgery, USA) were performed by three endoscopists with extensive experience in endoscopic suturing. We performed the procedure with the patient under general anesthesia. We adopted a “U-shaped” suture pattern starting at the distal body of the stomach, then progressing proximally, sparing the fundus [18]. We placed five or six suture plications to reduce the gastric volume by approximately 70–80%. After the procedure, we monitored the patients for 24 hours and then discharged them with antiemetics and proton pump inhibitors (Fig. 2a,b).

LSG

Two experienced bariatric surgeons performed all LSG procedures using laparoscopic guidance with the patients under general anesthesia. The patients were placed in the reverse Trendelenburg position and blunt-tip trocars were introduced. The gastrectomy was started 5 cm from the pylorus and progressed cephalad towards the angle of His over a 36-Fr bougie. We used two green staples and three to five blue staples with Seamguard (Gore, USA) to perform the gastrectomy (Fig. 2c). We achieved hemostasis and performed a leak test using methylene blue. The patients were discharged on the second or third postoperative day if there were no complications.

LGCP

Similarly to LSG, the patient was positioned in the reverse Trendelenburg position and five trocars were introduced. After complete dissection of the greater curvature from the prepyloric area up to almost 2 cm from the angle of His, we placed two rows of sutures over a 36-Fr bougie to achieve a fold plication. Both rows were created using two running sutures of non-absorbable monofilament stitches (Fig. 2d). A drain was left only in patients with bleeding or in difficult cases. Patients were started on oral intake when nausea and vomiting were well controlled, and discharge was planned for the second or third postoperative day.

Post-procedure follow-up

The patients were followed up at regular intervals by nutritionists, psychologists, and physiotherapists. Patients’ energy requirements were calculated from the Harris–Benedict formula. They were decreased by about 2.6 MJ/day based on their physical activity status to induce an approximate loss of between 0.5

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and 1 kg/week. In the first month (4 weeks), patients were maintained on a strict liquid diet. We subsequently escalated their intake to semi-solid and solid food as tolerated. Nutritional planning was based on the Spanish Society of Nutrition guidelines [19]. In the ESG cohort, the patients were followed up by an identical multidisciplinary team for 2 years. The initial post-procedure nutritional care and subsequent dietary escalation were similar between the groups.

Outcomes

The primary objective of this study was to compare the weight loss outcomes (TBWL, %TBWL, and BMI change) between ESG, LSG, and LGCP over the 2-year follow-up period.

The secondary outcome was to assess the complication rates of the three procedures.

Statistical methods

Continuous variables were expressed as mean and standard deviation (SD) or median and range. Categorical variables were reported as percentages. We assessed for normality using the Shapiro–Wilk test. Weight loss outcomes were compared between the three groups using the repeated measurements of TBWL, %TBWL, and BMI change at 6, 12, 18, and 24 months using the linear mixed model (LMM). We assessed the effect of each procedure, adjusting for time, age, sex, and BMI, with BMI categorized as < 40 kg/m² or ≥ 40 kg/m². We accounted for the variation among treatment centers by including a random effect for centers.

Using the contrast testing within LMM, we analyzed the overall effect of time on weight loss outcomes. Similarly, contrast testing provided the overall effect over time of LGCP and LSG on weight loss outcomes compared with ESG, reported as mean effect with 95% confidence interval (95%CI). Next, a sensitivity analysis was done to compare the weight loss outcomes at 1 year between completers (those who reached 2 years) and non-completers (those who dropped out after 1 year). The analysis was done using multiple linear regression adjusting for procedure type, age, sex, and BMI group.

Statistical analyses were performed using Stata 14.0 (Stata-Corp LP, Texas, USA). To adjust for the multiplicity of comparisons, we considered P<0.01 as significant.

Results

Patient characteristics

We reviewed the records of 353 patients who underwent surgery or ESG for obesity during the study period. We included 296 patients (ESG 199, LSG 61, LGCP 36) and excluded 57 patients with incomplete data. The distribution of cases is detailed in Fig.1. Their mean age was 44.4 (SD 10.3) years; mean BMI 39.6 (SD 4.8) kg/m² and initial weight 110.4 (SD 18.6) kg. There were no differences in age, sex, or baseline weight between the three groups (Table 1). The mean procedure time for ESG was 35 minutes (range 25–50 minutes) and was significantly lower compared with 51 minutes (40–80 minutes) for LSG, and 59 minutes (40–90 minutes) for LGCP. The average length of stay after ESG was significantly shorter compared with LSG and LGCP (1 vs. 3 vs. 3 days, respectively).

