Intragastric Balloon Versus Endoscopic Sleeve Gastroplasty for the Treatment of Obesity: a Systematic Review and Meta-analysis

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ORIGINAL CONTRIBUTIONS

Intragastric Balloon Versus Endoscopic Sleeve Gastroplasty for the Treatment of Obesity: a Systematic Review and Meta-analysis

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Abstract

Background We aimed to individually evaluate IGB and ESG procedures and compare the efficacy, durability, and safety of these procedures.

Methods Bibliographic databases were systematically searched for studies investigating the use of IGB and ESG for the treatment of obesity. Studies reporting percent total weight loss (%TWL) or percent excess weight loss (%EWL) with at least 12 months of follow-up were included.

Results A total of 28 studies were included in the final analysis. Only 1 study directly compared ESG to IGB, 9 studies evaluated ESG alone, while 18 studies evaluated IGB. At 12-month follow-up after ESG, mean %TWL was 17.51 (95% CI 16.44–18.58), and %EWL was 60.51 (95% CI 54.39–66.64). Mean %TWL and %EWL after IGB at 12 months was 10.35 (95% CI 8.38–12.32) and 29.65 (95% CI 25.40–33.91), respectively. Mean %TWL and %EWL after IGB were significantly decreased at 18 or 24 months compared to 6 months indicating weight regain after IGB removal. ESG achieved significantly superior weight loss compared to IGB, the difference in mean %TWL was 7.33 (95% CI 5.22–9.44, p value = 0.0001) at 12 months. Serious adverse events were observed in < 5% for both procedures.

Conclusion Although ESG and IGB are safe and effective for weight loss, our study suggests that ESG results in more significant and sustained weight loss. Nevertheless, a variety of approaches are essential to care for this underserved population, and there are several factors other than weight loss that should be considered in selecting the ideal therapy for individual patients.

Keywords Obesity · Intragastric balloon · Gastric balloon · IGB · Endoscopic sleeve gastroplasty · ESG · Endoscopic and bariatric therapy

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Introduction

Obesity is a global pandemic and is associated with significant morbidity and mortality. Most patients fail to achieve sustained weight loss with lifestyle modification and pharmacotherapy. Bariatric surgery is effective but carries a risk of complications and low patient acceptance with less than 2% of eligible patients ultimately undergoing surgery [1]. Endoscopic bariatric and metabolic therapies (EBMTs) have emerged over the years, to provide options beyond lifestyle modifications, medications, and surgery. EBMTs can provide a minimally invasive, effective, and safe treatment approach to obesity [2].

Among the armamentarium of EBMTs, intragastric balloons (IGBs) are the most well established. Currently, there are three FDA-approved IGBs on the market designed to treat obesity: ReShape Integrated Dual Balloon System (ReShape Lifesciences, San Clemente, CA, USA), Orbera Intragastric Balloon System (Apollo Endosurgery, Austin, TX, USA), and Obalon Balloon system (Obalon Therapeutics Inc., Carlsbad, CA, USA). Several studies have demonstrated the efficacy and safety of these IGBs [3, 4]. Another EBMT, endoscopic sleeve gastroplasty (ESG), has recently gained popularity for the treatment of obesity. ESG utilizes an endoscopic suturing device (OverStitch, Apollo Endosurgery, Austin, TX) to apply full-thickness sutures in the stomach, reduce gastric capacity, and delay gastric emptying. In 2012, Thompson and Hawes performed the first ESG using the current full-thickness suturing device [5]. Since then, many studies have demonstrated the safety and efficacy of this procedure [6, 7].

Data comparing these common EBMTs are lacking. The choice of one procedure over the other has been mainly driven by physician expertise, patient preference, and costs. Multiple EBMTs are now being developed, and it is imperative to evaluate and compare these procedures to inform physicians and patients about their safety and efficacy.

ASGE (American Society for Gastrointestinal Endoscopy) and the American Society for Metabolic and Bariatric Surgery (ASMBS) joint task force [8] defined thresholds of a mean minimum threshold of 25% excess weight loss (%EWL) measured at 12 months for an EBMT intended as a primary obesity intervention and 5% total body weight loss (%TWL) as absolute minimum threshold for any nonprimary EBMT such as bridging therapy. We aimed to individually evaluate IGB and ESG procedures as per the ASGE task force thresholds and compare the efficacy, durability, and safety among these procedures.

Methods

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The study was registered in the International Prospective Register of Systematic Reviews (PROSPERO) (ID CRD42019140945).

Data Source and Search Strategy

Electronic searches were performed by a medical librarian (A.C.) with input from the study investigators. Medline (PubMed), Scopus, Cochrane Register of Controlled Trials, and Web of Science databases were queried from their dates of inception to August 2019. There was no language restriction; however, we restricted our search query to observational and randomized controlled trials (RCT). The search strategy is detailed in Supplement 1.

All data were extracted from article texts, tables, and figures with any estimates made based on the presented data and figures. Two study investigators (S.S. and A.K.) independently reviewed the titles and abstracts of studies identified in the search, and its eligibility was determined based on prespecified inclusion and exclusion criteria. The full text of the relevant articles was evaluated. Any discrepancy was resolved by discussion and re-evaluation by senior authors (C.C.T. and D.T.H.M.).

Eligibility

All RCTs and observational studies in which patients underwent EBMT with either IGB or ESG procedure alone with or without lifestyle modification for obesity treatment were included. Studies that reported %TWL or %EWL at a follow-up of a minimum of 12 months were included to assess the weight loss as per the ASGE task force recommended threshold. Also, the objective was to compare the durability of these procedures beyond the initial treatment duration; therefore, only studies with a minimal follow-up of 12 months were included. In studies with more than one treatment arm, patients who underwent ESG or IGB alone with or without lifestyle modification were included.

Patients with prior or sequential EBMTs or bariatric surgery were excluded. Case reports and study with < 25 patients were excluded because of the bias associated with case reports/small case series and the learning curve associated with the EBMTs. ESG studies were excluded if endoscopic gastroplasty techniques using devices other than the OverStitch endoscopic suturing system were used. Studies with IGBs not approved by the US Food and Drug Administration (FDA) were excluded. Letters, editorials, expert opinions, and reviews without original data were excluded. Only the most updated study was selected for each institution/operator while other studies with overlapping patient cohorts were excluded.

Data Extraction, Quality Assessment, and Statistical Analysis

Following data were abstracted using a standardized data collection by two investigators: study characteristics, patient baseline characteristics, procedure-related data, weight loss outcomes at follow-up, adverse events, reversal of ESG procedure, or early removal of IGB and mortality. Primary outcomes of interest were %TWL or %EWL reported as mean change from baseline at follow-up periods 6, 12, 18, and 24 months when available and adverse events. Weight loss outcomes at 18 and 24 months were combined and reported together (18–24 months). Adverse events were classified and reported as per included studies.

Quality assessment of randomized controlled trials (RCTs) was done using the NIH Quality Assessment of Controlled Intervention Studies tool. For quality assessment of observational studies, the Newcastle-Ottawa scale (NOS) for quality assessment and bias assessment was used. The quality assessment of the studies was done by two independent authors (A.K. and S.S.). A disagreement on the score was discussed with a third reviewer (D.T.H.M.) and was resolved by consensus.

