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REVIEW

# Efficacy and Safety of Endoscopic Sleeve Gastroplasty at Mid Term in the Management of Overweight and Obese Patients: a Systematic Review and Meta-Analysis

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## Abstract

**Background** Endoscopic sleeve gastroplasty (ESG) has emerged as a promising technique in endoscopic bariatric and metabolic therapies (EBMTs). We aimed to perform a systematic review and meta-analysis to provide an update on its efficacy and safety.

**Methods** This is a systematic review and meta-analysis was performed following the PRISMA guidelines. MEDLINE, Cochrane, EMBASE, and LILACS were searched to identify the studies related to ESG.

**Results** Eleven studies with a total of 2170 patients were included. The average BMI pre-ESG was 35.78 kg/m$^2$. Pooled mean %TWL observed at 6, 12, and 18 months was 15.3%, 16.1%, and 16.8% respectively. Pooled mean %EWL at 6, 12, and 18 months was 55.8%, 60%, and 73% respectively. No procedure-related mortality was reported.

**Conclusion** ESG is a safe and effective procedure for primary obesity therapy with promising short- and mid-term results.

**Keywords** Overweight · Obesity · Endoscopy · Bariatric · Surgery · Gastroplasty · Sleeve · ESG

## Introduction

Obesity has become a pandemic with a prevalence that continues to rise despite all the healthcare measures. According to the World Health Organization (WHO) estimates in 2016, 650 million individuals were obese, and 1.9 billion individuals were in the overweight category [1, 2]. American Society for Metabolic and Bariatric Surgery (ASMBS) recommends bariatric surgery for patients with BMI ≥ 40 kg/m$^2$ (class III obesity) or BMI ≥ 35 kg/m$^2$ (class II obesity) with comorbidities related to obesity, who have failed the conservative management for weight loss [3]. Bariatric surgery is an effective and durable weight-loss intervention for the treatment of obesity and related comorbidities [4–6]. Despite its benefits, bariatric

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**Table 1** Risk of bias assessment (checklist for case series, Joanna Briggs Institute)

| JBI critical appraisal checklist for case series | Yes | No | Unclear |
|---|---|---|---|
| 1. Were there clear criteria for inclusion in the case series? | 9 (82%) | 0 (0%) | 2 (18%) |
| 2. Was the condition measured in a standard, reliable way for all participants included in the case series? | 11 (100%) | 0 (0%) | 0 (0%) |
| 3. Were valid methods used for identification of the condition for all participants included in the case series? | 11 (100%) | 0 (0%) | 0 (0%) |
| 4. Did the case series have consecutive inclusion of participants? | 5 (45.5%) | 5 (45.5%) | 1 (9%) |
| 5. Did the case series have complete inclusion of participants? | 2 (18%) | 5 (45.5%) | 4 (36.5%) |
| 6. Was there clear reporting of the demographics of the participants in the study? | 0 (0%) | 0 (0%) | 11 (100%) |
| 7. Was there clear reporting of clinical information of the participants? | 2 (18%) | 4 (36.5%) | 5 (45.5%) |
| 8. Were the outcomes or follow up results of cases clearly reported? | 10 (91%) | 1 (9%) | 0 (0%) |
| 9. Was there clear reporting of the presenting site(s)/clinic(s) demographic information? | 0 (0%) | 9 (82%) | 2 (18%) |
| 10. Was statistical analysis appropriate? | 11 (100%) | 0 (0%) | 0 (0%) |
| Total (%) | 55.4% | 21.9% | 22.7% |

Total number of studies, 11. Total number of patients, 2.170

surgery is an irreversible procedure that carries a small risk of complications [7–10]. Due to these concerns, most of the eligible patients show reluctance, and only less than 2% of patients pursue bariatric surgery [11]. Endoscopic bariatric and metabolic therapies (EBMTs) have emerged as a successful option to fill the gap between medical and surgical therapies. EBMT are minimally invasive procedures utilized as primary weight loss therapy or as a bridge to bariatric surgery in high-risk patients [12–15]. Endoscopic sleeve gastroplasty (ESG) is one of the EBMTs which has gained attention among physicians worldwide in the last few years. ESG uses an endoscopic suturing system (OverStitch, Apollo Endosurgery, Austin, TX) to apply full-thickness sutures in the stomach to reduce the stomach volume [16]. Its use is expanding all over the world, and multiple studies are accumulating each year. The objective of our study is to systematically review and analyze the efficacy and safety profile of ESG by including the most recent studies with an overall large number of patients.

## Methods

### Literature Search Strategy

We designed our search strategy according to the Cochrane Handbook for Systematic Reviews of Interventions and the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) [17]. The study protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) (number CRD42019137654). Electronic searches were performed using the Medline (PUBMED), Cochrane Library, EMBASE, and LILACS databases from their dates of inception to October 2019. In addition to the original articles, we searched for abstracts and presentations related to ESG presented at major scientific meetings.

The MeSH terms used for the searches included "Gastroplasty" OR "Gastroplasties" OR "Bariatric Surgery" AND "Endoscopy" OR "Endoscopic." Two independent investigators (AAMN and AMPN) reviewed the title and abstract of each article independently after the removal of duplicated articles. Articles that were found to be relevant were selected for full-text review. The final decision on the selection of the studies was based on predetermined inclusion and exclusion criteria. Any disagreement on the selection of studies was resolved by the senior investigator (DTHM) after discussion and review.

### Eligibility Criteria

We included randomized controlled trials (RCTs) or observational studies that were published or presented as original research articles or abstracts in the English or Spanish language. Studies with at least 15 participants who underwent ESG with a minimum follow up of at least 1 month were included. We excluded studies in which the endoscopic technique other than the OverStitch suture system was used, and outcomes were not reported as total weight loss (%TWL) or percentage excess weight loss (%EWL) or absolute weight loss (AWL). Additionally, we identified duplicate studies involving the same patient cohort and excluded the series with a smaller number of patients, or with less available data.

