Published online: 15.01.2020

Endoscopic sleeve gastroplasty in the management of weight regain after sleeve gastrectomy

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submitted 11.6.2019
accepted after revision 28.11.2019

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DOI https://doi.org/10.1055/a-1086-0627
Published online: 2020 | Endoscopy

ISSN 0013-726X

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Fig. 1s, Table 1s – 6s
Online content viewable at:
https://doi.org/10.1055/a-1086-0627

ABSTRACT

Background Sleeve gastrectomy is a well-standardized surgical treatment for obesity. However, rates of weight regain after sleeve gastrectomy in long-term follow-up are relatively high. This multicenter study is the first to evaluate the use of an endoscopic sleeve gastroplasty (ESG) technique for the management of this population.

Methods This was a multicenter retrospective study, including patients with weight regain following sleeve gastrectomy who underwent ESG for weight loss. Primary outcomes included absolute weight loss, percent total weight loss (%TWL), change in body mass index (BMI), percent excess weight loss (%EWL) at 6 and 12 months, and safety profile. Clinical success was defined as achieving ≥25% EWL at 1 year, ≤5% serious adverse event (SAE) rate following society-recommended thresholds, and %TWL ≥10%.

Results 34 patients underwent ESG after sleeve gastrectomy. Technical success was 100%. At 1 year, 82.4% and 100% of patients achieved ≥10%TWL and ≥25% EWL, respectively. Mean (SD) %TWL was 13.2% (3.9) and 18.3% (5.5), and %EWL was 51.9% (19.1) and 69.9% (29.9) at 6 months and 1 year, respectively. Mean (SD) %TWL was 14.2% (12.5), 19.3% (5.3), 17.5% (5.2), and 20.4% (3.3), and %EWL was 88.5% (52.8), 84.4% (22.4), 55.4% (14.8), and 47.8% (11.2) for BMI categories of overweight and obesity class I, II, and III, respectively, at 1 year. No predictors of success were identified in the multivariable regression analysis. No SAEs were reported.

Conclusion ESG appears to be safe and effective in the management of weight regain following sleeve gastrectomy.

Introduction

Obesity remains pandemic despite bariatric and metabolic surgery providing satisfactory long-term weight loss, reduction in cardiovascular risk factors, and improvement in obesity-related comorbidities [1, 2]. Laparoscopic sleeve gastrectomy, pioneered in 1999, has become a well-standardized therapeutic option for surgical treatment of different degrees of obesity and obesity-related diseases [3, 4]. However, the rate of weight regain after sleeve gastrectomy in long-term follow-up (>5 years) is relatively high (19.2 % – 75.6 % of patients) [5 – 10].

Weight regain has several definitions, including an increase in body weight of more than 10 kg from the nadir weight, an increase in body mass index (BMI) >5 kg/m^2 from the nadir BMI, any weight regain after type 2 diabetes mellitus remission, weight regain to a BMI >35 kg/m^2 after successful weight loss, and any amount of weight regain [5, 11]. Weight regain is associated with the recurrence of obesity-related comorbidities, including type 2 diabetes mellitus, and is likely to have a significant economic burden [5, 12]. Mechanisms for weight regain are not fully understood and the process is likely multifactorial. Predictors of weight regain include preoperative BMI, type of surgery, medical conditions, specific medications, physical activity, patient diet adherence, and psychiatric disorders [13].

Owing to the high rate of weight regain following sleeve gastrectomy, the number of conversion or revisional surgeries is increasing. Some of the surgical options for the treatment of weight regain following sleeve gastrectomy include repeat sleeve gastrectomy, conversion to Roux-en-Y gastric bypass (RYGB), conversion to single-anastomosis gastric bypass (also known as mini-gastric bypass), conversion to single-anastomosis duodeno-ileal bypass (SADI), and conversion to biliopancreatic diversion with duodenal switch (BPD-DS) [14 – 16]. Although revisional surgery for weight regain improves weight loss, it is usually associated with a higher risk than the primary procedure, with an adverse event rate of up to 14.3 %. Therefore, some patients elect not to undergo a second revisional surgical procedure [16 – 18].

As a result, there is a drive to develop less invasive and more cost-effective therapies to treat weight regain in this patient population. Endoscopic therapies are appealing as they are more effective than lifestyle modification/pharmacology and are associated with lower adverse event rates compared with revisional bariatric surgery [13, 18 – 20]. Endoscopic sleeve gastroplasty (ESG) is an incisionless, minimally invasive technique that involves remodeling the stomach via the placement of full-thickness sutures in an effort to reduce gastric capacity and delay gastric emptying [21]. ESG is usually performed as primary endoscopic bariatric therapy and has been demonstrated to be technically feasible, safe, and effective in a variety of clinical settings around the world [22 – 24]. Recently, a series including five patients showed that ESG can also be performed as a revisional procedure in patients with weight regain after sleeve gastrectomy, with favorable results [25]. However, since this initial case series, no further studies regarding ESG in the management of sleeve gastrectomy patients with weight regain have been published. Therefore, we performed this first international multicenter study to evaluate the efficacy and safety of ESG in the management of weight regain after sleeve gastrectomy.

