Influence of the Elipse Intragastric Balloon on Obesity and Metabolic Profile

A Systematic Review and Meta-Analysis

Daryl Ramai, MD, MScBR, Jameel Singh, MD,† Babu P. Mohan, MD,‡ Ogenetega Madedor, MD,§ Olivia W. Brooks, BS,*|| Mohamed Barakat, MD,¶ Andrew Ofosu, MD, MPH,# Shahab R. Khan, MBBS,** Saurabh Chandan, MD,†† Banreet Dhindsa, MD,‡‡ Amaninder Dhaliwal, MD,§§ Antonio Facciorusso, MD,|||| Stephanie McDonough, BS,‡ and Douglas G. Adler, MD, FACG, AGAF, FASGE‡*

Background: Intragastric balloons (IGBs) have been used to bridge the obesity treatment gap with the benefits of being minimally invasive but still required endoscopy. The Elipse IGB is a swallowable balloon that is spontaneously excreted at ~16 weeks. However, studies are limited by small sample sizes. The authors aim to assess clinically relevant endpoints, namely weight loss outcomes, metabolic profile, balloon tolerability, and adverse events.

Methods: A literature search was performed from several databases from inception to July 2020. The pooled means and proportions of our data were analyzed using a random effects model.

Results: Seven studies involving 2152 patients met our eligibility criteria and were included. The mean baseline body mass index ranged from 32.1 to 38.6. The pooled mean difference (MD) in body mass index was 0.88 [confidence interval (CI): 0.58-1.18, $I^2 = 98\%$]. Total body weight loss was 12% (CI: 10.1-14.3, $I^2 = 94\%$) and excess body weight loss was 49.1% (CI: 30.6-67.5, $I^2 = 97\%$). The MD in waist circumference was 0.89 (CI: 0.72-1.05, $I^2 = 53\%$). MD in triglyceride level was 0.66 (CI: 0.21-1.1, $I^2 = 96\%$). Pooled early deflation rate was 1.8% (CI: 0.6-5.1, $I^2 = 74\%$). Our study also showed that the Elipse balloon was associated with less adverse events when compared with other IGBs.

Conclusions: This meta-analysis demonstrates that the Elipse intragastric balloon is a safe, effective, and tolerable device for weight loss and obesity with a minimal side effect profile.

Key Words: intragastric balloon, Elipse balloon, endoscopic bariatric therapy, obesity, weight loss

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From the *Department of Internal Medicine; ¶Division of Gastroenterology, The Brooklyn Hospital Center, Brooklyn; †Department of Internal Medicine, Mathers Hospital, Port Jefferson, NY; ‡Division of Gastroenterology and Hepatology, University of Utah School of Medicine, Salt Lake City, UT; §Department of Medicine, Spectrum Health Hospital/Michigan State University, Grand Rapids, MI; ||St. George's University School of Medicine, Grenada, WI; #Division of Gastroenterology, Stanford University, Stanford, CA; **Division of Gastroenterology, Rush University Medical Center, Chicago, Il; ††Division of Gastroenterology and Hepatology, CHI Health Creighton University Medical Center; ‡‡Department of Gastroenterology and Hepatology, University of Nebraska Medical Center, Omaha, NE; §§Division of Gastroenterology, Moffitt Cancer Center, University of South Florida, Tampa, FL; and ||||Section of Gastroenterology, Department of Medical Sciences, University of Foggia, Foggia, Italy.

D.R.: conception and design. D.R., J.S., O.M.: study search, review, and selection. D.R., J.S., O.B., S.K., S.C., B.D.: data collection and synthesis. D.R., B.P.M.: statistical analysis of data and interpretation of results. D.R., J.S.: drafted the manuscript. M.B., A.O., A.D., A.F., D.G.A.: revised the manuscript for intellectual content. All authors: critical revision of the article for important intellectual content and final approval of the article.

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Address correspondence to: Douglas G. Adler, MD, FACG, AGAF, FASGE, Medicine, Department of Gastroenterology and Hepatology, University of Utah School of Medicine, Huntsman Cancer Center, 30N 1900E 4R118, Salt Lake City, Utah 84132 (e-mail: douglas.adler@hsc.utah.edu).