### Data Extraction and Outcomes

Data for study characteristics, patient baseline characteristics, procedure technique, weight loss outcomes at follow-up, and adverse events were collected for each study with its supplementary materials and organized in the form of a table. The primary outcomes studied were %TWL, %EWL, AWL (in kilograms), and adverse events. The severity of adverse events was graded according to the American Society for Gastrointestinal Endoscopy (ASGE) lexicon [18] as mild,

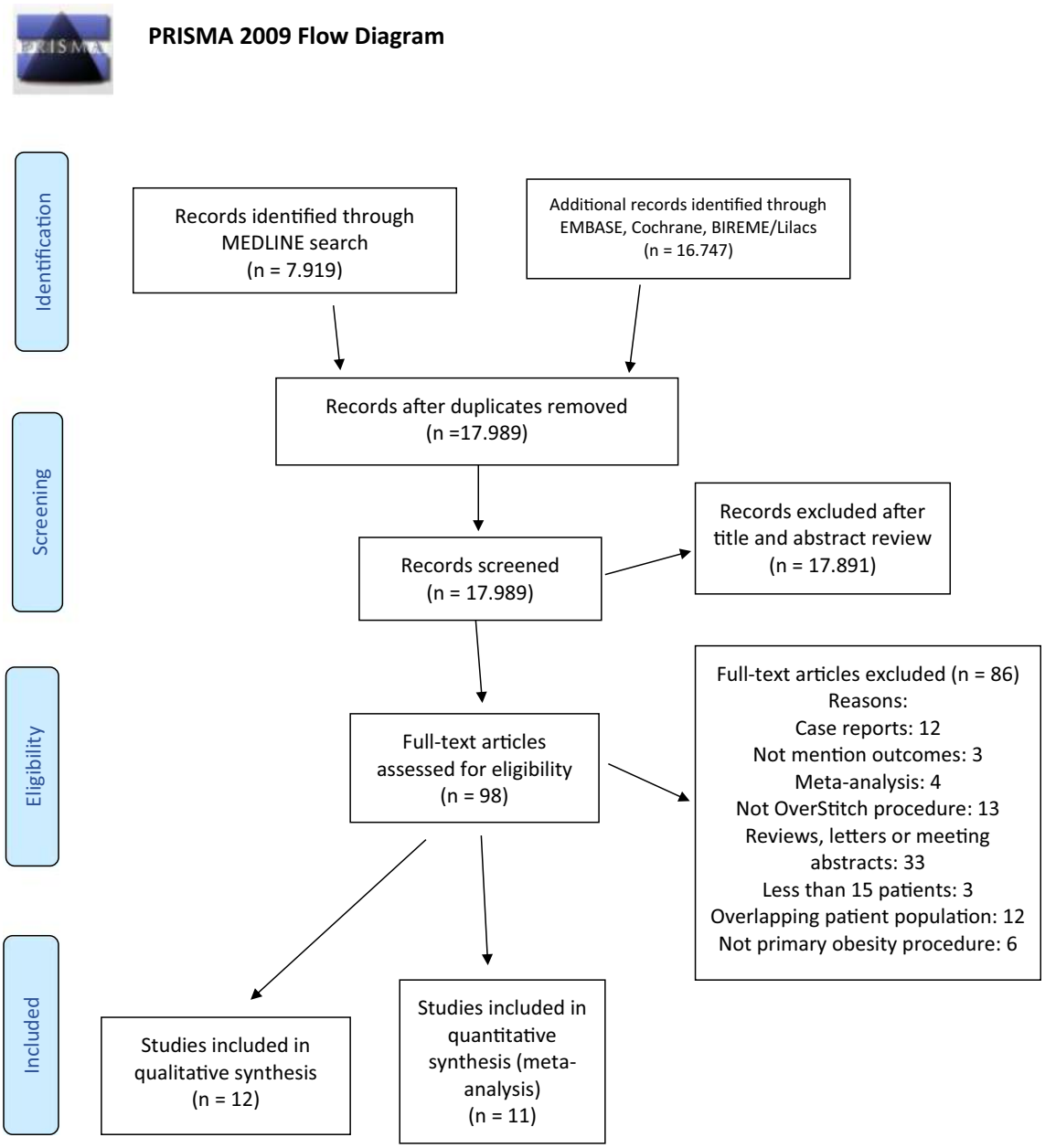


**Fig. 1** PRISMA flow diagram detailing the process of study selection

moderate, and severe. Nausea, vomiting, and mild abdominal pain were not considered as adverse events since they are expected post-procedure symptoms. Clinical success was defined based on the American Society of Gastrointestinal Endoscopy (ASGE) and the ASMBS joint task thresholds for primary EBMT defined as %EWL $\geq$ 25% at 12 months, %TWL > 10%, and $\leq$ 5% severe adverse events [19–21].

## Quality Assessment

The risk of bias for the observational studies was assessed using a critical appraisal tool made available by Joanna Briggs Institute (JBI) [22]. This checklist is composed of 10 items/questions, where answers mark each one as "yes," "no," or "unclear." In the end, the composite score for each evaluated study was calculated and represented as a percentage. This analysis is described in Table 1, available in the supplementary material. The quality of evidence was assessed utilizing the objective criteria from GRADE (Grading Recommendations Assessment, Development, and Evaluation) for each of the pre-specified results and outcomes using GRADEpro - Guideline Development Tool software (McMaster University, 2015; Evidence Prime, Inc., Ontario, Canada) [23].

**ENDOSCOPIC SLEEVE GASTROPLASTY compared to WITHOUT ENDOSCOPIC SLEEVE GASTROPLASTY for Overweight and obesity**

**Patient or population**: Overweight and obesity
**Setting**: Overweight and obesity
**Intervention**: ENDOSCOPIC SLEEVE GASTROPLASTY
**Comparison**: WITHOUT ENDOSCOPIC SLEEVE GASTROPLASTY

| Outcomes | № of participants (studies) Follow-up | Certainty of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | |
|---|---|---|---|---|---|
| | | | | Risk with WITHOUT ENDOSCOPIC SLEEVE GASTROPLASTY | Risk difference with ENDOSCOPIC SLEEVE GASTROPLASTY |
| Total Weight Loss (TWL) assessed with: % follow up: mean 1 months | 2538 (5 observational studies) | ⨁⨁◯◯ LOW | - | The mean total Weight Loss was **0** % | mean **8.5 % higher** (7.94 higher to 9.18 higher) |
| Total Weigth Loss (TWL) assessed with: % follow up: mean 3 months | 2296 (5 observational studies) | ⨁⨁◯◯ LOW | - | The mean total Weigth Loss was **0** % | mean **11.65 % higher** (10.76 higher to 12.53 higher) |
| Total Weigth Loss (TWL) assessed with: % follow up: mean 6 months | 2256 (9 observational studies) | ⨁⨁◯◯ LOW | - | The mean total Weigth Loss was **0** % | mean **15.32 % higher** (14.54 higher to 16.1 higher) |
| Total Weight Loss (TWL) assessed with: % follow up: mean 9 months | 948 (3 observational studies) | ⨁⨁◯◯ LOW | - | The mean total Weight Loss was **0** % | mean **15.15 % higher** (14.94 higher to 17.37 higher) |
| Total Weight Loss (TWL) assessed with: % follow up: mean 12 months | 1706 (9 observational studies) | ⨁⨁◯◯ LOW | - | The mean total Weight Loss was **0** % | mean **17.33 % higher** (16.3 higher to 18.36 higher) |
| Total Weight Loss (TWL) assessed with: % follow up: mean 18 months | 252 (2 observational studies) | ⨁⨁◯◯ LOW | - | The mean total Weight Loss was **0** % | mean **16.8 % higher** (13.02 higher to 20.58 higher) |