Pooled means for %TWL and %EWL at 6-, 12-, and 18–24-month follow-up were calculated for each type of EBMT. Studies that did not report standard deviations or if standard deviations could not be calculated, then the reported mean of the study was used as an estimate of its standard deviation to include them in the meta-analysis. Meta-analyses were performed using a DerSimonian and Laird random-effects approach given the degree of heterogeneity. We performed a subgroup analysis based on follow-up duration. To combine studies within a subgroup, we assumed a common among study variance component across subgroups (pool within-group estimates of tau-squared). Differences in the mean of %TWL and %EWL were calculated to compare all ESG and IGB procedures. To assess the impact of study-level covariates on outcomes, meta-regression analysis was performed. Meta-analyses for all outcomes were presented as forest plots with summary statistical estimates, 95% confidence intervals, and relative weights. A p value of less than 0.05 was considered statistically significant. Statistical heterogeneity was evaluated through Cochran's Q test and I^2 statistics. An I^2 value greater than 50% was considered to indicate high statistical heterogeneity. To analyze the safety of each type of EBMT, we reported an overall incidence of most common reported adverse events. All statistical analysis was conducted using Comprehensive Meta-Analysis Software Version 3 (Biostat; Englewood, NJ, USA).

Results

Search Strategy Yield and Study Characteristics

Figure 1 shows the PRISMA flow diagram detailing the process of study selection. Studies included in the meta-analysis are summarized in Table 1. A total of 28 EBMT studies [9–36] with a follow-up of at least 12 months were included in the final analysis. Out of these, only 1 study evaluated both ESG and IGB [18], 9 studies evaluated ESG alone, while 18 studies evaluated IGB. Therefore, a total of 10 ESG and 19 IGB datasets were included for meta-analyses. Phase II and phase III ESG studies by Kumar et al. [13] were included while phase I study performed to evaluate the safety and technical feasibility was excluded. A multicenter ESG study by Sartoretto et al. [37] was excluded since only 6-month follow-up was available. Several IGB studies have only reported outcomes at 6 months at the time of IGB removal, therefore excluded from the analysis.

No controlled or randomized ESG studies were identified. All included ESG studies were observational studies. Two studies were multicenter while the other eight studies were single-center experiences. Four IGB studies were RCTs while the remaining studies were observational. A total of 1979 patients underwent ESG procedure, and 3025 patients underwent IGB placement in the included studies. Table 2 compares the patient characteristics in the two groups. Results of the quality assessment of all included studies were considered adequate for analysis (Supplement 2).

Weight Loss Outcomes

ESG

Based on a meta-analysis of 9 studies, the pooled mean %TWL after ESG at 6- and 12-month follow-up was 15.34 (95% CI 14.33–16.35, I^2 = 92.23) and 17.51 (95% CI 16.44–18.58, I^2 = 88.35), respectively (Fig. 2a). Mean %TWL between 18- and 24-month follow-up was 17.85 (95% CI 15.85–19.86, I^2 = 69.57, 4 studies). In comparison of these subgroups, %TWL increased at 12 months (p value = 0.004) and 18–24 months (p value = 0.025) follow-up compared to 6 months. The %EWL was reported in 6 studies. The pooled mean %EWL at 6- and 12-month follow-up was 55.61 (95% CI 50.28–60.95, I^2 = 83.38) and 60.51 (95% CI 54.39–66.64, I^2 = 66.67) (Fig. 2b). Four studies also reported %EWL at follow-up 18–24 months with a pooled mean of 66.77 (95% CI 57.54–76.00, I^2 = 67.72). %EWL at 12 months was similar (p value = 0.22) but %EWL at 18–24 months (p value = 0.047) was increased as compared to 6-month follow-up.

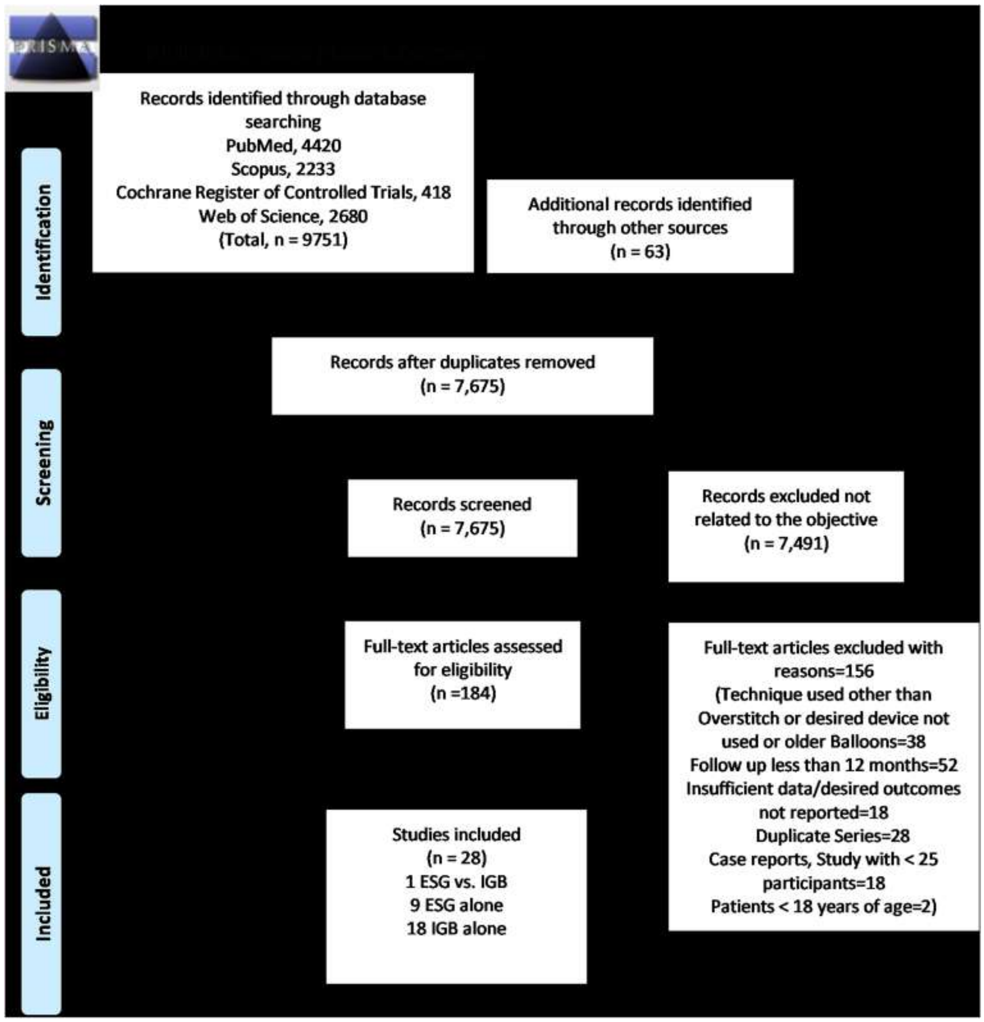

Fig. 1 PRISMA flow diagram detailing the process of study selection

IGB

The %TWL was reported in 4 RCTs and 5 observational IGB studies (Fig. 3). Overall pooled mean %TWL at 6- and 12-month follow-up after IGB was 12.16 (95% CI 10.37–13.95, I^2 = 91.32%) and 10.35 (95% CI 8.38–12.32, I^2 = 89.80%), respectively. The pooled mean %TWL at 18–24 months of follow-up was 6.89 (95% CI 3.78–10.01, I^2 = 96.50%, 3 studies). Mean %TWL with IGB showed a nonsignificant decrease at 12 months (p value = 0.13) but significantly lower %TWL at 18–24 months (p value = 0.003) compared to 6 months, indicating weight recidivism with IGB. %EWL was reported in 2 RCTs and 13 observational IGB studies (Fig. 3). The overall pooled mean %EWL at 6 and 12 months was 34.83 (95% CI 30.97–38.69, I^2 = 97.71%, 15 studies) and 29.65 (95% CI 25.40–33.91, I^2 = 97.51%, 13 studies), respectively (Fig. 3b). The mean %EWL at 18–24-month follow-up was 23.88 (95% CI 17.41–30.33, I^2 = 87.05%, 5 studies). %EWL showed a nonsignificant decrease at 12 months (p value = 0.10) but significantly lower %EWL at 18–24 months (p value = 0.001) as compared to 6-month follow-up.

