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Surgery for Obesity and Related Diseases 12 (2016) 420–429

SURGERY FOR OBESITY AND RELATED DISEASES

Review article

Effectiveness of intragastric balloon for obesity: A systematic review and meta-analysis based on randomized control trials

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Received August 19, 2015; accepted October 16, 2015

Abstract

Background: Obesity has become a worldwide epidemic, and many methods are currently used to reduce obesity. This systematic review shows the effectiveness of the intragastric balloon (IGB) method compared to the sham/diet (s/d) method.

Objective: To demonstrate the effectiveness of the IGB method compared to the s/d method.

Setting: Hospital das Clinicas da Universidade de São Paulo, Brazil, Public Hospital.

Methods: After searching MEDLINE, Embase, Cochrane, Lilacs, Scopus, and CINAHL, only enrolled randomized control trials comparing IGB/diet with s/d were analyzed. For qualitative analysis, 12 studies were selected, and 9 of these were acceptable for quantitative analysis.

Results: The IGB/diet is more effective than s/d when comparing body mass index (BMI) loss with a mean difference of 1.1 kg/m^2 by the Student's t test and 1.41 kg/m^2 by the meta-analysis, with significant differences in both. It is also more effective in weight loss (WL), with a mean difference of 2 kg by the Student's t test and 3.55 kg by the meta-analysis. In the qualitative analysis of % excess WL (%EWL), the mean %EWL is 14.0% in favor of the IGB group compared to the s/d group by the Student's t test; however, no significant difference was found between these groups by quantitative analysis.

Conclusion: Based on randomized control trial data alone, IGB >400 mL is more effective than sham/diet in achieving BMI loss, WL, and %EWL. (Surg Obes Relat Dis 2016;12:420–429.)

Keywords: Obesity; Intragastric balloon; Diet; Randomized

Introduction

It is estimated that somewhere between 147 to 210 billion USD are spent annually to treat co-morbidities associated with obesity in the United States, accounting for about 21% of health expenditures in the United States [1].

All authors were involved in writing the paper and had final approval of the submitted and published versions.

Violeta B. Popov and Cristopher Thompson: Both helped us with the English language and data reviews.

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http://dx.doi.org/10.1016/j.soard.2015.10.077

That obesity is associated with metabolic conditions, such as type 2 diabetes, hypertension, and osteoarthritis, is now a well-established fact [2]. It is also well established that a small weight loss of 5–10% is associated with significant health benefits, including a reduction in risk factors for cardiovascular disease and diabetes [3].

Currently, treatment for patients with severe or morbid obesity requires a multidisciplinary approach, with medical support along with dietary treatment and psychological support. A surgical approach is restricted to patients with BMI >40 kg/m^2 who have failed conservative management. A significant proportion of patients do not respond to medical therapy but are unable to or do not qualify for bariatric surgery. For this group, the insertion of an intragastric balloon (IGB) as a gastric volume reduction procedure is an attractive concept [4]. Preoperative treatment of extremely obese patients with the temporary placement of an IGB in association with dietary restriction has been proposed to reduce the risk of complications of surgical procedures [5].

Intragastric devices have been used to promote weight reduction for a while. At the end of the 1990s, several prospective controlled studies reported that the devices in use at the time – the Garren-Edwards® gastric bubble (American-Edwards Laboratories), the Ballobes® (DOT ApS), and the Taylor® (Limited Dunlop) IGB – had no significant effect as an adjunct device for weight reduction in obese patients [6–9].

The reasons for these results might have been the small balloon volume (220 mL for Garren-Edwards and 400 mL for Ballobes) and the weak mechanical effect from the cylinder type in the stomach wall. In addition, these devices have a high complication rate (gastric erosion: 26%; gastric ulcer: 14%; Mallory-Weiss tears: 11%) [7,8].

The second-generation of IGBs currently in use have undergone significant modifications, leading to improved efficacy and safety. The updated devices have been evaluated in multiple studies, and they have been found to be effective in promoting short-term weight loss (WL) and improvements in co-morbidities [8,9]. IGBs should be used as part of multidisciplinary weight loss programs, which continues after removal of the IGB to maintain the weight reduction [10].

The IGB filled with a fluid is the most commonly used; there are models that inflate with air, but no studies have shown that WL and mean percentage excess WL (%EWL) were significantly different between the 2 types of IGBs [6].

Clinical experience has shown a low rate of adverse events [11–13]. Some of the absolute contraindications to IGB use include abnormalities of the pharynx and esophagus, previous gastric surgery, esophageal varices, bulky hiatus hernia, nonsteroidal anti-inflammatory drug use or use of anticoagulants, pregnancy, and psychiatric disorders. Relative contraindications are esophagitis, ulceration, and acute injuries of the gastric mucosa. Some of the IGB complications are prolonged contact of the mucosa with balloon and IGB migration, which may result in esophageal and intestinal obstruction [14].