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

**CI:** Confidence interval

**GRADE Working Group grades of evidence**
**High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect
**Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
**Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
**Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

**Fig. 2** Quality of evidence for %TWL (% total weight loss) using GRADEpro (available in supplementary material)

## Statistical Analysis

The statistical analyses were carried out by using the Comprehensive Meta-Analysis Software Version 3 (Biostat; Englewood, NJ, USA). Mean values for %TWL, %EWL, and AWL were calculated as pooled mean values. When not provided by the manuscript, the percent of total weight loss was calculated with the following formula (%TWL): %TWL = [(initial weight) − (postop weight)]/[(initial weight)]/100, the percent excess weight loss (%EWL) %EWL = [(initial weight) − (postop weight)]/[(initial weight) − (ideal weight)] and the absolute weight loss (AWL):

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**Comparison**: WITHOUT ENDOSCOPIC SLEEVE GASTROPLASTY

| Outcomes | № of participants (studies) Follow-up | Certainty of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | |
|---|---|---|---|---|---|
| | | | | Risk with WITHOUT ENDOSCOPIC SLEEVE GASTROPLASTY | Risk difference with ENDOSCOPIC SLEEVE GASTROPLASTY |
| Excess Weight Loss (EWL) assessed with: % follow up: mean 1 months | 2100 (3 observational studies) | ⨁⨁◯◯ LOW | - | The mean excess Weight Loss was **0** % | mean **31.08 %** **higher** (20.79 higher to 41.36 higher) |
| Excess Weight Loss (EWL) assessed with: % follow up: mean 3 months | 1838 (3 observational studies) | ⨁⨁◯◯ LOW | - | The mean excess Weight Loss was **0** % | mean **46.13 %** **higher** (38.79 higher to 53.47 higher) |
| Excess Weight Loss (EWL) assessed with: % follow up: mean 6 months | 1816 (6 observational studies) | ⨁⨁◯◯ LOW | - | The mean excess Weight Loss was **0** % | mean **55.8 %** **higher** (50.61 higher to 60.99 higher) |
| Excess Weight Loss (EWL) assessed with: % follow up: mean 9 months | 912 (3 observational studies) | ⨁⨁◯◯ LOW | - | The mean excess Weight Loss was **0** % | mean **66.2 %** **higher** (57.54 higher to 74.86 higher) |
| Excess Weight Loss (EWL) assessed with: % follow up: mean 12 months | 1148 (6 observational studies) | ⨁⨁◯◯ LOW | - | The mean excess Weight Loss was **0** % | mean **60.07 %** **higher** (53.39 higher to 66.74 higher) |
| Excess Weight Loss (EWL) assessed with: % follow up: mean 18 months | 252 (2 observational studies) | ⨁⨁◯◯ LOW | - | The mean excess Weight Loss was **0** % | mean **73.04 %** **higher** (58.94 higher to 87.14 higher) |

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**GRADE Working Group grades of evidence**
**High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect
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**Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
**Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

**Fig. 3** Quality of evidence for %EWL (excess weight loss) using GRADEpro (available in supplementary material)

%TWL = postop weight − initial weight)] . Ideal weight was defined by the weight corresponding to a BMI of 25 kg/m$^2$. [24] Adverse events were also reported as pooled incidence. A random-effects model was used for meta-analysis given the heterogeneity among the individual studies. Heterogeneity was assessed with the use of $I^2$ statistic. The meta-analysis for each outcome was displayed as forest plots along with the summary statistical estimates, 95% confidence intervals, and relative weights. A $p$ value of less than 0.05 was selected as a cutoff for statistical significance.

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| Outcomes | № of participants (studies) Follow-up | Certainty of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | |
|---|---|---|---|---|---|
| | | | | Risk with WITHOUT ENDOSCOPIC SLEEVE GASTROPLASTY | Risk difference with ENDOSCOPIC SLEEVE GASTROPLASTY |
| Absolute Weight Loss (AWL) assessed with: Kg follow up: mean 1 months | 2020 (3 observational studies) | ⨁⨁◯◯ LOW | - | The mean absolute Weight Loss was **0** | mean **7.7 higher** (7.06 higher to 8.4 higher) |
| Absolute Weight Loss (AWL) assessed with: Kg follow up: mean 3 months | 1768 (3 observational studies) | ⨁⨁◯◯ LOW | - | The mean absolute Weight Loss was **0** | mean **10.23 higher** (8.44 higher to 12.03 higher) |
| Absolute Weight Loss (AWL) assessed with: Kg follow up: mean 6 months | 1730 (6 observational studies) | ⨁⨁◯◯ LOW | - | The mean absolute Weight Loss was **0** | mean **14.88 higher** (13.33 higher to 16.42 higher) |
| Absolute Weight Loss (AWL) assessed with: Kg follow up: mean 9 months | 878 (2 observational studies) | ⨁⨁◯◯ LOW | - | The mean absolute Weight Loss was **0** | mean **15.44 higher** (12.7 higher to 18.17 higher) |
| Absolute Weight Loss (AWL) assessed with: Kg follow up: mean 12 months | 1218 (7 observational studies) | ⨁⨁◯◯ LOW | - | The mean absolute Weight Loss was **0** | mean **17.32 higher** (15.66 higher to 18.99 higher) |
| Absolute Weight Loss (AWL) assessed with: Kg follow up: mean 18 months | 252 (2 observational studies) | ⨁⨁◯◯ LOW | - | The mean absolute Weight Loss was **0** | mean **15.96 higher** (10.95 higher to 20.95 higher) |

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**CI:** Confidence interval

**GRADE Working Group grades of evidence**
**High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect
**Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
**Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
**Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

**Fig. 4** Quality of evidence for AWL (absolute weight loss) using GRADEpro (available in supplementary material)

## Results

### Study Selection

We retrieved a total of 24,666 records from the electronic literature search, out of which 6677 duplicates were excluded. The detailed process of study selection in the form of a PRISMA flow diagram is shown in Fig. 1. A total of twelve studies were included in the final analysis. The quantitative analysis was performed with eleven studies, including 2170 patients [25–35]. We excluded the phase I study by Kumar et al. [29] since it was mainly a feasibility study and the study by Glaysher et al. [36],

