Endoscopic Sleeve Gastroplasty Is Feasible, Safe, and Effective in a Non-academic Setting: Short-Term Outcomes from a Community Gastroenterology Practice

Theodore W. James, Sumana Reddy, Trish Vulpis & Christopher E. McGowan

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ORIGINAL CONTRIBUTIONS

Endoscopic Sleeve Gastroplasty Is Feasible, Safe, and Effective in a Non-academic Setting: Short-Term Outcomes from a Community Gastroenterology Practice

Theodore W. James[1] · Sumana Reddy[2] · Trish Vulpis[3] · Christopher E. McGowan[4]

Abstract

Background and Aims Endoscopic sleeve gastroplasty (ESG) has demonstrated promising weight loss results with fewer adverse events and less new-onset gastroesophageal reflux disease (GERD) compared to laparoscopic sleeve gastrectomy. Publications on ESG have exclusively described the experience at large academic medical centers with little known about the implementation and outcomes of this procedure in community practice.

Methods We conducted a retrospective study of consecutive patients who underwent ESG at a private, community-based gastroenterology practice. Total body weight loss (TBWL), procedure duration, improvement in metabolic comorbidities, and adverse event (AE) rate and severity were assessed.

Results One hundred patients underwent ESG (86 women, mean age 45 ± 9 years) and were analyzed. Procedure duration was 59 ± 33 min with an improvement in procedural efficiency from the first quartile (mean 105 min) to the fourth quartile (mean 38 min). Mean 12-month TBWL was 29.80 ± 11.46 kg (23.1 ± 7.5%), with excess weight loss of 66.1 ± 21.5%. Over this time period, mean change in BMI was 9.43 ± 0.22. A multiple linear regression model found that higher starting weight ($P < 0.05$) and absence of suture reinforcement ($P = 0.037$) were associated with increased TBWL at 3 months. Fourteen of 20 cases of hypertension, and 5 of 10 cases of dyslipidemia, were in complete remission by post-procedure month 3.

Conclusions ESG performed in a community gastroenterology practice demonstrated comparable clinical outcomes to large tertiary referral centers. TBWL and excess body weight loss either met or exceeded previously reported data from these centers.

Keywords Endoscopic sleeve gastroplasty · Endoscopic suturing

Abbreviations
ESG Endoscopic sleeve gastroplasty

Background and Aims

Roux-en-Y gastric bypass and surgical sleeve gastrectomy are proven, well-studied treatments for morbid obesity and its associated comorbidities [1]. Despite this efficacy, only a small fraction of eligible patients undergoes bariatric surgery [2]. This discrepancy may be partially explained by operative risks, limited access, cost, and patient preference, ultimately hindering access to surgery. Additionally, current National Institutes of Health criteria for bariatric surgery remain an obstacle for patients with obesity [3].

In order to address this gap in bariatric treatments, endobariatrics has emerged to assist patients with obesity who are not eligible for, or do not desire, bariatric surgery [4]. Endoscopic sleeve gastroplasty (ESG) uses full-thickness endoscopic sutures in order to plicate and restrict the stomach to a sleeve-like configuration. The procedure was developed and first described in 2013 by Abu Dayyeh

✉ Christopher E. McGowan
christopher.e.mcgowan@gmail.com

[1] Division of Gastroenterology and Hepatology, University of North Carolina, Chapel Hill, NC, USA

[2] Department of Medicine, University of North Carolina, Chapel Hill, NC, USA

[3] WakeMed Cary Hospital, Cary, NC, USA

[4] Cary Gastroenterology Associates, 115 Kildaire Park Dr, Ste 201, Cary, NC 27518, USA

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et al. with a high technical success rate [5]. Subsequent studies of ESG efficacy have demonstrated promising results, with fewer adverse events and less new-onset gastroesophageal reflux disease (GERD) compared to laparoscopic sleeve gastrectomy (LSG) [6].

