#### **ORIGINAL ARTICLE**

# Revisional endoscopic sleeve gastroplasty of laparoscopic sleeve gastrectomy: an international, multicenter study

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**Background and Aims:** Laparoscopic sleeve gastrectomy (LSG) facilitates significant and durable weight loss; however, weight recidivism and need for revisional surgery occur in a subset of patients. Reduction of a dilated LSG using the revisional endoscopic sleeve gastroplasty (R-ESG) approach is an appealing and minimally invasive alternative to surgical revision that is congruent with obesity as a chronic relapsing disease model. In this study, we examine the safety and efficacy of the technique in a large multicenter international cohort.

**Methods:** Prospectively collected data from 9 centers for 82 consecutive adults who underwent R-ESG for weight regain after LSG using the OverStitch device (Apollo Endosurgery, Austin, Tex, USA) from March 2014 to November 2019 were reviewed. Total body weight loss (TBWL) and adverse events were reported up to 12 months. Univariable logistic regression was used to identify predictors of response at 12 months.

**Results:** Eighty-two adults (92.7% female) experienced 27.9  $\pm$  20.7 kg weight regain from post-LSG nadir weight, prompting R-ESG (mean age, 42.8  $\pm$  10.4 years) at a mean weight of 128.2  $\pm$  57.5 kg. Mean R-ESG procedure duration was 48.3  $\pm$  20.5 minutes, and the median number of sutures used was 4 (interquartile range, 3-4). After R-ESG, TBWL (follow-up %) was 6.6%  $\pm$  3.2% at 1 month (81.7%), 10.6%  $\pm$  4.4% at 3 months (74.4%), 13.2%  $\pm$  10.1% at 6 months (63.4%), and 15.7%  $\pm$  7.6% at 12 months (51.2%). In a per-protocol analysis,  $\geq$ 10% TBWL was achieved by 37 of 51 patients (72.5%) at 6 months and 34 of 42 patients (81.0%) at 12 months;  $\geq$ 15% TBWL was achieved by 20 of 46 patients (43.5%) at 6 months and 22 of 42 patients (52.4%) at 12 months. Only 1 moderate adverse event occurred in the form of a narrowed gastroesophageal junction, which resolved after a single endoscopic dilation.

**Conclusions:** R-ESG is a safe and effective means of facilitating weight loss for weight recidivism after LSG, with sustained results at 1 year. R-ESG should be considered before pursuing more-invasive surgical revisional options. (Gastrointest Endosc 2020;∎:1-9.)

(footnotes appear on last page of article)

#### INTRODUCTION

Obesity has now reached pandemic proportions.<sup>1,2</sup> A multitude of strategies exist to address this disease, the most effective of which, to date, is bariatric surgery.<sup>3</sup> Laparoscopic sleeve gastrectomy (LSG) is the most frequently performed bariatric surgery worldwide because it is technically easier to perform and demonstrates similar weight loss outcomes compared with Roux-en-Y gastric bypass (RYGB).<sup>4,5</sup> LSG involves resection of the greater curvature of the stomach to reduce its volume by

approximately 80%. It facilitates 48% to 72% excess weight loss (EWL) at 1 year, as well as improvement in obesity-related comorbidities, such as obstructive sleep apnea, diabetes, dyslipidemia, and hypertension, with durable mid-term outomes.<sup>2,6,7</sup>

Weight recidivism occurs in a subset of patients after LSG, potentially in the setting of sleeve dilation (Fig. 1). Weight gain or insufficient weight loss (<50% EWL) is estimated to occur in 14% to 37% of patients at  $\geq$ 7 years of follow-up, prompting revision rates of approximately 13% in the same time frame.<sup>5</sup> Revisions of LSG for

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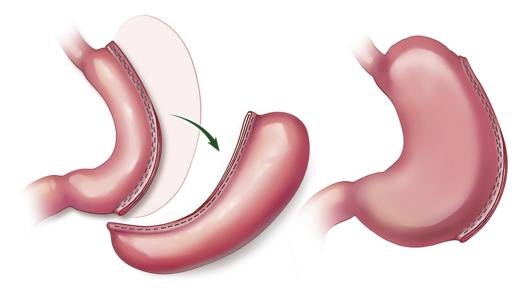