Various studies have been conducted in animals and humans to determine the optimal IGB volume; a minimum filling volume of 400 mL was found to be effective in achieving weight loss [15–17].

Ghrelin is an orexigenic peptide that is synthesized in the fundus of the stomach, intestines, pancreas, pituitary, and fat tissue [18,19]. Hypothetically, IGBs may potentiate the meal-induced ghrelin suppression and prevent the preprandial rise by delaying the gastric emptying, resulting in a prolonged stay of nutrients in the stomach and a delayed release of food into the intestines. However, to date, significant differences in hormone levels have not been found [20–22].

Objectives

The purpose of this systematic review and meta-analysis is to compare the efficacy of IGB/diet versus sham/diet (s/d) for the treatment of obesity in randomized control trials (RCT).

Protocol and registration

This systematic review of the literature was conducted in accordance with the PRISMA recommendations.

The review was registered on the PROSPERO international database under number CRD42015020875.

Eligibility criteria

a) Types of studies: RCT were searched and targeted for a later selection process. No language or publication dates restrictions were imposed.
b) Types of participants: Patients with body mass index (BMI) >27.
c) Types of intervention: Study group: use of IGB >400 mL/diet; controls: sham/diet.
d) Types of outcome measures: The main outcomes measures were %EWL, BMI, and WL.

Information sources

Searching electronic databases identified studies and scanning reference lists of articles. No limits were applied for language. MEDLINE, Embase, Cochrane, LILACS, Scopus, and CINAHL databases were reviewed. The last search was run on May 21, 2015.

Search

The search is in the supplementary material.

Study selection

Two reviewers performed eligibility assessment and selected screened records independently in an un-blinded, standardized manner. Disagreements between the reviewers were resolved by consensus. To summarize the study selection processes, an adapted PRISMA flow diagram was used.

Data collection process

The method of data extraction from each included study consisted of filling out information sheets after the paper was read. A Scottish Intercollegiate Guidelines Network-based checklist was gathered from www.sign.ac.uk. Relevant data were then extracted from each included study using a standardized extraction form. One review author extracted data from the included studies, and a second author checked the extracted data. Disagreements were resolved by discussion between the 2 review authors.

Data items

The selected articles included patients with BMI >27 and included studies using IGB with volume >400 mL (air and liquid) compared with s/d. The results extracted were % EWL, BMI, and WL.

Risk of bias in individual studies

To verify the validity of eligible studies, 2 reviewers, who worked independently and with adequate reliability, measured the risk of bias using the Jadad scale for randomized trials and the Scottish Intercollegiate Guidelines Network checklist. The topics evaluated by the Jadad scale included randomization, double blinding, and description of losses. A critical evaluation of selected works must present a note ≥ 3 out of a maximum 5 points. This information was applied subsequently in the data synthesis.

Planned methods of analysis

The analysis was performed using the Review Manager (RevMan, Cochrane, Copenhagen, Denmark) 5.3 software obtained from the website of the Cochrane Informatics & Knowledge Management Department. The analysis consisted of computing the risk differences of continuous variables using a random-effects model and providing the respective forest and funnel plots. Data on risk differences and 95% confidence intervals for each outcome were calculated using the Mantel-Haenszel test, and inconsistency (heterogeneity) was qualified and reported using the chi-squared (χ^2) method and the Higgins method, termed I^2. The advantages of the Higgins method are that it does not depend on the number of studies and is accompanied by an uncertainty interval. To assess the results of studies that do not provide the variance, we assumed that it presents a normal distribution and used a sampling variance from the Student's t test.

Risk of bias across studies

To evaluate the relation between sample size and effect size, a graphical method was used (forest plots) for each outcome. Risks of publication bias for outcomes across studies were plotted (funnel plots) and identified (outliers detection) along with I^2 quantitative analysis.

Results

Study selection

In the search, 3,151 articles were found and 32 were selected; 20 were excluded because 4 did not have a diet group, 5 were not RCT, 6 used IGB volumes that were lower than 400 mL, 3 used the same patients as other included study, one was a series of cases, and one was a review.

In summary, 12 articles were selected, and 3 studies were ineligible for quantitative synthesis because the data was without standard deviation; 9 were included in our quantitative and qualitative synthesis (Fig. 1). A summary of the characteristics of the included studies is shown in Table 1.

Risk of bias within studies

Through a systematic approach with defined criteria, the risk of bias was assessed. The data from each selected study are shown in Table 2.

Results of individual studies

Table 3 shows the results regarding BMI, WL, and % EWL.