To date, publications on ESG have exclusively described the experience at large academic medical centers. In this regard, little is known about the implementation and outcomes of this procedure in community practice and how it compares to previously published reports. Data on this topic would help to inform the adoption of the procedure by community endoscopists and help to better understand the role of ESG in the care of patients with obesity. The present study aims to describe the implementation of ESG in a community setting, along with technical and clinical outcomes.

Methods

This is a retrospective study of consecutive patients who underwent ESG at a private, community-based gastroenterology practice by a single endoscopist (CEM) between May 2018 and July 2019, with follow-up data until August 2019. This study represents the initial 100 consecutive patients treated at this center. Preoperative patient evaluation included a complete medical history, physical examination, metabolic panel, electrocardiogram (if BMI > 40 kg/m^2 and/or hypertension or cardiac risk factors), and upper GI series (if history of severe gastroesophageal reflux or clinical suspicion of hiatal hernia). All patients were treated on a same-day, outpatient basis, unless they expressed a specific preference for overnight observation due to out-of-town transit. Exclusion criteria included age less than 18 years, prior bariatric surgery (other than laparoscopic adjustable gastric band), bleeding disorder or coagulopathy, aspirin or nonsteroidal anti-inflammatory drug dependence, poorly controlled diabetes, severe cardiopulmonary disease, hiatal hernia greater than 4 cm, unwillingness to take a proton pump inhibitor, and active peptic ulcer disease.

Technique

All procedures were performed under general anesthesia with the patient in the left lateral decubitus position. All patients received one time oral doses of aprepitant 80 mg, gabapentin 300 mg, and acetaminophen 1000 mg 3 h prior to the procedure. All patients received intravenous levofloxacin 500 mg in the immediate preprocedural period followed by 500 mg daily by mouth for three additional days postprocedure. A diagnostic upper endoscopy was first performed to assess for contraindications to ESG, including active peptic ulcer, neoplastic pathology, and hiatal hernia > 4 cm. ESG was performed using a standard U-shaped pattern extending from the incisura to the level of the gastroesophageal junction, as previously described [7]. Following the procedure, patients were observed for 1–2 h, then discharged home. Patients received three liters of intravenous crystalloid solution as part of routine care on the day of the procedure. All patients were followed by a physician and registered dietician postoperatively at week 1, month 1, month 3, and every 2–3 months thereafter. Diet was advanced from clear liquids, to full liquids, purees, soft solids, and regular solids over a 5-week period under dietician supervision. Body mass index (BMI) was calculated as weight in kilograms divided by the square of height in meters. Ideal body weight was calculated as BMI of 25, as per the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program registry [8]. Excess body weight was calculated as actual body weight − ideal body weight. Excess body weight loss was calculated as percentage using starting weight minus weight at time 3, 6, or 12 months divided by excess body weight, per American Society for Metabolic and Bariatric Surgery guidelines [9].

Study Endpoints

The primary outcome of interest was total body weight loss; secondary outcomes of interest included procedure duration, improvement in metabolic comorbidities, and adverse event (AE) rate and severity. Severity of AEs was graded according to the American Society for Gastrointestinal Endoscopy (ASGE) lexicon [10]. Postprocedural pain scores and nausea scores were rated 0–3 (none, mild, moderate, severe) based on data collected in the postanesthesia care unit and need for pain and nausea medications in the first 48 h.

Statistical Analysis

Continuous variables were reported as means with standard deviations (SD) or, for skewed data, medians with interquartile ranges (IQRs). Comparison of linear variables was performed with the *t* test and categorical variables by using the chi-square test. A level of significance of $P < 0.05$ was adopted for all inferential testing. A multiple linear regression model was created using the variables age, gender, starting weight (kg), number of sutures, and suture reinforcement (yes/no) with 3-month total weight loss as the outcome of interest, as this time point included the highest number of patients (64). Statistical analysis was performed using STATA version 15.1 (StataCorp LLC; College Station, TX).