Figure 1. Laparoscopic sleeve gastrectomy (left) with postsurgical sleeve dilation (right).

weight recidivism have primarily taken the form of repeat sleeve,<sup>8-14</sup> conversion to RYGB,<sup>14,15</sup> surgical and duodenal switch.<sup>5,16</sup> There remains a paucity of data to determine which revision procedure is optimal.<sup>8</sup> Each carries a significant rate of morbidity, with overall adverse event rates for surgical revision of LSG ranging from 5% to 20%, much higher than the risk associated with the initial surgical intervention.<sup>13,17</sup> Given the chronic relapsing nature of obesity, the growing popularity of LSG, and the increasingly younger age at which patients are offered LSG, there is a need for a safe revisional option to induce weight loss and remission of obesity-related comorbidities after the primary LSG has diminished in efficacy.

The advent of endoscopic bariatric and metabolic therapies has helped to address the widening management gap in the obesity pandemic. Their use has also been reported for management of weight recidivism after RYGB.<sup>18-21</sup> Although gastric suturing, such as that performed in the endoscopic sleeve gastroplasty using the OverStitch device (Apollo Endosurgery, Austin, Tex, USA), may not induce as much weight loss as its surgical counterpart for the primary treatment of obesity, using this endoscopic technique to restrict the volume of a dilated LSG for management of suboptimal weight loss or weight regain is appealing. The revisional endoscopic sleeve gastroplasty (R-ESG) approach has multiple advantages over traditional surgical revision options, including improved safety, technical ease, and organ-sparing nature that allows for further revisional surgery. R-ESG is particularly poised to serve a role in the poorly understood landscape of LSG revision, with a pilot study of 5 patients showing early promise.<sup>18</sup>

To address the knowledge gaps in the safety and efficacy of R-ESG using the OverStitch device as a revisional intervention for weight recidivism after LSG, we conducted an international multicenter retrospective review of prospectively collected data from 82 consecutive patients at 9 centers with expertise in bariatric endoscopy, with a focus on total body weight lost over the course of 1 year, as well as safety and potential predictors associated with improved weight loss after R-ESG.

#### **METHODS**

This study was approved by the Mayo Clinic Institutional Review Board (IRB 19-009875), which served as the primary site of data consolidation and authorship, although IRB approval was obtained independently for all sites involved. Given the retrospective nature of this study, informed consent was not required. Consecutive patients were reviewed from the following 9 centers: New You Medical Center (n = 32), Weill Cornell Medical College (n = 11), Borland Groover Clinic (n = 8), University of Chicago (n = 7), Orlando Health (n = 6), Ibrahim Bin Hamad Obaid Allah Hospital (n = 5), Kaiser Clinica (n = 5), Mayo Clinic, Rochester (n = 4), and Johns Hopkins University (n = 4).

#### Patient selection and endoscopic procedure

Patients were identified as potential candidates at their respective institutions if they experienced weight regain after LSG. All weight management options were discussed with the patients, including the safety and expected weight loss of each intervention. Only 1 patient reported taking obesity pharmacotherapy therapy before R-ESG. This patient was started on liraglutide 3 mg daily, which was stopped 1 month before R-ESG. Patients had undergone LSG between 2001 and 2019. R-ESG occurred from March 2014 to November 2019. The general purpose of R-ESG is

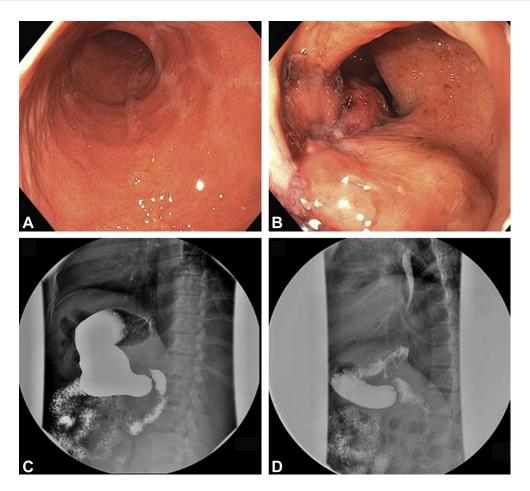


Figure 2. Gastric anatomy before and after revisional endoscopic sleeve gastroplasty (R-ESG) of laparoscopic sleeve gastrectomy. Endoscopic view of the gastric reservoir before R-ESG (**A**) and 4 weeks after R-ESG (**B**). The corresponding upper GI series before R-ESG (**C**) and 4 weeks after R-ESG (**D**).