Methods

Study design and patient selection

This was a retrospective analysis of prospectively collected data from 12 international bariatric centers. All consecutive patients who underwent ESG for the treatment of weight regain following sleeve gastrectomy between January 2018 and February 2019 were included. None of these patients had been included in previous studies. The inclusion criteria were patients with weight regain after sleeve gastrectomy who underwent ESG. Following previous publications [8, 9, 26 – 28], weight regain was defined in this study as increase in body weight of more than 10 kg. Patients using medication for weight loss were excluded from the analysis. The procedure was not offered to patients with severe gastroesophageal reflux disease following sleeve gastrectomy or hiatal hernia and thus, these patients were not included in the analysis. Additionally, patients with a small sleeve volume or sleeve stenosis/angulation were not offered the procedure because it was not possible to safely perform the suturing procedure. All patients were seen in a bariatric clinic before the procedure to discuss the various options for the treatment of weight regain, including lifestyle modification, and medical, endoscopic, and surgical therapies. Additionally, patients were required to see a nutritionist and psychologist prior to the procedure.

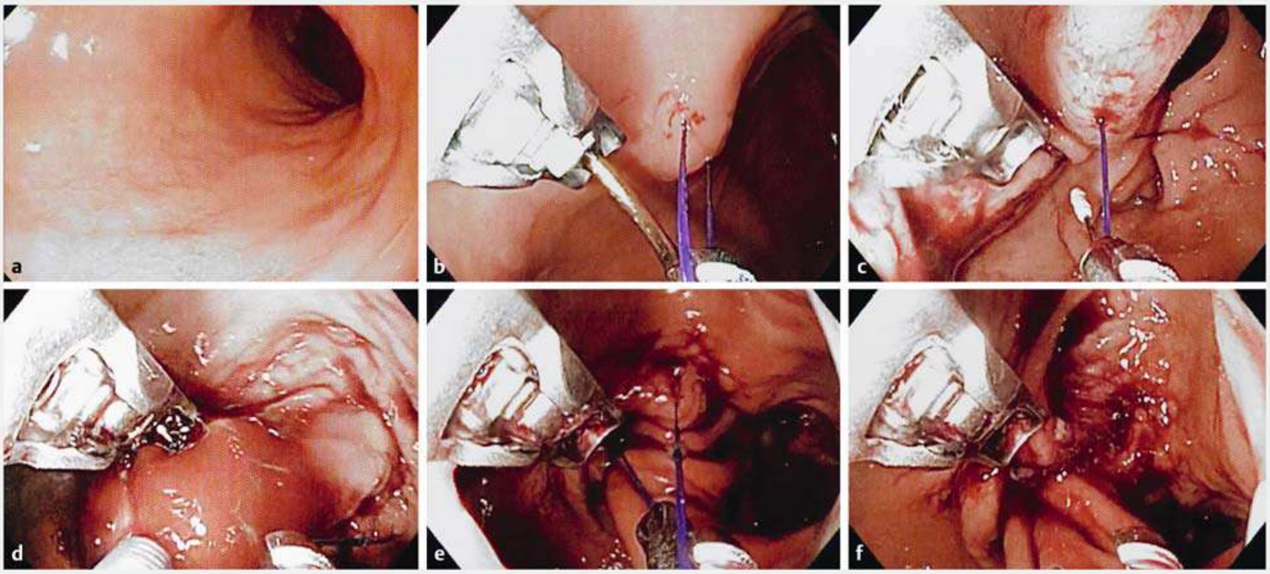
Ethical concerns

Institutional review board approval was obtained from each center prior to data collection. Written informed consent was obtained from all patients prior to the procedures.

Technique

All procedures were performed under general anesthesia in the endoscopy unit. Carbon dioxide insufflation was used in all cases. Patients were placed in a left-lateral position. All patients received prophylactic antibiotics intraprocedurally.

A diagnostic esophagogastroduodenoscopy was performed first to confirm that the anatomy was appropriate for the procedure. An esophageal overtube was placed to allow advancement of the suturing device and to avoid air leakage during the procedure. The endoscopic suturing device, which was mounted onto a double-channel gastroscope, was advanced to the gastric lumen. Using the suturing device, 2/0 polypropylene running sutures were placed, beginning from the level of the incisura angularis to 1 – 2 cm below the gastroesophageal junction. No suture pattern was specified; however, in general, each suture was started at the anterior wall of the sleeve, with subsequent bites progressing along the “greater curvature/staple line” and to the more proximal posterior wall. A tissue helix was used to assist with tissue grasping to ensure full-thickness bites. Upon completion of each suture run, the needle was released, anchoring the leading end of the suture. Using the cinching device, the suture was pulled tight to bring the tissue



