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Endoscopic Sleeve Gastroplasty: Suturing the Gastric Fundus Does Not Confer Benefit

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Conflict of Interest: Christopher McGowan is a consultant for Apollo Endosurgery.

Mouen A. Khashab is a consultant for Boston scientific, Medtronic, and Olympus America.

Vivek Kumbhari is a consultant for Medtronic, Pentax Medical, Boston Scientific, FujiFilm, Apollo Endosurgery, and Obalon. He receives research support from ERBE USA and Apollo Endosurgery.

All other authors have none to declare.

Abstract:
Background and Aims: There is heterogeneity regarding the technical aspects of endoscopic sleeve gastroplasty (ESG) such as applying fundal sutures (FS). Our aim was to determine whether ESG with FS (ESG-FS) affects weight loss and serious adverse event (SAE) rate when compared to ESG without FS (ESG-NFS).
Methods: We conducted a two-center retrospective analysis of 247 patients who underwent ESG with or without FS. The primary outcome was percent excess weight loss (%EWL) at 3, 6, and 12-months post-ESG. The secondary outcomes include the SAE rate and procedure duration.
Results: At 3, 6, and 12-months, ESG-NFS had a significantly greater mean %EWL compared to ESG-FS (38.4± 15.3% vs 31.2± 13.9%, p=0.001; 54.7± 19.2% vs. 37.7± 17.3%, p<0.001; 65.3± 21.1% vs. 40.6± 23.5% respectively, p<0.001). There was no statistically significant difference in SAE rate between ESG-NFS (n=2; 2.0%) and ESG-FS (n=4; 2.6%) (p=1). The mean procedure time was significantly shorter in the ESG-NFS, 59.1 ± 32.7 vs. 93.0 ± 35.5 minutes (p<0.001), in the setting of a lower mean number of sutures 5.7 ± 1.1 vs 8.4 ± 1.6 (p<0.001).
Conclusion: ESG-NFS demonstrated greater efficacy and shorter procedure duration. Therefore, fundal suturing should not be performed.

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Title Page

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ABSTRACT

Background and Aims: There is heterogeneity regarding the technical aspects of endoscopic sleeve gastroplasty (ESG) such as applying fundal sutures (FS). Our aim was to determine whether ESG with FS (ESG-FS) affects weight loss and serious adverse event (SAE) rate when compared to ESG without FS (ESG-NFS).

Methods: We conducted a two-center retrospective analysis of 247 patients who underwent ESG with or without FS. The primary outcome was percent excess weight loss (%EWL) at 3, 6, and 12-months post-ESG. The secondary outcomes include the SAE rate and procedure duration.

Results: At 3, 6, and 12-months, ESG-NFS had a significantly greater mean %EWL compared to ESG-FS (38.4± 15.3% vs 31.2± 13.9%, p=0.001; 54.7± 19.2% vs. 37.7± 17.3%, p<0.001; 65.3± 21.1% vs. 40.6± 23.5% respectively, p<0.001). There was no statistically significant difference in SAE rate between ESG-NFS (n=2; 2.0%) and ESG-FS (n=4; 2.6%) (p=1). The mean procedure time was significantly shorter in the ESG-NFS, 59.1 ± 32.7 vs. 93.0 ± 35.5 minutes (p<0.001), in the setting of a lower mean number of sutures 5.7 ± 1.1 vs 8.4 ± 1.6 (p<0.001).

Conclusion: ESG-NFS demonstrated greater efficacy and shorter procedure duration. Therefore, fundal suturing should not be performed.

INTRODUCTION

The endoscopic sleeve gastroplasty (ESG) is at the forefront of the minimally invasive endoscopic bariatric therapies (EBTs). By placing full thickness sutures along the greater curvature of the stomach, ESG results in sufficient volume reduction to induce restriction and early satiety, and subsequent weight loss [1]. Delayed gastric emptying may also contribute to early satiation [2]. Multiple independent studies have demonstrated ESG's clinically significant weight loss outcomes and low rate of adverse events [3]. However, there remains significant heterogeneity regarding the technical aspects of performing ESG such as suture pattern, number of sutures placed, and plication of the gastric fundus.

