Obesity Surgery
https://doi.org/10.1007/s11695-018-3335-4

REVIEW ARTICLE

The Effectiveness of Endoscopic Gastroplasty for Obesity Treatment According to FDA Thresholds: Systematic Review and Meta-Analysis Based on Randomized Controlled Trials

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Abstract
Endoscopic bariatric therapies (EBTs) are promising alternatives to conventional surgery for obesity. The aim of this study is to compare efficacy and safety through a systematic review and meta-analysis of the endoscopic gastroplasty techniques versus conservative treatment. We searched MEDLINE, EMBASE, Cochrane CENTRAL, Lilacs/Bireme. Randomized controlled trials (RCTs) enrolling obese patients comparing endoscopic gastroplasty to sham or diet/exercise were considered eligible. Among 6014 records, three RCTs were selected for meta-analysis. The total sample was 459 patients (312 EBTs vs 147 control). Mean total body weight loss in the intervention group (IG) was 4.8% higher than the control group (CG) at 12 months ($p = 0.01$). The IG responder rate was 44.31% at 12 months. Therefore, the endoscopic gastroplasty is more effective than conservative therapies but do not achieve FDA thresholds.

Keywords Obesity · Gastroplasty · Endoscopy · Endoluminal therapy · Endoscopic therapy · Endoscopic suture · Systematic review · Meta-analysis

Introduction

Obesity is increasingly becoming one of the world's greatest public health problems, and its prevalence is as high as 36% in the USA [1]. It is estimated that in the USA, US$147–210 billion is spent every year in treating comorbidities associated with obesity. This amount represents approximately 21% of the country's health expenditure [2]. Moreover, obesity is an important risk factor for cardiovascular diseases, particularly acute myocardial infarction and stroke, which were the primary causes of death in 2012, in addition to cancer and bone and joint disease [3]. It is well-known that even modest weight

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Published online: 16 June 2018

loss (5–10%) has significant health benefits, including a reduction in the risk of cardiovascular diseases and diabetes [4].

Bariatric surgery is unquestionably effective for weight loss and also decreases obesity-related morbidity and mortality [5–8]. However, one disadvantage is the non-negligible morbidity and mortality rates related to the procedure [9, 10]. Furthermore, access to bariatric surgery is limited: less than 2% of the patients who have indication for the procedure undergo surgery [11–13]. The reasons for that include high surgical risk and morbidity, cost, access to treatment, and patient preference [11]. Thus, although endoscopic gastroplasty (EG) is also an expensive method and limited to few tertiary centers, it might be appropriate for high-risk patients and for those who refuse surgical approach. In addition, comprehensive programs for the treatment of obesity (such as those for colorectal cancer screening) might facilitate access to EG. In contrast, non-invasive treatments, including lifestyle intervention and medication, are largely ineffective because they have a tendency for long-term weight gain and low rate of sustained weight loss. A majority of patients who receive conservative treatment fail to achieve 5% total weight loss (TWL) in 10 years [14]. Therefore, endoscopic bariatric therapy (EBT) is a convenient alternative because it is less invasive than bariatric surgery and presents potentially more consistent results than conservative treatments [15].

Three endoscopic gastroplasty (EG) techniques have been described: (i) endoscopic sleeve gastroplasty (ESG), in which stomach capacity is reduced by making full-thickness sutures along the greater curvature using the OverStitch endoscopic suturing system (Apollo Endosurgery, Inc., Austin, Texas, USA) [16]; (ii) Primary Obesity Surgery Endolumenal (POSE) procedure, in which the gastric fundus is reduced by making transmural plications using the Incisionless Operating Platform device (USGI Medical, Inc., San Clemente, California, USA) [17, 18]; and (iii) Transoral Endoscopic Vertical Gastroplasty (TOGa®), in which a pouch is created along the lesser curvature using two devices, the TOGa Sleeve Stapler and TOGa Restrictor [19]. According to the US Food and Drug Administration (FDA), the effectiveness thresholds for moderately invasive endoscopic procedures (such as EG) are as follows: %TWL at least 8% greater than that in the sham group at 12 months or ≥ 50% of patients with %TWL > 5% [20].

