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# Comparative analysis of post-procedural symptom patterns after intragastric balloon and endoscopic sleeve gastroplasty

**Lidia Castagneto-Gissey[1], Maria Francesca Russo[1], Ilaria Ernesti[1], Loredana Gualtieri[1], Martina Genco[2], Giovanni Casella[1], Nicola Di Lorenzo[1]**

[1]Department of Surgery, Sapienza University of Rome, Rome 00161, Italy
[2]UniCamillus-Saint Camillus International University of Medical Sciences, Rome 00131, Italy

**Correspondence to:** Dr. Giovanni Casella, Department of Surgery, Sapienza University of Rome, Viale Regina Elena, 324, Rome 00161, Italy. E-mail: giovanni.casella@uniroma1.it

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## Abstract

**Aim:** Endoscopic bariatric and metabolic therapies (EBMTs) offer minimally invasive approaches for obesity management, with intragastric balloon (IGB) and endoscopic sleeve gastroplasty (ESG) being amongst the most prominent interventions. While both are effective, their comparative impact on post-procedural gastric symptoms remains underexplored.

**Methods:** Single-center retrospective study was designed to evaluate the incidence of post-procedure symptoms in patients undergoing IGB and ESG. Incidence and severity of gastric symptoms were assessed using visual analog scales at various time points. Weight outcomes and medication usage were also recorded. Changes at different time points (baseline, one and four months) were compared by means of Mann-Whitney U Test. Bivariate correlations were carried out through Pearson correlation.

**Results:** Thirty patients undergoing IGB placement and 13 patients undergoing ESG were included in the analysis. ESG group showed a significant reduction in BMI at four months compared to IGB (32.2 ± 4.2 *vs.* 34.4 ± 5.3, $P = 0.05$). ESG demonstrated significantly lower rates of post-procedural gastric symptoms compared to IGB, including nausea, regurgitation, vomiting, and abdominal cramps and greater satiety ($P < 0.001$) in the early postoperative period. Medication usage differed between groups, with higher usage of antispasmodics and antiemetics among IGB patients during the first week ($P < 0.001$). Symptom severity correlated with the need for antiemetics and antispasmodics.

**Conclusion:** This study provides insights into the management of gastric symptoms following two prominent EBMTs. While both endoscopic interventions offer viable options for obesity management, ESG emerges as a favorable choice due to its significantly lower incidence of early post-procedural gastric symptoms. Further research is warranted to refine symptom management strategies and elucidate differences in symptom profiles between IGB and ESG procedures, ultimately aiming to optimize treatment efficacy and patient satisfaction in the field of endoscopic obesity interventions.

**Keywords:** Nausea, vomiting, intragastric balloon, endoscopic sleeve gastroplasty, bariatric endoscopy

## INTRODUCTION

Endoscopic bariatric and metabolic therapies (EBMTs) have emerged as valuable alternatives to traditional modalities such as lifestyle adjustments, pharmacological treatment, and surgical interventions, offering patients minimally invasive, effective, and secure approaches for the management of obesity[1-5]. Within the armamentarium of EBMTs, the intragastric balloon (IGB) stands out as the most established intervention[3]. Extensive research has affirmed the effectiveness and safety of IGBs[5]. Another EBMT garnering attention over the past few years is the endoscopic sleeve gastroplasty (ESG), which employs an endoscopic suturing device to apply sutures within the stomach, thereby reducing its capacity and delaying gastric emptying. Subsequent studies consistently affirmed its enduring efficacy in terms of weight loss and safety with low rates of major complications[6].

Adverse events such as nausea, vomiting, regurgitation, and epigastric pain are generally expected after gastric procedures, especially EBMTs[7]. Nausea and vomiting appear to be the most frequent and distressing occurrences in the initial week after IGB placement in over 55% of patients[8-10]. This prompted the exploration of diverse antiemetic strategies to reduce nausea and vomiting following IGB insertion. Early approaches featuring ondansetron or analogous serotonin 5-HT3 receptor antagonists, complemented by prokinetic agents such as metoclopramide and domperidone, or benzodiazepines such as midazolam yielded suboptimal outcomes[11,12]. However, a notable paradigm shift in the past few years has seen the incorporation of aprepitant, a chemotherapy-associated antiemetic, in conjunction with ondansetron, emerging as a preferred regimen for effectively managing post-IGB placement nausea and vomiting[13,14]. Nausea and vomiting have also been shown to affect patients undergoing ESG with an estimated incidence of 32.3%[10]. However, this undesired effect might be likely underrated as it is considered a mild event; hence, it is not reported in all cases[15].