In particular, there is no consensus with regards to whether the gastric fundus should be plicated or intentionally left open. The conceivable benefit of suturing the gastric fundus is that it more closely emulates the anatomical appearances of a surgical sleeve gastrectomy, a well-established weight loss therapy. However, the argument for not suturing the fundus is that it adds procedure time as it is technically challenging and could possibly compromise the safety of the procedure. At the present juncture, the paucity of data and lack of consensus does not clearly guide clinicians as to whether they should suture the fundus or not. This is not only important from a clinical practice perspective, but also with regards to how practitioners are being trained to perform ESG. Our present aim was to compare weight loss outcomes and adverse event rates between ESG performed with and without fundus sutures (FS).

METHODS

This was a retrospective review of prospectively maintained data of 247 consecutive patients who underwent ESG with or without FS between March 2016 and August 2019 at two centers. The group that did not undergo FS was termed ESG-NFS, whereas the cohort that underwent FS was referred to as ESG-FS. The study included patients with obesity older than 18 years that had not benefitted from diet and exercise alone. Exclusion criteria are listed in Supplementary Methods 1. These patients have been included in previously published studies [4-8].

Patient demographics, medical history (hypertension, diabetes mellitus type 2), baseline weight, and the procedural variables (fundal suturing, total number of sutures, and suture pattern) were

extracted. Serious adverse events (SAEs) were defined as any of the following: death, gastric perforation, perigastric abscess, and gastrointestinal bleed requiring an intervention for hemostasis. Pre- and post-procedural medication administration and follow up is described in Supplementary Methods 2. The primary outcome was the mean percent excess weight loss (%EWL) at 3, 6 and 12-months post-ESG. The secondary outcomes included SAE rate and procedure duration. Institutional Review Board approval for a retrospective analysis was procured for this study. Additionally, written informed consent was obtained from all patients before the procedures.

Procedure technique:

The procedure was performed by two endoscopists with extensive experience performing ESG. V.K trained C.M to perform ESG, prior to C.M performing the procedure alone. The difference between the two techniques was limited to the plication of the gastric fundus, which was only performed by V.K. In ESG-NFS, suturing was repeated until the proximal gastric body was reached. The fundus was additionally sutured in ESG-FS. Both endoscopists performed the procedures in separate endoscopy suites under general anesthesia. Prophylactic antibiotics were administered prior to the procedure in all patients at both centers. ESG technique at each center is described in detail in Supplementary Methods 3. In ESG-NFS, suturing was repeated until the proximal gastric body was reached. The fundus was additionally sutured in ESG-FS.

Statistical analysis involved use of R software (online at http://www.R-project.org, the R Foundation for Statistical Computing, Vienna, Austria). Refer to Supplementary Methods 4 for further description of analysis.

RESULTS

Baseline Characteristics:

Baseline demographic characteristics were similar, except for a significantly greater proportion of females in ESG-NFS (85.7% vs 71.8 %; p=0.017) **(Table 1)**. The baseline body mass index was 38.3 ±5.6 kg/m^2 and 39.4 ±7.3 kg/m^2 in ESG-NFS and ESG-FS, respectively (p=0.210). Baseline weight in kilograms (kg) was similar at 106.7±21.2 kg and 111.9±24.1 kg (p=0.082). A total of 199, 181, and 123 patients completed follow up at 3, 6 and 12 months respectively.

The mean procedure time was significantly shorter in the ESG-NFS group, 59.1 ± 32.7 vs 93.0 ± 35.5 minutes (p<0.001), in the setting of a lower mean number of sutures used 5.7 ± 1.1 vs 8.4 ± 1.6 (p<0.001) as depicted in **Table 2**.