▶ **Fig. 1** Sequence of endoscopic sleeve gastroplasty (ESG) after sleeve gastrectomy. **a** Stomach prior to ESG. **b** Successful bite with first full-thickness stitch placed. **c** Cinching device upon completion of the first suture. **d** Use of helix to grasp tissue. **e** Needle release upon completion of suturing to facilitate tightening of the suture. **f** Final appearance after successful ESG.

together, and the trailing end of the suture was cut and anchored. Approximately 6 – 10 bites per suture were performed. The suture was then continued in a retrograde fashion, with the subsequent suture located at approximately 1 cm proximal to the first suture. In some cases, a reinforcing interrupted suture was performed on the medial side of the running sutures. Typically, 3 – 5 sutures were used per patient (▶ **Fig. 1**, ▶ **Video 1**).

Patients were discharged on the same day and given a course of oral antibiotics, daily proton pump inhibitors, and oral antiemetics and analgesics as needed. Post-procedure diet consisted of 3 – 6 weeks of liquid diet, followed by 2 weeks of soft food, and then transitioning to a regular diet, with a maximum intake of 1200 kcal/day. All patients participated in a lifestyle modification program, which included routine follow-ups with the nutritionist, endoscopist, and psychologist for 1 year after the procedure.

Outcomes

Patient information, including age, sex, baseline weight, and BMI, were collected. Changes in BMI, absolute weight loss (AWL), percent total weight loss (%TWL), and percent excess weight loss (%EWL) were also collected at baseline and at 3, 6, 9, and 12 months after the procedure.

Technical success, clinical success, and safety profile were evaluated. Technical success was defined as successful ESG, resulting in a narrowing of the sleeve. Clinical success was defined as achieving ≥ 25 % EWL at 1 year with ≤ 5 % serious adverse event (SAE) rate following the American Society for Gastrointestinal Endoscopy (ASGE) and American Society for Metabolic and Bariatric Surgery (ASMBS) threshold [29]. Additionally, a %TWL ≥ 10 % was also analyzed as a measure of clinical success.

Subgroup analyses of the weight loss outcomes in patients from different BMI categories were also performed (overweight 25 – 29.9 kg/m^2; obese class I 30 – 34.9 kg/m^2; class II 35 – 39.9 kg/m^2; and class III ≥ 40 kg/m^2). SAEs were defined as per the ASGE guidelines [30], including unplanned admission or hospital stay for more than 10 nights, intensive care unit admission for more than 1 night, and surgery for adverse events.

Statistical analysis

Descriptive statistics were calculated for all demographic and clinical variables and presented as mean with standard deviation (SD) for continuous variables or proportion (%) for categorical variables. Statistical analysis was done using chi-squared test for two groups. Friedman's nonparametric test was used to compare repeated measurements from the same cohort at more than two time points. Kruskal-Wallis test was also used in nonparametric samples to compare three or more unmatched samples. Spearman correlation test was used for correlation analysis. Boxplot was used to display median, minimum – maximum range, interquartile range, and outliers. Univariable and multivariable logistic regression using Firth's bias-reduced penalized-likelihood logistic regression analyses were then performed to assess predictors of success at 6 months and 1 year. Given the number of outcomes, three predictors (< 45 years old and > 45 years old), sex, and BMI category (overweight, class I, class II, and class III obesity) were entered into the multivariable model and these were chosen a priori. For BMI categories, an effect coding analysis was used. Analyses were performed using R software version 3.4.3 (R Foundation for Statistical Computing, Vienna, Austria; http://www.R-project.org/) and SPSS Statistics 22 (IBM Corp, Armonk, New York, USA). Two-si-

▶ **Video 1** Endoscopic sleeve gastroplasty after sleeve gastrectomy.
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https://doi.org/10.1055/a-1086-0627

ded *P* value was used. Statistical significance was determined a priori at $P<0.05$.

Results

Patient characteristics

A total of 34 patients from 12 centers (see **Table 1s** in the online-only supplementary material) who underwent ESG for weight regain after sleeve gastrectomy were included in the analysis. These included 12 men (35.3 %) and 22 women (64.7 %), with an average age of 42.5 years (SD 9.9). The mean pre-sleeve gastrectomy weight was 116.9 kg (SD 20.5) and mean nadir weight was 78.9 kg (SD 11.8). The weight prior to ESG was 92.7 kg (SD 10.6). Patient characteristics are described in ▶ **Table 1**.

Among the 34 patients, one has not yet reached 3 months' follow-up and one was lost to follow-up. All other patients completed at least 6 months of follow-up, and all 17 patients who were eligible completed 1 year of follow-up.

Efficacy

Technical success occurred in all cases. When considering %TWL ≥ 10 % as clinical success, 81.3 % (26/32) and 82.4 % (14/17) of patients achieved clinical success at 6 months and 1 year, respectively. When considering %EWL ≥ 25 % as clinical success, 90.6 % (29/32) and 100 % (17/17) of patients achieved clinical success at 6 months and 1 year, respectively.