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| Outcomes | № of participants (studies) Follow-up | Certainty of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | |
|---|---|---|---|---|---|
| | | | | Risk with WITHOUT ENDOSCOPIC SLEEVE GASTROPLASTY | Risk difference with ENDOSCOPIC SLEEVE GASTROPLASTY |
| Mild Adverse Events (AE) assessed with: número absoluto follow up: range 1 months to 18 months | 2050 (2 observational studies) | ⨁⨁◯◯ LOW | not estimable | 0 per 100 | **0 fewer per 100** (0 fewer to 0 fewer) |
| Moderate Adverse Events (AE) assessed with: número absoluto follow up: range 1 months to 18 months | 3232 (6 observational studies) | ⨁⨁◯◯ LOW | not estimable | 0 per 100 | **0 fewer per 100** (0 fewer to 0 fewer) |
| Severe Adverse Events (SAE) assessed with: número absoluto follow up: range 1 months to 18 months | 1108 (3 observational studies) | ⨁⨁◯◯ LOW | not estimable | 0 per 100 | **0 fewer per 100** (0 fewer to 0 fewer) |
| Total Adverse Events (AE) assessed with: número absoluto follow up: range 1 months to 18 months | 3698 (7 observational studies) | ⨁⨁◯◯ LOW | not estimable | 0 per 100 | **0 fewer per 100** (0 fewer to 0 fewer) |

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**CI:** Confidence interval

**GRADE Working Group grades of evidence**
**High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect
**Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
**Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
**Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

**Fig. 5** Quality of evidence for adverse events (mild, moderate, severe, and total) using GRADEpro (available in supplementary material)

where outcomes were reported in median rather than mean and standard deviation. Twelve studies [16, 37–47] were excluded due to overlapping patient cohort.

## Quality of Evidence

Assessment for risk of bias for each study is available in Table 1. According to GRADE criteria, we found low-quality evidence levels for every presented outcome (Figs. 2, 3, 4, and 5), available in the supplementary material.

## Descriptive Results

All included studies were observational, and no controlled or randomized study was identified. Seven studies were single-center experiences, while the other four were multi-center. Most of these centers were from North America ($n = 4$) and Europe ($n = 4$), followed by South America ($n = 2$) and Asia ($n = 2$), and Central America ($n = 1$).

The total number of participants in the included studies was 2170 with a mean age of 42.3 years (95% CI 39.94–44.76), and 393 (18.11%) were males. The preprocedural mean BMI was 35.78 kg/m$^2$ (95% CI 34.89–36.67), and the initial

**Table 2** Characteristics of the studies included in the meta-analysis

| Author (publication year) | Study design | Number | Country | Gender, (male) | Age range (mean) | Weight pre-ESG (kg) | BMI pre-ESG (kg/m$^2$) | Number of sutures (mean) | Procedure Time (min) | Hospitalization (days) | Follow-up (months) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Abu Dayyeh BK, 2017 | Observational, prospective, single-center | 25 | USA | 4 (16%) | 47.6 (10) | NR | 35.5 (2.6) | 16 (5) | 98–127 | 1.5 (1–4) | 6, 9, 12, 20 |
| Lopez-Nava G, 2017 | Observational, prospective, single-center | 154 | Spain | 46 (29.87%) | 44.9 (9.5) | 107 (19.1) | 38.3 (5.5) | NR | NR | 1 | 1, 6, 12, 24 |
| Saumoy M, 2018 | Observational, prospective, single-center | 128 | USA | 42 (32.81%) | 43.62 (11.37) | NR | 38.92 (6.95) | 5* (2–15)/3** (2–9) | 82.5 (76.4–88.8) | NR | 6, 12 |
| Kumar N, 2017 | Observational, prospective, multi-center | 99 | Dominican Republic, USA, Spain | Phase II: NR Phase III: 18 (18.1%) | 41.3 (1.1) | Phase II: NR Phase III: 99.4 (1.8) | Phase II: 34.3 (1) Phase III: 36.1 (0.6) | Fase II: 9/Fase III: NR | NR | 1–3 | 6, 12 |
| Sartoretto A, 2018 | Observational, retrospective, multi-center | 112 | Australia | 35 (31%) | 45.1 (11.7) | NR | 37.9 (6.7) | 7.5 (2.2) | NR | 1 | 1, 3, 6 |
| Grau Morales J, 2018 | Observational, retrospective, single-center | 148 | Spain | 27 (18.24%) | 41.53 (10) | 98.7 (17) | 35.11 (5.5) | 4 | 45–50 | 1 | 3, 6, 9, 12, 18 |
| Alqahtani A, 2019 | Observational, prospective, single-center | 1000 | Saudi Arabia | 103 (10.3%) | 34.4 (9.5) | NR | 33.3 (4.5) | 4–6 | 61 (16) | 1–3 | 1, 3, 6, 9, 12, 18 |
| Barrichello S, 2019 | Observational, prospective, multi-center | 193 | Brazil, USA | 45 (23.31%) | 42.3 (9.6) | 93.4 (10.31) | 34.11 (2.97) | 4–6 | 76 (24) | 1 | 6, 12 |
| Espinet Coll, 2018 | Observational, prospective, single-center | 15 | Spain | 15 (50%) | 46.9 (15.5) | 107.89 (19.1) | 38.82 (6.78) | 5–6 | NR | 1 | 12 |
| Bhandari M, 2019 | Observational, retrospective, single-center | 53 | India | 10 (18.86%) | 40.54 (13.79) | 89.12 (16.2) | 34.78 (5.2) | NR | 68.96 (11.19) | 2 (1–3) | 1, 3, 6, 12 |
| Neto MG, 2019 | Observational, prospective, multi-center | 233 | Brazil | 63 (27%) | 41.1 (10.5) | Class 1: 90.4 (10.1) Class 2: 105.5 (13.6) | 34.7 (2.6) | NR | NR | 1 | 1, 3, 6, 9, 12 |

*NR*: not reported, *USA* United States of America, *BMI* body mass index, *ESG* endoscopic sleeve gastroplasty