Ponce et al., 2014 [23]: This study included 326 patients with BMI between 30 and 40, co-morbidities, and failure in WL programs. Treatment with IGB (800–900 mL) in 187 patients were compared to s/d in 139 patients for 24 to 48 weeks. The results showed a significant increase ($P < .05$) in %EWL in the IGB group (27.9 $\pm$ 21.3%) compared to the s/d group (12.3% $\pm$ 22.1).

Mathus-Vliegen et al., 2014 [4]: This study included 40 patients with BMI >32 and failure in WL programs and compared treatment with IGB (500 mL) in 19 patients with s/d in 21 patients for 13 to 26 weeks. The results showed there is no difference ($P > .05$) between the final BMI when comparing the IGB patients (38.5 $\pm$ 4.9) with the s/d patients (39.4 $\pm$ 7.2) and that there is a significant reduction of WL in the IGB group (8.1 kg) compared to the s/d group (3.2 kg).

Ponce et al., 2013 [20]: This study included 30 patients with BMI between 30 and 40 and compared treatment with IGB (900 mL) in 21 patients with s/d in 9 patients for 24 to 48 hours. The results indicated no significant increase in

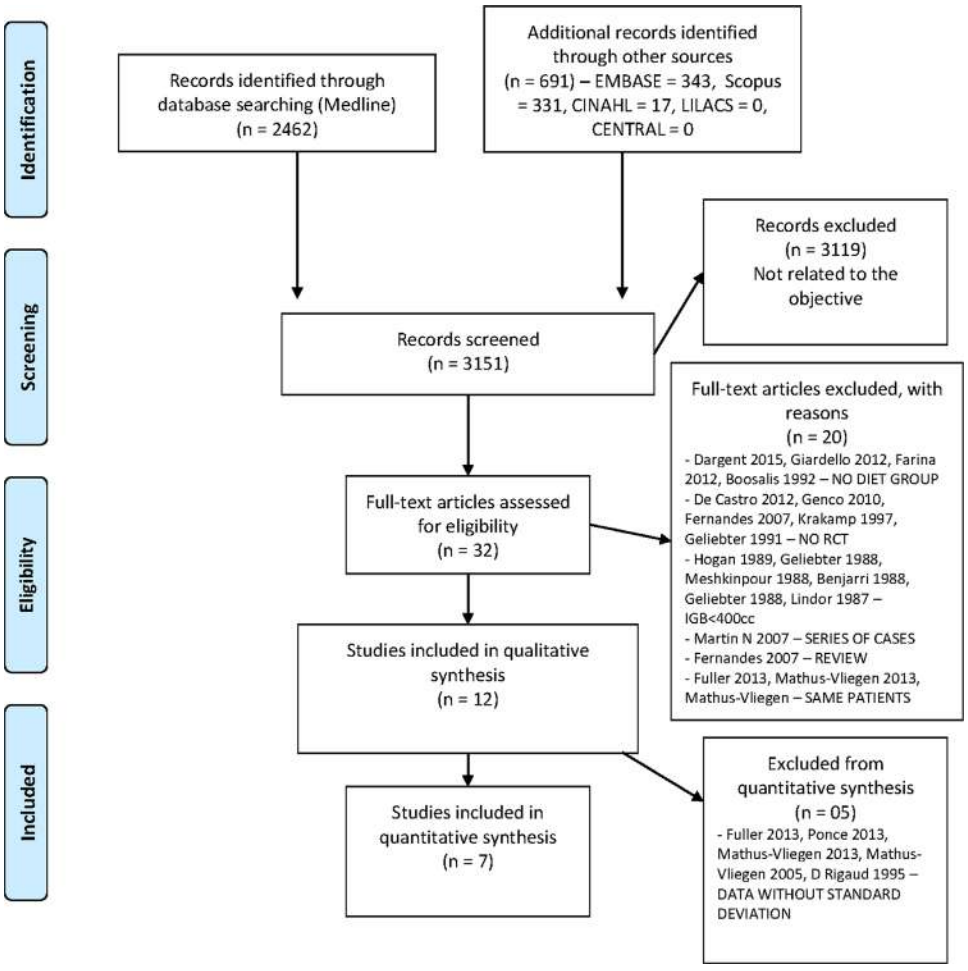

Fig. 1. Search strategy. RCT, randomized control trial; IGB, intragastric balloon. *Adapted from:* Moher D, Liberati A, Tetzlaff J, Altman DG; The PRISMA Group. Preferred Reporting Items for Systemic Reviews and Meta-Analyses: The PRISMA Statement. 2009.

%EWL between the IGB group (31.8%) and the s/d group (18.3%).

Fuller et al., 2013 [19]: This study included 66 patients with BMI between 30 and 40 and compared treatment with IGB (450–700 mL) in 31 patients with treatment with s/d in 35 patients for 24 to 48 weeks. The results showed a significant reduction ($P > .05$) in WL in the IGB group (14.2%) compared to the s/d group (4.8%).