Descriptive reviews about this topic are available in the literature, but systematic reviews and meta-analyses are lacking [15, 21, 22]. In addition, individual results of randomized studies on EG have not been convincing [17–19]. This study is the first systematic review and meta-analysis to evaluate the effectiveness and safety of this method. The objective of this study is to compare the effectiveness and safety of different EG techniques using full-thickness suture or plication devices and those of sham groups and conservative treatments, including diet and lifestyle changes, based on the effectiveness thresholds determined by FDA.

Methods

Protocol and Registration

This study followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [23]. It was registered in the international PROSPERO database (number CRD42017065604) and was approved by the Research Ethics Committee of University of São Paulo (registration number 292/17).

Eligibility

Only randomized controlled trials (RCTs) were selected, without restrictions on language or publication year. The eligibility criteria were as follows:

1. Participants: patients with obesity [body mass index (BMI), > 30 kg/m^2]
2. Intervention types: EG with full-thickness suture or plication devices
3. Comparison types: sham or diet and lifestyle changes
4. Types of outcomes: absolute weight loss (AWL), percent excess weight loss (%EWL), percent TWL (%TWL), responder rate (%TWL ≥ 5%), and potential complications in 6 and 12 months

The exclusion criteria were studies with follow-up periods < 1 month, those involving revision endoscopic procedures after bariatric surgery, and those involving patients who were overweight (BMI, 25–30 kg/m^2).

Information Sources

Studies were searched on electronic databases, including MEDLINE [PubMed], Embase, Cochrane Central, and LILACS/BIREME. Moreover, a gray search was performed in books, thesis databases, and references from the included studies.

Search

A full search was made up to November 2017 using the largest number of subject-related terms to find the highest possible number of studies.

For the MEDLINE (PubMed) database, we used the following search strategy: [(POSE OR gastroplasty OR gastric plication OR sleeve OR restrictive implant system OR suturing OR gastroplasty OR bariatric* OR gastroplication OR Apollo method OR vertical band gastroplasty OR sewing machine OR gastric reduction OR sleeve gastroplasty OR vertical gastroplasty OR gastric volume reduction OR bariatric surgery) AND (endoscopic OR endoscopy OR transoral* OR

peroral OR endolum*) AND (obese OR obesity OR overweight OR bariatric*)].

Simpler search strategies were used for Embase, Cochrane Central, and LILACS/BIREME databases.

Selection of Studies

Studies were selected by initially analyzing study titles and then the abstracts. The studies were included after evaluating the full text based on the eligibility criteria. Two researchers independently searched and selected the studies. After applying the inclusion and exclusion criteria, the selected studies were evaluated. Divergences about study inclusion were resolved by consensus with a third researcher. An algorithm adapted from PRISMA [23] was used to conduct the search and selection.

Data Extraction and Evaluation

The relevant data from the studies were collected and organized into spreadsheets and then divided according to population characteristics, outcomes related to weight loss, and outcomes related to complications.

The following data were evaluated: study characteristics, study criteria for participant inclusion and exclusion, population characteristics, type of intervention performed considering the device used, and outcomes related to weight loss and complications.

Evaluation of Biases and Quality of Studies

The Jadad quality score was used to measure the studies' risk of bias [24]. The quality of the included studies was evaluated according to GRADE standards using the GRADEpro Guideline Development Tool software (McMaster University, 2015; Evidence Prime, Inc., Ontario, Canada) [25].

Data Analysis

Absolute numbers, means, and standard deviations were used for quantitative data analysis. For studies that did not determine standard deviations, the standard error and confidence interval were estimated using mathematical formulas [26]. Review Manager version 5.3.5 (RevMan 5.3—The Cochrane Collaboration, The Nordic Cochrane Centre, Copenhagen, Denmark) was used to conduct the meta-analysis and develop the forest plot graphs. Comprehensive meta-analysis software version 3 (©2006–2017 Biostat, Inc.) was used for extracting the means and standard deviations of outcomes in the EG group. For continuous variables, the mean difference between the groups was calculated using the mean, standard deviation, and sample size of each group. For dichotomous variables, the risk difference was determined by calculating the number of events and sample size of each group.

Heterogeneity was evaluated using the chi-square test, and funnel plot analysis was performed to identify outlier studies. Heterogeneity values > 50% were considered high. In cases in which it was impossible to correct heterogeneity by excluding the outlier, a random analysis model was changed to a fixed model.