Weight Loss Outcomes: (Table 3)

At 3-months post-procedure, ESG-NFS had a significantly greater %EWL 38.4 ± 15. 3% versus 31.2 ± 13.9% (p=0.001) in the ESG-FS group. The greater %EWL at 3-months remained significant on multiple regression analysis after controlling for other covariates such as age, gender, hypertension, diabetes mellitus, number of sutures, and baseline BMI (B =-6.988, 95% CI: -12.843 to -1.132, p=0.02).

The % EWL was significantly greater in the ESG-NFS group at both at 6 and 12-months when comparing to the ESG-FS group (6 months: 54.7 ± 19.2 vs 37.7 ± 17.3, p<0.001; 12 months: 65.3 ± 21.1 vs 40.6 ± 23.5, p<0.001). The latter remained significant after adjusting for covariates (6 months: B =-16.248, 95% CI: -23.622 to -8.874, p<0.001; 12 months: B =-24.103, 95% CI: -34.432 to -13.775, p<0.001).

Adverse Events (AEs):

SAE's occurred in 2.43% of patients, and included bleeding (ESG-NFS: n=0; ESG-FS: n= 3), (p=0.279), perigastric abscess (ESG-NFS: n=1; ESG-FS: n= 1; p=1), and gastric perforation (ESG-NFS: n=1; ESG-FS: n= 0; p=0.396). SAEs were comparable between the two groups **(Table 4)**.

DISCUSSION

Weight loss outcomes after bariatric procedures are the result of a complex interaction between physiologic, behavioral, and procedural factors. The hallmark of a technically successful therapy is efficacy, without compromising safety. Thus, bariatric endoscopists continue to strive to optimize existing procedures to attain maximal weight loss outcomes by identifying technical nuances that may contribute to superior weight loss. Since its inception, ESG has evolved technically in terms of the number of sutures used, the suture pattern, interrupted versus continuous, spacing, tightness, and frequency of bites [9]. To our knowledge, a comparison

between fundal plication and lack thereof has not been reported in the literature, signifying the importance of this study.

This is the first study comparing the weight loss outcomes and adverse events of ESG with and without FS. As opposed to LSG, which involves the longitudinal resection of the gastric fundus, ESG is a predominantly restrictive procedure. LSG achieves greater %TBWL when compared to ESG at 6 and 12-months [6,10]. The exact mechanism contributing to the superiority in weight loss outcomes of LSG may be the result of both irreversible restriction and alteration of fundal hormones like ghrelin [11]. In an attempt to emulate the hormonal changes demonstrated by LSG, FS were placed in ESG, however, studies have shown limited hormonal disruption as a result of ESG with or without FS [2,12]. Our study has demonstrated that sparing the fundus results in superior mean %EWL at 3, 6, and 12-months (Table 3). Both cohorts achieved a %EWL that exceeded the recommended 25% EWL [13,14]. Interestingly, the number of sutures was not independently associated with weight loss on multivariable analysis.

Historically, endoscopists have been reluctant to suture the fundus due to the fear of adverse events. On average the gastric wall thickness of the antrum, body, and fundus are 3.1, 2.4, and 1.7mm respectively [15]. In light of the thin fundal anatomy, it has been postulated that transfundic sutures would increase the risk of leaks, perforation and formation of perigastric fluid collections [16]. Fundal plication has fallen out of favor despite the absence of studies comparing the safety and weight loss outcomes of ESG with and without transfundic sutures. James et al. had described a case of a perigastric abscess as a delayed adverse event of ESG with transfundic sutures [17]. Our study demonstrates a similar adverse events rate in patients who had fundal suturing versus those who did not (2.6% and 2% respectively). Although not statistically significant, there was a trend towards more bleeding in the ESG-FS cohort. The proximity of the fundus to the short gastric arteries could potentially contribute to the bleeding.

