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Editorial Board Member of *World Journal of Gastrointestinal Endoscopy*, Naoki Hosoe, FACC, MD, PhD, Associate Professor, Center for Diagnostic and Therapeutic Endoscopy, School of Medicine, Keio University, Tokyo 1608582, Japan

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## Endoscopic sleeve gastropasty: From whence we came and where we are going

Diogo Turiani Hourneaux de Moura, Eduardo Guimarães Hourneaux de Moura, Christopher C Thompson

**ORCID number:** Diogo Turiani Hourneaux de Moura (0000-0002-7446-0355); Eduardo Guimarães Hourneaux de Moura (0000-0003-1215-5731); Christopher C Thompson (0000-0002-6105-5270).

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**Diogo Turiani Hourneaux de Moura, Christopher C Thompson,** Division of Gastroenterology, Hepatology and Endoscopy, Brigham and Women's Hospital, Harvard Medical School, Boston, MA 02115, United States

**Diogo Turiani Hourneaux de Moura, Eduardo Guimarães Hourneaux de Moura,** Department of Endoscopy of Clinics Hospital of São Paulo University, São Paulo 05403-00, Brazil

**Corresponding author:** Diogo Turiani Hourneaux de Moura, MD, MSc, PhD, Academic Fellow, Postdoctoral Fellow, Research Fellow, Surgeon, Division of Gastroenterology, Hepatology and Endoscopy, Brigham and Women's Hospital, Harvard Medical School, 45 Francis St, Boston, MA 02115, United States. [dthmoura@hotmail.com](mailto:dthmoura@hotmail.com)  
**Telephone:** +1-857-2509586

### Abstract

The most effective and durable treatment for obesity is bariatric surgery. However, less than 2% of eligible patients who fulfill the criteria for bariatric surgery undergo the procedure. As a result, there is a drive to develop less invasive therapies to combat obesity. Endoscopic bariatric therapies (EBT) for weight loss are important since they are more effective than pharmacological treatments and lifestyle changes and present lower adverse event rates compared to bariatric surgery. Endoscopic sleeve gastropasty (ESG) is a minimally invasive EBT that involves remodeling of the greater curvature. ESG demonstrated favorable outcomes in several centers, with up to 20.9% total body weight loss and 60.4% excess weight loss (EWL) on 2-year follow-up, with a low rate of severe adverse events (SAE). As such, it could be considered safe and effective in light of ASGE/ASMBBS thresholds of > 25% EWL and ≤ 5% SAE, although there are no comparative trials to support this. Additionally, ESG showed improvement in diabetes mellitus type 2, hypertension, and other obesity-related comorbidities. As this procedure continues to develop there are several areas that can be addressed to improve outcomes, including device improvements, technique standardization, patient selection, personalized medicine, combination therapies, and training standardization. In this editorial we discuss the origins of the ESG, current data, and future developments.

**Key words:** Endoscopy; Surgery; Bariatric; Obesity; Overweight; Comorbidities; Gastropasty; Sleeve; Endoscopic sleeve gastropasty; Editorial

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**Core tip:** Given the worsening obesity epidemic, there is increased demand for less invasive therapies. Considering the minimally invasive nature of Endoscopic sleeve gastroplasty (ESG), the reproducibility among centers, the favorable clinical outcomes in several studies, ESG could be regarded as safe and effective in light of ASGE/ASMBS thresholds of > 25% excess weight loss and ≤ 5% severe adverse events, although there are no comparative trials to support this. As this procedure is more widely adopted, high standards of care must be maintained to guarantee satisfactory clinical outcomes. In this editorial we discuss the origins of the ESG, current data, and future developments.

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## ENDOSCOPIC SLEEVE GASTROPLASTY: FROM WHENCE WE CAME AND WHERE WE ARE GOING

Obesity is a disease that is characterized by inflammation of adipose tissue and increased levels of systemic inflammatory cytokines, which are associated with debilitating comorbidities. Obesity has been deemed a pandemic by the World Health Organization, effecting approximately 700 million adults worldwide with an additional 2 billion overweight. It is associated with metabolic conditions, such as type 2 diabetes, cardiovascular diseases, hyperlipidemia, fatty liver, hypertension, osteoporosis, and other diseases. Additionally, obesity is second only to tobacco as a preventable risk factor for a number of cancers<sup>[1,2]</sup>. The most effective and durable treatment for obesity is bariatric and metabolic surgery<sup>[3-5]</sup>. However, disadvantages include the irreversible nature of the procedures and the non-negligible morbidity and mortality rates<sup>[6-14]</sup>. Furthermore, less than 2% of eligible patients who fulfill the criteria for bariatric surgery undergo the procedure. The reasons for this are multifactorial and likely include perceived surgical risk, morbidity, costs, access, and patient preference<sup>[15,16]</sup>.