Lee et al., 2012 [24]: This study included 18 patients with BMI >27 with failures in WL programs and compared treatment with IGB (500 mL) in 8 patients with s/d in 10 patients for 24 weeks. The results showed no significant difference in the final BMI between the IGB group (28.7 ± 8.1) and the s/d group (31.6 ± 9.5).

Martinez-Brocca et al., 2007 [22]: This study included 22 patients with obesity and surgical treatment indication and compared the use of IGB (600 mL) in 11 patients with treatment of s/d in 11 patients during 16 weeks. The results showed that was no difference in final weight in the IGB group (131.1 ± 32.6) compared to the s/d group (129.9 ± 25.6) and that there is no difference in the final BMI between the IGB group (45.7 ± 9.7) and the s/d group (48.3 ± 7.8).

Genco et al., 2006 [25]: This study included 32 patients with obesity and surgical treatment indication and compared the use of IGB (500 mL) in 16 patients with s/d in 16 patients for 12 weeks. The results indicated that there was no significant difference ($P < .05$) for %EWL when comparing the IGB group (34.0 ± 4.8%) to the s/d group (2.1 ± 1.0%) and that there was a significant increase in the loss of BMI ($P < .05$) in the IGB group (5.8 ± .5) compared to the s/d group (.4 ± .2).

Mathus-Vliegen et al., 2003 [26]: This study included 28 patients with a BMI of 32 and failure in weight loss programs and compared treatment with IGB (500 mL) in 11 patients with s/d in 17 patients for 13 to 26 weeks. The results indicated that there is a significantly ($P < .05$) less reduction of WL in the IGB group (112.5 ± 21.8) compared to the s/d group (117.2 ± 21.5).

Mathus-Vliegen et al., 2002 [27]: This study included 43 patients with BMI >32 and failures in WL programs and compared treatment with IGB (500 mL) in 20 patients

Table 1
Summary of included studies

Study	Study design	Comparing	Patients included in the analysis	Median age	Intragastric balloon	Inclusion criteria	Exclusion criteria	Follow up	Outcomes
Ponce et al. [23]	RCT Multicenter	Dual balloon × Sham	326 IGB: 187 Sham: 139	IGB: 43.8 ± 9.5 Sham: 44 ± 10.2	ReShape Duo Intragastric balloon (800–900 mL)	Age: 21–60 30 < BMI < 40 Obesity co-morbid Failed weight loss program Consent	Gastrointestinal disease	24–48 weeks	%EWL BMI WL Nausea and vomiting
Mathus-Vliegen et al. [4]	RCT	IGB × Sham	40 IGB: 19 Sham: 21	41.5 ± 10.7	Bioenterics (500 mL saline)	Age >18 3 month stabile BMI >32 Failed weight loss Consent	Gastrointestinal disease	13–26 weeks	BMI WL Grelin
Ponce et al. [20]	RCT Multicenter	Dual balloon × Sham	30 IGB: 21 Sham: 9	IGB: 39.9 ± 9.1 Sham: 45.3 ± 6.3	ReShape Duo Intragastric balloon (900 mL)	30 < BMI < 40 Previous endoscopy Term consent	Peptic ulcer, gastric masses Hiatal hernia >2 cm Patulous pyloric channel, erosion, esophagitis, varices, angiectasis Barrets, esophageal strictures	24–48 weeks	%EWL BMI WL
Fuller et al. [19]	RCT	IGB × Diet	66 IGB: 31 Sham: 35	N/A	Orbera (450–700 mL)	Age; 18–60 30 < BMI < 40 (2 years) Consent Failed weight loss program Metabolic syndrome	Gastrointestinal disease Major surgery (3 months) Cerebrovascular or cardiovascular disease, epilepsy, hepatic or renal insufficiency, phisiatric disorder, NSAID agents, anticoagulant, alcoholism, drugs	24–48 weeks	WL Hormones
Lee et al. [24]	RCT	IGB × Sham	18 IGB: 8 Sham: 10	IGB: 43 ± 19.75 Sham: 47 ± 15.00	500 mL	Age: 21–65 NASH BMI >27 Failed weight loss	Gastrointestinal disease Steroids, anticoagulants, anti-inflammatory alcoholism, drugs Prior intestinal surgery	24 weeks	BMI Liver hystologic
Martinez-Brocca et al. [22]	RCT	IGB × Sham	22 IGB: 11 Sham: 11	IGB: 34.8 ± 10.8 Sham: 37.7 ± 8.8	600 mL	National Institute of Health criteria and national guidelines for obesity surgery	Gastrointestinal disease Steroids, anticoagulants, anti-inflammatory drugs for weight loss Antidepressant Neuroleptics Persistent HP infection	16 weeks	WL BMI Hormones Satiety