Comparative Analysis ESG Versus IGB

ESG achieved significantly higher %TWL and %EWL than IGB. The difference in mean %TWL between ESG and IGB at 6, 12, and 18–24 months was 3.07 (95% CI 1.46–4.67, p = 0.002), 7.33 (95% CI 5.22–9.44, p value = 0.0001), and 11.51 (95% CI 5.33–17.69, p value = 0.0003), respectively. The difference in mean %EWL between ESG and IGB at 6, 12, and 18–24 months was 20.80 (95% CI 12.50–29.10, p value = 0.0001), 30.99 (95% CI 22.81–39.16, p value = 0.0001), and 43.78 (95% CI 35.98–51.58, p value = 0.0001), respectively.

Meta-regression

Meta-regression with multiple covariates (type of EBMT, mean age, mean BMI, and percentage of males) was performed to assess if differences in characteristics of studies

Table 1 Characteristics of studies included in the meta-analysis

• Study (year published)	Design	Setting	Country	Intervention	Inclusion criteria	Exclusion criteria	Total patients, *N*	Age, years mean (S.D)	BMI pre-procedure (S.D)	%TWL	%EWL	Serious adverse events, *N* (%)
Saumoy (2018)	Observational	Single-center	USA	ESG	BMI > 30 kg/m^2 with failed noninvasive weight loss measures OR BMI > 40 kg/m^2 and nonsurgical candidates or declined surgery	History of gastric lesions, neoplastic changes or gastric cancer, contraindications, or at high risk to undergo general anesthesia	128	43.6 (11.3)	38.92 (6.9)	13.4 (7.4) at 6 months 15.8 (9.5) at 12 months	NA	2 (1 perigastric leak, 1 perforation)
Alqahtani (2019)	Observational	Single-center	Saudi Arabia	ESG	BMI > 40 kg/m^2 or 35 kg/m^2 with comorbidities	Bleeding disorders, large hiatal hernia, and active peptic ulcer disease	1000	34.4 (9.5)	33.3 (4.5)	13.7 (6.8) at 6 months 15.0 (7.7) at 12 months 14.8 (8.5) at 18 months	64.3 (56.2) at 6 months 67.5 (52.3) at 12 months 64.7 (55.4) at 18 months	24 (8 severe abdominal pain, 7 post-procedure bleeding, 4 perigastric collections with pleural effusion, 5 post-procedure fever with no sequelae)
Abu Dayyeh (2017)	Observational	Single-center	USA	ESG	BMI between 30 and 40 kg/m^2 with stable weight for 3 months	Anticoagulation, previous gastric surgery, gastric ulceration, hiatal hernia ≥ 5 cm, or pregnancy	25	47.6 (10.0)	35.5 (2.6)	NA	54 (40) at 6 months 54 (40) at 12 months 45 (41) at 20 months	3 (1 perigastric fluid collection, 1 pulmonary embolism, 1 pneumoperitoneum/pneumothorax)
Lopez-Nava (2017)	Observational	Single-center	Spain	ESG	BMI > 30 kg/m^2 who committed for 1-year multidisciplinary follow-up	Acute, potentially bleeding gastric mucosal lesions (ulcers, acute gastritis), neoplastic lesions, hiatus hernia > 3 cm, coagulopathy, and psychiatric disorders	154	44.9 (9.5)	38.3 (5.5)	15.8 (7.1) at 6 months 18.2 (10.1) at 12 months 19.5 (10.5) at 24 months	47.8 (29.4) at 6 months 52.6 (31.3) at 12 months 60.4 (31.1) at 24 months	No serious adverse events
Morales (2018)	Observational	Single-center	Spain	ESG	BMI > 30 to > 40 kg/m^2	Potentially bleeding lesions, such as ulcers or erosive duodenitis, preneoplastic or neoplastic findings, contraindications, or at high risk to undergo general anesthesia	148	41.5 (10.0)	35.11 (5.5)	15.4 (5.9) at 6 months 17.5 (7.6) at 12 months 18.6 (7.3) at 18 months	64.9 (51) at 6 months 75.4 (85) at 12 months 79.25 (43) at 18 months	1 (mild GI bleeding)

Table 1 (continued)

• Study (year published)	Design	Setting	Country	Intervention	Inclusion criteria	Exclusion criteria	Total patients, *N*	Age, years mean (S.D)	BMI pre-procedure (S.D)	%TWL	%EWL	Serious adverse events, *N* (%)
Barrichello (2019)	Observational	Multicenter	Brazil (6 centers, USA (1 center)	ESG	Overweight or obese patients who failed diet and lifestyle modifications	Previous gastric surgery, anticoagulation, acute gastric ulceration, cancer, hiatal hernia > 5 cm, gastroesophageal motility disorder, and pregnancy	193	42.3 (9.6)	34.11 (2.97)	14.2 (5.3) at 6 months 15.1 (5.2) at 12 months	56.1 (22.9) at 6 months 59.4 (25.7) at 12 months	4 (2 GI bleeding, 2 perigastric fluid collections)
Sartoretto (2019)	Observational	Single-center	Australia	ESG	BMI > 27 kg/m^2 and failed multiple diet and lifestyle modifications	Personal or family history of gastric cancer, active gastric ulcers, presence of any gastric condition which required endoscopic surveillance (e.g., known gastric intestinal metaplasia), known vascular abnormalities, decompensated organ failure, obligate therapeutic anticoagulation, pregnancy/lactation	121	43.0 (11.9)	36.7 (4.9)	16.4 (6.8) at 6 months 19.6 (8.4) at 12 months	49.7 (22) at 6 months 55.7 (25) at 12 months	No serious adverse events
Bhandari (2019)	Observational	Single-center	India	ESG	BMI > 28 kg/m^2 and failed attempts to lose weight conservatively	Gastric neoplasm, family history of gastric cancer, large hiatus hernia. Individuals with mental health disorders, significant medical comorbidities precluding sedation, coagulopathies, previous bariatric surgery	53	40.5 (13.8)	34.78 (5.20)	14.2 (6.2) at 6 months 19.9 (4.9) at 12 months	NA	No serious adverse events
Kumar (2017)	Observational	Multicenter	Phase II Dominican Republic, USA Phase III Dominican	ESG	BMI > 30 kg/m^2 with unsuccessful diet and lifestyle modifications	Bleeding disorders, gastrointestinal disease, prior gastric surgery, active use of weight loss	Phase II 22	39.2 (1.6)	34.3 (1.0)	17.3 (1.7) at 6 months 17.3 (2.6) at	NA	No serious adverse events

Table 1 (continued)