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Bariatric surgery is an effective method for treating obesity that is resistant to lifestyle modifications and pharmacotherapy. Bariatric surgery results in improvement or remission of many obesity-related comorbid conditions, as

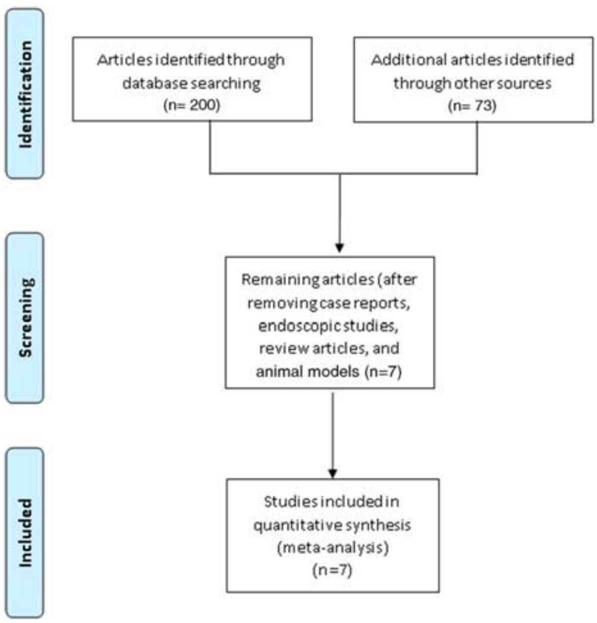

FIGURE 1. Study flow chart. full color online

TABLE 1. Study Characteristics

References	Country	Study Design	Setting	Patients	Age	Male	Female	Balloons	Volume (mL)	BMI Before Balloon
Raftopoulos et al[20]	Greece	Prospective	Single center	12	41 (18-59)	5	7	11	550	36.1 (3.2)
Alsabah et al[21]	Kuwait	Prospective	Multicenter	135	33.49 (9.10)	24	111	135	550	33.72 (3.60)
Machytka et al[22]	Greece and Czeech Republic	Prospective	Multicenter	34	42 (11)	11	23	33	550	34.8 (3.7)
Jamal et al[23]	Kuwait	Prospective	Single center	112	31.3 (9.1)	28	78	112	550	34.3 (5.1)
Al-Subaie et al[24]	Kuwait	Prospective	Single center	51	33.6 (18–65)	4	47	51	550	32.1 (3.2)
Genco et al[25]	Italy	Prospective	Single center	38	46.4 (10.6)	10	28	38	550	38.6 (6.7)
Ienca et al[26]	Italy, Kuwait, Spain, France, Belgium, UAE, Qatar	Prospective	Multicenter	1770	38.8 (12)	506	1264	1770	550	34.4 (5.3)

well as sustained weight loss and improvement in quality of life.[1,2] Endoscopic approaches have emerged as an alternative to traditional surgical methods. Endoscopic bariatric therapy can bridge the gap in patients who do not fit the body mass index (BMI) criteria for surgery and/or fail conservative or medical therapy.[3–5] endoscopic bariatric therapy can entail of any of the following endoluminal procedures, namely, intragastric balloon (IGB) placement, endoscopic sleeve gastroplasty, gastric-bypass revision, and aspiration therapy.[3,6]

Several different types of endoscopic balloons are available including the Orbera Reshape Duo, Obalon, and Spatz Adjustable.[7] These 4 balloons are endoscopically placed in the stomach of patients and subsequently retrieved at completion. More recently, the Elipse balloon (Allurion Technologies, Wellesley, MA) was developed which does not require placement by an endoscopist. The Elipse balloon is swallowed and then inflated with 550 mL of liquid through a connect catheter which is then removed. The balloon has an internal valve that fails after 4 months causing the liquid to be emptied. The device is then completely deflated, and the balloon is passed in the stool.[8]

In theory the Elipse does not require endoscopy. As such, hospitalization for placement and retrieval should not be required, potentially decreasing the overall cost. However, large clinical studies are lacking. To this end, we performed a systematic review with meta-analysis to determine the influence of the Elipse procedureless IGB on weight loss, wait circumference, metabolic profile, tolerability, and adverse events.

METHODS

Search Strategy

We conducted a comprehensive search of several databases and conference proceedings including PubMed, EMBASE, and Google-Scholar databases to April 2020. An experienced medical librarian using inputs from the study authors helped with the literature search. We followed the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines by using a predefined protocol to identify studies reporting on the use of the Elipse balloon for endobariatric therapy including weight loss.[8,9]

Key words used in the literature search included a combination of "endoscopic bariatric therapy," "Elipse balloon," "intragastric balloon," "procedure-less balloon,, "balloon therapy," "weight loss," and "obesity." The search was restricted to studies performed on human subjects and published in the English language in peer-reviewed journals. Two authors (D.R., J.S.) independently reviewed the title and abstract of studies identified in the primary search and excluded studies that did not address the research question, based on prespecified exclusion and inclusion criteria. The full text of the remaining articles was reviewed to determine whether it contained relevant information. Any discrepancy in article selection was resolved by consensus, and in discussion with a co-author. The bibliographic section of the selected articles, as well as the systematic and narrative articles on the topic were manually searched for additional relevant articles.