Genco et al. [25]	RCT	IGB × Sham	32 IGB: 16 Sham: 16	IGB: 36.2 ± 5.2 Sham: 36.3 ± 5.9	Bioenterics (500 mL saline)	National Institute of Health criteria and national guidelines for obesity surgery	Gastrointestinal disease drugs for weight loss alcoholism, drugs	12 weeks	%EWL BMI Epigastric pain Nauseas and vomiting
Mathus-Vliegen et al. [26]	RCT	IGB × Sham	28 IGB: 11 Sham: 17	40.9 ± 11.2	Bioenterics (500 mL saline)	Age >18 3 month stabile BMI >32 Failed weight loss Consent	Gastrointestinal disease Major surgery Steroids, anticoagulants, anti-inflammatory Poor physical conditions	13–26 weeks	Gastroesophageal reflux Nauseas and vomiting Pirose WL
Mathus-Vliegen et al. [27]	RCT	IGB × Sham	43 IGB: 20 Sham: 23	41.4	Bioenterics (500 mL saline)	Age >18 3 month stabile BMI >32 Failed weight loss Consent	Hormonal or genetic cause for obesity Gastrointestinal disease Steroids, anticoagulants, anti-inflammatory	13 weeks	WL BMI Gastroesophageal reflux
Mathus-Vliegen et al. [28]	RCT	IGB × Sham	17 IGB: 8 Sham: 9	IGB: 32.1 ± 2.06 Sham: 33.4 ± 2.23	Air balloon (500 mL)	Super morbid obese (BMI >50 or weight at least 150 kg)	History of peptic ulcer disease or prior gastric surgery	16 weeks	Gastroesophageal reflux WL
Rigaud et al. [29]	RCT	IGB × Sham	20 IGB: 11 Sham: 9	IGB: 41.8 ± 3.1 Sham: 42.1 ± 3.3	Air balloon (480–500 mL)	IMC >40 At least 2 complications of obesity	Gastrointestinal disease Recent myocardial infarction Psychiatric diseases Alcoholism	16 weeks	WL
Mathus-Vliegen et al. [30]	RCT	IGB × Sham	27 IGB: 14 Sham: 13	33.9 (24–51)	Air balloon (475 mL)	BMI >50 20 < Age < 55 Failed weight loss Obesity >5 years Failure of all usual medical and behavioral	Gastrointestinal disease Endocrine disorders Several renal or liver disease Recent infarction Pregnancy or lactation	17 weeks	%EWL WL BMI

BMI = Body mass index; EWL = excess weight loss; HP = helicobacter pylori; IGB = intragastric balloon; N/A = not available; NASH = nonalcoholic steatohepatitis; NSAID = nonsteroidal anti-inflammatory drug; RCT = randomized control trial; WL = weight loss.

Table 2
Quality measures of the analyzed studies – Scottish Intercollegiate Guidelines Network (SIGN) and Jadad Scale – Bias measures

Study	Sign	Jadad
Ponce et al. [23]	HIGH	5
Mathus-Vliegen et al. [4]	ACCEPTABLE	3
Fuller et al. [19]	ACCEPTABLE	3
Ponce et al. [20]	HIGH	5
Lee et al. [24]	ACCEPTABLE	3
Martinez-Brocca et al. [22]	HIGH	5
Genco et al. [25]	HIGH	5
Mathus-Vliegen et al. [26]	HIGH	5
Mathus-Vliegen et al. [27]	HIGH	5
Mathus-Vliegen et al. [28]	HIGH	5
Mathus-Vliegen et al. [30]	HIGH	5
Rigaud et al. [29]	HIGH	5

with s/d in 23 patients for 13 weeks. The results showed no significant reduction ($P < .05$) for the final BMI in the IGB group (38.4 ± 1.12) compared to the s/d group (39.8 ± 1.52) and that there was no significant reduction for the final weight in the IGB group (111.0 ± 4.63) compared to the s/d group (114.7 ± 4.54) either.

Mathus-Vliegen et al., 1996 [28]: This study included 17 patients with BMI >50, or at least 150 kg, and compared treatment with IGB (500 mL) in 8 patients with s/d treatment in 9 patients for 16 weeks. The results indicated there is no difference in the final weight of the IGB group in comparison with the s/d group (129.8 kg).

Rigaud et al., 1995 [29]: This study included 20 patients with BMI >40 and at least 2 complications associated with obesity and compared treatment with IGB (480 to 500 mL) in 11 patients with s/d in 9 patients for 16 weeks. The results showed there is greater weight loss in the s/d (9.1 kg) group compared to the IGB (8.6 kg) group.