• Study (year published)	Design	Setting	Country	Intervention	Inclusion criteria	Exclusion criteria	Total patients, *N*	Age, years mean (S.D)	BMI pre-procedure (S.D)	%TWL	%EWL	Serious adverse events, *N* (%)
			Republic, Spain, USA			medication, eating disorders, or uncontrolled or severe psychiatric disease	Phase III 77	41.3 (1.1)	36.1 (0.6)	12 months 16.0 (0.8) at 6 months 17.4 (1.2) at 12 months	NA	No serious adverse events
Fayad (2019)	Observational	Single-center	USA	ESG	BMI > 30 kg/m^2 in patients who had been previously unsuccessful in losing weight through diet, exercise, and/or medications	History of gastric cancer, a family history of gastric cancer, active *Helicobacter pylori* infection, active gastric ulcer, gastric intestinal metaplasia, vascular abnormalities, decompensated organ failure, prior foregut surgery, and pregnancy/lactation	58	48.2 (11.8)	41.5 (8.2)	19.5 (5.7) at 6 months 21.3 (6.6) at 12 months	NA	3 (2 upper gastrointestinal bleeding, 1 perigastric fluid collection)
				IGB (ReShape, Orbera)	BMI > 27 kg/m^2 in patients who had previously been unsuccessful in losing weight through diet, exercise, and/or medications	History of gastroesophageal surgery and active anticoagulation	47	47.7 (12.4)	34.5 (6.7)	15.0 (7.6) at 6 months 13.9 (9.0) at 12 months	NA	Early removal because of nausea and vomiting (n = 4, 8.5%) Balloon hyperinflation (n = 1), non-obstructing balloon resting in the antrum (n = 1)
Agnihotri (2018)	Observational	Multicenter	USA	Reshape	BMI > 30 kg/m^2 who had Reshape Duo IGB inserted for weight loss therapy	No exclusion criteria mentioned	202	47.8 (10.8)	36.7 (6.6)	11.4 (6.7) at 6 months 14.7(11.8) at 12 months	29.9 (18.2) at 6 months 36.4(28.1) at 12 months	Early removal (n = 13, 6.4%) Esophagitis (n = 6) (n = 3), ulcer (n = 1), bleeding (n = 1)
Angrisani (2006)	Observational	Single-center	Italy	Orbera	NA	Emergency BIB removal for balloon rupture and those with early BIB removal for psychological intolerance	175	37.1 (11.6)	54.4 (8.1)	NA	51.7(16.3) at 6 months 27.1(95% CI, 25.01–29.19) at 12 months	Early removal due to rupture (n = 2, 1.1%), due to intolerance (n = 7, 7.8%)
	Observational	Single-center	UK	Orbera	NA	NA	207		57.7 (11.5)	NA		

Table 1 (continued)

• Study (year published)	Design	Setting	Country	Intervention	Inclusion criteria	Exclusion criteria	Total patients, *N*	Age, years mean (S.D)	BMI pre-procedure (S.D)	%TWL	%EWL	Serious adverse events, *N* (%)
Ashrafian (2017)								44.7 (13.0)			14.5 at 6 months 17.6 at 12 months 17.2 at 24 months	Early removal due to intolerance ($n = 8$, 3.8%) Mortality rate 3 (1.4%), 2 within 10 days due to acute gastric perforation secondary to excess vomiting. 1 patient suffered cardiac arrest at 4 weeks postoperatively.
Bozkurt (2012)	Observational	Single-center	Turkey	Orbera	High-risk patients, noncompliant patients, or who refused surgery with BMI ≥ 35 kg/m^2 or patients with BMI ≤ 35 kg/m^2 to integrate medical therapy	Conditions precluding safe endoscopy, esophagitis, large hiatal hernia (> 5 cm), chronic therapy with steroids or nonsteroidal drugs, active peptic ulcer or its previous complications, previous gastric surgery, pregnancy, and inability to maintain regular follow-up	251	34.37	39.11	NA	25.5 at 6 months 15.3 at 12 months	Early removal due to intolerance ($n = 27$, 8.3%)
Courcoulas (2017)	RCT	Multicenter	USA	Orbera	Adults aged 18–65 years, with BMI of ≥ 30 and ≤ 40 kg/m^2, or a history of obesity for at least 2 years with failed conservative weight loss attempts	History of foregut or gastrointestinal (GI) surgery (except uncomplicated cholecystectomy or appendectomy), GI obstruction, adhesive peritonitis, or clinically significant hiatal hernia	160	38.7 (9.4)	35.0	10.2 (6.5) at 6 months 7.6 (7.5) at 12 months	26.5 (95%CI 23.6–29.3) at 6 months 23.2 (95% CI 20.3–26) at 12 months	Early IGB removal ($n = 30$, 18.8%) Severe dehydration ($n = 2$), gastric outlet obstruction ($n = 1$), gastric perforation ($n = 1$), aspiration pneumonia ($n = 1$), severe abdominal cramping ($n = 1$), severe GERD ($n = 1$), esophagitis ($n = 4$)
Crea (2009)	Observational	Single-center	Italy	Orbera	BMI > 30 kg/m^{2}without the criteria for a surgical treatment, superobese patients for reducing perioperative risk, and selection of patients for a gastric restrictive surgery	Absolute contraindications: hiatus hernia (> 5 cm), abnormalities of the pharynx and esophagus, esophageal varices, use of anti-inflammatory or anticoagulant drugs, pregnancy	143	36.2 (9.7)	36.2 (9.7)	14.1(5.7) at 6 months 12.0 (5.6) at 12 months 11.2 (4.6) at 18 months	29.3 (4.8) at 6 months 27.4 (4.7) at 12 months 26.1 (4.9) at 18 months	Early removal due to intolerance ($n = 2$, 1.4%) Balloon migration ($n = 2$), rupture ($n = 1$)

Table 1 (continued)

• Study (year published)	Design	Setting	Country	Intervention	Inclusion criteria	Exclusion criteria	Total patients, *N*	Age, years mean (S.D)	BMI pre-procedure (S.D)	%TWL	%EWL	Serious adverse events, *N* (%)
						and psychiatric disorders. Relative contraindications: esophagitis, ulceration, and acute lesions of the gastric mucous membrane						
Dargent (2015)	RCT	Multicenter	France	Orbera	Age 18–65 years and BMI > 27 kg/m^2	History of gastric surgery, gastric or duodenal ulcer, or active *Helicobacter pylori* infection	101	36.8	34.1 (3.7)	8.0 (1.6) at 6 months 6.5 (1.1) at 12 months 3.3 (1.2) at 24 months	NA	Early removal due to intolerance ($n = 8$)
Dogan (2013)	Observational	Single-center	Turkey	Orbera	BMI 30–35 kg/m^2 with severe obesity-related diseases, BMI ≥ 35–40 kg/m^2 who failed 6-month weight control program, BMI ≥ 50 kg/m^2 with IGB as bridge therapy for bariatric surgery	Hiatal hernia (> 5 cm), or presence of gastrointestinal tract lesions such as inflammatory or cancerous diseases, peptic ulcer or esophageal/fundus varices, or H/o of alcoholism or drug addiction	50	37.9 (10.6)	44.7 (12.4)	9.3 (8.8) at 6 months 6.8 (9.5) at 12 months	NA	No serious adverse events
Farina (2012)	RCT	Single-center	Italy	Orbera	Not defined	Exclusion criteria were diabetes mellitus, systemic, neurological or psychiatric disorders, including history of bulimia or anorexia and drug or alcohol abuse, presence of gastric or duodenal ulcer or *Helicobacter pylori* infection, uncontrolled hypertension (i.e., blood pressure > 145/95 mmHg) or tachycardia (pulse rate > 90	30	36.6 (1.5)	42.3 (1.0)	14.5 (1.2) at 6 months 14.3 (2.7) at 12 months	NA	No serious adverse events