Results

During the study period, 100 consecutive patients underwent ESG (86 women, mean age 45 ± 9 years). Mean preprocedural weight was 106.39 ± 20.24 kg, mean BMI 38.41 ± 5.44, and

mean excess body weight of 37.50 ± 16.54 kg. Patient comorbidities included hypertension (29 patients), hyperlipidemia (13 patients), and diabetes mellitus (4 patients). Two patients had previously undergone Nissen fundoplication for GERD and one patient previously had a laparoscopic adjustable gastric band. Two patients were previously treated with intragastric balloons. Patient demographic data are presented in Table 1.

Procedure duration was 59 ± 33 min with an improvement in procedural efficiency from the first quartile (mean 105 min) to the fourth quartile (mean 38 min). Procedure duration over time is presented in Fig. 1. Number of sutures used was 4 (5 patients), 5 (46 patients), 6 (30 patients), 7 (6 patients), 8 (8 patients), and 9 (2 patients), and 42 patients had reinforcing sutures placed. Procedural data are presented in Table 2.

Post-procedural pain was none (5 patients), mild (44 patients), moderate (29 patients), and severe (19 patients). Mean postprocedural pain score in those with reinforcement sutures was 2.05 ± 0.91 as compared to the mean for patients without reinforcement sutures, 1.33 ± 0.67 ($P < 0.0001$). Two mild AEs occurred in the cohort due to dehydration from decreased oral intake in the first 72 h. Both patients were treated with intravenous fluid hydration on an outpatient basis. Two severe AEs occurred in the cohort. One patient developed a perigastric abscess 20 days postprocedure, requiring aspiration under computed tomography guidance and IV antibiotics. A second patient developed an abdominal infection 4 days postprocedure requiring laparoscopy with surgical washout and repair of a small gastrotomy. Both severe AE patients recovered completely.

Mean 3-month total body weight loss was 13.57 ± 5.41 kg (12.47 ± 3.50%), with excess weight loss of 38.1 ± 16.8%. Mean 6-month total weight loss was 18.91 ± 7.79 kg (16.41 ± 5.4%) with excess weight loss of 48.9 ± 19.9%. At 12 months, total weight loss was 29.80 ± 11.46 kg (23.1 ± 7.5%), with excess weight loss of 66.1 ± 21.5%. Over this time period, mean change in BMI was 9.43 ± 0.22. Weight loss data are presented in Fig. 2. Follow-up data at 3 months, 6 months, and 12 months was available for 64/70 (91%), 34/46 (74%), and 12/20 (63%) of patients, respectively. The percentage of patients achieving a 10% or greater reduction in total body weight at 3, 6, and 12 months was 80%, 97%, and 100%, respectively.

A multiple linear regression model found that higher starting weight ($P < 0.05$) and absence of suture reinforcement ($P = 0.037$) were associated with increased total body weight loss at 3 months. Age, gender, and total number of sutures did not demonstrate significant associations with weight loss over the same time period. Fourteen of 20 cases of hypertension, and 5 of 10 cases of dyslipidemia, were in complete remission by postprocedure month 3.

Table 1 Patient demographic data

Age (years)	45 ± 9
Women, no.	86
Pre-procedural weight (kg), mean ± SD	106.39 ± 20.24
Height (cm), mean ± SD	166.04 ± 8.11
Ideal body weight (kg), mean ± SD	68.94 ± 6.85
Excess body weight (kg), mean ± SD	37.5 ± 16.54
BMI, mean ± SD	38.4 ± 5.4
Comorbidities	
Hypertension, no.	29 (29%)
Hyperlipidemia, no.	13 (13%)
Diabetes mellitus, no.	4 (4%)
Surgical history	
Prior Nissen fundoplication, no.	2
Prior laparoscopic adjustable gastric band, no.	1