*First suture line

**Second suture line

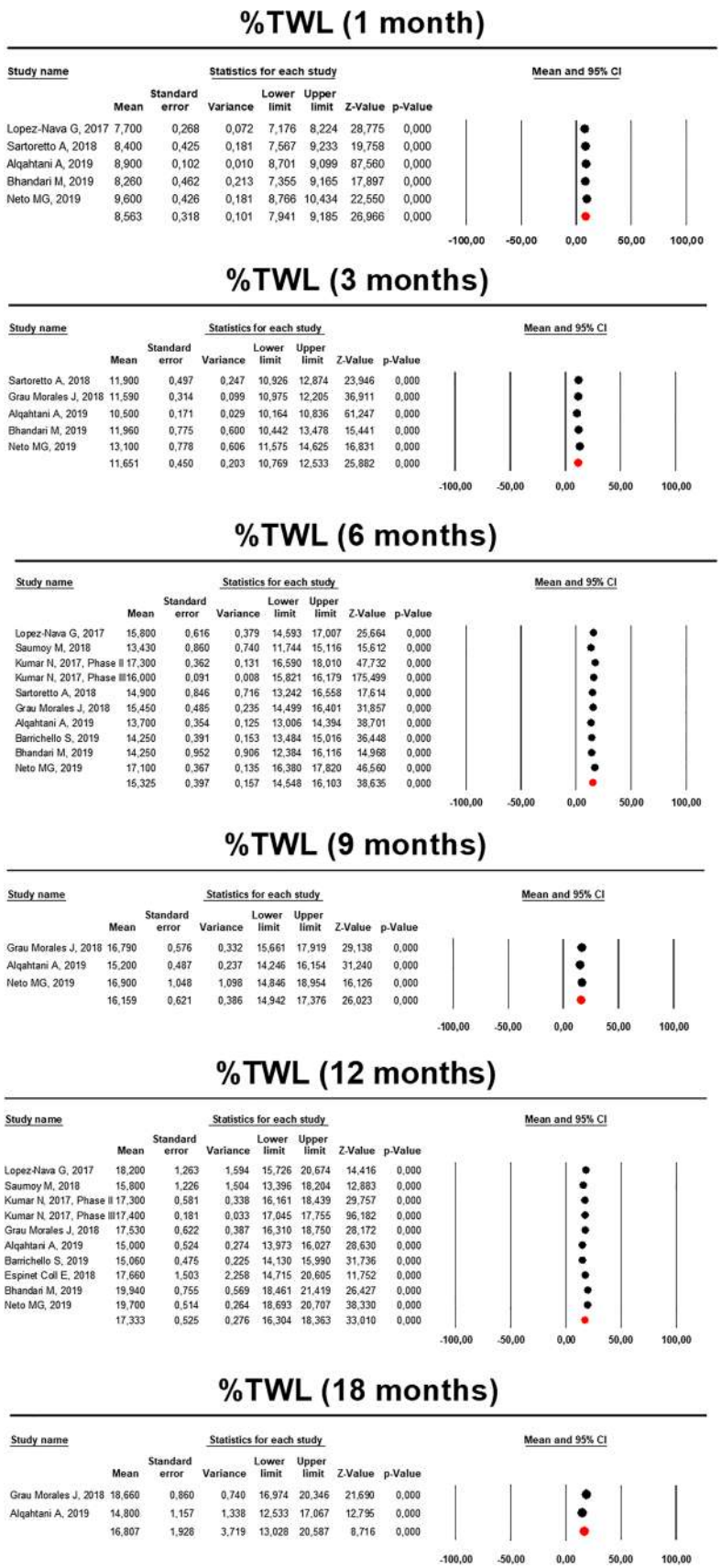


**Fig. 6** Forest plot reporting mean %TWL at 1, 3, 6, 9, 12, and 18 months follow-up (%TWL % total weight loss)


**Fig. 7** Pooled mean %TWL and %EWL after ESG (%TWL % total weight loss, %EWL % excess weight loss, ESG endoscopic sleeve gastroplasty)

average weight was 98.43 kg (95% CI 94.73–102.13). The study characteristics and patient demographics of the included studies are summarized in Table 2.

## Primary Outcomes

### %TWL

The %TWL was evaluated at the 1, 3, 6, 9, 12, and 18 months after ESG (Fig. 6). The pooled mean %TWL was 8.56 (95% CI 7.94–9.18, $I^2$ 0.3%, 5 studies) at 1 month, 11.65 (95% CI 10.76–12.53, $I^2$ 0%, 5 studies) at 3 months, 15.32 (95% CI 14.54–16.10, $I^2$ 15.3%, 9 studies) at 6 months, 16.15 (95% CI 14.94–17.37, $I^2$ 0%, 3 studies) at 9 months, 17.33 (95% CI 16.30–18.36, $I^2$ 10.8%, 9 studies) at 12 months, and 16.80 (95% CI 13.02–20.56, $I^2$ 0%, 2 studies) at 18 months. The pooled mean %TWL and %EWL at follow-up after ESG is graphed in Fig. 7.

### %EWL

The pooled mean %EWL was 31.08 (95% CI 20.79–41.36, $I^2$ 0%, 3 studies) at 1 month, 46.13 (95% CI 38.79–53.47, $I^2$ 0%, 3 studies) at 3 months, 55.80 (95% CI 50.61–60.99, $I^2$ 15.09%, 6 studies), at 6 months, 66.20 (95% CI 57.54–74.86, $I^2$ 8.52%, 3 studies) at 9 months, 60.07 (95% CI 53.39–66.74, $I^2$ 18.09%, 6 studies) at 12 months, and 73.04 (95% CI 58.94–87.14, $I^2$ 0%, 2 studies) at 18 months (Fig. 8).

### AWL

The pooled mean AWL was 7.73 (95% CI 7.06–8.40, $I^2$ 16.82%, 3 studies) at 1 month, 10.23 (95% CI 8.44–12.03, $I^2$ 0%, 3 studies) at 3 months, 14.88 (95% CI 13.33–16.42, $I^2$ 0%, 6 studies), at 6 months, 15.44 (95% CI 12.70–18.17, $I^2$ 0%, 2 studies), at 9 months, 17.32 (95% CI 15.65–18.99, $I^2$ 0%, 7 studies), at 12 months, and 15.95 (95% CI 10.95–20.95, $I^2$ 0%, 2 studies) at 18 months (Figs. 9 and 10).

## Adverse Events

No deaths were reported as a result of the ESG procedure. Seven studies reported the occurrence of adverse events after the procedure, with a total of 38 events (Table 3).

From the total population, we observed a rate of 1.5% (95% CI 0.5–4.3, $I^2$ 0%, 2 studies) for mild, 1.7% (95% CI 0.9–3.1, $I^2$ 8.16%, 6 studies) for moderate, and 0.8% (95% CI 0.3–2.0, $I^2$ 0%, 3 studies) for severe adverse events (Fig. 11). Overall, a 2.3% (95% CI 1.2–4.1, $I^2$ 24.08%, 7 studies) rate of adverse events was observed.

## Discussion

The results of our systematic review and meta-analysis, including 2170 patients, showed that ESG has good short-term efficacy and safety profile. The pooled mean %TWL at 1, 3, 6, 9, 12, and 18 months was 8.56, 11.65, 15.32, 16.15, 17.33, and 16.80, respectively. Similarly, %EWL at 1, 3, 6, 9, 12, and 18 months was 31.08, 46.13, 55.80, 66.20, 60.07, and 73.04, respectively. The pooled incidence of severe adverse events was 0.8%, comprising mainly GI bleeding and perigastric fluid collection. According to the ASGE and ASMBS joint task force, any new primary obesity therapy should provide at least 25% EWL at 1 year with no more than 5% serious adverse events. The weight loss achieved with ESG observed in our work met these criteria for weight loss and safety.