Table 1 (continued)

• Study (year published)	Design	Setting	Country	Intervention	Inclusion criteria	Exclusion criteria	Total patients, *N*	Age, years mean (S.D)	BMI pre-procedure (S.D)	%TWL	%EWL	Serious adverse events, *N* (%)
						beats per minute), glaucoma, cancer, other cardiovascular, endocrine, renal, or hepatic diseases. Pregnancy, lactation, or also childbearing potential because not taking adequate contraceptive pre cautions were exclusion criteria						
Fuller (2013)	RCT	Single-center	Australia	Orbera	Age 18–60 years, with BMI of 30–40 kg/m^2 for a minimum of 2 years and metabolic syndrome, who failed supervised weight reduction programs	Inflammatory, structural, motility, or bleeding disorders of the GI tract, large hiatus hernia (> 5 cm in diameter), prior gastric surgery or insertion of an IGB, or major surgery within previous 3 months, cerebrovascular or cardiopulmonary disease, uncontrolled blood pressure (160/95 mmHg), epilepsy, type 1 diabetes, undiagnosed thyroid disease or hypothyroidism in which the dose of thyroxine replacement had not been stable for at least 3 months, hepatic or renal insufficiency, psychiatric disorder,	31	43.4 (9.4)	36.0 (2.7)	14.2 at 6 months 9.2 at 12 months	50.3 at 6 months 32.7 at 12 months	Early removal due to intolerance 3 (9.7%)

Table 1 (continued)

• Study (year published)	Design	Setting	Country	Intervention	Inclusion criteria	Exclusion criteria	Total patients, *N*	Age, years mean (S.D)	BMI pre-procedure (S.D)	%TWL	%EWL	Serious adverse events, *N* (%)
						pregnancy, alcoholism, drug abuse or patients on prescription or non-prescription medications or supplements with known effects on appetite or weight, or aspirin, NSAIDs, anticoagulants, or other gastric irritants						
Genco (2008)	Observational	Single-center	Italy	Orbera	Age = 18 to 60 years with BMI > 35 or < 35 with at least one comorbidity	Prior gastric surgery, chronic drug use with high risk of gastric bleeding, hiatus hernia > 5 cm and/or GERD with second degree esophagitis with active gastric or duodenal ulcer, endocrine causes for obesity, psychiatric contraindications, pregnancy alcoholism and drug addiction	130	38.0 (10.9)	42.1 (6.5)	NA	33.9 (18.1) at 6 months 21.3 (19.7) at 24 months	No serious adverse events
Genco (2009)	Observational	Single-center	Italy	Orbera	NA	NA	80	40.9 (9.3)	54.1 (2.9)	NA	34.7 (6.1) at 6 months 35.1 (4.8) at 12 months	No serious adverse events
Herve (2005)	Observational	Single-center	France	Orbera	NA	NA	100	34.8	34.0	NA	39.8 at 6 months 26.8 at 18 months	Early removal due to intolerance ($n = 5$, 5%), peptic ulcer ($n = 2$), esophagitis ($n = 5$), dehydration ($n = 5$)
Al Kahtani (2010)	Observational	Single-center	Saudi Arabia	Orbera	NA	Gastrointestinal lesions such as large (> 5 cm) hiatus hernia, grade 3–4 esophagitis, active peptic ulceration, varices, or	173	34.5 (11.6)	46.7 (14.1)	NA	19.6 (21.8) at 6 months 18.0 (25.8) at 12 months	Early removal ($n = 33$, 19.8%)

Table 1 (continued)

• Study (year published)	Design	Setting	Country	Intervention	Inclusion criteria	Exclusion criteria	Total patients, *N*	Age, years mean (S.D)	BMI pre-procedure (S.D)	%TWL	%EWL	Serious adverse events, *N* (%)
						angiodysplasia; and previous bariatric or abdominal surgery, patients on anticoagulants or nonsteroidal anti-inflammatory drugs or definite hormonal or genetic cause for the obese state, malignancy, pregnancy, any documented history of alcoholism, or drug abuse						
Kotzampassi (2012)	Observational	Single-center	Greece	Orbera	Obese patients who refused bariatric surgery or failed to meet the IFSO standards for surgery	Presence of hormonal or genetic cause of obesity; alcohol or drug abuse; malignancy, pregnancy, GI tract lesions, already known or identified at endoscopy, such as a large > 5-cm hiatus hernia; grade C–D esophagitis, peptic ulcer, or esophageal/fundus varices	500	39.4 (11.5)	44.3 (8.4)	NA	43.9 (18.8) at 6 months 42.7 (18.9) at 12 months 27.7 (13.4) at 18 months	Early removal ($n = 26$, 5.2%) (3 wanted surgery, 11 wanted early removal due to satisfaction with results, 8 patients had copious vomiting, 2 pregnancy, 1 ruptured and migrated)
Mui (2010)	Observational	Single-center	China	Orbera	NA	NA	119	37.8 (10)	38.4 (8)	NA	45.1 (35.3) at 6 months 32.9 (48.7) at 12 months	Early removal due to intolerance ($n = 4$, 3.3%)
Nikolic (2011)	Observational	Single-center	Croatia	Orbera	Adults with BMI ≥ 35 kg/m^2 and failure to attain ≥ 10% of initial weight loss with conservative treatments	NA	43	20–60	42.1	NA	BMI < 40 37.0, BMI > 40 27.6 at 6 months BMI < 40 27.8, BMI > 40 37.4 at 12 months	No major adverse events
Sallet (2004)	Observational	Single-center	Brazil	Orbera	NA	NA	483	37.5 (12.4)	38.2 (9.4)	NA	57.4 (26.4) at 6 months	Early removal due to intolerance ($n = 11$, 3.4%), balloon impaction ($n = 2$,

Table 1 (continued)

• Study (year published)	Design	Setting	Country	Intervention	Inclusion criteria	Exclusion criteria	Total patients, *N*	Age, years mean (S.D)	BMI pre-procedure (S.D)	%TWL	%EWL	Serious adverse events, *N* (%)
											50.9 (28.8) at 12 months	0.6%), intestinal obstruction (*n* = 1, 0.3%)

might influence %TWL and %EWL. Type of EBMT (ESG or IGB) had a significant impact on %TWL (p value = 0.0001) and %EWL (p value = 0.0001), with all other covariates held constant. ESG was associated with significantly higher %TWL and %EWL than IGB (Supplement 3: Fig. 1a and b).

Only one ESG study had patients with a mean BMI > 40 [18]; otherwise, the mean BMI for all ESG studies was < 40. A total of 9 IGB studies had patients with a mean BMI > 40. Pooled mean %TWL at 12 months for IGB studies with mean BMI > 40 was 11.03 (95% CI 6.91–15.15) and was not significantly different from studies with BMI < 40 (p value = 0.73). Similarly, pooled mean %EWL at 12 months for IGB studies with BMI > 40 was 28.76 (95% CI 20.01–35.51), similar to BMI < 40 (p value = 0.70) (Fig. 4).

Adverse Events

Adverse events were not uniformly described in the included studies; therefore, the crude incidence of adverse events was calculated (Fig. 4).