predicated on 2 primary aims: (1) to reduce the volume of the dilated gastric sleeve and (2) to shorten its length. R-ESG was performed using endoscopic full-thickness 2-0 Proline sutures applied in a variety of suturing patterns (predominately U-shaped) to imbricate the anterior/ greater curvature/posterior gastric wall to create a tubular, restricted sleeve along the lesser curvature of the stomach (Fig. 2).

The following section summarizes the steps of the R-ESG. With the patient under general anesthesia and in the left lateral position, a dual-channel gastroscope (Olympus, Tokyo, Japan) is inserted with or without an esophageal overtube. Initial surveillance gastroscopy is performed, delineating the exact anatomy of the sleeve, assessing for dilated or remnant areas in the antrum, body, and fundus, and planning for subsequent suture placements. The gastroscope is withdrawn and the OverStitch system (Apollo Endosurgery, Austin, Tex, USA) is mounted on the distal end of a double-channel endoscope. Suturing typically begins on the anterior wall at the level of incisura anteriorly, as in primary endoscopic sleeve gastroplasty. A tissue helix burrows through the full thickness of the gastric wall and pulls the acquired tissue within the jaws of the suturing device. The needle and suture are passed through the intervening tissue and exchanged to permit a running suture pattern (Fig. 3). The tissue helix is then released. The process is repeated along the greater curvature and then the posterior wall. The gastroscope is then repositioned proximally, and the suture line is carried back toward the anterior wall of the sleeve. Finally, the needle t-tag is released, tension is applied externally to tighten the suture, and a cinch is deployed to secure the first suture. The total number of sutures and bites taken per suture were not fixed, because this depended on tissue configuration, degree of sleeve dilatation, and endoscopist's discretion.

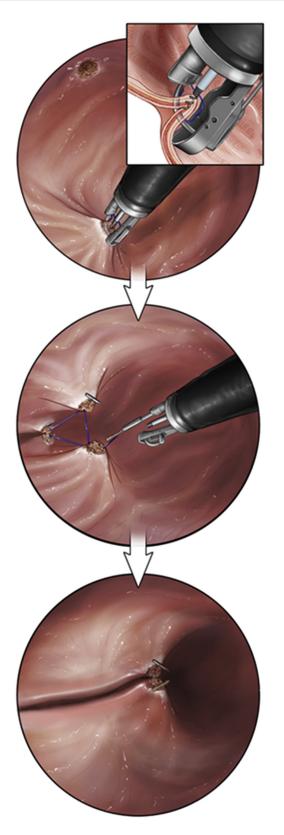
## Follow-up, data collection, and statistical analysis

Patients were followed by standard practices at their respective institutions, all of which involved follow-up with a multidisciplinary team that included a registered dietician before and after revision. As a practice, postprocedural endoscopy was not routinely performed for

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**Figure 3.** Revisional endoscopic sleeve gastroplasty technique. The Apollo OverStitch device is operated to create full-thickness sutured plications of gastric tissue in a dilated surgical sleeve. The middle image demonstrates the triangular suture pattern that is typically used.

asymptomatic patients after the R-ESG. Data were prospectively collected for the following: date of LSG, patient sex, date of R-ESG, age at time of R-ESG, weight before LSG, weight nadir after LSG, weight gain from nadir at time of R-ESG, time from LSG to R-ESG, endoscopic findings at time of R-ESG, procedural time of R-ESG, number of sutures used per R-ESG, suturing pattern, and adverse events. Serious adverse events were defined as any of the following: death, perforation, infection/abscess, GI bleed requiring an intervention for hemostasis, procedure-related acute cardiopulmonary event, and need for hospitalization  $\geq 4$  nights or  $\geq 1$  night in the intensive care unit as a consequence of the procedure. Serious adverse events were graded using the American Society for Gastrointestinal Endoscopy lexicon for endoscopic adverse events.<sup>22</sup> Presence, resolution, or development of GERD was based on patient-reported symptoms consistent with GERD.