Absolute weight decreased from 99.6 kg (SD 15.1) to 86.2 kg (SD 12.1) and 83.6 kg (SD 10.3) at 6 months and 1 year, respectively ($P=0.001$) (▶ **Fig. 2**). BMI decreased from 34.8 kg/m^2 (SD 4.4) to 30.2 kg/m^2 (SD 4.1) at 6 months and to 28.9 kg/m^2 (SD 4.4) at 1 year.

AWL and BMI were statistically significant between pre-procedure, 6 months, and 1 year in obesity class I, II, and III groups. In the overweight group, a reduction in weight loss and BMI was also noted, although this difference was not statistically significant.

On avarage, %TWL was 13.2 % (SD 3.9) at 6 months and 18.3 % (SD 5.5) at 1 year. Obesity class I and III had higher %TWL at 1 year, with a %TWL of 19.3 (SD 5.3) and 20.4 (SD 3.3), respectively (▶ **Fig. 3**). The %EWL was 51.9 % (SD 19.1) at 6 months and 69.9 % (SD 29.9) at 1 year. Overall, %EWL was > 50 % at 6 months and 1 year (▶ **Fig. 4**). ▶ **Table 2** summarizes the results of the study, including all results relating to AWL, %TWL, BMI, and %EWL, including BMI subgroups.

Correlation between weight regain and %TWL after ESG

There was no correlation between percent of weight regain after sleeve gastrectomy and %TWL after ESG at 3, 6, 9, and 12 months (**Fig. 1s**).

Correlation between number of sutures and weight loss

The number of suture used during the procedure was related to greater weight loss when comparing 5 sutures with 3 sutures at 6 months. However, at 1 year, no statistical difference was found (▶ **Fig. 5**).

Bivariable analysis

In the bivariable analysis, the chi-squared test showed no significant association between achieving clinical success and several variables including sex, age, and BMI at 6 months and 1 year (**Table 2s**, **Table 3s**).

▶ **Table 1** Patient characteristics.

Characteristics	Population	Male	Female
Patients, n (%)	34 (100)	12 (35.3)	22 (64.7)
Age, mean (SD), years	42.5 (9.9)	42.2 (9.9)	42.7 (9.8)
Weight before sleeve gastrectomy, mean (SD), kg	116.9 (20.5)	133.8 (19.5)	106.7 (13.1)
Nadir weight, mean (SD), kg	78.9 (11.8)	88.0 (9.8)	73.6 (9.3)
Weight pre-ESG, mean (SD), kg	92.7 (10.6)	111.1 (14.4)	92.7 (10.6)
BMI pre-ESG, mean (SD), kg/m^2	34.8 (4.8)	33.9 (3.6)	35.4 (4.8)
BMI subclass, n (%)			
▪ Overweight	4 (11.7)	2 (16.7)	2 (9.1)
▪ Obesity class I	19 (55.9)	7 (58.3)	12 (54.5)
▪ Obesity class II	7 (20.6)	1 (8.3)	6 (27.3)
▪ Obesity class III	4 (11.8)	2 (16.7)	2 (9.1)

SD, standard deviation; ESG, endoscopic sleeve gastroplasty; BMI, body mass index.

Univariable and multivariable logistic regression

Univariable and multivariable regression analyses were performed to identify predictors of success for %TWL ≥ 10 % and %EWL ≥ 25 % at 6 months and 1 year. In both analyses no significant predictors were found (**Table 4s**, **Table 5s**, **Table6s**). As all patients achieved %EWL ≥ 25 % at the 1-year follow-up, logistic regression could not be performed in this specific analysis.

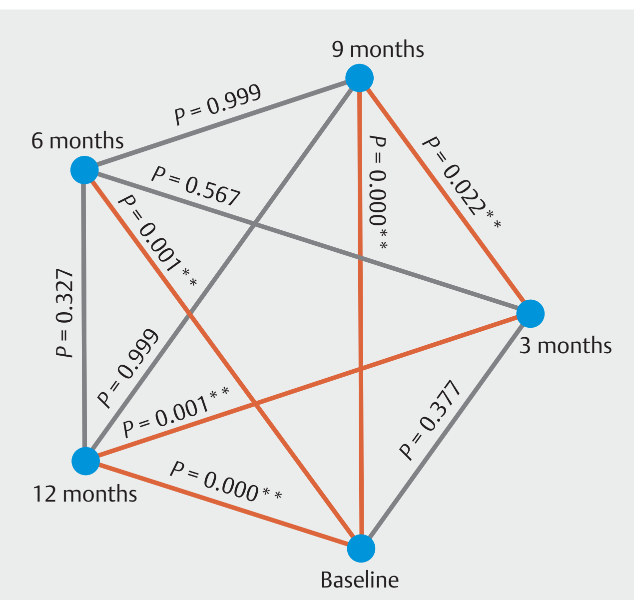
Safety

No intraprocedural complications were reported. All patients were discharged on the day of the procedure. No patient required hospitalization after the procedure. Mild adverse events such as post-procedural abdominal pain, nausea, or vomiting not requiring further medical attention were not recorded. No moderate or SAEs were reported.