Weight loss outcomes

Among the study cohort, 210 patients (ESG 135, LSG 43, LGCP 32) completed 1 year of follow-up, and 102 patients reached 2 years (ESG 46, LSG 34, LGCP 22). We found that, at 2 years, all the procedures induced significant weight loss meeting the American Society for Gastrointestinal Endoscopy (ASGE) PIVI criteria [20].

In LMM analysis, adjusting for baseline confounding factors, we noticed that the TBWL, %TBWL, and BMI decline were significantly lower with ESG compared with LSG and LGCP at all time points (Table 2, Table 3, and Table 4). We did not observe any differences between LSG and LGCP. At 2 years, the adjusted mean (95%CI) %TBWL with ESG was 18.5% (16.6% to 20.5%) compared with 28.3% (26.2% to 30.4%) with LSG, and 26.9%...
Similarly, the adjusted mean (95% CI) decline in BMI with ESG was 7.4 (6.6 to 8.2) kg/m² compared with 11.5 (10.7 to 12.4) kg/m², and 10.9 (10 to 11.8) kg/m² with LGCP.

Examination of the relationship between baseline factors and %TBWL over the entire follow-up period showed older age ($b = -0.3$; 95% CI $-0.3$ to $-0.2$) correlated negatively with %TBWL. We found patients with a BMI $\geq 40$ kg/m² ($b = 5.5$; 95% CI 4.0 to 6.9) had significantly higher %TBWL than those with a lower BMI. There was no significant difference in %TBWL between men and women ($b = -1.3$; 95% CI $-2.8$ to 0.3). There was no heterogeneity between the treatment centers in terms of the outcome: SD for center random effect at 0.76 was small and had a negligible impact on the results. The fixed effect portion of the center was not significant.
Completers vs. Non-completers

We defined completers as those who reached 2 years of follow-up and non-completers as those who dropped out after the first year. We compared their weight loss results at the 1-year time point (▶Table 5).

At 1 year, in the completer group (n = 102), we found ESG achieved significantly lower mean (95 %CI) %TBWL compared with LSG (20.5 % [17.9 % to 23.1 %] vs. 30.1 % [26.9 % to 33.2 %]) and LGCP (29.3 % [25.7 % to 32.8 %]). Likewise, in the non-completer group (n = 108), ESG resulted in significantly lower weight loss both compared with LSG (16.9 % [14.7 % to 19.0 %] vs. 26.5 % [23.0 % to 29.9 %]) and LGCP (25.6 % [21.7 % to 29.6 %]). There were no significant differences between LSG and LGCP within each group. From contrast testing, on average for any procedure type, the %TBWL and BMI change were 3.6 (95 %CI 0.7 to 6.6) and 1.3 (95 %CI 0.1 to 2.5) units higher for completers compared with non-completers, respectively.

Complications

We graded adverse events according to the Clavien–Dindo classification, where a higher grade represents a more severe degree of complication [21]. The majority of the patients (91 %) had a normal postoperative course without the need for additional intervention. Adverse events were significantly more common in the LSG and LGCP groups compared with the ESG group.

In the ESG group, one patient (0.5 %) developed a mild hemoperitoneum (grade 2) from a splenic laceration that was treated conservatively without any further intervention. The rest of the patients had no adverse events. In the LSG cohort, three patients (4.9 %) developed hemoperitoneum. Two of them required surgery (grade 3b), while the other patient was treated conservatively (grade 2). In the LGCP group, three patients (8.3 %) developed complications (one hemoperitoneum, one gastric stricture, and one perigastric abscess). The hemoperitoneum required surgical intervention (grade 3b), and the gastric stricture required conversion to LSG (grade 3b). The perigastric abscess was treated with antibiotics and radiology-guided drainage (grade 3a). No mortality occurred with any of the procedures.

Discussion

Our study showed that all three procedures achieved significant weight loss at 12 and 24 months. Although the results for weight loss were lower, ESG demonstrated a lower complication rate and required a shorter hospital stay compared with LSG and LGCP.

Minimally invasive therapies have now become the gold standard for the treatment of many diseases, including obesity. In the last decade, there has been a surge in technological inno-

▶ Fig. 3 Margins plot of predicted percentage body weight loss (% TBWL) with 95 % confidence interval (CI) for all three procedures over 2 years. ESG, endoscopic sleeve gastroplasty; LSG, laparoscopic sleeve gastrectomy; LGCP, laparoscopic greater curve plication.