Mathus-Vliegen et al., 1990 [30]: This study included 27 patients with a higher BMI of 50, failed WL medication and behavioral change, and obesity for >5 years and compared treatment with IGB (475 mL) in 14 patients and treatment with s/d in 13 patients for 17 weeks. The results showed that there is no significant difference ($P > .05$) for %EWL in the treatment with IGB (52.3 ± 13.7%) compared to s/d (57.6 ± 20.7%).

Of the 12 studies selected, only 3 showed no statistical difference in the results with respect to BMI, WL, and/or % EWL. The explanations for this could be that Martinez-Brocca et al. [22] and Mathus-Vliegen et al. [27] may not have shown statistical differences between the groups due to exhaustive periodic assessment of dietetic habits. Also, Ponce et al. [20] may be restricted due to their small sample size.

Synthesis of results

BMI loss

The studies that evaluated BMI totaled 538 patients [4,20,22–25,27,30].

Table 3
Results regarding BMI, WL, and %EWL

Study	Initial BMI	Final BMI/loss	Initial weight	%EWL	Final weight/loss
Ponce et al. [23]	T: 35.3 ± 3.6 C: 35.4 ± 2.6	T: 2.7 ± 1.9 C: 1.3 ± 2.3	T: 209.2 ± 25.8 C: 213.2 ± 25.5	T: 27.9 ± 21.3 C: 12.3 ± 22.1	T: 7.6 ± 5.5% C: 3.6 ± 6.3%
Mathus-Vliegen et al. [4]	T: 43.2 ± 7.1 C: 43.0 ± 5.5	T: 38.5 ± 4.9 C: 39.4 ± 7.2	T: 122.5 ± 19 C: 124 ± 21.1	N/A	T: 8.1 kg (7.8%) C: 3.2 kg (3.4%)
Ponce et al. [20]	T: 34.7 ± 2.6 C: 35.6 ± 2.0	T: 18.3% C: 14.6%	T: 100.0 ± 11.6 C: 96.9 ± 10.7 kg	T: 31.8 C: 18.3	T: 8.4% C: 7.5%
Fuller et al. [19]	Mean 36 kg/m^2	N/A	N/A	N/A	T: 14.2% C: 4.8%
Lee et al. [24]	T: 30.3 ± 5.7 C: 32.4 ± 9.1	T: 28.7 ± 8.1 C: 31.6 ± 9.5	N/A	N/A	N/A
Martinez-Brocca et al. [22]	T: 50.2 ± 9.6 C: 51.3 ± 6.1	T: 45.7 ± 9.7 C: 48.3 ± 7.8	T: 143.8 ± 31.2 C: 138.8 ± 24.5	N/A	T: 131.1 ± 32.6 C: 129.9 ± 25.6 (Total)
Genco et al. [25]	T: 43.9 ± 1.1 C: 43.6 ± 1.8	T: 8.0 ± 2.6\5.8 ± .5 C: 43.1 ± 2.8\.4 ± .2	T: 43.5 ± 12.9 C: 42.9 ± 13.2	T: 34.0 ± 4.8 C: 2.1 ± 1	N/A
Mathus-Vliegen et al. [26]	T: 44.0 ± 7.8 C: 46.8 ± 5.4	N/A	T: 124.3 ± 23 C: 124.7 ± 16.6	T: 11.2 C: 12.9	T: 112.5 ± 21.8 C: 117.2 ± 21.5
Mathus-Vliegen et al. [27]	T: 43 ± 1.26 C: 43.6 ± 1.58	T: 38.4 ± 1.12 C: 39.8 ± 1.52	T: 124 ± 4.83 C: 125.9 ± 4.72	N/A	T: 111 ± 4.63 C: 114.7 ± 4.54
Mathus-Vliegen et al. [28]	T: 53.6 ± 1.75 C: 173.5 ± 4.73	N/A	T: 176.2 ± 6.43 C: 173.5 ± 4.37	N/A	Mean 129.8 (108.2–161.6)
Rigaud et al. [29]	T: 45.4 ± 3.3 C: 42.8 ± 3.2	N/A	T: 128.7 ± 6.3 C: 121.1 ± 13.3	N/A	T: 8.6 kg C: 9.1 kg
Mathus-Vliegen et al. [30]	54.6 ± 5.9	T: 11.5 ± 2.7 C: 12.4 ± 4.6	172 ± 19.8	T: 52.3 ± 13.7 C: 57.6 ± 20.7	T: 36.3 ± 10.8 C: 39.8 ± 16.4

BMI = Body mass index; C = control; %EWL = percentage of excess weight loss; N/A = not available; T = therapeutic; WL = weight loss.