Discussion

This is the first multicenter study of ESG in the management of weight regain after sleeve gastrectomy, including patients who were overweight or obese across the full BMI spectrum. This study showed that ESG can induce significant weight loss in this broad cohort for at least 1 year, according to the minimal thresholds of 25 % EWL and ≤ 5 % SAE recommended by the ASGE/ASMBS for endoscopic bariatric and metabolic therapies [29].

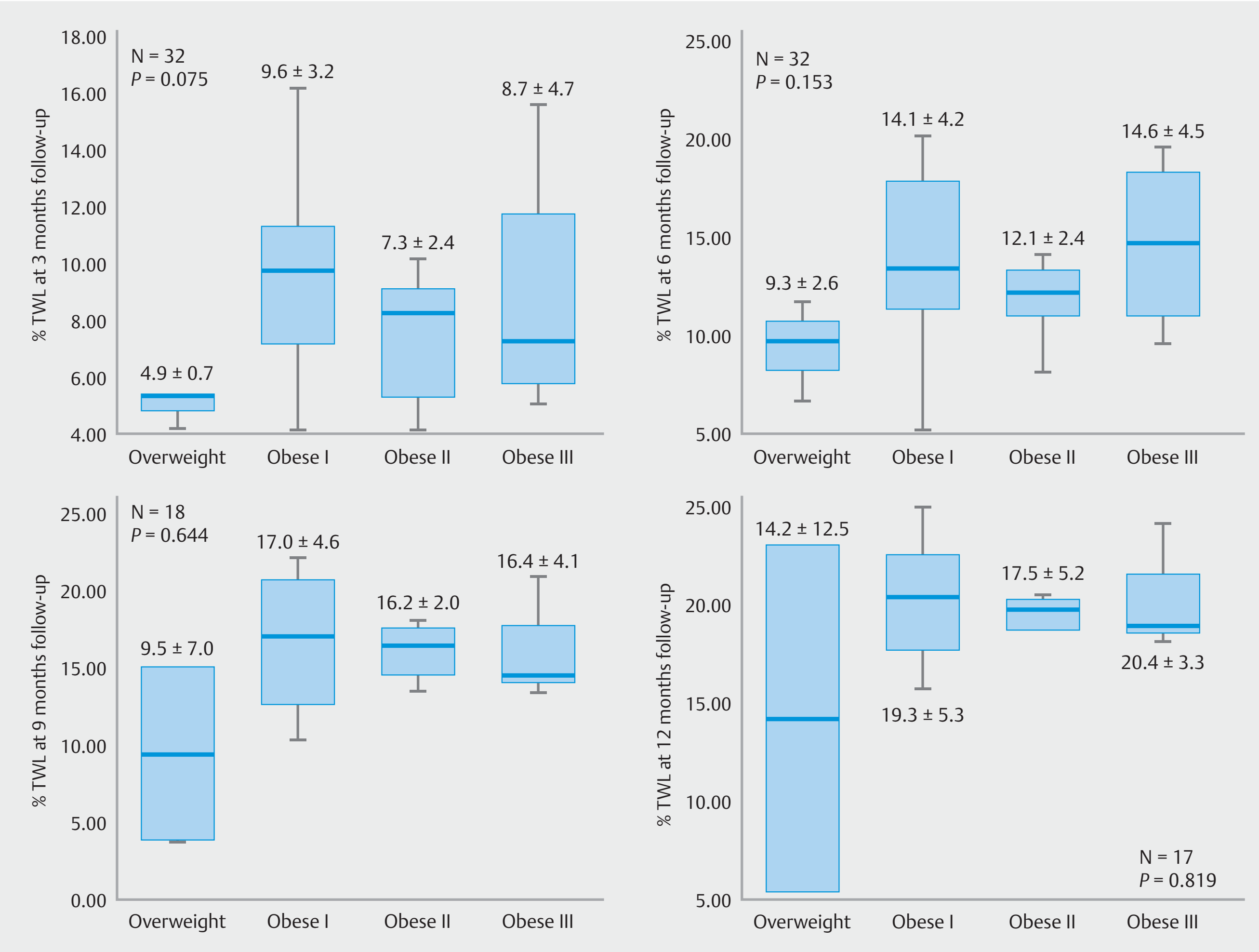
Although bariatric surgery is the most effective and durable treatment for obesity, weight regain is common and has become a considerable challenge [5, 11]. Weight regain is often multifactorial and the initial step in the management of this condition is a comprehensive evaluation of contributing factors. A multidisciplinary evaluation, including dietary and lifestyle factors, and a general medical history and examination are essential [4, 13]. Although lifestyle therapies including diet, exercise, and behavior modification are fundamental to the treatment of weight regain, they typically have limited efficacy when used alone [13]. The next step in the management of weight regain after sleeve gastrectomy is an anatomic evaluation. A systematic review identified that sleeve size and sleeve dilation may contribute to weight regain after sleeve gastrectomy [5]. Recently, an international expert consensus [4] agreed that conversion of sleeve gastrectomy to an alternative procedure is indicated in the presence of sleeve dilation and weight regain or insufficient weight loss (80.8 % agreed). Additionally, conversion to an alternative procedure is preferable in the presence of a retained fundus (72 % agreed). The expert group agreed that SADI is a reasonable procedure to treat this patient population. Additionally, more than 90 % agreed that BPD-DS is superior to RYGB in terms of weight loss. In contrast to conversion, revision of sleeve gastrectomy, including repeat sleeve gastrectomy or gastric antrum resection, were not considered an indication for insufficient weight loss or weight regain in the presence of dilation of the sleeve or isolated antral dilation. The majority of experts thought that there was not enough clinical evidence to conclude that repeat sleeve gastrectomy is a safe and effective revisional procedure for weight regain or poor weight loss after index sleeve. Additionally, gastric band was not considered an effective revisional intervention [4].