ESG reduces the gastric volume by forming a sleeve along the stomach body and reducing the stomach volume, similar to laparoscopic sleeve gastrectomy (LSG). However, it is different from LSG in many aspects. ESG does not require

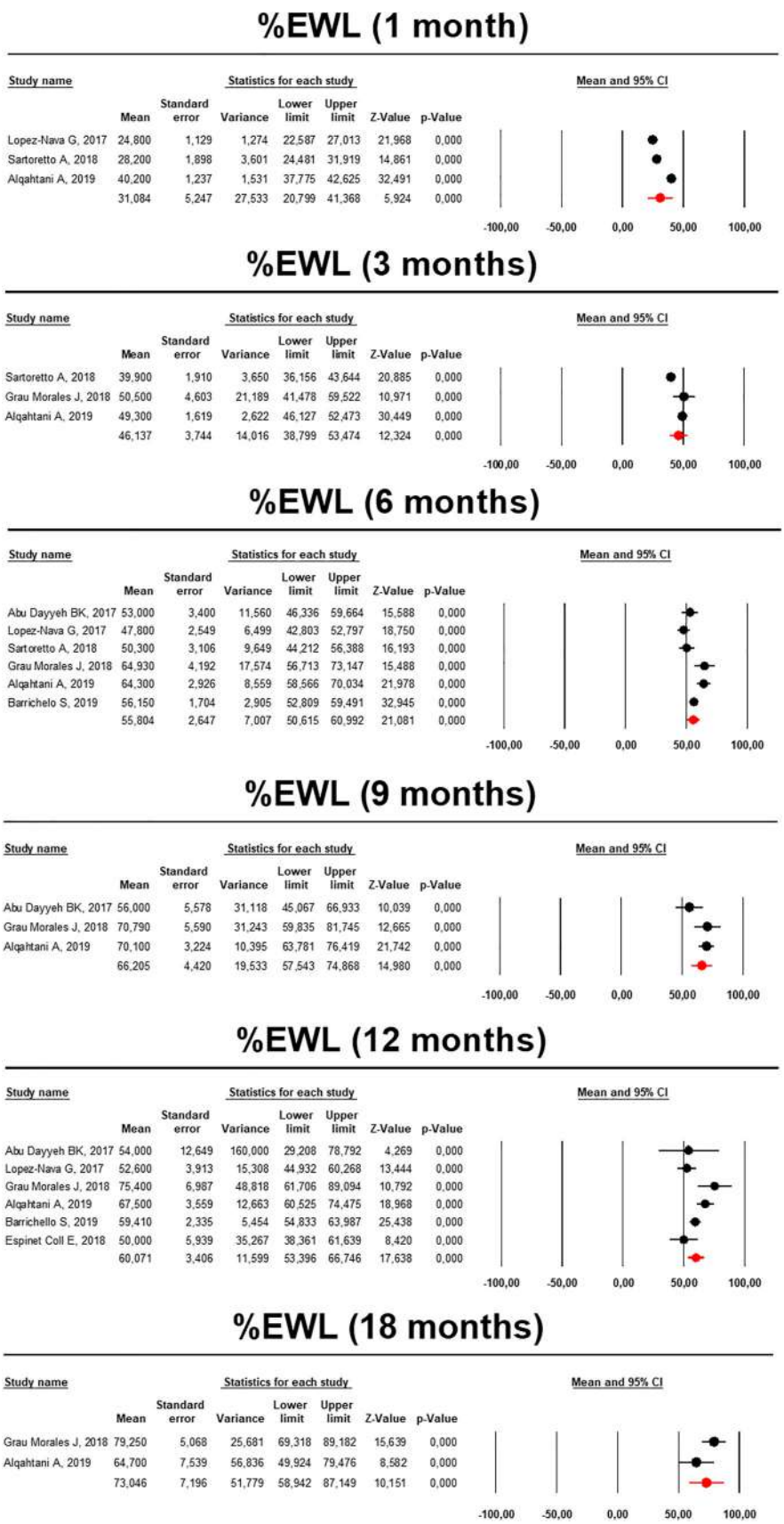


**Fig. 8** Forest plot of studies reporting mean %EWL at 1, 3, 6, 9, 12, and 18 months follow up (%EWL % excess weight loss)