ESG Most patients had mild to moderate abdominal pain (50.65%) and nausea (32.31%) post-procedure that was managed with medications. Severe abdominal pain was reported in only 2.20% of patients. In one study [16], only 3 out of 1000 patients required reversal of ESG due to persistent symptoms with an overall incidence of 0.15%. Serious adverse events were rare and included gastrointestinal (GI) bleeding (0.61%), perigastric fluid collection (0.45%), perforation (0.10%), post-procedure fever (0.25%), and pulmonary embolism and DVT (0.10%). Overall, these adverse events were seen in 1.52% of the patients. No mortality associated with ESG was reported in the included studies.

IGB Abdominal pain (32.51%) and nausea (55.09%) were also the most common symptoms reported with IGB placement. Early removal of IGB was approximately 5.92% due to intolerance. Adverse events reported were balloon hyperinflation (0.03%), balloon resting in antrum (0.10%), severe dehydration (0.77%), esophagitis (2.33%), GI bleeding (0.21%), obstruction (0.10%), perforation (0.10%), ulcers (0.24%), and severe GERD (0.17%). Overall these adverse events were seen in 3.97% of the patients. Mortality was reported in 3 patients (0.10%), 2 were due to acute gastric perforation, and 1 patient suffered cardiac arrest at 4 weeks postoperatively.

Discussion

We report the results of a meta-analysis indirectly comparing ESG and IGB for the treatment of obesity. We found that the mean %TWL achieved with ESG and IGB at 12 months was

Table 2 Comparison of endoscopic sleeve gastroplasty and intragastric balloon patient characteristics and weight loss outcomes

	Endoscopic sleeve gastroplasty ($N = 1979$)	Intragastric balloon ($N = 3025$)
Age mean (years)	42.23 (95% CI 40.06–44.39)	39.06 (95%CI 37.49–40.62)
Males (%)	22.52 (95% CI 16.07–30.62)	21.36 (95% CI 16.64–26.99)
BMI	36.08 (95% CI 35.06–37.09)	41.70 (95% CI 38.59–44.80)
%TWL		
6 months	15.34 (95% CI 14.33–16.35)	12.16 (95% CI 10.37–13.95)
12 months	17.51 (95% CI 16.44–18.58)	10.35 (95% CI 08.38–12.32)
18–24 months	17.85 (95% CI 15.85–19.86)	06.89 (95% CI 03.78–10.01)
%EWL		
6 months	55.61 (95% CI 50.28–60.95)	34.83 (95% CI 30.97–38.69)
12 months	60.51 (95%CI 54.39–66.64)	29.65 (95% CI 25.40–33.91)
18–24 months	66.77 (95% CI 57.54–76.00)	23.88 (95% CI 17.41–30.33)

17.51 and 10.35, respectively. Mean %EWL achieved at 12 months was 60.51 with ESG and 29.65 with IGB. The weight loss outcomes for both ESG and IGB surpass the ASGE joint task force defined threshold (> 25 %EWL at 12 months) for a primary obesity intervention to be incorporated into clinical practice.

Excellent weight loss outcomes were seen after ESG. Mean %TWL after ESG at 6-, 12-, and 18- to 24-month follow-up was 15.34, 17.51, and 17.85, respectively. Our results are comparable to a recently published study by Galvao Neto et al. [38] which included a total of 233 ESG patients and showed %TWL of 17.1 at 6 months and 19.7 at 12 months. On indirect comparison to IGB, ESG resulted in significantly superior weight loss compared with IGB placement. The difference in mean %TWL between ESG and IGB was 3.07 at 6 months, 7.33 at 12 months, and 11.51 at 18–24 months. Similarly, the difference in mean %EWL between ESG and IGB at 6, 12, and 18–24 months was 20.80, 30.99, and 43.78, respectively. These results were consistent with the only previous observational study directly comparing ESG and IGB [18].

Weight loss with ESG was durable, %TWL, and %EWL showed a slight increase at 12- and 24-month follow-up as compared to 6 months. Whereas weight loss with IGB decreased at 12-month and 24-month follow-up, suggesting weight regain after removal of the balloon at 6 months. Weight regain is a significant drawback with IGB reported in multiple studies [39, 40]. An adjustable fluid-filled balloon implanted in the stomach for 1 year is currently under investigation in the USA. The extended implantation period can result in superior weight loss at 12 months [41]; however, patients can regain weight after balloon removal. Sequential therapy with a second IGB after the first balloon was removed can also be used to combat weight regain. The durability of weight loss will ultimately depend on the weight loss program and continued maintenance of lifestyle modification [42]. Additionally, weight loss medications can also be used in conjunction with IGB. The use of concurrent pharmacotherapy with IGB did not result in weight regain at 12-month follow-up [27, 43], suggesting that the use of pharmacotherapy can help maintain weight loss after IGB removal.

Many IGB studies had patients with a mean BMI of > 40 or severe obesity. Mean %TWL and %EWL at 12 months in these studies were 11.03 and 28.75, respectively. The ASGE joint task force recommended 5% TWL as an absolute minimum threshold for any nonprimary EBMT such a bridging therapy. IGB surpasses these thresholds and successfully used as a bridge therapy for severely obese patients in many studies [21, 44]. Almost all ESG studies had patients with a mean BMI between 30 and 40. There is limited evidence on the safety and efficacy of bariatric surgery after ESG. LSG can be technically challenging after an ESG, although one small single-center study [45] has reported safe and feasible LSG after ESG. The presence of sutures, anchors, and cinches in the stomach greater curvature can obstruct the surgical field during LSG [45]. However, during ESG, sutures are not applied in the fundus; therefore, if Roux-en Y gastric bypass is a better option after ESG remains to be investigated. For obese patients who do not qualify for bariatric surgery or are nonsurgical candidates, ESG is still an attractive alternative as primary bariatric therapy because of superior and durable weight loss.

ASGE task force recommended that the risk associated with EBMT should equate to a ≤ 5% incidence of serious adverse events (SAE). SAE profile was acceptable for both ESG and IGB. Most of the reported adverse events with ESG and IGB can be classified as mild to moderate adverse events, according to ASGE Quality Task Force recommendations [46]. Mild to moderate abdominal pain was a predominant complaint after ESG, while nausea was a more common occurrence after IGB. Most of these patients were managed conservatively with medications. Approximately 6% of IGB patients underwent early removal of IGB due to intolerance. Whereas, only few ESG patients required reversal of ESG