Results

The database search yielded 6014 studies, among which 67 were selected for full-text analysis. From these, three RCTs were included in the qualitative analysis and meta-analysis based on the eligibility criteria (Fig. 1).

The total population of the three included studies comprised 459 patients, including 312 in the intervention group and 147 in the control group. The techniques used were POSE and TOGa. In two of the studies, the control group underwent a sham procedure; in the third study, the control group underwent diet and exercise. With regard to demographic data, the mean age was similar in both groups, with 38.3–44.2 years in the intervention group and 38.5–45.3 years in the control group. Similarly, the mean BMI was similar between the two groups, with 36–36.2 kg/m^2 in the intervention group and 36.2–37 kg/m^2 in the control group. In two studies, the sample comprised patients with grade I or II obesity; the other study comprised patients with grade II or III obesity. The mean duration of the procedure was 39.7–71.0 min (Table 1).

Table 2 shows the detailed bias and quality analysis. In short, all studies received a Jadad score of 3, indicating adequate study quality. The quality of the obtained data was assessed using the GRADE methodology based on the type of evaluated outcome.

% Total Weight Loss (%TWL)

Two studies were included, with a total of 376 patients, including 121 in the control group and 255 in the EG group [17, 18]. The mean %TWL in the EG group was 5.87% (standard deviation (SD), 7.12%). The mean 12-month %TWL difference between the groups was 4.8% (95% CI, 1.1–8.51) and was significantly higher in the intervention group than in the control group ($p = 0.01$) (Fig. 2).

% Excess Weight Loss (%EWL)

All three selected studies evaluated %EWL [17–19]. However, Sullivan et al. [17] did not provide enough information for calculating a standard deviation for each group. Therefore, it was not possible to include that study in the