▶ Table 5 Comparison of weight loss outcomes between completers and non-completers.

<table>
<thead>
<tr>
<th>Procedure type</th>
<th>Adjusted mean (95 %CI) for %TBWL at 1 year</th>
<th>Adjusted mean (95 %CI) for BMI decline at 1 year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Completers (n = 102)</td>
<td>Non-completers (n = 108)</td>
</tr>
<tr>
<td>ESG</td>
<td>20.5 (17.9 to 23.1)</td>
<td>16.9 (14.7 to 19.0)</td>
</tr>
<tr>
<td>LSG</td>
<td>30.1 (26.9 to 33.2)</td>
<td>26.5 (23.0 to 29.9)</td>
</tr>
<tr>
<td>LGCP</td>
<td>29.3 (25.7 to 32.8)</td>
<td>25.6 (21.7 to 29.6)</td>
</tr>
<tr>
<td>ESG</td>
<td>8.2 (7.1 to 9.2)</td>
<td>6.9 (6.0 to 7.8)</td>
</tr>
<tr>
<td>LSG</td>
<td>12.2 (10.9 to 13.5)</td>
<td>10.9 (9.5 to 12.3)</td>
</tr>
<tr>
<td>LGCP</td>
<td>11.9 (10.4 to 13.3)</td>
<td>10.6 (8.9 to 12.2)</td>
</tr>
</tbody>
</table>

CI, confidence interval; ESG, endoscopic sleeve gastroplasty; LSG, laparoscopic sleeve gastrectomy; LGCP, laparoscopic greater curve plication; %TBWL, percentage total body weight loss; BMI, body mass index.

1 Results adjusted for age, sex, body mass index group, and procedure type
2 ESG had lower results than LSG and LGCP in completer and non-completer groups. There were no differences between the LSG and LGCP groups.
vations, and a wide array of minimally invasive procedures for obesity have been developed. Alongside these, several new therapies targeting different pathways of obesity are under development [22]. To date, ESG using the OverStitch device has gained the most interest and is now being offered as an alternative treatment for obesity in many expert and non-academic centers [22, 23]. There are several reasons for its increasing acceptance, including its technical ease, short procedure time, low complication rate, and its resemblance to LSG or LGCP. Multiple studies have demonstrated its short- and medium-term efficacy [24]; however, long-term studies assessing its effectiveness are lacking. A study published only in abstract form showed that ESG achieved a %TBWL of 14.5% at 5 years [25]. The weight loss reported in our study is consistent with the published results at 2 years.

Although ESG is considered structurally analogous to the LSG or LGCP procedures, the mechanism of weight loss differs significantly between the endoscopic and surgical procedures. In a recent meta-analysis, Vargas et al. showed that sleeve gastrectomy reduced gastric emptying T½ by 29.2 minutes and retarded gastric emptying for solids. In contrast, ESG delayed gastric emptying T½ by 90 minutes and slowed the emptying of solids [27]. The retention of food in ESG resulted in earlier meal termination (11 minutes) and decreased food intake [28].

Fayad et al. compared the effectiveness of ESG with LSG in the short-term and showed that LSG achieved significantly higher weight loss at 6 months (23.6% vs. 17.1%; P<0.01) [16]. Novikov et al., in a retrospective study, compared the effectiveness of ESG with LSG and gastric bands and showed, at 1 year, that LSG achieved more significant weight loss compared with the other two procedures. They reported similar %TBWL in all three groups in patients with a BMI <40 kg/m² [17]. The results of our study were similar to their 1-year data; however, we found the %TBWL was still higher for surgery compared with ESG, irrespective of the patients’ BMI.

Several factors contribute to the higher weight loss observed with LSG and LGCP, compared with ESG. Although all restrict the gastric lumen identically, the suture strength and durability may vary between procedures. Studies assessing durability after ESG demonstrate dehiscence and loosening of sutures over time. Runge et al., in a retrospective study involving five patients, showed dehiscence of most sutures by 2 years after ESG [29]. Pizzicannella et al. demonstrated that the weight loss with ESG correlated with endoscopic appearance over time. Around 83% of patients had either intact or partially intact sutures at 1 year on endoscopic evaluation [30]. In addition, animal studies have revealed the role played by the gastric mucosa in regulating food intake and obesity. Khumberi et al., in a three-arm randomized trial, showed that devitalization of the gastric mucosa in a porcine model resulted in weight loss and improvement in visceral adiposity compared with sham treatment [31]. Furthermore, gastric mucosal devitalization achieved similar weight loss to sleeve gastrectomy at 4 weeks. These findings highlight that the gastric resection in LSG may be an additional factor that contributes to the higher weight loss compared with ESG, where the mucosa is preserved.