Categorical variables were summarized as frequencies, and continuous variables were summarized as means with standard deviation or medians with interquartile ranges (IQRs). The outcome variables of weight were considered to follow a normal distribution. Statistical analysis software (JMP, Version 14.1.0. SAS Institute Inc, Cary, NC, USA, 1989-2019) was used for the analysis. Univariable analysis for total body weight loss (TBWL)  $\geq$ 15% at 12 months was performed on inputs of age at time of R-ESG, weight nadir after LSG, time from LSG to R-ESG, use of weight loss medications, number of sutures in R-ESG, and presence of dilated stomach noted at time of R-ESG.

#### RESULTS

Eighty-two adults (92.7% female) across 9 centers underwent LSG at a mean weight of 159.5  $\pm$  75.0 kg, with a mean post-LSG weight nadir of 104.1  $\pm$  46.1 kg. All patients regained weight from their post-LSG weight nadir, with a mean of 27.9  $\pm$  20.7 kg. This prompted R-ESG at a median of 5 years (IQR, 4-7 years) from LSG. At the time of R-ESG, the mean age was 42.8  $\pm$  10.4 years and the mean weight was 128.2  $\pm$  57.5 kg. A median of 4 sutures (IQR, 3-4 sutures) was used per procedure. Mean procedural duration was 48.3  $\pm$  20.5 minutes. Patient and procedural characteristics are provided in Table 1.

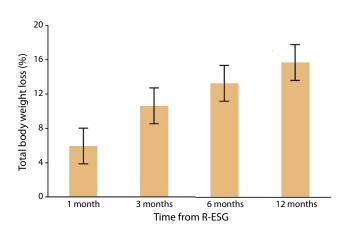
After R-ESG, TBWL (follow-up %) was  $6.6\% \pm 3.2\%$  at 1 month (81.7%),  $10.6\% \pm 4.4\%$  at 3 months (74.4%),  $13.2\% \pm 10.1\%$  at 6 months (63.4%), and  $15.7\% \pm 7.6\%$  at 12 months (51.2%). Mean TBWL trajectory over the duration of the study is depicted in Figure 4. EWL (follow-up %) was  $18.5\% \pm 10.7\%$  at 1 month (68.3%),  $34.9\% \pm 18.8\%$  at 3 months (63.4%),  $44.3\% \pm 21.2\%$  at 6 months (57.3%), and  $47.6\% \pm 26.6\%$  at 12 months (47.6%). For those with data collected at 6 months (per-protocol analysis), 37 of 51 patients (72.5%) achieved  $\geq 10\%$  TBWL

#### TABLE 1. Demographic and procedural information

| Patient and procedural characteristics                                  | Distribution<br>(n = 82)          |
|-------------------------------------------------------------------------|-----------------------------------|
| Sex (% female)                                                          | 92.7                              |
| Weight at time of LSG (kg), mean $\pm$ SD                               | 159.5 $\pm$ 75.0                  |
| Lowest weight after LSG (kg), mean $\pm$ SD                             | $104.1\pm46.1$                    |
| Weight regain after LSG (kg), mean $\pm$ SD                             | $\textbf{27.9} \pm \textbf{20.7}$ |
| Time from LSG to revision (years), median (IQR)                         | 5 (4-7)                           |
| Weight at R-ESG (kg), mean $\pm$ SD                                     | $128.2\pm57.5$                    |
| Age at R-ESG (years), mean $\pm$ SD                                     | $\textbf{42.8} \pm \textbf{10.4}$ |
| BMI at endoscopic revision (kg/m²), mean $\pm$ SD                       | $\textbf{37.2} \pm \textbf{5.7}$  |
| No. of patients with dilated surgical sleeve noted at time of R-ESG (%) | 36 (44)                           |
| Procedure duration (minutes), mean $\pm$ SD                             | $48.3\pm20.5$                     |
| No. of sutures used, median (IQR)                                       | 4 (3-4)                           |

Distributions of the 82 patients are presented as means + standard deviations or medians with interquartile ranges (IQRs).