The mean procedure time was significantly shorter when the fundus was not sutured (59.1 ± 32.7 vs 93.0 ± 35.5 minutes ($p<0.001$)), and in the setting of a lower mean number of sutures (5.7 ± 1.1 vs 8.4 ± 1.6 ($p<0.001$)). This prolonged procedure duration increases exposure to general anesthesia without added morbidity or mortality. Also, given the use of more sutures and prolonged procedure duration, suturing the fundus increases the opportunity cost and thus the

total cost of the procedure. Moreover, FS placement is performed in a partially retroflexed view, which adds to the technical difficulty of the procedure.

One concern when comparing the same procedure performed by two different practitioners is to control for the level of experience with regards to the procedure of interest. The learning curve in ESG has been explored in two studies both highlighting procedure duration as the primary outcome from which procedure efficiency, mastery, and learning plateau was derived [18,19]. Based on the small number of procedures required before reaching the learning plateau, we believe that the subtle difference in experience between the endoscopists minimally influenced the outcomes.

This study has limitations inherent to a retrospective chart review, including lack of randomization and loss to follow-up. We have no data on compliance at each site with regard to aftercare. Moreover, the possible effects of race and other comorbidities on weight loss outcomes were not analyzed. Further studies with longer follow-up would be helpful to assess long-term durability of ESG with and without FS.

Due to the increased procedural duration, the inferior weight loss outcomes, and the potential for a higher AE rate, suturing the fundus does not present a clear added benefit to the patient. At this juncture, based on the results of this study, ESG with suturing of the fundus should not be performed.

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TABLES

Table 1: Baseline Characteristics

Baseline characteristics	ESG-FS	ESG-NFS	p-value
Number of subjects	149	98	
Age (mean (SD))	47.16 (11.47)	44.94 (9.39)	0.111
Male (%)	42 (28.2)	14 (14.3)	0.017
Hypertension (%)	37 (24.8)	29 (29.6)	0.496
Type 2 Diabetes Mellitus (%)	12 (8.1)	4 (4.1)	0.329
Baseline Weight in kilograms (mean (SD))	111.93 (24.09)	106.71 (21.18)	0.082
Baseline Body Mass Index (mean (SD))	39.38 (7.33)	38.34 (5.56)	0.210
Height (mean (SD))	1.68 (0.09)	1.66 (0.08)	0.074

SD, standard deviation; ESG-FS, endoscopic sleeve gastroplasty with fundal suturing; ESG-NFS, endoscopic sleeve gastroplasty without fundal suturing

Table 2: Procedural characteristics

Procedural characteristics	ESG-FS	ESG-NFS	p-value
Number of sutures (mean (SD))	8.41 (1.58)	5.72 (1.10)	<0.001

Procedure time (min) (mean (SD))	92.96(35.5)	59.13(32.7)	<0.001

SD, standard deviation; ESG-FS, endoscopic sleeve gastroplasty with fundal suturing; ESG-NFS, endoscopic sleeve gastroplasty without fundal suturing

Table 3: Weight-related Outcomes

Time	Weight loss outcome	Technique	N	Mean ± Std. Deviation	p-value
3 months follow up	%TBWL	ESG-NFS	90	12.3± 3.3	0.183
		ESG-FS	109	13.0± 4.9	
	%EWL	ESG-NFS	90	38.4± 15.3	0.001
		ESG-FS	109	31.2± 13.9	
6 months follow up	%TBWL	ESG-NFS	82	17.3± 4.5	0.203
		ESG-FS	99	16.2± 7.0	
	%EWL	ESG-NFS	82	54.7± 19.2	<0.001
		ESG-FS	99	37.7± 17.3	
12 months follow up	%TBWL	ESG-NFS	57	21.3± 6.2	0.012
		ESG-FS	66	17.5± 10.2	
	%EWL	ESG-NFS	57	65.3± 21.1	<0.001
		ESG-FS	66	40.6± 23.5	

ESG-FS, endoscopic sleeve gastroplasty with fundal suturing; ESG-NFS, endoscopic sleeve gastroplasty without fundal suturing