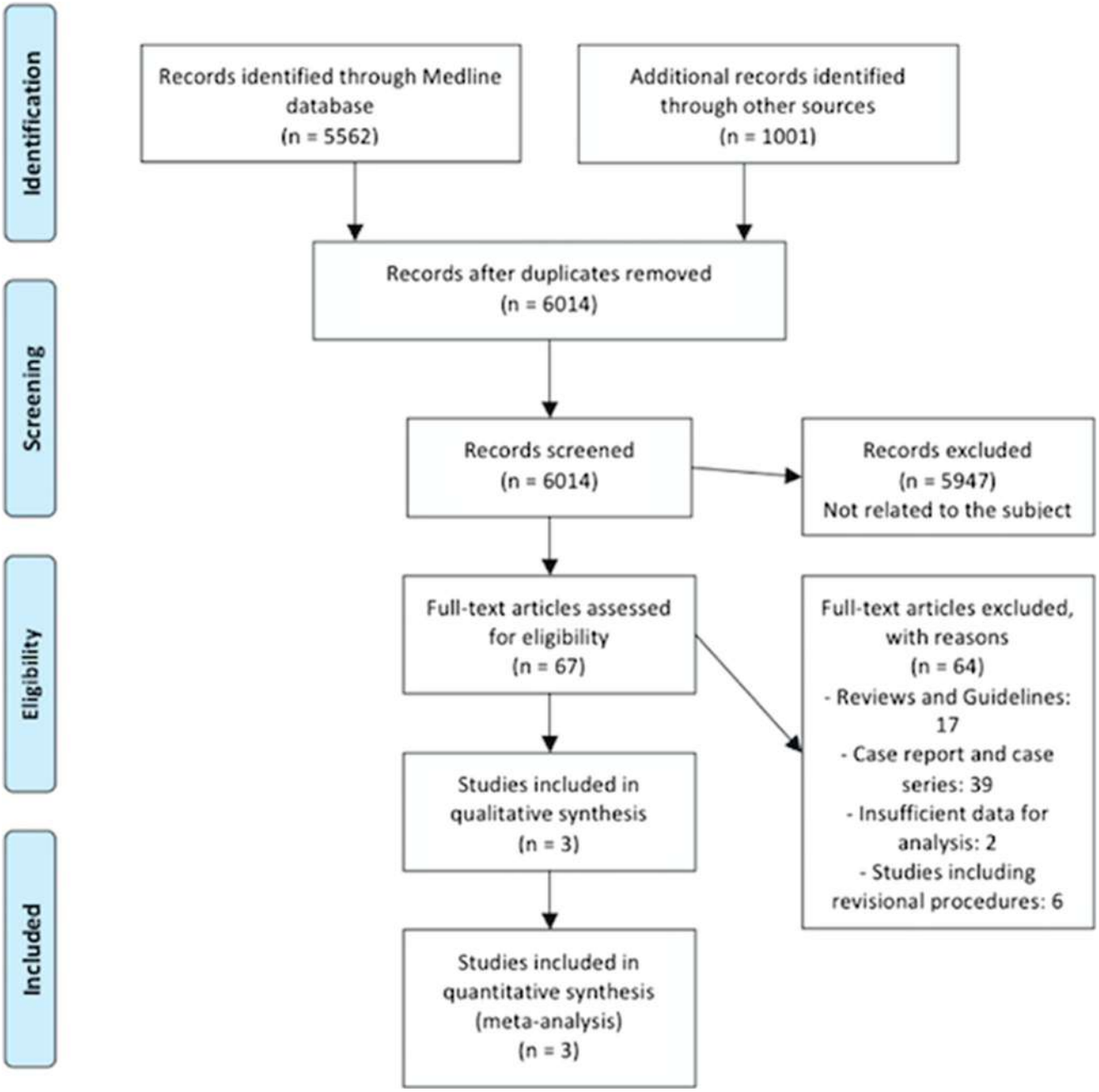

Fig. 1 Flowchart of the study selection (adapted from PRISMA)

meta-analysis. Sullivan et al.'s study presented the difference in %EWL between the groups. In the 6- and 12-month follow-up periods, %EWL difference was 8.7% (95% CI, 3.96–13.4; $p = 0.004$) and 11.8% (95% CI, 6.21–17.4; $p < 0.0001$), respectively, favoring the intervention group compared with the control group.

Therefore, the total sample for our analysis included 127 patients from the other two studies (91 patients in the intervention group and 36 patients in the conservative treatment group) [18, 19]. There was no significant difference between the groups, although the EG group presented higher %EWL than the control group, with a difference of 17.87% between the groups in 6 months (95% CI, − 1.8 to 37.54; $p = 0.07$) and 16.01% in 12 months (95% CI, − 1.48 to 33.5; $p = 0.07$) (Fig. 3). %EWL of patients who underwent EG was 27.06 ± 16.20% at 6 months and 27.34 ± 22.34% at 12 months.

Absolute Weight Loss (AWL)

All the included studies evaluated this outcome [17–19]. However, Sullivan et al. [17] did not provide the data necessary for execution of the meta-analysis. The results from that

Table 1 Population characteristics and interventions performed in the intervention and control groups

Study			
	Miller K, 2017	Sullivan S, 2017	Jonnalagadda, 2012
Technique	POSE	POSE	TOGA
Population	44	332	83
Intervention group (IG)	34	221	57
Control group (CG)	Diet/exercise10	SHAM	SHAM
		111	26
Age	–	–	41 (SD ± 9.5)
IG age	38.3 (SD ± 10.3)	44.2 (SD ± 8.6)	–
CG age	38.5 (SD ± 12.5)	45.3 (SD ± 9.1)	–
BMI (kg/m^2)	36.5 (SD ± 3.4)	–	44.8(SD ± 4.7)
IG BMI (kg/m^2)	36.2 (SD ± 3.3)	36 (SD ± 2.4)	–
CG BMI (kg/m^2)	37.2 (SD ± 3.7)	36.2 (± 2.2)	–
Obesity grade	I and II	I and II	II and III
Procedure time (min)	51.8 (SD ± 14.5)	39.7 (SD ± 12.9)	71
Number of plicatures	13 (SD ± 1.8)	13.5 (10–17)	–

study indicated that patients who underwent EG lost 2.77 kg (95% CI, 1.37–4.18; $p = 0.0001$) and 3.6 kg (95% CI, 1.93–5.28; $p < 0.0001$) more than the control group at 6 and 12 months, respectively.

The meta-analysis comprised the same 127 patients included in the %EWL analysis. The EG group showed greater weight loss than the control group: 7.05 and 4.99 kg at 6 and 12 months, respectively (Fig. 4). Considering the intervention group alone, the mean AWL was 13.25 ± 6.81 and 12.65 ± 9.20 kg at 6 and 12 months, respectively.