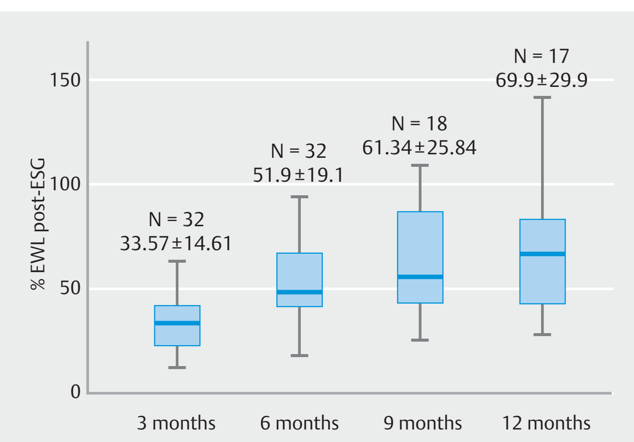
▶ **Fig. 2** Comparison between absolute weight loss at baseline and 3, 6, 9, and 12 months after endoscopic sleeve gastroplasty.

Although revisional surgery for weight regain improves weight loss, it is associated with a higher risk of complications than primary bariatric surgery, with an adverse event rate of up to 14.3 %. Additionally, some patients do not want to undergo a second surgical procedure or to convert the procedure to another technique [16 – 18, 31 – 33]. Repeat sleeve gastrectomy, as mentioned above, is not yet considered a safe and effective procedure in the management of weight regain after sleeve gastrectomy. Therefore, there is an increased demand for less invasive and safer procedures to manage weight regain following sleeve gastrectomy. Several endoscopic bariatric therapies have been used in the management of patients with weight regain after RYGB, with satisfactory results [13, 19, 20]. Following the favorable results of endoluminal revision therapies in RYGB patients and the satisfactory results of ESG in patients without previous surgery, several centers have recently started to perform ESG as a revisional procedure in patients with weight regain after sleeve gastrectomy. However, there are few reports in the literature.

In our study, a significant reduction in BMI was reported. The BMI decreased from 34.8 kg/m^2 (SD 4.4) to 30.2 kg/m^2 (SD 4.1) and 28.9 kg/m^2 (SD 4.4) at 6 months and 1 year, respectively. These results are similar to surgical revisional procedures as demonstrated in a systematic review, in which the BMI decreased from 41.9 kg/m^2 to 36.5 kg/m^2 and 33.7 kg/m^2 after RYGB and from 38.5 kg/m^2 to 34.0 kg/m^2 and 30.4 kg/m^2 after repeat sleeve gastrectomy at 6 months and 1 year, respectively [6]. In our study, we also individually evaluated the reduction in BMI in patients who were overweight and obese. All obesity



► **Fig. 3** Comparison between percent total weight loss (%TWL) at 3, 6, 9, and 12 months after endoscopic sleeve gastroplasty in all body mass index subgroups.