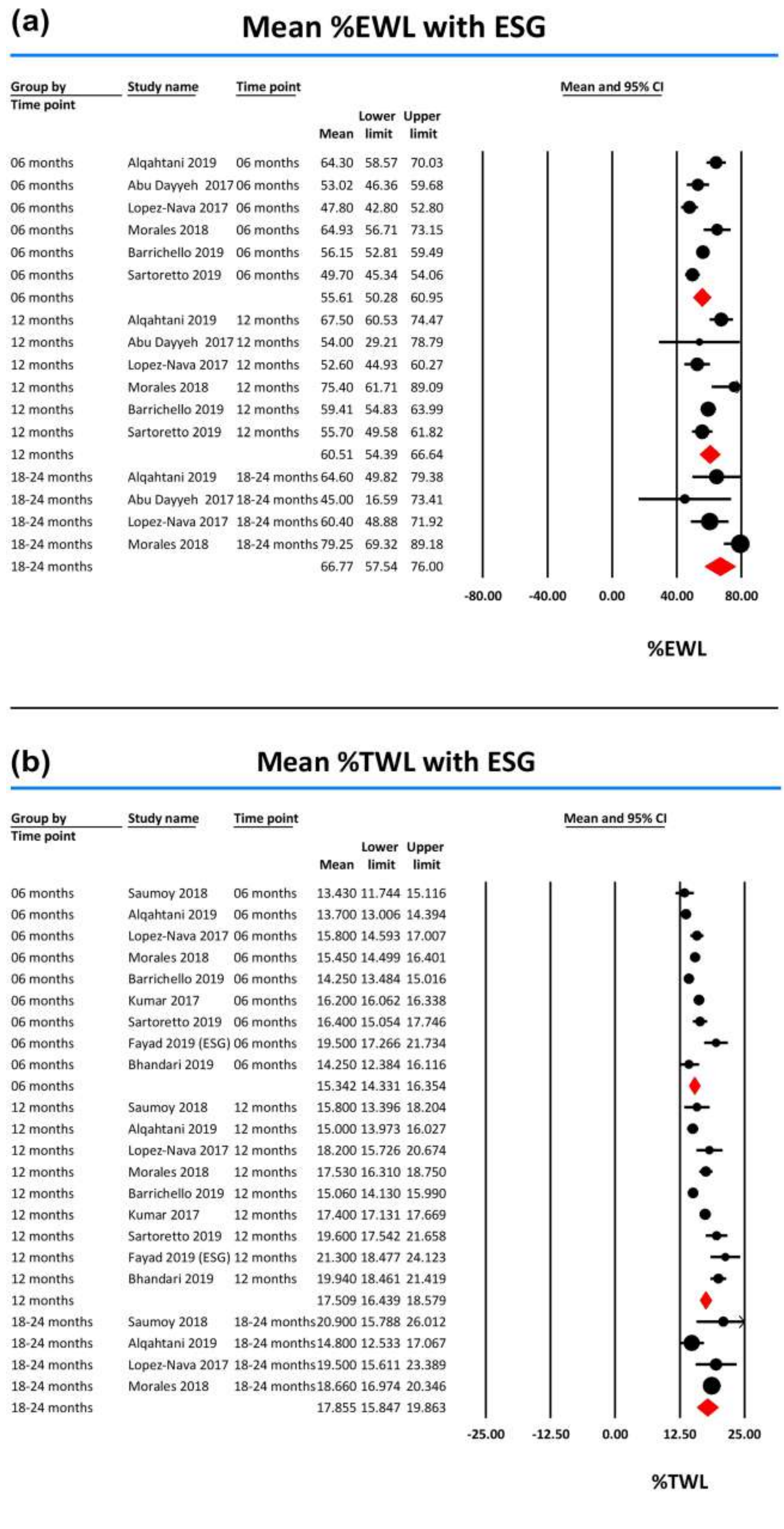

Fig. 2 **a**, **b** Forest plot of studies reporting the percentage of percent total weight loss (%TWL) and percentage of excess weight loss (%EWL) after endoscopic sleeve gastroplasty (ESG)

due to persistent symptoms, suggesting ESG was better tolerated. Lower rates of ESG reversal may be explained by the technically challenging nature of the procedure compared to IGB removal. An adjustable IGB under investigation in the

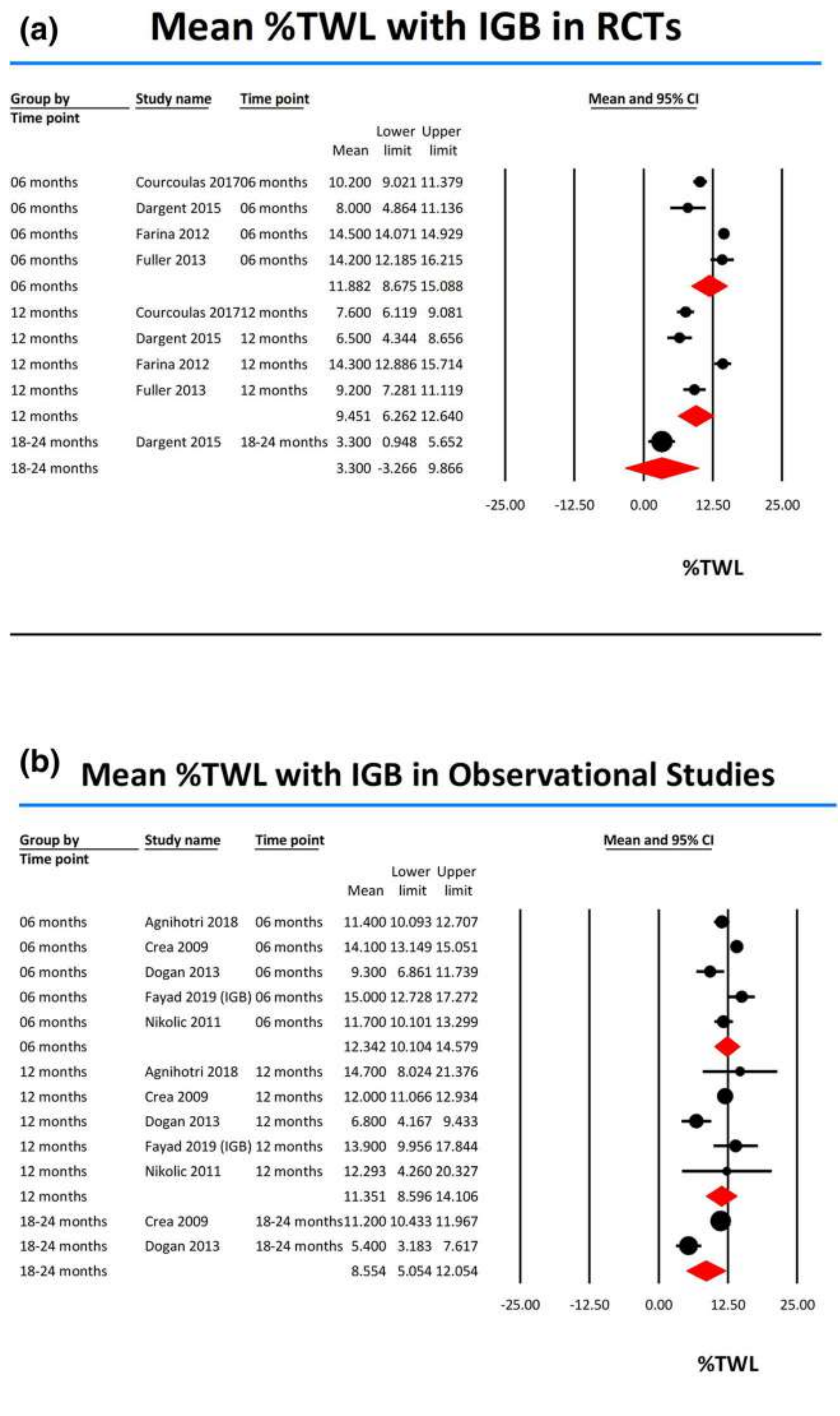

Fig. 3 **a**–**d** Forest plot of studies reporting the percent total weight loss (%TWL) and percentage of excess weight loss (%EWL) after intragastric balloon (IGB)

USA permits intragastric volume adjustment according to patient tolerability and thus may reduce the incidence of early removal. There was no mortality reported in patients with ESG, and the mortality associated with IGB was only 0.1% in the included studies. Despite the recent FDA alerts, IGBs remain a safe endoscopic bariatric treatment. A recent meta-analysis [47] of 15 RCTs including 886 IGBs showed no mortality. In our analysis, mortality in 2 out of the 3 patients was related to gastric perforation [21], underlining the importance of a proper evaluation before placement; adequate periprocedural management of retching, nausea, and vomiting; early and continual vigilance for side effects and urgent intervention upon suspicion of signs preempting perforation; and other serious events [48]. A strategy for appropriate patient selection and close follow-up in a multidisciplinary program should be implemented.