Responder Rate

The responder rate was evaluated in 376 patients from two studies (255 patients in the intervention group and 121 in the conservative treatment group). The results are presented as the percentage of patients with %TWL ≥ 5% [17, 18].

The responder rate was 44.31% in the EG group and was 21% higher than that in the control group after 12 months (95% CI, 12–30; $p < 0.0001$).

Adverse Events

The lack of uniformity in describing adverse events did not allow us to perform meta-analysis on this variable.

The total rate of adverse events in the EG group was 52.9–77.8%, of which 5.0–5.2% of the events were severe. Sullivan et al. [17] reported the following severe adverse events: one case of extragastric bleeding, which required laparoscopy and transfusion of blood products; one case of liver abscess, which required hospitalization, intravenous antibiotic therapy, and radiologically guided drainage; and persistent nausea, vomiting, and abdominal pain. In contrast, the severe adverse events reported by Jonnalagadda et al. [19] included one case of esophageal perforation and two cases of gastrointestinal bleeding.

Discussion

The present study is the first to conduct a systematic review and meta-analysis of RCTs on ESG using the PRISMA methodology [23]. Our analysis indicated that ESG was more effective than conservative treatment (sham or dietary and lifestyle changes). However, the safety profile of ESG could not be evaluated.

The meta-analysis indicated that the mean %TWL in EG was 5.87% in 12 months. This value is 4.8% higher than that of conservative treatment. According to FDA, the effectiveness of moderately invasive procedures for obesity management, including EG, is confirmed in cases in which these procedures have a %TWL of > 8% than the sham group after a 12-month follow-up or ≥ 50% of patients have a %TWL of > 5% [20]. It is also known that %TWL, especially > 10%, is correlated with an improvement in the incidence of comorbidities due to obesity [27, 28]. The American Society for Metabolic and Bariatric Surgery (ASMBS) considers %TWL to be the choice parameter to evaluate weight loss [29]. Therefore, although EG was shown to be more effective than conservative treatment, the former failed to reach the effectiveness thresholds established by FDA for the most important weight loss evaluation parameter, according to ASMBS.

With respect to %EWL, the EG group showed a greater loss than the conservative treatment group. However, there was no significant difference in %EWL between the two

Table 2 Evaluation of bias risk and evidence quality. a JADAD Scale. b GRADE System

Tab. 2a

Study	JADAD					
	Randomization	Appropriate Randomization	Blinding	Appropriate Blinding	Withdrawals and Dropouts Description	TOTAL
Sullivan S *et al* (2017)						
	YES	NO	YES	NO	YES	3
Miller K *et al* (2017)						
	YES	NO	YES	NO	YES	3
Jonnalagadda SS *et al* (2012)						
	YES	NO	YES	NO	YES	3

Tab.2b

Outcomes	Certainty
Total Body Weight Loss (12 months)	⊕⊕⊕○ MODERATE
Excess Weight Loss (6 months)	⊕○○○ VERY LOW
Excess Weight Loss (12 months)	⊕○○○ VERY LOW
Absolute Weight Loss (6 months)	⊕⊕○○ LOW
Absolute Weight Loss (12 months)	⊕⊕○○ LOW
Responder Rate (TBWL >5%) (12 months)	⊕⊕⊕○ MODERATE

groups in 6 and 12 months. The mean %EWLs in the intervention group were 27.06 and 27.34% for the evaluated periods, respectively. According to a joint task force of ASMBS and the American Society for Gastrointestinal Endoscopy, EBTs for obesity management should achieve a %EWL of at least 25% in 12 months and a significant %EWL difference from the control group of at least 15% [30].

With regard to absolute weight loss, the difference was significantly greater in the EG group than in the control group, with a mean loss of 13.25 and 12.65 kg in the former group in 6 and 12 months, respectively. We emphasize that absolute weight loss is an imprecise measurement because it tends to be overvalued in patients who are more obese and undervalued in patients who are less obese. Therefore, this measurement is not considered by bariatric surgery societies, including ASMBS and the Brazilian Association for Studies on Obesity and Metabolic Syndrome [29, 31].

The responder rate at 12 months was 21% greater in the EG group than in the conservative treatment group. A little less than 45% of patients who underwent EG reached a %TWL value > 5% at 12 months. This value does not reach the FDA-established thresholds of at least 50% of patients in that period [20].