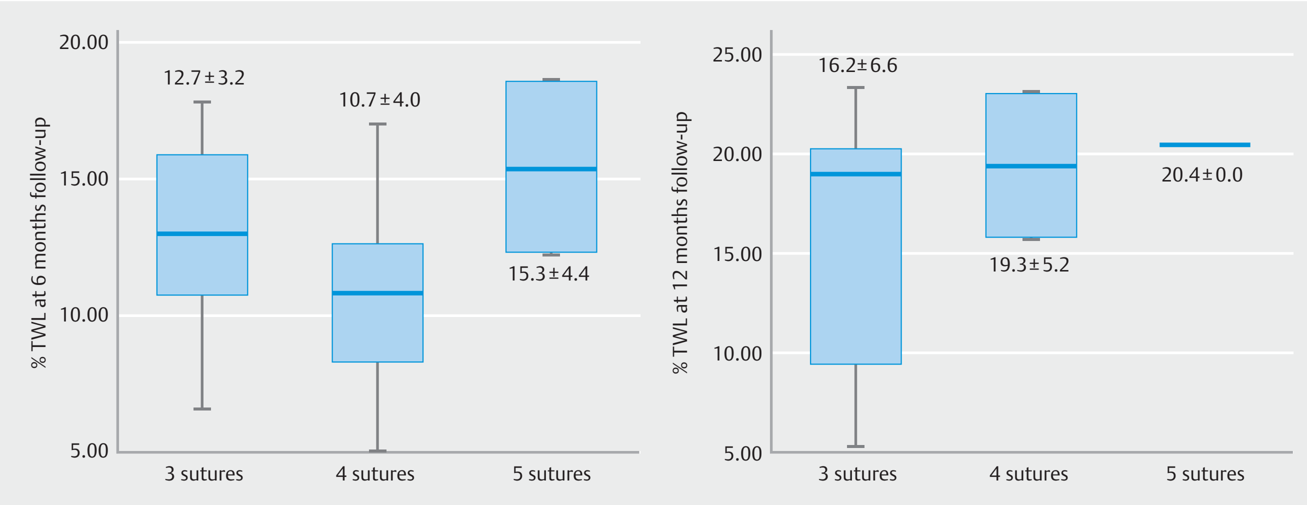


► **Fig. 4** Percent excess weight loss (%EWL) at 3, 6, 9, and 12 months after endoscopic sleeve gastroplasty (ESG).

classes showed a significant reduction in BMI; however, results in overweight patients did not reach statistical difference in BMI reduction.

When analyzing AWL and %EWL, our study also demonstrated similar results to a study comparing conversion to RYGB vs. repeat sleeve gastrectomy, which showed a reduction from 125.1 kg to 94 kg after RYGB and from 113.75 kg to 95 kg after repeat sleeve gastrectomy at 1 year [14]. In our study, AWL significant reduced from 99.6 kg (SD 15.1) to 83.6 kg (SD 10.3) at 1-year follow-up. Regarding %EWL, a systematic review reported 60 % EWL after conversion to RYGB and 68 % after repeat sleeve gastrectomy at 1 year [6]. These results are similar to the 69.9 % (SD 29.9) reported in our study.

Regarding %TWL after conversion surgery, in accordance to the expert consensus [4], a systematic review showed that SADI/BPD-DS achieved significantly higher %TWL by 10.22 %, when compared with RYGB [16]. In our study, %TWL appeared



▶ **Fig. 5** Correlation between number of sutures used during endoscopic sleeve gastroplasty and percent total weight loss (%TWL) at 6 months and 1 year.

▶ **Table 2** Mean weight loss in all body mass index groups after endoscopic sleeve gastroplasty.[1]

Variables	Baseline (pre-ESG) (n = 32)	6 months (n = 32)	1 year (n = 17)	*P* value[2]
Absolute weight	99.6 (15.1)	86.2 (12.1)	83.6 (10.3)	< 0.05
▪ Overweight	92.3 (12.9)	83.4 (9.9)	77.5 (5.5)	> 0.05
▪ Obesity class I	94.6 (10.9)	81.2 (9.1)	79.8 (9.8)	< 0.05
▪ Obesity class II	99.9 (4.9)	87.9 (5.8)	83.9 (8.7)	< 0.05
▪ Obesity class III	127 (14.3)	107.9 (8.7)	95.8 (5.1)	< 0.05
%TWL	–	13.2 (3.9)	18.3 (5.5)	–
▪ Overweight	–	9.3 (2.6)	14.2 (12.5)	–
▪ Obesity class I	–	14.1 (4.2)	19.3 (5.3)	–
▪ Obesity class II	–	12.1 (2.4)	17.5 (5.2)	–
▪ Obesity class III	–	14.6 (4.5)	20.4 (3.3)	–
BMI	34.8 (4.4)	30.2 (4.1)	28.9 (4.4)	< 0.05
▪ Overweight	29.4 (0.3)	26.7 (0.5)	25.4 (2.4)	> 0.05
▪ Obesity class I	32.9 (1.2)	28.4 (1.7)	26.2 (1.5)	< 0.05
▪ Obesity class II	36.7 (1.3)	32.2 (1.8)	30.2 (1.7)	< 0.05
▪ Obesity class III	43.9 (4.4)	37.7 (5.4)	35.8 (4.5)	< 0.05
%EWL	–	51.9 (19.1)	69.9 (29.9)	–
▪ Overweight	–	62.0 (12.3)	88.5 (52.8)	–
▪ Obesity class I	–	59.1 (19.0)	84.4 (22.4)	–
▪ Obesity class II	–	38.6 (8.6)	55.4 (14.8)	–
▪ Obesity class III	–	35.7 (12.5)	47.8 (11.2)	–