LSG, Laparoscopic sleeve gastrectomy; SD, standard deviation; IQR, interquartile range; R-ESG, revisional endoscopic sleeve gastroplasty; BMI, body mass index.



**Figure 4.** Total body weight loss (TBWL) after revisional endoscopic sleeve gastroplasty (R-ESG). TBWL (follow-up %) was  $6.6\% \pm 3.2\%$  at 1 month (81.7%),  $10.6\% \pm 4.4\%$  at 3 months (74.4%),  $13.2\% \pm 10.1\%$  at 6 months (63.4%), and  $15.7\% \pm 7.6\%$  at 12 months (51.2%).

and 20 of 46 patients (43.5%) achieved  $\geq$ 15% TBWL. For those with data collected at 12 months, 34 of 42 patients (81.0%) achieved  $\geq$ 10% TBWL and 22 of 42 patients (52.4%) achieved  $\geq$ 15% TBWL. For those with the necessary values collected at 12 months, 30 of 39 patients (76.9%) achieved the  $\geq$ 25% EWL threshold for clinical success as defined by the American Society for Gastrointestinal Endoscopy/American Society for Metabolic and Bariatric Surgery task force for endoscopic approaches to obesity.<sup>23</sup>

Thirteen patients (15.9%) were started on weight loss medications within 1 year after R-ESG, and these included phentermine (15 mg, n = 1; 37.5 mg/day, n = 8), and phentermine/topiramate (15 mg/25-30 mg/day; n = 4)

(Table 2). For those started on weight loss medications after R-ESG who had the 12-month follow-up (n = 7), TBWL was 18.0%  $\pm$  7.7%, and for those not on weight loss medications after R-ESG who had the 12-month follow-up (n = 31), TBWL was 10.4%  $\pm$  11.7% (*P* = .15).

On univariable analysis, factors of age at time of R-ESG, weight at LSG, weight nadir after LSG, time from LSG to R-ESG, use of weight loss medications, number of sutures in R-ESG, and presence of dilated stomach noted at time of R-ESG were not associated with achieving TBWL  $\geq$ 15% at 12 months (Table 3). Given the lack of associations, multivariable analysis was not pursued.

No serious adverse events were reported in any of the 82 patients during the 12-month study period. One adverse event, graded moderate in severity and definitely attributable according to the lexicon,<sup>22</sup> was observed in a patient who experienced non-bloody emesis 12 days from R-ESG, attributed to narrowing at the gastroesophageal junction, diagnosed on an upper GI series. This required 2-day hospitalization, and symptoms resolved with a single endoscopic dilation. Mild adverse events from R-ESG included 4 instances (4.9%) of dehydration requiring intravenous fluids but not requiring hospitalization or a repeat endoscopic procedure. Of special interest was the impact of R-ESG on symptoms of GERD. Fifteen (18.3%) patients had symptoms of GERD at the time of R-ESG; within the 12 months of this study; 4 of these patients (26.7%) experienced GERD resolution and 11 (73.3%) experienced GERD persistence. Of the 67 patient who did not have GERD at the time of R-ESG, 6 (9.0%) developed GERD symptoms within the 12 months of the study. Adverse event frequency is listed in Table 4.

#### DISCUSSION

This international, multicenter study of adult patients undergoing R-ESG demonstrated that endoscopic volume reduction of a surgically created gastric sleeve is safe, feasible, and consistently effective for inducing sustained weight loss. In a per-protocol analysis, TBWL exceeded 10% in 72.5% of patients at 6 months and 81.0% of patients at 12 months.