Endoscopic sleeve gastroplasty (ESG) with the OverStitch Endoscopic Suturing System was not included in this systematic review and meta-analysis because no RCTs used this technique and only case series are available. A non-comparative multicenter study evaluated 248 patients in a 24-month follow-up period and found a %TWL of 18.6% (95% CI, 15.7–21.5), and 53% of the sample presented a %TWL of ≥ 10% and a 2% incidence of severe adverse events associated with the procedure [16]. However, we emphasize that this study was a case series and there was a large patient loss during follow-up: only 37% of patients (92/248) completed the 2-

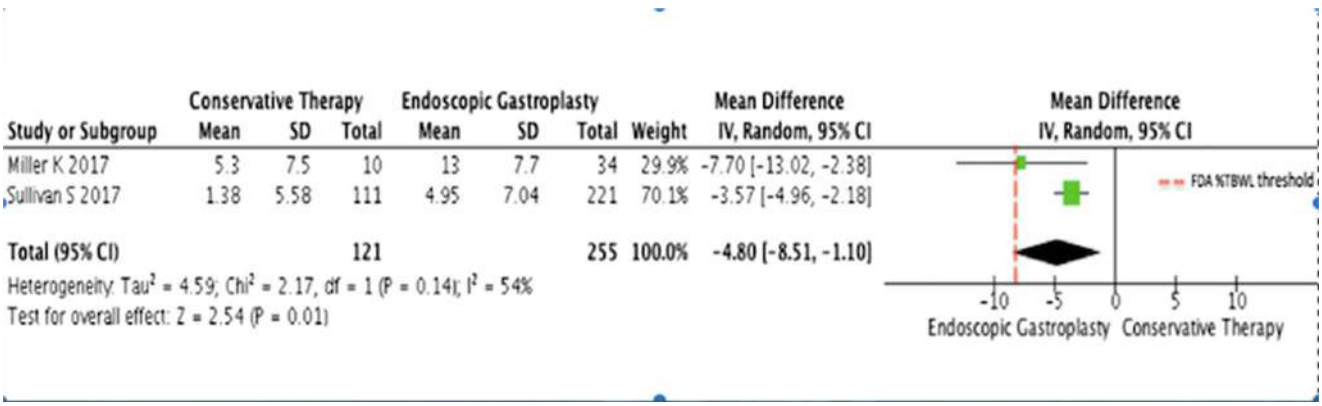

Fig. 2 %TWL comparison after 12 months between endoscopic gastroplasty and conservative treatment. FDA threshold: %TWL at least 8% higher than that in the sham group