Discussion

Obesity is a global pandemic, afflicting over 30% of adults in the USA alone [11], and results in serious comorbidities, such as hypertension, hyperlipidemia, diabetes, and non-alcoholic fatty liver disease [12]. While lifestyle interventions and pharmacological therapies can help achieve weight loss, their outcomes are mild and difficult to sustain due to the strong counter-regulatory physiologic responses, favoring weight regain [13]. The most successful long-term strategy continues to be bariatric and metabolic surgeries, which enable patients to lose between 50% and 75% of excess body weight [14]. However, despite the success of bariatric surgery, only a small proportion of obese patients eventually undergo these invasive interventions. Endoscopic interventions have been developed to fill the treatment gap between lifestyle modification and bariatric surgery, and include intragastric balloons, aspiration therapy, and ESG. Available prospective and retrospective studies of ESG have demonstrated its safety and efficacy, though have been performed entirely in the academic or university setting. A systematic review and meta-analysis of ESG, including 1772 patients across 8 academic centers, found an average TBWL of 17.2% and excess weight loss of 67% at 24 months. Total body weight loss as high as 20.6% has been reported more recently at a single academic center. However, how well ESG performs outside of large tertiary referral centers has thus far been an unanswered question.

In the present study, we demonstrate the technical feasibility of performing the procedure in an outpatient setting without an associated tertiary referral center. Our results demonstrate that despite a steep learning curve, ESG is feasible in the non-academic setting. Procedural efficiency can be achieved after 35 cases, similar to previously published data by Saumoy et al. [15] In our cohort, weight loss at the 12-month mark was

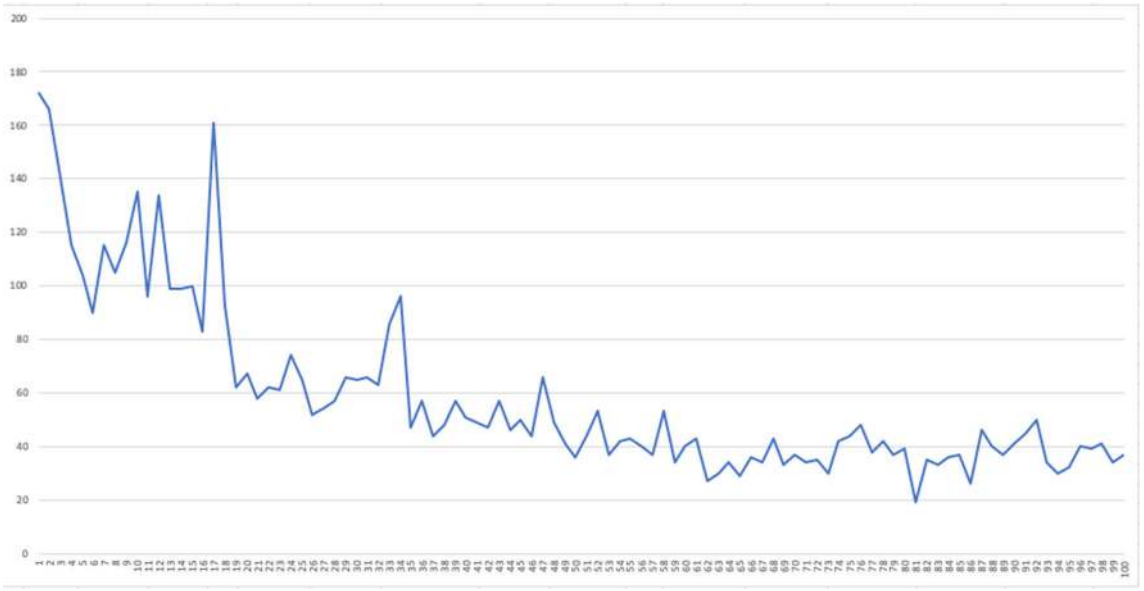

Fig. 1 Procedure duration over time

significant, consistent with or above prior reported studies, and nearly equivalent to surgical sleeve gastrectomy [16]. We suspect our weight loss outcomes may be higher than those previously published due to our ability to maintain very frequent patient contact and follow-up in our private practice setting, though these outcomes may potentially trend toward the published mean as additional follow-up data are accumulated.