SD, standard deviation; ESG, endoscopic sleeve gastroplasty; TWL, percent total weight loss; BMI, body mass index; %EWL, percent excess weight loss.
[1] All data are mean (SD) in kg.
[2] Friedman test.

superior to surgical techniques, with a %TWL of 13.2% (SD 3.9) at 6 months and 18.3% (SD 5.5) at 1 year. However, our study had a lower baseline BMI compared with the surgical studies, which may have introduced a selection bias. Our satisfactory results appear to be reproducible, as reported in two series [25, 34]. The first case series (five patients) describing ESG after sleeve gastrectomy reported %TWL of up to 17.2% [25]. Additionally, a multicenter series including nine patients reported 12.7% TWL at 6 months and 18.5% at 1 year [34]. However, unlike in our study, some patients in this series received weight loss medication at 6 months to further enhance weight loss.

Our results are comparable to ESG as a primary treatment for obesity in the 6-month follow-up analysis. We demonstrated a %TWL of 13.2% (SD 3.9), which is similar to the results of the largest series of primary ESG (13.7% [SD 3.9]) [24]. The %EWL of 51.9% (SD 19.1) was also similar to 53% (SD 17) of another primary ESG study at 6-month follow-up [23]. However, when we analyzed the 1-year follow-up data, our study showed a slight improvement in weight loss compared with primary ESG. We demonstrated a %TWL of 18.3% (SD 5.5) compared with 15.0% (SD 7.7) in the largest ESG study [24], and a %EWL of 69.9% (SD 29.9) compared with 54% (SD 40) from the Mayo Clinic study [23]. We believe that this slight improvement is in part related to the relatively narrow caliber of the stomach before ESG in the revisional procedures. Additionally, patients with previous sleeve gastrectomy may have altered gastric physiology, which could favor weight loss following ESG in sleeve gastrectomy.

Overall, ESG after sleeve gastrectomy was well tolerated. Similarly to most ESG studies in the literature, mild adverse events such as abdominal pain, nausea, and emesis were not analyzed in detail because they are expected and managed conservatively, with improvement observed after a few days [22, 23]. However, Alqahtani et al. [24], reported 3 procedure reversals among 1000 ESG patients owing to intractable abdominal pain. In our study, no patient required hospitalization after the procedure and no moderate or SAEs were reported. In the literature, there are some reports of moderate and SAEs after ESG, including bleeding and perigastric fluid collections; however, the reported mean SAE rate is 2.3% [21]. Therefore, ESG is considered safe in light of the threshold set by the ASGE/ASMBS position paper [29]. When compared with surgical revision, the benefit of ESG regarding adverse events is evident. In a retrospective analysis including 34 patients who underwent conversion of sleeve gastrectomy to RYGB, 4 early SAEs were reported (11.7%), including gastrojejunostomy leak, intestinal wound, strangulated hernia at the trocar port, and exploratory laparoscopy for abdominal discomfort. Additionally, three late SAEs were reported (8.7%) [17]. In other series including 84 revisional procedures due to weight regain (53.6%) or refractory complications (46.4%), overall adverse events were 14.3% [18]. As our study is the first to evaluate ESG as a revisional procedure, there are no studies with which to compare adverse event data. However, a recent matched cohort study comparing the outcomes of ESG vs. sleeve gastrectomy as a primary procedure showed significantly lower rates of adverse events in the ESG group (5.2% vs. 16.9%) [35].

We recognize the limitations of our study. First, there is no standardized definition for weight regain after sleeve gastrectomy. We used the most common definition, which is an increase of at least 10 kg from nadir weight [5]. Second, this is a retrospective study with the inherent limitations expected, such as potential selection bias, lack of randomization, and loss to follow-up. Third, this cohort includes the first cases of ESG in the management of weight regain after sleeve gastrectomy performed at some centers, thus the learning curve could impact clinical results. Additionally, our study is limited to 1 year of follow-up. Further studies with longer follow-up would be helpful to assess the durability of the procedure. Finally, prospective studies comparing an endoscopic to a surgical technique, or assessing the effect of combination therapy with medication would also be of interest.

In summary, given the rise in number of sleeve gastrectomies being performed worldwide, there is an increasing demand for a minimally invasive endoscopic treatment option for weight regain following sleeve gastrectomy. Considering the minimally invasive outpatient nature of ESG, the reproducibility among centers, the low prevalence of SAEs, and the favorable clinical outcomes, ESG following sleeve gastrectomy appears to be safe and effective and may offer a solution for the treatment of this challenging patient population.

Competing interests

Dr. E. G. H. de Moura is a consultant (with nonfinancial support) for Boston Scientific and Olympus. Dr. Galvão Neto has received grants and personal fees from Fractyl Labs, GI dynamics, GI windows, Apollo Endosurgery, Olympus, Medtronic, and M.I. Tech. Dr. Thompson has received grants from Apollo Endosurgery and Olympus, and personal fees from Medtronic, Boston Scientific, Apollo Endosurgery, and Olympus.

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