As a result, there is a drive to develop less invasive and cost-effective therapies to combat this epidemic. It is well established that a total body weight loss (TWL) of at least 10% is most effective in improving obesity-related comorbidities<sup>[17,18]</sup>. Lifestyle modifications, diet and pharmacotherapies rarely can achieve 10% TWL, and when initially effective, weight regain is common<sup>[19]</sup>. Endoscopic bariatric therapies (EBT) are important since they are more effective than pharmacological therapy and lifestyle modification and present lower adverse event rates compared with bariatric surgery<sup>[20-23]</sup>.

In 2011, a joint task force convened by the American Society for Gastrointestinal Endoscopy (ASGE) and the American Society for Metabolic and Bariatric surgery (ASMBS) defined thresholds regarding safety and efficacy for EBT<sup>[24,25]</sup>. Subsequently, a Preservation and Incorporation of Valuable endoscopic Innovations document was created by the ASGE based on this consensus<sup>[26]</sup>. The results of this process are described below: (1) For primary obesity therapies in patients with obesity class II and III a minimum of 25% excess weight loss (EWL) at 12 mo, with a statistical difference > 15% above the control group is required; (2) For non-primary EBT such as metabolic therapy, bridging to surgery, and early intervention, a minimum of 5% TWL is necessary; and (3) Serious adverse events ≤ 5% is recommended for all EBT.

An EBT that meets these criteria is considered appropriate to incorporate into clinical practice after adequate training<sup>[26]</sup>.

Endoscopic sleeve gastroplasty (ESG) is an incisionless, minimally invasive technique that involves remodeling of the greater curvature, via the placement of full-thickness sutures, in an effort to reduce gastric capacity and delay gastric emptying<sup>[27,28]</sup>.

ESG with full-thickness suturing has demonstrated clinical effectiveness and safety, nevertheless, the technique continues to evolve. This concept was originally inspired by two older procedures, an abandoned endoscopic technique (endoluminal vertical gastroplasty) performed by Fogel *et al*<sup>[29]</sup> that focused on emulating a vertical banded gastroplasty along the mid-proximal gastric body not involving the greater curvature, and the surgical gastric imbrication procedure. The original greater curvature ESG

performed in 2008 using a superficial suction-based suturing device had limited results due to early suture loss<sup>[30,31]</sup>. Subsequently, ESG was performed using the current full-thickness suturing device in 2012 by Thompson and Hawes<sup>[28,32]</sup>. ESG has since been the focus of many studies worldwide. These studies have demonstrated technical feasibility, safety, and efficacy for this procedure in terms of weight loss and resolution of metabolic comorbidities<sup>[28,30,31,33-39]</sup>.

Although the exact mechanisms of weight loss following ESG are not clear, the procedure is performed with the intention of reducing gastric volume and altering motility<sup>[27,34,37,38]</sup>. This is achieved via a reduction in both gastric width and length. Since the first ESG report, different numbers of sutures, orientation of sutures, spacing and frequency of bites, and tightness of cinching have been reported<sup>[40]</sup>. A variety of suture patterns have been used, including “M”, “Z”, and “U” patterns<sup>[41,42]</sup>, as the procedure has evolved, with the main focus remaining greater curvature remodeling. An important element of all suture patterns is the distal to proximal movement within each running suture that is placed along the greater curvature, contracting the stomach longitudinally to confer the intended gastric shortening while simultaneously narrowing the lumen. Another difference is the use of reinforcement sutures which may be used in an attempt to further reduce volume, minimize tension on running sutures, and potentially improve durability. Nevertheless, no one suture pattern has yet been proven to achieve better efficacy<sup>[33,35,38,40-42]</sup>. The durability of weight loss may be less related to suture retention than it is to alteration in gastric function, which may persist even after suture loss. The gastric foreshortening partly reduces fundic capacity, however, this is achieved without placing any stitches directly into the fundus. In fact, the fundus is intentionally avoided to allow formation of a small pocket proximal to the sleeve to serve as a reservoir for food which may contribute to the prolonged gastric retention and improved satiety. Furthermore, fundic tissue is particularly thin and prone to leaks, and is in proximity to the spleen. Avoiding direct suture placement into the fundus minimizes the risk of adverse events.