Table 2 Procedure and outcomes data

Procedure duration (minutes), mean ± SD	59.4 ± 32.6
Number of sutures used:	
4, no.	5
5, no.	46
6, no.	33
7, no.	6
8, no.	8
9, no.	2
Suture reinforcement, no.	42
Postprocedural pain score, mean ± SD	2 ± 1
Postprocedural nausea score, mean ± SD	1 ± 1
Adverse events	
Perigastric abscess requiring radiologic drainage, no.	1
Dehydration necessitating outpatient intravenous fluid administration, no.	2
Infectious fluid collection requiring surgical washout, no.	1
3 month excess weight loss (%), mean ± SD	39.0% ± 16.9%
3 month total body weight loss (kg), mean ± SD	13.58 ± 5.45
6 month excess weight loss (%), mean ± SD	48.6% ± 19.9%
6 month total body weight loss (kg), mean ± SD	18.91 ± 7.79
12 month excess weight loss (%), mean ± SD (12 patients)	66.1% ± 21.5%
12 month total body weight loss (kg), mean ± SD (12 patients)	27.44 ± 11.75

Overall, the AE rate in our series was low, consistent with prior studies of ESG implementation, and below the overall adverse event rate seen with LSG [17]. The more invasive nature of LSG, longer procedure duration, and longer recovery time may account for the higher rate of AEs seen with LSG. Despite this low AE rate in our cohort, there are clear risks that need to be considered. In published series, the pooled post-ESG adverse event rate is 2.2%, with peri-gastric leak or fluid collection observed in 0.48% of procedures. We previously reported our case of delayed peri-gastric abscess [9]. Following this AE, we refined our procedure to strictly avoid suturing the fundus in all cases. Suturing within the thin-walled fundus, with its close proximity to adjacent structures (diaphragm, spleen, gastrosplenic ligament), may significantly increase procedural risks and should be avoided. We recommend demarcating the level of the gastroesophageal junction using argon plasma coagulation prior to initiating suture placement [7].

The second AE in our series was an early postoperative intra-abdominal infection requiring surgical exploration. Operative inspection of the gastric body revealed a small gastrotomy that appeared to result from a full-thickness suture pulling through the muscularis layer, requiring repair. Gastric leak has previously been reported following ESG [18]. We believe our AE resulted from a reinforcement suture, typically placed to add strength to the primary suture line. There is significant debate whether reinforcement sutures are necessary or beneficial. In our experience, reinforcement sutures led to increased postoperative pain, without an improvement in weight loss outcomes. We hypothesize that reinforcement