Weight regain after LSG is common, observed in upward of one-third of patients, usually occurring between the third and sixth postsurgical year.<sup>24</sup> Subsequent revisions of LSG for weight regain have been shown in a meta-analysis to exceed 13% at >7 years.<sup>5</sup> There is incomplete understanding of the influencing factors for weight recidivism after LSG. It has been suggested that excessive sleeve size—either by use of an oversized bougie to create the sleeve or by postoperative sleeve dilatation—may drive this result.<sup>8,25,26</sup> Failure to detect a hiatal hernia, which may hide gastric tissue, or incomplete resection of the fundus, which is a major site of secretion of the orexigenic hormone, ghrelin, and a Revisional endoscopic sleeve gastroplasty of laparoscopic sleeve gastrectomy

TABLE 2. Weight loss medications used concomitantly with R-ESG during the study

| Weight loss medication | Maximum dose per day (mg) | Start date (month after R-ESG) | Site                   |
|------------------------|---------------------------|--------------------------------|------------------------|
| Phentermine            | 15.0                      | 9                              | Мауо                   |
| Phentermine            | 37.5                      | 3                              | Borland Groover Clinic |
| Phentermine            | 37.5                      | 3                              | Orlando Health         |
| Phentermine            | 37.5                      | 6                              | Borland Groover Clinic |
| Phentermine            | 37.5                      | 6                              | Borland Groover Clinic |
| Phentermine            | 37.5                      | 6                              | Borland Groover Clinic |
| Phentermine            | 37.5                      | 6                              | Borland Groover Clinic |
| Phentermine            | 37.5                      | 6                              | Borland Groover Clinic |
| Phentermine            | 37.5                      | 6                              | Borland Groover Clinic |
| Phentermine/topiramate | 15/92                     | 1                              | Orlando Health         |
| Phentermine/topiramate | 15/92                     | 1                              | Orlando Health         |
| Phentermine/topiramate | 15/92                     | 3                              | Orlando Health         |
| Phentermine/topiramate | 15/92                     | 3                              | Orlando Health         |

Thirteen patients were prescribed either phentermine (n = 8) or phentermine/topiramate (n = 5) after the revision of their LSG to enhance weight loss.

R-ESG, Revisional endoscopic sleeve gastroplasty; LSG, laparoscopic sleeve gastrectomy.

| TABLE 3. Univariable analysis for predicting $\geq$ 15% TBWL at 12 months |                          |         |  |
|---------------------------------------------------------------------------|--------------------------|---------|--|
| Variable                                                                  | Unadjusted<br>odds ratio | P value |  |
| Age at time of R-ESG (years)                                              | 1.01                     | .71     |  |
| Weight at LSG (kg)                                                        | 1.00                     | .11     |  |
| Lowest weight after LSG (kg)                                              | 1.01                     | .13     |  |
| Time from LSG (years)                                                     | 0.90                     | .34     |  |
| Use of weight loss medications with R-ESG                                 | 0.81                     | .80     |  |
| Sutures used for R-ESG (n)                                                | 0.75                     | .29     |  |
| Dilated stomach noted at time of R-ESG                                    | 0.45                     | .24     |  |

Odds ratios and corresponding P values are shown.

R-ESG, Revisional endoscopic sleeve gastroplasty; LSG, laparoscopic sleeve gastrectomy.

major target of LSG in a complete resection, are also postulated to play a role in weight recidivism.<sup>25</sup> Nevertheless, although studies of postsurgical sleeve volume do show an increase in sleeve size after the initial operation, weight regain has not been definitively linked to volume increase as determined by CT volumetry<sup>27</sup> or upper GI contrast studies.<sup>28</sup>

Regardless of the cause, weight recidivism after LSG must be targeted to prevent recurrence or worsening of obesity and associated comorbidities. Endoscopic therapies have been important tools for the management of postoperative adverse events of LSG, such as for dilation of sleeve stenosis<sup>29</sup> or for stent placement of staple line leaks and fistulae, but their role in the management of weight recidivism after bariatric surgery is far more nascent.<sup>18-20</sup> To our knowledge, this is the largest study of endoscopic revision after LSG with the purpose of facilitating weight loss.