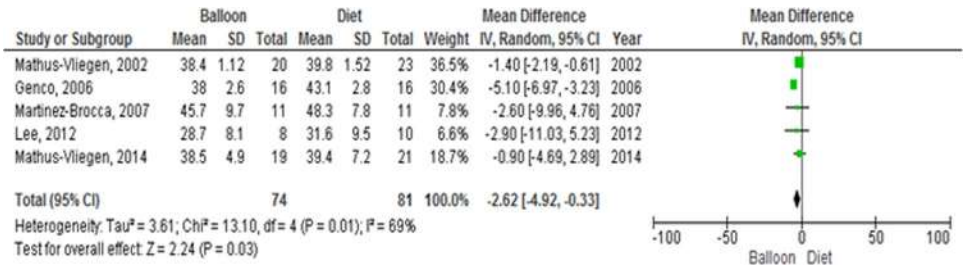

Fig. 2. Comparing BMI loss. BMI, body mass index; SD, standard deviation; CI, confidence interval.

The mean percentage reduction of BMI obtained (n = 538) with the IGB (n = 296) is 5.21 ± 2.96 compared to the s/d group (n = 242) 4.1 ± 3.62; therefore, there is a significant decrease (P < .05) by the Student's t test in BMI of 1.1.

Meta-analyzing the results of BMI – excluding studies that did not provide the average of standard deviations in both groups [20,23,30] – also demonstrates a significant reduction of 2.62 (95% CI 4.92 to .33) in BMI in patients treated with IGB compared with s/d. The P value was < .00001, indicating statistical significance; however, significant heterogeneity was detected within this comparison (χ^2 = 13.10, df = 4 [P = .01], and I^2 = 69%) (Fig. 2). Sensitivity analysis, through a funnel plot, identified that one study differed from others (Fig. 3). Exclusion of one study [25] decreased the statistical heterogeneity to 0% and did not affect the findings in favor of the IGB group.

In the new pooled analysis, BMI loss is greater in the IGB/diet group than the s/d group (mean difference = -1.41, 95% confidence interval [CI] = -2.17 to -.64), P value was .0003, I^2 = 0%. IGB treatment led to greater reduction in BMI compared s/d.

Weight loss

The studies that evaluated WL totaled 553 patients [4,20,22,23,26–30].

The average WL achieved in treatment of these patients (n = 553) within the IGB group (n = 302) was 12.86 ± 16.25 kg compared to the s/d group (n = 251) with 14.86 ± 13.72 kg; therefore, there was a significant reduction (P < .05) by the Student's t test in weight loss of 2.00 kg.

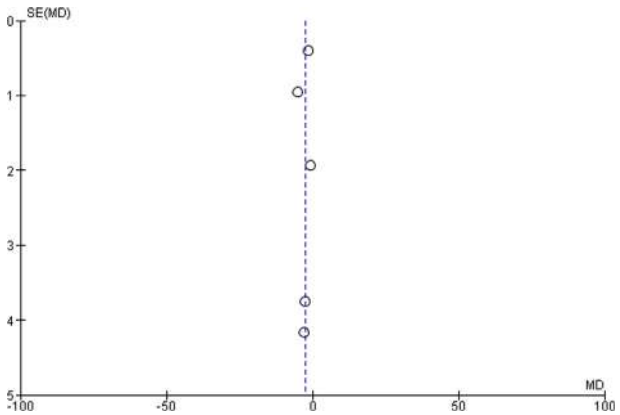

Fig. 3. Distribution of BMI loss. BMI, body mass index; SE, standard error; MD, mean difference.

For the meta-analyzing, we excluded 5 studies [4,20,23,29,30], as they did not provide standard deviations in both groups. The pooled mean difference of weight loss between the IGB group (n = 50) and the s/d group (n = 60) was 3.55 kg (95% CI -6.20 to -.90), P value was .009, I^2 = 0% greater with IGB (Fig. 4).

%EWL

The studies that evaluated %EWL totaled 415 patients [20,23,25,30].

The mean %EWL obtained in the treatment of these patients (n = 415) with the IGB group (n = 238) is 36.5 ± 10.8% compared with the s/d group (n = 177) 22.5 ± 24.2%, showing a significant increase (P < .05) of 14.0% by the Student's t test.

The meta-analysis of the results of %EWL included 4 studies [20,23,25,30]. One trial did not provide SD and was not included in the meta-analysis [20]. This study demonstrated benefit in favor of the s/d, as seen in Fig. 5, although significant heterogeneity was detected within this comparison (χ^2 = 29.55, df = 2, and I^2 = 93%). Sensitivity analysis, through a funnel plot, identified that one study differed from the others [25], as seen in Fig. 6.

In the new pooled analysis, there was no significant increase (-.89 to 31, 63 - P > .05) in the %EWL in patients treated with IGB compared to s/d.

Discussion

More than a third of American adults are obese [2]. Obesity is associated with an increased risk of cardiovascular mortality, accounting for about 2.5 million preventable deaths each year [2,3,5]. There is an urgent need to address the obesity epidemic to reduce the complications associated with this disease.