As with many other novel procedures, in the beginning ESG was seen with a mix of enthusiasm and caution by the medical community. ESG was considered by some as a revolutionary technique that would treat obesity with the same efficacy as bariatric surgery. However, others remembered the transient effects of procedures performed with partial-thickness suturing devices that were plagued by early suture loss, and were far more skeptical. The results of the new ESG studies were not superior or similar to bariatric surgery in terms of efficacy, although they realized significant weight loss with fewer adverse events. On long-term follow-up endoscopy the stomach appears to be similar to its original size, however, with some peripheral bridging of tissue, and questions remain regarding the durable impact this may have on gastric function and long-term weight loss.

The largest ESG study, including 1000 patients, was recently published<sup>[39]</sup>. This study showed satisfactory results of ESG in the management of obesity with a mean %TWL at 6, 12, and 18 mo of 13.7% ± 6.8%, 15.0% ± 7.7%, and 14.8% ± 8.5%, respectively. The mean %EWL at 6, 12, and 18 mo were 64.3% ± 56.2%, 67.5% ± 52.3%, and 64.7% ± 55.4%, respectively. There are two multicenter studies<sup>[33,43]</sup> evaluating ESG in obese patients. In the study<sup>[43]</sup> including 112 consecutive patients, the average %TWL and %EWL were 11.9% and 39.9% at 3 mo, and 14.9% and 50.3% at 6 mo follow-up, respectively. By 6 mo post-ESG, 81% and 53.8% of patients had a %TWL greater than 10% and 15%, respectively. The proportion of patients who achieved greater than 25% EWL was 86.5% at 6 mo. The other multicenter study<sup>[33]</sup>, including 248 patients, reported the longest ESG follow-up to date. At 6 mo and 24 mo, %TWL was 15.2% and 18.6%, respectively, with similar weight loss between centers. The percentage of patients achieving ≥ 10% TWL was 84.2%. Additionally, in both univariable and multivariable regression analysis, weight loss at 6 mo predicted weight maintenance at 24 mo. Achieving less than 10% TWL at 6 mo was an early predictor of poor long-term results and adjunctive therapy to enhance weight loss in these patients may be recommended. Lopez-Nava *et al*<sup>[44]</sup>, also reported results up to 2 years follow-up. At 24 mo after the procedure baseline mean body mass index (BMI) changed from 38.3 to 30.8 kg/m<sup>2</sup>; %TWL and %EWL were 19.5% and 60.4%, respectively. In this study, 85.7% of patients achieve greater than 25% EWL.

Most studies report the success of ESG specifically for weight loss. However, some studies also analyzed comorbidities related to obesity<sup>[38,39]</sup>. Sharaiha *et al*<sup>[38]</sup> studied 91 patients with BMI higher than 30 kg/m<sup>2</sup> who underwent ESG, with a follow-up up to 24 mo. Patients had significant reductions in levels of hemoglobinA1c, systolic blood pressure, waist circumference, alanine aminotransferase, and serum triglycerides. In this study a mean %TWL of 14.4%, 17.6%, and 20.9% were reported at 6 months, 1 year, and 2 year follow-up. Alqahtani *et al*<sup>[39]</sup> reported 76.5% complete remission in type 2 diabetes by the third month following the procedure, with all remaining

patients showing improvement. Additionally, all patients with hypertension and dyslipidemia had complete remission at the time of last follow-up. Despite few studies evaluating obesity-related comorbidities, these results are in keeping with what would be expected with this degree of weight loss.

Procedure durability remains unclear, as the longest follow-up published to date is 2 years<sup>[33,44]</sup>. It is important to note that redo ESG is an available minimally invasive option. Combination with medical therapy is also effective and should be considered for weight maintenance as needed. Additionally, if ESG fails, bariatric surgery is not contraindicated and has been shown to be effective. A major concern regarding surgical conversion is that the suture T-tags may cause the stapler to misfire resulting in a leak. However, in most suture patterns the gastric cardia is spared, minimizing this risk in conversion to RYGB. Additionally, conversion to sleeve gastrectomy has been successfully performed without adverse events<sup>[39]</sup>.