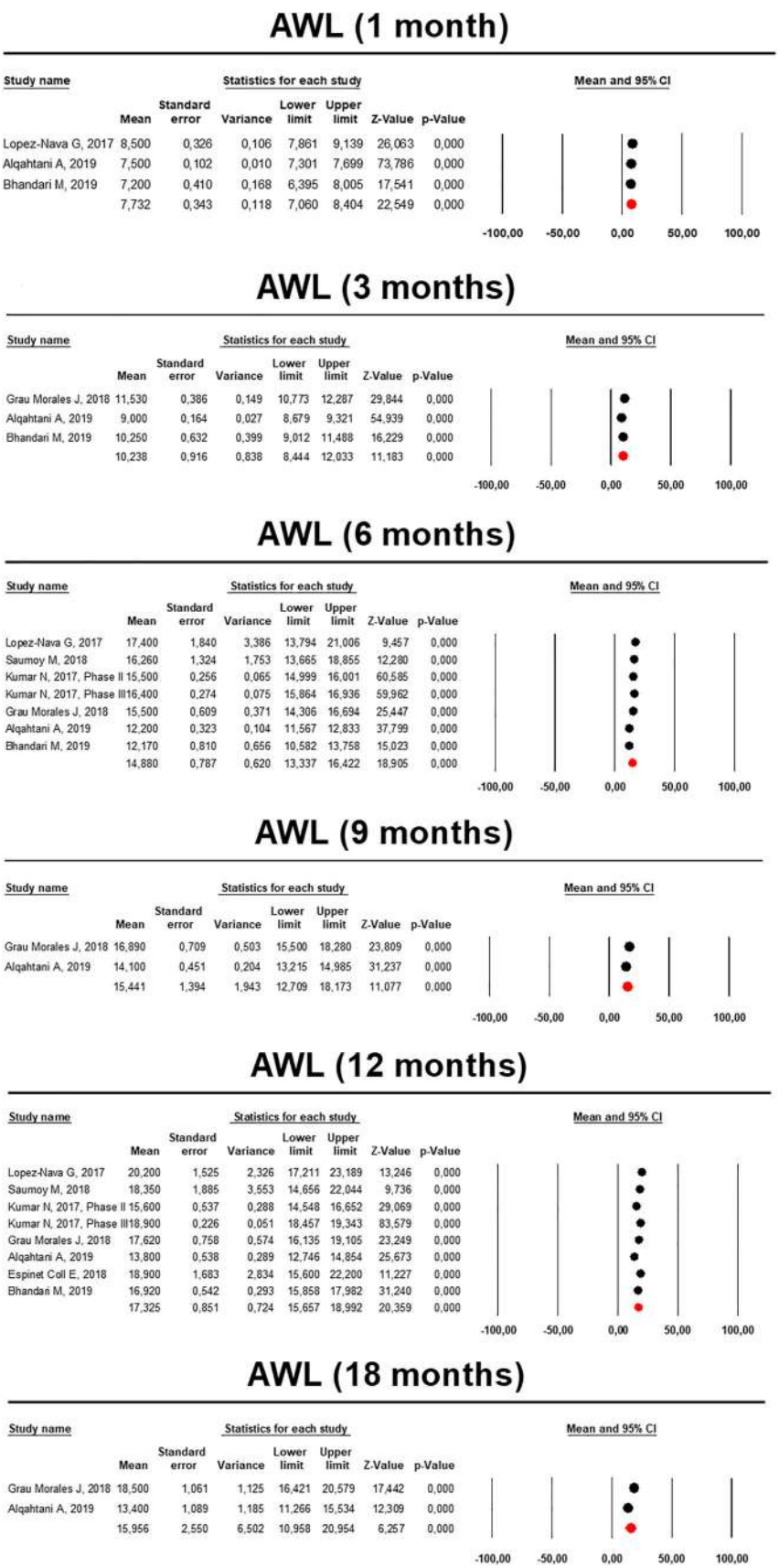


**Fig. 9** Forest plot of studies reporting mean AWL at 1, 3, 6, 9, 12, and 18 months follow-up. (AWL absolute weight loss)


**Fig. 10** Pooled mean AWL after ESG (AWL absolute weight loss, ESG endoscopic sleeve gastroplasty)

abdominal incisions, operating room, and the patient can be discharged home after few hours of observation. ESG may result in remodeling of the stomach but does not significantly alter the stomach anatomy permanently as opposed to LSG and is likely reversible in some cases in the early post-procedural period. In a comparative study performed by Fayad et al. [44], weight loss achieved with LSG was higher than ESG (23.6 vs. 17.1 %TWL, $P < 0.001$) at 6 months follow-up but at the cost of more adverse events (16.9% vs. 5.2%, $P < 0.05$). Almost half of the patients who underwent LSG also reported new-onset or worsening of the gastro-esophageal disease.

Data comparing different EBMT is lacking. Fayad et al. [47] has compared intragastric balloon (IGB) devices with ESG and the weight loss achieved with ESG was comparable to IGB at 6 months (19.5, $P = 0.01$, vs. 15.07, $P < 0.01$, %TWL). However, weight loss associated with IGB is subjected to weight recidivism after a device removal, which is not seen after ESG. Also, a significantly higher proportion of adverse events were reported in the IGB group in comparison to ESG (17% vs. 5.2%, $P = 0.048$). A recent systematic review and meta-analysis [48] reported a mean %EWL of 36.5 at 6 months follow-up after IGB insertion. In our study, we observed a %EWL of 55.8% after ESG during a similar follow-up, thus suggesting a greater weight loss in comparison to IGB.

**Table 3** Number of adverse events reported in studies

| | Mild | Moderate | Severe | Fatal | Total |
|---|---|---|---|---|---|
| Abu Dayyeh BK, 2017 | 1 | 2 | – | – | 3 |
| Saumoy M, 2018 | – | 1 | 1 | – | 2 |
| Sartoretto A, 2018 | – | 3 | – | – | 3 |
| Grau Morales J, 2018 | – | 1 | – | – | 1 |
| Alqahtani A, 2019 | 11 | 13 | – | – | 24 |
| Barrichello S, 2019 | – | 2 | 2 | – | 4 |
| Neto MG, 2019 | – | – | 1 | – | 1 |
| Total, 7 | 12 | 22 | 4 | 0 | 38 |

In another recent systematic review and meta-analysis of randomized controlled trials (RCTs), Madruga et al. [49] assessed the efficacy of primary obesity surgery endoluminal (POSE) and transoral gastroplasty (TOGa), and both of the techniques failed to achieve the threshold of weight loss set up by the Food and Drug Administration (FDA). In contrast to that, ESG surpassed the criteria for weight loss established by the ASGE and ASBMS. However, the lack of RCTs for ESG raises concern about the quality of evidence and risk of bias.

Our analysis showed some variability in weight loss between different studies. We observed a consistent increase in AWL, %TWL, and %EWL from 1 to 12 months follow-up after ESG. Beyond the 12 months follow-up, no significant weight loss was seen, suggesting that weight loss might have the plateaued off. However, a limited number of patients attained this follow-up beyond 12 months, which impairs a more adequate assessment. More studies are needed to confirm that the weight loss achieved with ESG can be sustained for more than 2 years. Only the study by Lopez-Navas G et al. [26] reached a follow-up of 24 months. In this study, the authors observed that between 12 and 24 months of follow-up, there was an increase in %TWL (18.2 ± 10.1 against 19.5 ± 10.5, respectively) and %EWL (52.6 ± 31.4 against 60.4 ± 31.1). Variations of procedure technique were also reported, and the main difference was the number of sutures used and the suturing patterns described as "Z" "U," and triangular. However, a layer of reinforcement sutures was reported in many studies.

In contrast to prior studies, our meta-analysis is the first one to categorize adverse events into mild, moderate, and severe, as per the ASGE Quality Task Force recommendations (Cotton et al. [18]). Seven studies included in our meta-analysis reported a total of 38 adverse events,