Our study aimed to evaluate and compare the incidence and patterns of gastric symptoms after IGB placement and ESG and its response to a specific antiemetic protocol.

## METHODS

### Study design

This is a single-center retrospective study designed to evaluate the incidence of post-procedure gastric symptoms after IGB placement and ESG. A prospectively collected database of procedures performed between January 2022 and December 2023 was completed. Our annual surgical volume was somewhat reduced during the study period due to the COVID-19 pandemic aftermath[16].

Patients affected by obesity and eligible for IGB placement or ESG according to National and International guidelines were considered for the present study and included in the database[17,18]. The criteria for inclusion encompassed individuals aged between 18 and 65 years, with a body mass index (BMI) ranging from ≥ 27 kg/m$^2$ to ≤ 45 kg/m$^2$, who had previously attempted dietary treatments without success. Excluded from the study were individuals with a history of major abdominal surgery.

Participants were followed up for at least four months after either endoscopic procedure. The incidence and severity degree of gastric symptoms, namely nausea, vomiting, satiety, regurgitation, cramps, and epigastric pain, was evaluated during the first seven days, at one and four months by using a visual analog scale (VAS) score of 1 to 10 for each item. Weight outcomes were also recorded at each time point during the outpatient clinic follow-up evaluation.

Patients underwent a thorough preoperative evaluation according to institutional, national, and international protocols, which encompassed a comprehensive medical history and physical examination, standard laboratory assessments, esophagogastroduodenoscopy (EGD), and evaluations by nutritionists and psychologists. Further diagnostic tests or consultations with specialists were conducted as deemed necessary based on clinical indications.

After the procedure, patients were monitored through regular outpatient visits, which included physical examinations and routine blood analyses at one and four months.

The study was approved by the Ethical Committee of this University hospital. Written informed consent was obtained before all endoscopic procedures.

### Intragastric balloon

The Elipse System, developed by Allurion Technologies in Natick, MA, USA, features an innovative balloon encased within a swallowable capsule. After ingestion, the balloon is filled with 500 ml of saline solution via a catheter, a procedure completed during a concise outpatient visit, obviating the need for endoscopy or sedation. Verification of the balloon's precise placement is ensured through abdominal X-ray, with catheter removal following completion of filling. The Elipse balloon autonomously deflates via a valve mechanism after a four-month interval, facilitating its natural excretion.

### Endoscopic sleeve gastroplasty

All procedures were performed on patients under general anesthesia, in supine position. Initially, a diagnostic EGD was conducted to exclude contraindications to ESG, such as ulcers, severe esophagitis, neoplastic lesions, and hiatal hernias exceeding 3 cm in size. Subsequently, the Apollo OverStitch Sx suture system (Boston Scientific, Boston, Massachusetts, USA) loaded on a single channel gastroscope (Olympus GIF-H190) was introduced into the stomach. Full-thickness sutures were performed between the anterior and posterior gastric wall, along the gastric curvature, starting from the gastric incisura to the proximal body. The gastric wall is grasped using a Tissue "Helix" and each suture stitch is closed by the use of a cinch. A "U" suture pattern was adopted with approximately 4-6 sutures per thread. This process achieves a stomach reduction of approximately 70% of the initial volume. The fundus is preserved to act as a reservoir, potentially increasing satiety duration and delaying gastric emptying.

### Antiemetic protocol

A single intravenous (iv) administration of 150 mg of Fosaprepitant [neurokinin 1 (NK1) receptor antagonist] was infused two hours before all endoscopic procedures. During general anesthesia induction 8 mg of dexamethasone and 0.15 mg per kg ondansetron (serotonin 5-HT3 receptor antagonist) were

infused. After each procedure, medication was continued with omeprazole 40 mg two times daily for the first week after the procedure and then once a day for the following six months. In case of need, crampy abdominal pain or nausea was managed with the use of Hyoscine butylbromide 10 mg iv and ondansetron 8 mg, up to a maximum of 3 and 2 administrations daily, respectively.

### Statistical analysis

Continuous variables are expressed as mean ± SD in case of normal distribution, or medians. All changes at different time points (baseline, one month, and four months) in the IGB group and the ESG group have been compared by means of a Mann-Whitney *U* Test. Bivariate correlations have been carried out through Pearson correlation. SPSS version 27 was used (IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp).

## RESULTS

Thirty patients who underwent IGB placement and 13 patients who underwent ESG were included in the analysis. In the IGB group, eight patients (26.7%) were male while in the ESG group, four patients (30.8%) were male. Changes in weight and BMI at different time points are reported in Table 1. Post-interventional symptoms, namely satiety, nausea, regurgitation, vomiting, epigastric pain, and abdominal cramps, were assessed by means of VAS scores at different time points; T0-T1-T2-T3 are reported in Table 2.