We noticed that the maximum weight loss in all three procedures occurred in the first 18 months and then gradually regressed toward the 6-month values (Fig. 3). It has been shown that around 5%–6% of patients experience weight regain after surgery in the second year, and our patients demonstrated a similar trend [32]. Managing weight regain after bariatric surgery can be challenging. The morbidity associated with revision procedures can be higher than with primary surgery. In contrast, ESG can be easily repeated as a day procedure, with no significant increase in the adverse event rate [33]. This advantage observed with ESG may offset its lower weight loss results compared with surgery.

In our study, we observed there was a considerable loss of follow-up by 2 years. Follow-up loss is a significant problem when managing patients with obesity. One possible reason for the observed rate of follow-up loss could be that the patients achieved their target weight loss by 1 year and were able to self-manage their condition. However, continued adherence to monitoring is crucial for achieving higher weight loss and weight maintenance in the long term [34].

One of the primary concerns with bariatric surgery is the risk of complications, such as bleeding, leak, fistula, stricture, and development of new-onset gastroesophageal reflux disease (GERD). The reported complication rate with LSG and LGCP has ranged between 10%–15% [17, 35]. The SM-BOSS trial showed that 32% of patients developed GERD symptoms after LSG [36]. In another study, about 4% of patients required conversion to Roux-en-Y gastric bypass because of severe reflux [37]. It has been postulated that the lower resting esophageal sphincter pressure and lower maximal distal contractile integral may underpin the mechanism behind GERD after LSG [38]. In contrast, the risk of adverse events with ESG in our study was low, in keeping with the published literature [39]. Similarly, the rate of new-onset GERD after ESG was negligible, as the fundus of the stomach is left intact, and the neuronal innervation of the stomach is maintained [24, 39]. These findings, along with its better weight loss results, may make ESG a patient-preferred treatment option.

Our study has several strengths and certain limitations. We are presenting results from a relatively large multicenter data-set on three weight loss procedures. To date, there are no mid- or long-term comparisons, and our study is the first to assess the effectiveness of surgical and endoscopic procedures at 2 years. The ESG procedures were technically similar, and the suture pattern was identical in all three centers. The post-ESG follow-up was comparable, and an identical multidisciplinary team followed the patients at regular intervals.

Our study was however limited by its retrospective design, and prospective comparative studies are required to establish the replicability of our results. Although the follow-up protocol and the procedure technique were alike, multiple surgeons and endoscopists performed the procedures, and a difference in the technique and experience might have contributed to a variation in results. We observed, in the ESG group, one center contributed more cases than others. This is likely related to the prac-

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tice set-up. The obesity unit in Sanchinarro University Hospital is a dedicated tertiary care center receiving referrals from the region.

We did not compare the co-morbid outcomes at 2 years as our primary objective was mainly weight loss comparison. Nonetheless, other studies have demonstrated improvement in co-morbidities with > 10% TBWL [10, 12, 32], which all the patients in the three groups achieved. It is well known that bariatric surgery, additionally to the weight loss effect, alters the physiological regulation of gut and metabolic hormones and has a weight-independent mechanism for metabolic improvement. We analyzed the gut and metabolic hormone changes after ESG in our previous study. We showed the significant weight loss achieved with ESG resulted in a marked lowering of leptin levels, a change in insulin secretory pattern, and improvement in insulin resistance at 6 months, which would result in co-morbid improvement [40]. Lastly, we did not record the incidence of GERD after ESG and LSG in our cohort.

In conclusion, all three procedures induced significant weight loss in obese patients at 2 years. The better safety profile and shorter hospital stay may make ESG an attractive alternative treatment option for obesity. Future extensive studies are required to evaluate its durability, long-term efficacy, and cost-effectiveness.

Competing interests

G. Lopez-Nava is a consultant for Apollo Endosurgery and USGI Medical, USA. E. Espinet Coll is a consultant for Apollo Endosurgery. The remaining authors declare that they have no conflict of interest.

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