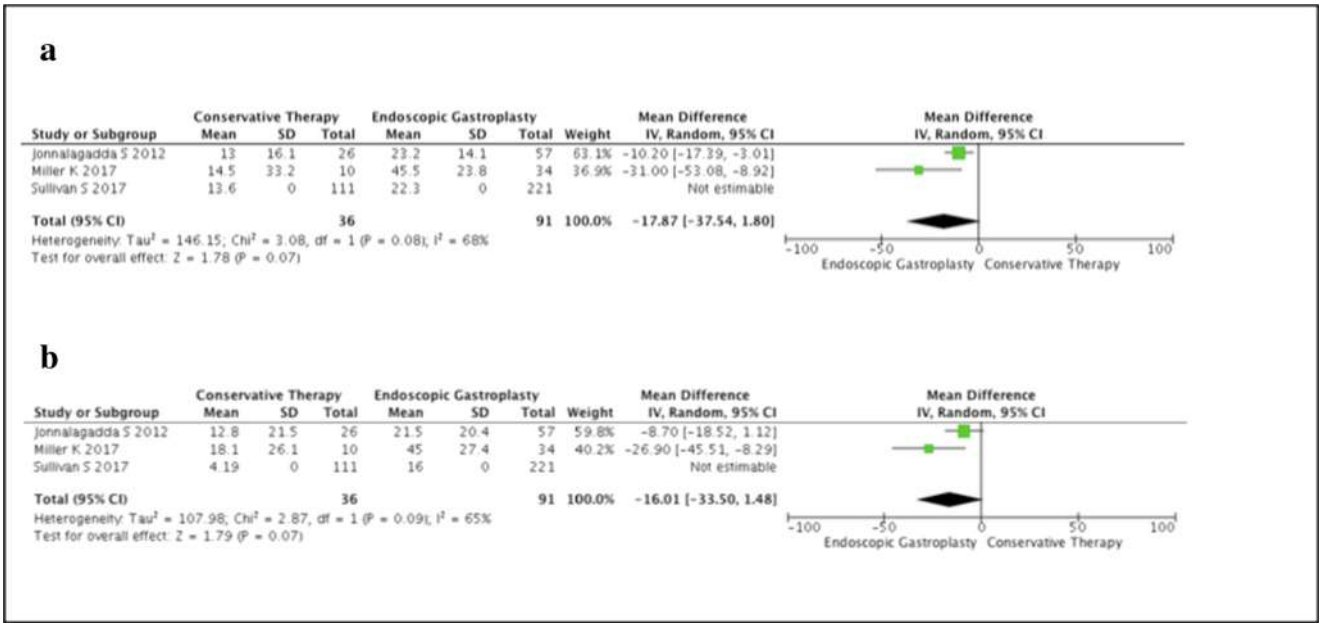

Fig. 3 Comparison of the percent excess weight loss between endoscopic gastroplasty and conservative treatment. **a** Results at 6 and **b** 12 months

year follow-up. A review presented the results of nine case series, but it was neither a systematic review nor a meta-analysis [32]. Therefore, RCTs involving ESG are needed because the design of studies using the OverStitch Endoscopic Suturing System does not allow an accurate assessment of the effectiveness and safety of the procedure.

It is known that bariatric surgery is the most effective modality for weight loss therapy. However, this procedure is associated with a non-negligible incidence of complications. EG is anatomically analogue to laparoscopic sleeve gastrectomy (LSG). A recent systematic review assessed LSG efficacy and safety. %EWL at 12 months, 18 months, 24 months, and 5 years were 67.3% (± 11.2%), 67.5% (± 6.9%), 70.9% (± 10.4%), and 69.4% (± 7.5%). Regarding safety, the mean surgery-related complication rate was 8.7% (± 7.5%) [13]. Another meta-analysis of RCTs showed a complication rate for LSG of 13% (CI 95% 0.7–44%) [33]. In the same article, data from observational studies presented mean %EWL at 3 years of 59.42% (CI 95%, 48.05–70.78%) [33]. Such complication rates are particularly distinct from the data we found concerning AE rates following EG. However, the most common AEs reported in EG articles (nausea, vomiting and abdominal pain) are not mentioned in studies describing LSG which probably justifies the aforementioned difference. A retrospective cohort compared endoscopic sleeve gastroplasty (ESG), LSG, and laparoscopic adjustable gastric banding (LAGB) [34]. LSG presented higher %TWL at 12 months than ESG and LAGB (29.28 vs 17.57 vs 13.30%, $p < 0.001$); ESG is the safest procedure with the shortest length of stay (0.34 ± 0.73 days vs 3.09 ± 1.47 (LSG) vs 1.66 ± 3.07