No significant difference in weight reduction was observed between the two groups at T0, T1, or T2, with *P*-values ranging from 0.203 to 0.740 for weight, while the ESG group showed a significant reduction in BMI at four months compared to the IGB group (32.2 ± 4.2 *vs.* 34.4 ± 5.3 respectively, $P = 0.05$) [Table 1].

A significantly lower rate of post-procedural gastric symptoms was noted for ESG compared to IGB, particularly in terms of nausea ($P = 0.003$ at T0), regurgitation ($P < 0.001$ at T0), vomiting ($P < 0.001$ at T0), and abdominal cramps ($P < 0.001$ at T0). Most symptoms subside at T2 and T3 after both procedures except for satiety which is greater after ESG at T1 and T2 [Table 2]. On the contrary, satiety was greater after ESG compared to the IGB group ($P = 0.005$ at T1, $P < 0.001$ at T2).

At one week post-procedure, a significantly higher proportion of patients in the IGB group took antispasmodics compared to the ESG group (83.3% *vs.* 38.5%, respectively; $P < 0.001$), as well as antiemetics (66.7% *vs.* 15.4%, respectively; $P < 0.001$). Conversely, a higher percentage of ESG patients were prescribed proton pump inhibitors (PPIs) compared to the IGB group (100% *vs.* 10%, respectively; $P < 0.001$). Additionally, all ESG patients were prescribed multivitamin supplements and protein supplements at this time point, while only a fraction of IGB patients received these supplements ($P = 0.488$ and $P < 0.001$, respectively). At one-month post-procedure, there were no significant differences in the usage of antiemetics, antispasmodics, PPIs, or multivitamin supplements between the two groups at this time point. Data are reported in Table 3.

Scores collected at T1 in patients undergoing IGB but not ESG directly correlate with the need for antiemetics and antispasmodics, meaning that the higher the score the greater the probability of needing to take those medications ($P < 0.001$).

Furthermore, in the ESG group at T0, nausea correlates with the need to take a lower dosage of antispasmodics with respect to the IGB group ($P = 0.036$).

**Table 1. Weight outcomes at baseline (T0), 1 month (T1) and 4 months (T2) postoperatively**

| | | IGB, *n* = 30 | ESG, *n* = 13 | *P* value |
|---|---|---|---|---|
| Weight (kg) | T0 | 108 ± 21.5 | 115.5 ± 29.7 | 0.692 |
| | T1 | 100.4 ± 19.6 | 101.5 ± 16.5 | 0.740 |
| | T2 | 97.9 ± 20.2 | 96.8 ± 16.2 | 0.234 |
| BMI (kg/m$^2$) | T0 | 38.5 ± 6.7 | 36.5 ± 3.9 | 0.526 |
| | T1 | 35.5 ± 5.5 | 33.3 ± 4.7 | 0.203 |
| | T2 | 34.4 ± 5.3 | 32.2 ± 4.2 | 0.050 |
| TWL (%) | T1 | 6.9 ± 2.3 | 7.4 ± 3.7 | 0.614 |
| | T2 | 10.4 ± 5.0 | 11.1 ± 6.5 | 0.837 |

IGB: Intragastric balloon; ESG: endoscopic sleeve gastroplasty; BMI: body mass index; %TWL: percent total weight loss.