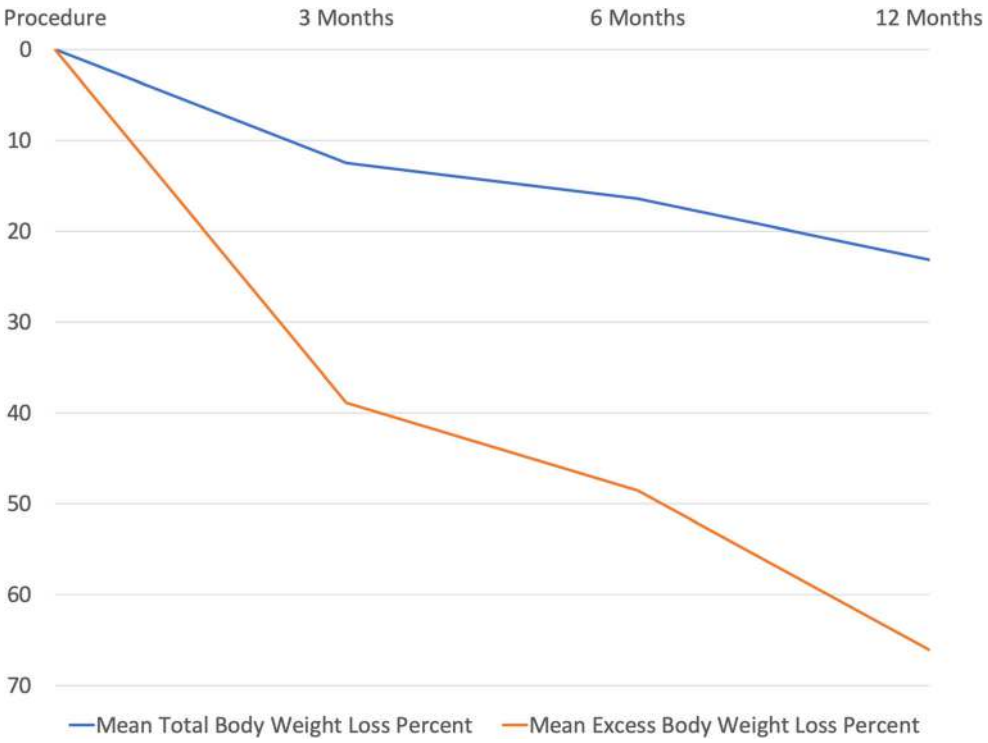

Fig. 2 Weight loss data

sutures place undue tension and stress on the gastric tissue, which has already been plicated and has less compliance; this may increase the risk of complications. We therefore no longer place reinforcement sutures and advise against their use. Patients and clinicians must be aware that ESG is not without risk, and particularly as it is an outpatient procedure, diligent follow-up and communication with patients must be exercised to identify early signs of an adverse event.

Though our series demonstrates the feasibility of performing ESG in a private gastroenterology practice, there are specific challenges inherent to implementing ESG in this setting. These are summarized in Fig. 3. While gastroenterologists are uniquely positioned to perform this complex endoscopic procedure, they typically lack the infrastructure necessary for obesity management, particularly in the community setting. ESG is not a stand-alone procedure, and patients require intensive management and follow-up with a registered dietician, and ideally with available behavioral and psychologic support. For practices without ready access to a registered dietician, virtual dietician services may be a reasonable alternative, such as platforms offered by Apollo Endosurgery (Austin, TX) and Virtual Health Partners (New York, NY), among others. ESG is currently a self-pay procedure, which limits widespread adoption and requires dedicated marketing to capture patients. Community gastroenterology practices may not be adept at direct-to-consumer marketing, and more commonly rely on referrals. Employing a dedicated coordinator to help with patient recruitment and management is critical. Providers must also carefully consider the financial implications of performing ESG, particularly the time commitment required. We dedicated a half-day to each ESG in the beginning, which resulted in significantly less availability to perform general gastroenterology procedures. Time must also be allocated for patient consultations and follow-up. These visits are typically bundled within the patient ESG fee, so margins must be closely scrutinized. One of the greatest challenges is negotiating with hospitals and ambulatory surgery centers to determine facility and anesthesia fees. It is not uncommon for these fees to be in the many thousands of dollars, and negotiation should hinge not on the initial expected procedural time,

Fig. 3 Specific challenges inherent to implementing ESG

- Need for multidisciplinary obesity team, including Registered Dietician
- Financial pressures
- Time allocation for procedures and patient follow-up
- Negotiating hospital/ASC facility and anesthesia rates
- Patient recruitment and marketing
- Clinician knowledge of obesity management
- Clinician comfort level with complications from elective procedures
- Collaboration with bariatric surgeons

but the anticipated time once efficiency is reached. Finally, with an emerging non-surgical obesity treatment such as ESG, "turf wars" between gastroenterologists and surgeons are anticipated, and collaboration rather than competition should be sought.

In conclusion, the present study demonstrates the feasibility of implementing ESG in a community gastroenterology practice with comparable clinical outcomes to large tertiary referral centers. Total body weight loss and excess body weight loss either met or exceeded previously reported data from these centers. Additionally, the procedure duration at our center similarly paralleled previously reported data with a rapid increase in efficiency over time. Further studies to assess patient and procedural factors associated with increased weight loss are needed and will ideally be performed in a randomized, controlled fashion comparing against both conservative management and traditional bariatric surgery. For now, ESG represents a compelling alternative to traditional bariatric surgery and a welcome treatment for obesity, for which additional therapies are greatly needed.

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Compliance with Ethical Standards

Conflict of Interest Dr. McGowan is a consultant for Apollo Endosurgery.

Statement of Informed Consent Informed consent was obtained from all individual participants included in the study.

Statement of Human and Animal Rights/Ethical Approval This is a retrospective chart review study and as such was exempt from institutional review board approval.

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