Table 4: Serious Adverse Events

Serious Adverse Events	Total (n (%))	ESG-FS (n (%))	ESG-NFS (n (%))	p-value
	247	149	98	
Perigastric abscess	2 (0.8)	1 (0.0)	1 (1.0)	1
Perforation	1 (0.4)	0 (0.0)	1 (1.0)	0.396
Bleeding	3 (1.2)	3 (1.9)	0 (0.0)	0.279
Overall	6 (2.4)	4 (2.6)	2 (2.0)	1

ESG-FS, endoscopic sleeve gastroplasty with fundal suturing; ESG-NFS, endoscopic sleeve gastroplasty without fundal suturing

Supplementary methods 1: Exclusion criteria

They had no contraindication to ESG such as a gastroesophageal motility disorder, active neoplastic lesions, gastric bleeding, use of anticoagulants, pregnancy, or hiatal hernia greater than 5cm in size. Patients were seen in the outpatient clinic before the procedure and informed of the risks, benefits, and pharmacologic, endoscopic or surgical alternatives of the procedure.

Supplementary methods 2: Pre- and post-procedural follow up

In both centers, patients were discharged on the same day and prescribed daily proton pump inhibitor, oral anti-emetics, and analgesics as needed. Under the supervision of a dietician, the diet was advanced from clear liquids to full liquids, to purees, to soft solids, and regular solids over a 5 week period. Both centers offered patients an ancillary weight management program for diet and lifestyle modifications that included a registered dietician, obesity medicine specialist, gastroenterologist, and behavioral psychologist. The respective programs were offered for at least 12 months following the endoscopic procedure.

Supplementary methods 3: ESG technique

The Apollo Overstitch device (Apollo Endosurgery, Austin, Texas) was mounted on a double-channel gastroscope (GIF2T 180 series; Olympus Medical, Tokyo, Japan). ESG was performed using the U-shaped running suture pattern with 2-0 polypropylene sutures placed immediately proximal to the incisura angularis on the anterior wall. Sequential full-thickness bites were taken using a catheter-type tissue helix (Apollo Endosurgery, Austin, Texas) in the following direction: anterior wall, greater curvature, posterior wall, and then 1 cm proximally in the opposite direction: posterior wall, greater curvature, anterior wall [1].The needle was released upon completion of the running suture pattern, anchoring the leading end of the suture. The trailing end of the suture was anchored by deploying a cinch, and the suture was pulled tightly to plicate the gastric tissue. Each subsequent suture was placed 1cm proximal to the prior suture and the same pattern was repeated. To avoid the development of longitudinal pockets, the proximal sutures are arranged such that they are not in line with the distal sutures. On completion, the stomach achieved the typical appearances of a sleeve, with the lumen measuring approximately 15mm in diameter.

Supplementary methods 4: Statistical analysis

Categorical variables were compared using Fisher's exact test, Chi-squared test or Chi-squared trend test. Continuous variables were tested for normal distribution by Kolmogorov-Smirnov test. In accordance with the result of this test, the statistical significance of differences in continuous variables was tested using the Student t-test or Mann–Whitney U test. In case of non-parametric distribution, Mann–Whitney U test was used to compare continuous variables between the two cohorts. Finally, multivariable linear regression analyses was performed to build a model with FS as a candidate predictor variable for weight loss. Other candidate predictor variables were based on age, gender, hypertension, type 2 diabetes mellitus, and number of sutures. In case of continuous data, variables were presented as mean value ± standard deviation (SD). Categorical variables were presented as frequency or percentages. All reported p values are two-tailed. Associations were considered statistically significant at a two-tailed of 0.05.

Supplementary references:

1. Sartoretto A, Sui Z, Hill C et al. Endoscopic sleeve gastroplasty (ESG) is a reproducible and effective endoscopic bariatric therapy suitable for widespread clinical adoption: a large, international multicenter study. Obesity surgery 2018; 28: 1812-1821