**Table 2. Post-procedural symptoms at 1 day (T0), 1 week (T1), 1 month (T2), and 4 months (T3)**

| | Symptoms | IGB, *n* = 30 | ESG, *n* = 13 | *P* value |
|---|---|---|---|---|
| Satiety | T0 | 9.4 ± 1.3 | 9.6 ± 0.4 | 0.889 |
| | T1 | 8.6 ± 1.4 | 9 ± 0.07 | 0.443 |
| | T2 | 6.2 ± 2.8 | 8.5 ± 1.05 | 0.005 |
| | T3 | 4.3 ± 2.3 | 7.1 ± 1.6 | < 0.001 |
| Nausea | T0 | 5.9 ± 2.8 | 3.1 ± 1.3 | 0.003 |
| | T1 | 2.4 ± 3.2 | 1.2 ± 1.5 | 0.044 |
| | T2 | 0.15 ± 0.8 | 0.3 ± 0.9 | 0.233 |
| | T3 | 0 ± 0 | 0 ± 0 | 0.281 |
| Regurgitation | T0 | 4.3 ± 3.5 | 0 ± 0 | < 0.001 |
| | T1 | 2 ± 2.9 | 0.3 ± 0.8 | 0.038 |
| | T2 | 0.7 ± 2.3 | 0.15 ± 0.5 | 0.671 |
| | T3 | 0.3 ± 1.1 | 0 ± 0 | - |
| Vomiting | T0 | 3.2 ± 3.5 | 0 ± 0 | < 0.001 |
| | T1 | 0.6 ± 1.7 | 0 ± 0 | 0.149 |
| | T2 | 0.03 ± 0.2 | 0 ± 0 | 0.480 |
| | T3 | 0 ± 0 | 0 ± 0 | - |
| Epigastric pain | T0 | 3.6 ± 3.4 | 3.7 ± 0.9 | 0.640 |
| | T1 | 2 ± 2.9 | 1.4 ± 2.4 | 0.091 |
| | T2 | 1.1 ± 2.4 | 0 ± 0 | 0.095 |
| | T3 | 0 ± 0 | 0 ± 0 | - |
| Abdominal cramps | T0 | 6.7 ± 2.4 | 3.3 ± 1 | < 0.001 |
| | T1 | 2.0 ± 2.9 | 1.4 ± 1.7 | 0.092 |
| | T2 | 0.6 ± 1.7 | 0.9 ± 1.2 | 0.213 |
| | T3 | 0 ± 0 | 0 ± 0 | - |

IGB: Intragastric balloon; ESG: endoscopic sleeve gastroplasty.

## DISCUSSION

The present study aimed to evaluate and compare the incidence and patterns of gastric symptoms after IGB placement and ESG, along with their response to a specific antiemetic protocol.

The findings revealed a significantly greater reduction in BMI at four months in the ESG group compared to the IGB group (32.2 ± 4.2 *vs.* 34.4 ± 5.3, respectively, $P = 0.05$). Furthermore, ESG demonstrated a significantly lower rate of post-procedural gastric symptoms compared to IGB especially during the first

**Table 3. Medications taken at 1 week and 1 month follow-up**

| | Medications | IGB, *n* = 30 | ESG, *n* = 13 | *P* value |
|---|---|---|---|---|
| 1 week post-procedure | Antispasmodics, *n* (%) | 25 (83.3%) | 5 (38.5%) | < 0.001 |
| | Antiemetics, *n* (%) | 20 (66.7%) | 2 (15.4%) | < 0.001 |
| | PPI, *n* (%) | 3 (10%) | 13 (100%) | < 0.001 |
| | Multivitamin supplement, *n* (%) | 26 (86.7%) | 13 (100%) | 0.488 |
| | Protein supplement, *n* (%) | 3 (10%) | 13 (100%) | < 0.001 |
| 1 month post-procedure | Antispasmodics, *n* (%) | 3 (10%) | 1 (7.7%) | 0.233 |
| | Antiemetics, *n* (%) | 1 (3.3%) | 0 | 0.505 |
| | PPI, *n* (%) | 26 (86.6%) | 13 (100%) | 0.488 |
| | Multivitamin supplement, *n* (%) | 25 (83.3%) | 12 (92.3%) | 0.975 |
| | Protein supplement, *n* (%) | 1 (3.3%) | 7 (53.8%) | < 0.001 |

IGB: Intragastric balloon; ESG: endoscopic sleeve gastroplasty; PPI: proton pump inhibitor.

week after the procedure, particularly in terms of nausea, regurgitation, vomiting, and abdominal cramps, while satiety was substantially greater after ESG. This suggests a potential advantage of ESG over IGB in terms of post-procedural symptom management. However, most symptoms subside already after the first month post-intervention after both procedures. Additionally, significant differences were observed in medication intake between the groups during the first week post-procedurally, with higher usage of antispasmodics and antiemetics among IGB participants.

Of particular note, our results indicate a correlation between symptom severity and the need for antiemetics and antispasmodics, highlighting the clinical relevance of symptom assessment and management. Furthermore, in the ESG group, nausea correlated with a lower dosage of antispasmodics compared to the IGB group, suggesting potential differences in symptom profiles and management strategies between the two procedures.

Nausea and vomiting represent common adverse events following IGB placement, often leading to frequent hospital readmissions and premature balloon removal, thus impeding the success of treatment. Various studies have highlighted the efficacy of a combined therapy involving aprepitant and ondansetron in mitigating vomiting among patients post-IGB placement[13,14]. In contrast, treatments solely relying on ondansetron have shown limited effectiveness, with patients typically experiencing elevated levels of vomiting and nausea within the initial week post-IGB insertion[19]. The incorporation of midazolam has demonstrated a notable reduction in the incidence of nausea and vomiting during the first 24 h following IGB insertion. Recent findings from a prospective multicenter study underscore the substantial decrease in vomiting rates among patients receiving IGB placement when treated with a combination of ondansetron and aprepitant, compared to those treated with either medication alone[12]. Notably, while these studies indicate a reduction in nausea with combination therapy, the results were not consistently reported across all studies.