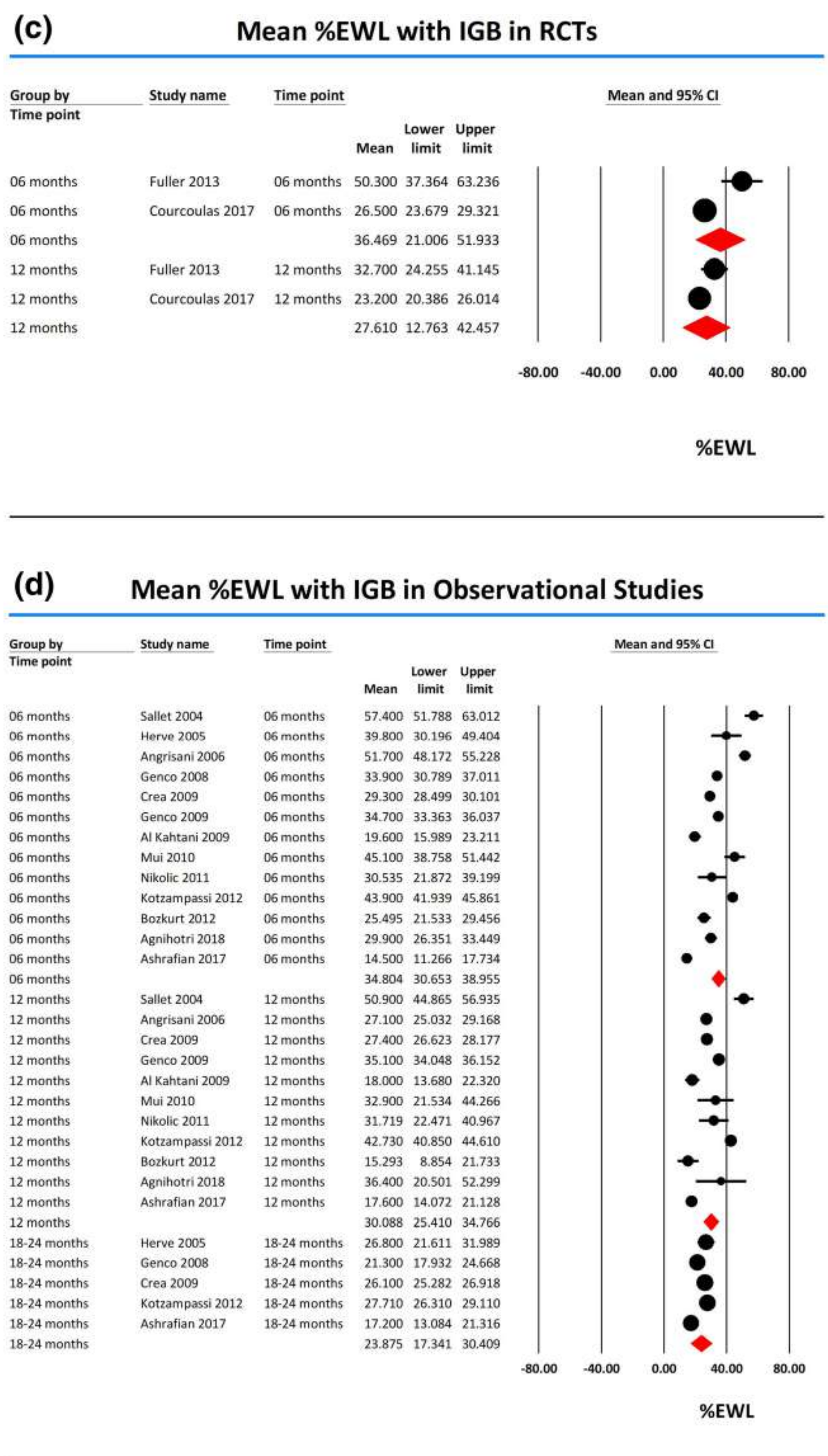

Fig. 3 continued.

IGB is the most well established and readily available EBMT. Whereas, ESG has recently gained popularity and is currently performed at selected centers [49]. ESG is a technically complex procedure as compared to IGB and is associated with a longer learning curve. One study showed that about 38 ESG procedures by a single operator are required to attain efficiency (refining performance to decrease procedure time), while mastery (absence of outliers) was attained after 55 procedures [9]. Standardized ESG training and credentialing methods are required for widespread expansion of the procedure. Both ESG and IGB are mostly self-pay procedures in the USA. The cost of ESG is slightly higher than IGB; however, the superior weight

Fig. 4 Comparison of endoscopic sleeve gastroplasty (ESG) and intragastric balloon (IGB) adverse events

loss may offset the higher cost related to ESG. ESG is a single endoscopic procedure, whereas most IGBs require two procedures (one of IGB insertion and another for removal). An air-filled swallowable balloon requires only one endoscopic procedure for removal but is currently not FDA-approved. Identifying the right patient phenotype and physiology for these procedures will be essential for optimizing outcomes.

We performed a comprehensive systematic review and meta-analysis and analyzed weight loss outcomes up to 24-month follow-up. We included most updated studies from multiple centers with an overall large number of patients. Despite our rigorous criteria, our study has several limitations. The quality of the included studies limits the quality of our systematic review and meta-analysis. Although ESG outcomes were reproducible at centers worldwide, no controlled ESG studies are available. Only 4 IGB studies were RCTs; otherwise, all studies were observational of variable sample size. Nonetheless, the outcomes of the observational IGB studies were consistent with the RCTs. ESG has recently gained momentum, and long-term follow-up data is not available. Reduction in metabolic comorbidities constitutes a promising outcome for EBMTs; however, they were not reported by all studies and were not included in the analysis. Many of the included studies did not clarify the concomitant use of weight loss medications during follow-up. Considerable heterogeneity was seen in our estimates. Differences in patient characteristics were seen although we did control for possible study-level moderators in the meta-regression analysis. Other endoscopic gastroplasty techniques such as primary obesity surgery endoluminal (POSE) and Endomina did not meet the inclusion criteria and were not included. Included IGB studies consisted of only two types of the FDA-approved fluid-filled balloons, while studies with other types of IGBs did not meet the inclusion criteria. Multiple IGB studies were excluded due to less than 12 months of follow-up. However, outcomes for our IGB analysis were consistent with previous IGB meta-analysis [2]. Lack of standardized definition for SAE in included studies also may affect the comparison.

Conclusion In conclusion, ESG and IGB are minimally invasive, safe, and effective endoscopic bariatric procedures for weight loss. ESG achieved superior weight loss as a primary obesity therapy compared to IGB. Based on these studies, weight loss with ESG is durable while weight regain is common following IGB removal. Nevertheless, a variety of approaches are essential to optimally care for this underserved population and there are several factors other than weight loss that should be considered in selecting the ideal therapy to care for individual patients.

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Compliance with Ethical Standards

Conflict of Interest Shailendra Singh, Diogo Turiani Hourneaux de Moura, Ahmad Khan, Mohammad Bilal, Monica Chowdhry, Michele B. Ryan, Ahmad Najdat Bazarbashi declare that they have no conflict of interest. Christopher C Thompson is a consultant for Apollo Endosurgery, USGI medical, Fractyl, Boston Scientific, Medtronic, Olympus, and GI dynamics.

Ethical Approval Statement All procedures performed in included studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Statement Informed consent does not apply.

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