Overall ESG is well tolerated. In the literature, mild and moderate adverse events such as abdominal pain, nausea and emesis are usually not analyzed in detail because they are expected and managed conservatively with improvement after few days<sup>[34,37,41]</sup>. A recent study<sup>[39]</sup> reported 92.4% of nausea or abdominal pain controlled with medication and resolved during the first week. Of 1000 patients, 24 were readmitted with no mortality. Causes for readmission included: severe abdominal pain, postprocedure bleeding, perigastric fluid collection, and post procedure fever. Additionally, another study<sup>[45]</sup> reported 24.2% moderate abdominal pain and 31.2% nausea and emesis in the first 48 h. Compared to other endoscopic techniques, ESG appears to have favorable outcomes regarding these symptoms. Intra-gastric balloons and duodenal jejunal bypass sleeves are also associated with approximately 7% and 18% early removals, respectively<sup>[26]</sup>, whereas ESG reversal is extremely rare<sup>[39]</sup>. In the largest series of ESG, only 0.003% of procedures required reversal due to persistent symptoms<sup>[39]</sup>. Severe adverse events (SAE) after ESG are rare<sup>[27,34-36,43]</sup>. A recent review<sup>[42]</sup>, including 9 ESG studies reported a 2.3% SAE rate, including gastric leaks, perigastric fluid collections, pulmonary embolism and pneumoperitoneum with pneumothorax. In the literature there are 7 reports of gastric leaks/perigastric fluid collections and all of these cases were treated without surgical intervention<sup>[33,38,39,46]</sup>. In general, ESG is associated with a lower rate of SAE, and no mortality, compared to surgical bariatric procedures which has up to a 20% SAE rate with 0.04% mortality rate<sup>[9,47,48]</sup>. Additionally, the SAE rate of less than 5% achieves the threshold set by ASGE/ASMBS position paper<sup>[24,25]</sup>.

ESG studies notably demonstrate some variability in weight loss outcomes, ranging from 15% to 19% TWL at 1 year<sup>[28,39]</sup>. The reasons for this are unclear and likely multifactorial. Baseline patient characteristics, number of sutures, suture pattern, use of reinforcement sutures, post-procedure diet, concomitant weight loss medication use, intensity of life-style modification, and follow-up plan of care all may be important factors influencing these results. Number of sutures and pattern are particularly important from a financial standpoint for many centers. Using fewer sutures is less costly and reduces procedure time, which ultimately may allow broader adoption. Although there is no rigorous evidence regarding number of sutures or ideal pattern, we believe that reinforcement sutures are associated with better efficacy and should be incorporated into suture patterns when possible. Post-procedure plan of care also differs among centers with unique diet recommendations, follow-up schedules, and pharmacotherapy use, which no doubt impact clinical outcomes and likely contribute to this variability as well.

In addition to ideal technique, experience level and patient characteristics required for optimal outcomes are also not well understood. Regarding recommended experience level, a multicenter study<sup>[31]</sup> showed that 34 cases were statistically significant to achieve a satisfactory %TWL, however, no formal learning curve assessment was performed. Similarly, there are little data to guide patient selection. A univariable analysis showed that younger age was significantly associated with weight loss at 1-year follow-up. Additionally, as one proposed mechanism is prolonged gastric retention, patients with underlying gastroparesis may be poorer candidates for this procedure.

As this field continues to develop there are several areas that can be addressed to improve outcomes. We are already seeing procedure and device improvements to simplify technical aspects and enhance durability. Technique standardization is still needed and will likely occur when better data are available. Patient selection is always an important consideration for optimizing patient outcomes. Moving towards personalized medicine, several factors are being investigated including baseline demographics, gastric motility, autonomic function, bile acid metabolism, gut hormones, genetics, and microbiome. Combination therapies also hold the promise of improved efficacy. Endoscopic device combinations, applied simultaneously or sequentially, that employ different mechanisms of action and combination with

pharmacotherapies are now actively being studied. It is also time for randomized controlled trials to better address many of these questions and provide level 1A evidence to confirm satisfactory outcomes. This will also help establish best medical practices and contribute towards broader reimbursement. Finally, as use of this procedure grows, standardized training and credentialing processes will be required to ensure patient safety and maintain good clinical outcomes.

In summary, given the worsening obesity epidemic, there is increased demand for less invasive bariatric therapies. Considering the minimally invasive outpatient nature of ESG, the reproducibility among centers with different experience levels, and the favorable clinical outcomes in several studies, ESG could be regarded as safe and effective in light of ASGE/ASMBS thresholds of > 25% EWL and ≤ 5% severe adverse events, however, there are no comparative trials to date. As this procedure is more widely adopted, high standards of care must be maintained to guarantee satisfactory clinical outcomes.

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