On the other hand, severe abdominal pain has been reported following ESG, as several studies indicate that post-procedure abdominal pain and nausea are prevalent occurrences, although typically transitory and manageable without intervention. In a previous observational study, 25% of the 91 participants reported experiencing abdominal pain, while roughly one-third suffered from nausea[20]. Similarly, a multicenter study involving 248 patients categorized abdominal pain, nausea, and vomiting as mild occurrences that might not always prompt formal reporting[21]. Another international multicenter study with 112 participants noted the widespread occurrence of nausea and abdominal pain without providing specific prevalence

estimates[22]. Across various studies, a considerable proportion of ESG patients received oral pain relievers and anti-nausea medications, with only a small subset requiring brief hospital stays due to abdominal discomfort, typically resolving with pain medication within a day[23,24]. Whereas a large retrospective study found that a small fraction of patients necessitated hospitalization for the investigation and management of abdominal pain, including a few who requested the removal of sutures[25]. Overall, it appears that post-ESG pain and nausea are common issues that can usually be addressed through conservative measures on an outpatient basis.

The observed differences in symptom profiles between the two interventions prompt consideration of potential mechanistic variances underlying their respective modes of action. IGBs operate primarily through mechanical means, occupying space within the stomach to induce a sense of satiety and thereby reducing food intake. In contrast, ESG involves the creation of a gastric sleeve through endoscopic suturing, which not only restricts gastric volume but may also alter gastric motility and hormone secretion. These mechanistic distinctions likely contribute to the divergent symptom profiles observed, with ESG potentially offering a more physiological alteration of gastric function.

The incorporation of a standardized antiemetic protocol in this study provides valuable insights into the management of post-procedural nausea and vomiting, common adverse events associated with both IGB and ESG interventions. While the protocol employed demonstrated efficacy in mitigating these symptoms, notably with higher usage of antispasmodics among ESG participants, further optimization may be warranted to tailor antiemetic strategies to the specific needs of each EBMT. Additionally, the correlation between symptom severity and medication usage highlights the importance of proactive symptom management in optimizing patient outcomes and satisfaction.

This study has some limitations that should be acknowledged. The single-center retrospective design may limit the generalizability of the findings. Additionally, the study period was influenced by the COVID-19 pandemic, which may have affected the annual surgical volume and patient follow-up, possibly introducing selection bias.

Overall, this study contributes to the growing body of evidence supporting the role of EBMTs in the management of obesity and highlights the importance of considering both weight outcomes and tolerability profiles when selecting between available interventions. Future research should focus on elucidating the underlying mechanisms driving differential symptom profiles and optimizing antiemetic strategies to further enhance patient outcomes in the era of endoscopic obesity therapies.

In conclusion, our study provides insights into the management of gastric symptoms following two prominent EBMTs, IGB and ESG. While both endoscopic interventions offer viable options for obesity management, ESG emerges as a favorable choice due to its significantly lower incidence of post-procedural gastric symptoms. Nevertheless, no procedure is ideal and decision-making should be tailored based on each patient's comorbidities, needs and expectations. Overall, our results contribute to the evolving landscape of EBMTs, providing valuable evidence for clinicians to optimize patient care and improve outcomes in the management of obesity through minimally invasive endoscopic interventions. Further research is warranted to refine symptom management strategies and elucidate differences in symptom profiles between IGB and ESG procedures, ultimately aiming to optimize treatment efficacy and patient satisfaction in the field of endoscopic obesity interventions.

## DECLARATIONS

### Authors' contributions

Conception and design: Castagneto-Gissey L, Russo MF, Casella G, Di Lorenzo N
Provision of study materials or patients: Ernesti I, Gualtieri L, Genco M
Collection and assembly of data: Russo MF, Castagneto-Gissey L
Data analysis and interpretation: Russo MF, Castagneto-Gissey L, Casella G
All authors contributed to the writing of the manuscript and approved the final version.

### Availability of data and materials

Raw data will be shared upon reasonable request.

### Financial support and sponsorship

None.

### Conflicts of interest

All authors declared that there are no conflicts of interest.

### Ethical approval and consent to participate

The approval of this study was waived by the Ethical Committee of Sapienza University of Rome due to its retrospective nature. Written informed consent was obtained before all endoscopic procedures.

### Consent for publication

Not applicable.



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