Although the precise execution of the procedure varied by endoscopist in this study, in general, the technique of R-ESG echoes that of primary endoscopic sleeve gastroplasty.<sup>30</sup> There are 2 noteworthy considerations for patient safety and tolerance. First, the endoscopist must be wary of taking bites that traverse the diameter of the lumen because there is a risk of closing the lumen with the first suture at the level of the incisura. Second, the lumen itself will be reduced in caliber from the outset, resulting in poor visualization of the suturing tool's jaws on subsequent suture placement(s). This increases the risk of damaging the gastric wall, especially at the level of the thin-walled fundus. Other nuanced distinctions from endoscopic sleeve gastroplasty include that the site of previous resection can be incorporated without major concerns and that the gastric wall is expected to be thicker compared with that in patients who have not undergone sleeve gastrectomy, and thus it is routine to perform 2 or more complete turns of the helix to secure full-thickness bites of gastric tissue. Ultimately, the homologous approaches of R-ESG and endoscopic sleeve gastroplasty imply that the former should be readily performed by those trained in the latter.

Surgical options for weight recidivism after LSG that have been previously reported include re-do sleeve gastrectomy or revision to another bariatric surgery. Conversion to duodenal switch induces weight loss of approximately 18%, RYGB to 18% to 22%, and 1 anastomosis/omega-loop/mini-gastric bypass to 30%.31 Although effective, the safety profile of these more invasive strategies warrants consideration. On conversion to one of the aforementioned surgical interventions, 10% to 15% of patients developed significant adverse events that included anastomotic/bile leak, postoperative bleeding, ulcer, or significant gastroesophageal reflux.<sup>32-36</sup> These outcomes, as well as weight regain, may compel re-revision, an undertaking fraught with an even greater

#### TABLE 4. Adverse events after R-ESG

| TABLE 4. Adverse events after R-ESG                             |                                                        |                     |             |                                                      |  |  |
|-----------------------------------------------------------------|--------------------------------------------------------|---------------------|-------------|------------------------------------------------------|--|--|
| Adverse event                                                   | Proportion of patients with<br>adverse events, n/N (%) | Severity<br>grading | Attribution | Therapy provided                                     |  |  |
| Dehydration requiring intravenous fluids                        | 4/82 (4.9)                                             | Mild                | Definite    | Intravenous fluids                                   |  |  |
| New GERD symptoms                                               | 4/67 (9.0)                                             | Mild                | Probable    | Oral proton pump inhibitor therapy                   |  |  |
| Vomiting, narrowed gastroesophageal junction on upper Gl series | 1/82 (1.2)                                             | Moderate            | Definite    | Single endoscopic dilation,<br>2-day hospitalization |  |  |

Adverse events were collected and reported according to the American Society for Gastrointestinal Endoscopy lexicon.<sup>22</sup> No serious adverse events were observed. Incident GERD symptoms were reported for 67 patients instead of 82 because 15 had baseline GERD at the time of R-ESG. *Resistorial endoscopic sleeve gastroplasty.* 

burden of risk to patients. For instance, a quarter of patients who underwent a re-revision to duodenal switch or RYGB for weight regain after re-do sleeve gastrectomy developed postoperative adverse events that included bleeding, mid-gastric stenosis, and anastomotic leaks.<sup>37,38</sup> Although the weight loss facilitated by R-ESG is less robust than these surgical options, the safety profile and the anatomy-preserving nature of the R-ESG are likely to be more favorably received by patients and ostensibly reduce the risk of surgical re-revision, should that need arise.

In addition to a favorable safety profile, R-ESG likely saves resources compared with surgical intervention. Although the procedural time of surgical revision of sleeve gastrectomy was 43 minutes (range, 29-70 minutes) and the mean duration of R-ESG in this study was  $48.3 \pm$ 20.5 minutes, patients with endoscopic revision are discharged on the same day, compared with a mean hospital stay of 3.9 days (range, 3-16 days) after a bariatric surgical revision.<sup>39</sup> For conversion of LSG to RYGB, one series cited a mean procedural time of 27 minutes (range, 71-227 minutes) and a mean length of stay of 1.9 days (range, 1-8 days).<sup>15</sup>