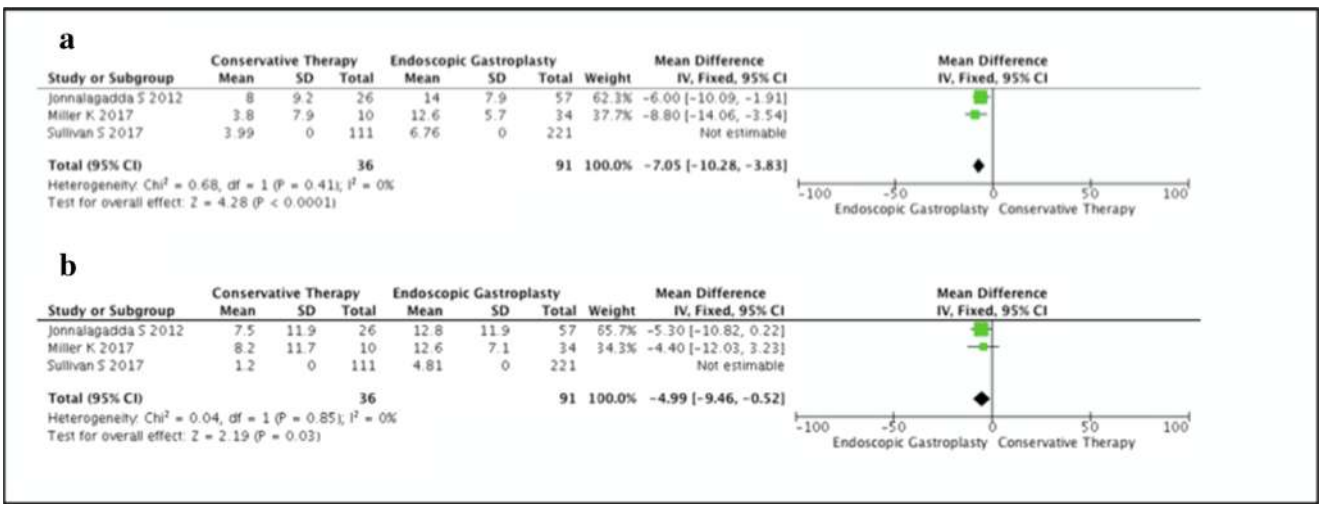

Fig. 4 Comparison of absolute weight loss between endoscopic gastroplasty and conservative treatment. **a** Results at 6 and **b** 12 months

(LAGB); $p < 0.01$) and has the lowest AEs rate (2.2 vs 9.17% (LSG) vs 8.96% (LAGB), $p < 0.05$) [34]. Thus, LSG is more effective but EG appears to be the safest method. The classic indication for bariatric surgery is BMI ≥ 40 kg/m^2 or BMI ≥ 35% kg/m^2 associated with obesity-related comorbidities [35–37]. However, < 2% of patients for whom bariatric surgery is indicated undergo the procedure. The reasons for that include high surgical risk and morbidity, cost, access to treatment, and patient preference [11, 12]. Therefore, EG becomes a good option for such patients who for various reasons cannot undergo bariatric surgery. Therefore, it is fundamental that studies comparing both therapeutic methods be conducted. This would help determine the endoscopic method's effectiveness and safety profile.

One of the difficulties in conducting this study was obtaining complete data from the selected studies. For example, although the study by Sullivan et al. [17] had the largest sample, it did not include relevant data, such as the standard deviations of %EWL and absolute weight loss, which would have been fundamental for performing the meta-analysis. The lack of uniformity in describing adverse events should also be emphasized. It was impossible for us to obtain detailed data about the incidence of total or severe adverse events that would enable a meta-analysis. Current literature, however, provide some information concerning AEs. A review of eight cases series about ESG, totaling 279 patients, showed that major complications occurred in three studies: [1] perigastric leak (1 in 91 cases); [2] perigastric inflammatory collection (1/25); [3] pulmonary embolism (1/25); [4] pneumoperitoneum and pneumothorax (1/25); [5] intraoperative gastric bleeding (1/20) [32]. The most common minor complications were abdominal pain and nausea with incidence ranging from 27.47 to 80% and 38.46 to 80%, respectively [32]. Among the EBTs, the intragastric balloon (IGB) is the most commonly employed technique. The American Society for Gastrointestinal Endoscopy (ASGE) performed a recent meta-analysis showing that the most frequent adverse events were abdominal pain and nausea, occurring in 33.7 and 29% of patients, respectively. Early removal occurred in 7.5%. Serious adverse events were rare, with an incidence of balloon migration and perforation of 1.4 and 0.1%, respectively [38]. Another limitation of the present study is that the same analysis grouped procedures with different accessories (for suture and plication). This could create biases and heterogeneity, but we emphasize that the rationale of both devices is the same: the apposition of the total thickness of tissue to reduce gastric volume. Furthermore, the impact of heterogeneity was reduced using a random model. The small number of studies included in the meta-analysis is compensated by the large total sample (312 patients in the EG group and 147 in the conservative treatment group) and by the selection of studies only with high methodological quality and bias control, as shown in Table 2.

Finally, we emphasize this study's importance for being the first systematic review and meta-analysis on endoscopic gastroplasty, rigorously following the norms of PRISMA [23] and selecting only RCTs with high-quality methodology.

Conclusion

Endoscopic gastroplasty is more effective than conservative treatments in the primary management of obesity, but it does not reach FDA's effectiveness thresholds, and its safety cannot be evaluated from the data found in the current literature. New RCTs are needed for an adequate evaluation of effectiveness and safety results of ESG in the primary management of obesity.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Ethical Approval Statement All procedures performed in 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 Does not apply.

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