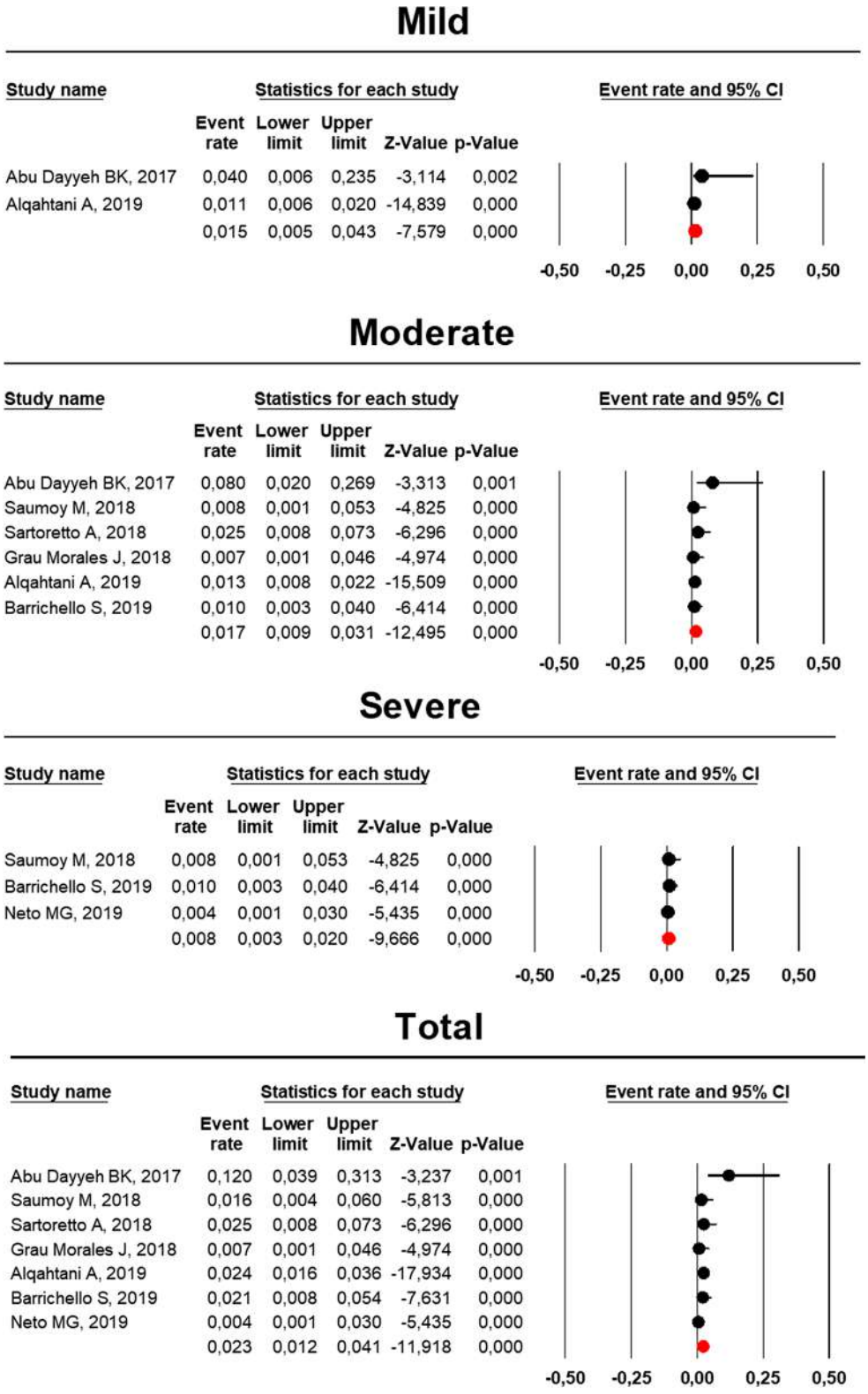


**Fig. 11** Forest plot of studies reporting incidence of adverse events

out of which 12 were mild, 22 moderate, and only 4 were severe adverse events. No procedure-related mortality was reported in any of the included studies. GI bleeding with a total of 13 (34.2%) incidents followed by perigastric collections in 10 (26.3%) cases were the most common major adverse events reported. Most of these adverse events were managed conservatively; however, 2 of the GIB required sclerotherapy, and 3 of the cases with

perigastric fluid collection required surgical interventions. The surgical interventions included cavity drainage in two patients while one patient developed a gastric fistula, which required closure and reversal of ESG. There were 8 cases of severe abdominal pain, 5 cases of fever, which were also managed conservatively. Only one case of deep vein thrombosis (DVT) was reported, which was treated with full anticoagulation, and one case pneumothorax was reported, which required thoracic drainage. A total of 2.3% adverse events were observed, which is significantly lower than the threshold defined by the ASGE and ASMBS.

Our meta-analysis included many updated studies from multiple centers with an overall large number of patients, which were not included in previous systematic reviews [50]. A recent single-center study by Bhandari et al. [35] and another recent multi-center study by Neto et al. [27] included in our study has not been analyzed in any previous reviews. We rigorously analyzed the outcomes reported in studies, but our study has several limitations. The quality of the included studies limits the quality of our meta-analysis. All included ESG studies were observational; thus, lack of RCTs introduces a risk of bias and confers to low quality of evidence. Considerable heterogeneity was seen in our outcomes likely due to differences in the patient population, lifestyle interventions, and procedural characteristics. The technique employed by the endoscopists in included studies was not standardized and the studied population was not homogeneous. Long term data with ESG is lacking, and there are only a few studies with follow-up over 18 months. Also, comprehensive data regarding the impact of ESG on obesity-related comorbidities are not available. Lastly, studies did not consistently report adherence or the intensity of lifestyle interventions post ESG procedure, which can significantly impact the weight loss outcomes.

The use of ESG is expanding, and more physicians are getting trained; therefore, it is imperative to set up protocols for standardized training and credentialing methods. It is also essential to select the proper patient population to optimize outcomes. The reason for weight loss after ESG is not well understood. In addition to the decrease in stomach volume, Abu Dayyeh et al. [25] suggested that ESG can result in a delay in gastric emptying in a small cohort of patients. Bariatric surgery has a significant impact on gastric and intestinal hormones, such as ghrelin, GLP-1, and PYY, where levels of ghrelin decrease and GLP-1 and PYY are intensified [51]. For still being a relatively new procedure, there are not enough data to study the impact of ESG on the regulation of these hormones.

The assessed ESG outcomes have shown encouraging results; however, it is important to also critically evaluate the presented data, since there is a moderate risk of bias and low quality of evidence.

## Conclusion

ESG has demonstrated safety and efficacy in the short and mid term, with a lower rate of adverse events and is a minimally invasive alternative promising in the treatment of obesity.

**Author Contributions** Miranda Neto, AAM: acquisition of data, analysis, interpretation of data, drafting the article, revising the article, final approval. Moura, DTH: analysis and interpretation of data, revising the article. Ribeiro, IB: acquisition of data, drafting the article, revising the article, final approval. Khan, A: analysis and interpretation of data, drafting the article, final approval. Shailendra, S: revising, editing and drafting article, final approval. Ponte Neto, AM: revising, editing and drafting article, final approval. Madruga Neto, AC: revising, editing and drafting article, final approval. Monte Junior, ES: revising, editing and drafting article, final approval. Tustumi, F: revising, editing and drafting article, final approval. Bernardo, WM: revising, editing and drafting article, final approval. de Moura, EGH: analysis and interpretation of data, drafting the article, revising the article, final approval.

## Compliance with Ethical Standards

**Conflict of Interest** Dr. Moura reports personal fees from Boston Scientific, personal fees from Olympus, outside the submitted work.

**Ethical Statement** The study was approved by the Research Ethics Committee of the University of São Paulo School of Medicine *Hospital das Clínicas*.

**Consent Statement** Informed written consent was obtained from all participants.

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