The major limitation of this study was the lack of a standardized approach to endoscopic revision and unequal distribution of procedures between contributing centers, which prevented direct comparisons. This heterogeneity rendered our ability to obtain predictors of outcomes less precise. For instance, a dilated stomach was defined subjectively by the performing endoscopist at the time of R-ESG and not governed by exact volumetric standards on uniform imaging tests, and suturing patterns, which may take the form of a triangle, U, or square, were left to the discretion of the performing endoscopists and were often dictated by the configuration and dilation of the sleeve itself. However, the finding of a dilated sleeve, as well as the suturing pattern to restrict it, likely have physiologic relevance and may provide further insights into the mechanisms of weight loss after R-ESG that ostensibly include alteration in gastric accommodation and motility. Data regarding the method of surgical sleeve construction, including distance from pylorus, size of the calibrating tube, and degree of fundus resection, were not available

to the authors and may have an influential role in weight loss. It is probable that this degree of heterogeneity clouds the ability to discern contributing factors to successful clinical outcomes, as was seen in our univariable analysis, although a similar report of endoscopic revision of sleeve gastrectomy also did not identify predictors of clinical success.<sup>40</sup> Finally, although our study revealed that concomitant use of weight loss medications after R-ESG did not lead to significant greater TBWL at 12 months than those who were not exposed to weight loss medications in that interval, larger prospective studies with more regimented drug initiations, doses, and durations are required to more definitively elucidate any additive or synergistic benefits of such medications that may have passed undetected here due to the smaller sample size, retrospective nature, and overall heterogeneity of the present study.

Given the promising role of endoscopic suturing for the management of weight recidivism after LSG based on this series, there are ample data to support its clinical utility; nevertheless, explicit society-level standards do not vet exist for this revisional paradigm, as they do for bariatric surgery and endoscopic therapies for primary obesity. For instance, after bariatric surgery, Reinhold's criteria describes EWL of 50% to 75% as successful and 25% to 50% as fair weight loss.<sup>41</sup> In 2011, surgical and endoscopic societies convened to establish the Preservation and Incorporation of Valuable Endoscopic Innovations (PIVI) thresholds, recommending that endoscopic bariatric and metabolic therapies be considered effective if EWL exceeded 25% at 12 months.42-44 Although EWL was not uniformly available from participating institutions in this study, in the 39 patients for whom these data were collected, 30 (77.0%) exceeded the 25% EWL PIVI threshold. Noting a potentially analogous observation that revisional LSG induces less weight loss than primary LSG,<sup>45</sup> it will similarly be incumbent on future research endeavors to calibrate metrics for success in endoscopic revision of bariatric surgeries rather than relying on mileposts established for primary endoscopic weight loss interventions.<sup>18</sup>

Future studies of R-ESG should evaluate improvement in obesity-related comorbidities, such as hypertension, diabetes mellitus, nonalcoholic fatty liver disease, obstructive sleep apnea, and, critically, GERD. The scope of this study did not have the granularity to address GERD in a regimented manner, and the presence, resolution, or post R-ESG development of GERD was based on patient-reported symptoms and the judgment of the treating clinician. Our reported GERD symptom resolution (26.7%), persistence (73.3%), and development (9.0%) within the 12 months after R-ESG compels further study with more objective measurement of pathologic esophageal acid exposure pre- and postendoscopic revision. GERD is a major obesity-related condition and the second most common reason for LSG revision; given the hypothesized role of fundic retention in weight recidivism and reflux pathogenesis, there is likely a patient population with post-LSG reflux who would benefit from endoscopic remodeling of the gastric sleeve, thereby avoiding surgical conversion to the RYGB, and this warrants further examination.<sup>8</sup>

#### CONCLUSION

R-ESG is a safe and effective means of facilitating weight loss in those with weight recidivism after LSG. This transoral, anatomy-preserving, same-day procedure should be considered before more invasive, morbid surgical revisions are pursued.

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Abbreviations: EWL, excess weight loss; IQR, interquartile range; LSG, laparoscopic sleeve gastrectomy; R-ESG, revisional endoscopic sleeve gastroplasty; RYGB, Roux-en-Y gastric bypass; SD, standard deviation; TBWL, total body weight loss.

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