Lifestyle modification is recommended as the first step to treat obesity. However, this leads to a modest decrease in weight [2,9,14]. Despite its proven effectiveness, it is estimated that <1% of obese individuals who fit the inclusion criteria for bariatric surgery opt for this procedure [12,26]. The explanation for this is probably multifactorial,

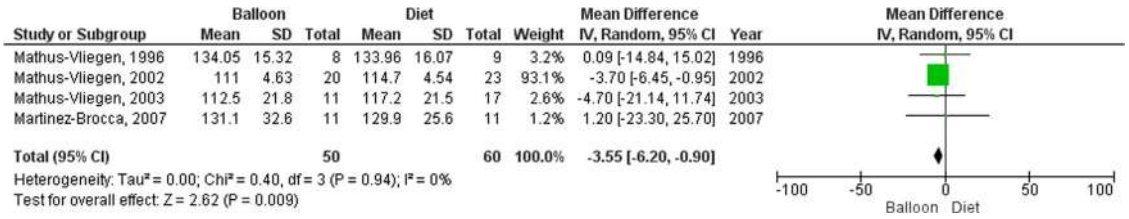

Fig. 4. Comparing weight loss. SD, standard deviation; CI, confidence interval.

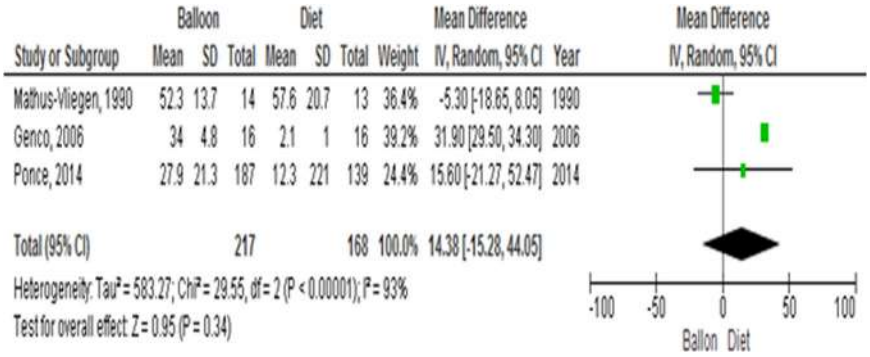

Fig. 5. Comparing % excess weight loss. SD, standard deviation; CI, confidence interval.

including high surgical costs, patient preference, access to care, and the morbidity and mortality associated with surgery. IGB before bariatric surgery in super-obese was associated with a less operative time, conversion rate, and hospitalization time [31].

There is a need for less invasive weight loss interventions, such as IGBs.

This systematic review and meta-analysis showed that IGB therapy in combination with diet alone was more effective than diet alone for weight loss. The quantitative analysis showed statistically significant differences in favor of IGB group for %EWL, though in the qualitative analysis there were no significant differences due to a significant loss of studies in this analysis.

Recently, Abu Dayyeh et al. [32] reviewed bariatric endoscopic therapies, including IGBs. That study pooled data from cases, case-controls, and nonrandomized and randomized trials, losing the characteristic of an adequate systematic review. The fundamental element of high quality evidence from randomized clinical trials is comparison or control.

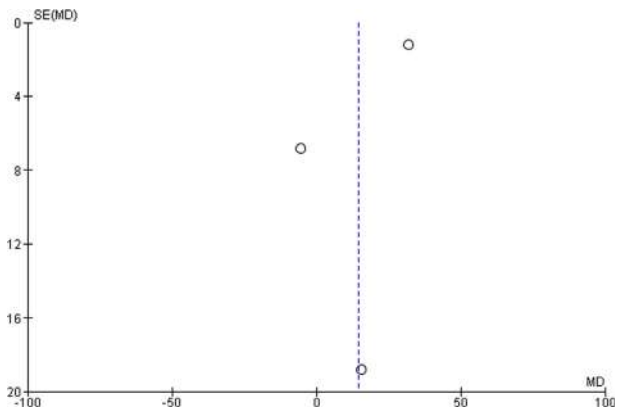

Fig. 6. Distribution of % excess weight loss. SE, standard error; MD, mean difference.

Limitations

As with any systematic review, even with the careful use of only RCTs, this review has some limitations. The main limitation comes from the variation of the BMI for patients whose BMI ranged between 27 and 50.

Another limitation is the variation in IGB usage follow-up, which range from 13 to 24 weeks.

Considering the IGB was typically used for 6 months, most studies evaluated the weight loss after 4 months, which could affect the final results.

Conclusion

Based on RCT data alone, IGB >400 mL is more effective than s/d in achieving BMI loss, WL, and %EWL.

Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.soard.2015.10.077.

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