Study Selection

We included studies reporting clinical outcomes using the Elipse intragastric balloon (EIGB). Studies irrespective of the sample-size, inpatient/outpatient setting, and geography were included as long as they reported the clinical outcomes and data needed for analysis.

Inclusion criteria were as follows: (1) Patients older than or equal to 18 years who underwent placement of the EIGB. Exclusion criteria included: (1) pediatric (age <18 y) studies, (2) case reports or case series with <10 patients, and (3) studies not published in the English language. In the event of multiple publications from the same cohort and/or overlapping cohorts, data from the most recent and/or most appropriate comprehensive report were retained.

Data Abstraction and Quality Assessment

Study references and citations were collected in EndNote X9 (Thomson Reuters, New York, NY). Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia) was used to further screen and extract relevant studies. The full text of each selected article was reviewed to verify that it contained relevant information. In order to identify other potentially eligible publications, the bibliographic section of the selected articles, were manually searched for additional relevant articles. Data on study-related outcomes in the individual studies were abstracted by 2 authors (D.R., J.S.), and 2 authors (D.R., J.S.) did the quality scoring independently. The Jadad scale for randomized clinical trial was used to assess the quality of studies.[10] The Newcastle-Ottawa scale was used for cohort studies.[11]

Outcomes assessed in study cohorts were as follows:

(1) BMI.
(2) Total body weight loss (%TBWL).
(3) Excess body weight loss (%EBWL).
(4) Waist circumference.

TABLE 1. *(continued)*

BMI after 3-4 Mo	Average Weight Before Balloon (Kg)	Average Weight at 3-4 Mo (Kg)	%TBWL at 3-4 Mo	%EBWL at 3 - 4 Mo	Waist Before (cm)	Waist After (cm)	Triglyceride Before (mg/dL)	Triglyceride After (mg/dL)
	103.5 (15.8)		–		117.6 (14.9)	102.8 (13.1)	121.9 (64.2)	91.5 (33.7)
28.79 (3.45)	88.78 (13.51) 101.8 (17.1)	75.75 (11.58)	15.11% (9.52) 10.0% (6.6)					
30.9 (4.6)	92.2 (20.7)	82.8 (17.3)	10.7% (5.5)	55.4 (35.7) 32.7 (19.7)				
28.7 (3.0)	83.9 (12.3)	75.0 (1.5)	10.44% (7.75)	40.84 (25.5)	95.3 (9.2)	86.7 (8.1)		
34.4 (5.4)	109.7 (21.9)	97 (12.7)			123.5 (16.9)	111 (16.2)	152 (22)	118 (29)
29.5 (2.0)	94.6 (18.9)	13.5 (5.8)	14.2 (5.0)	67.0 (64.1)			145.1 (62.8)	99.4 (21.8)

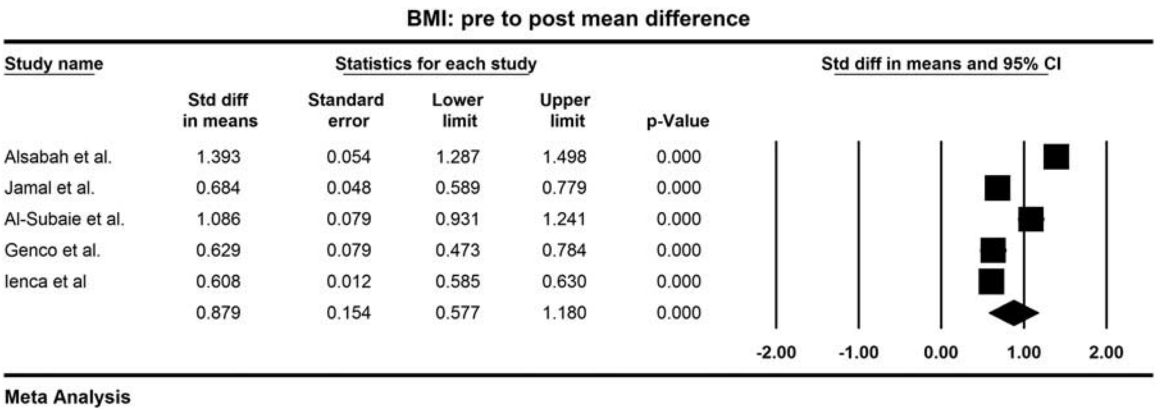

FIGURE 2. Forrest plot of body mass index. CI indicates confidence interval.

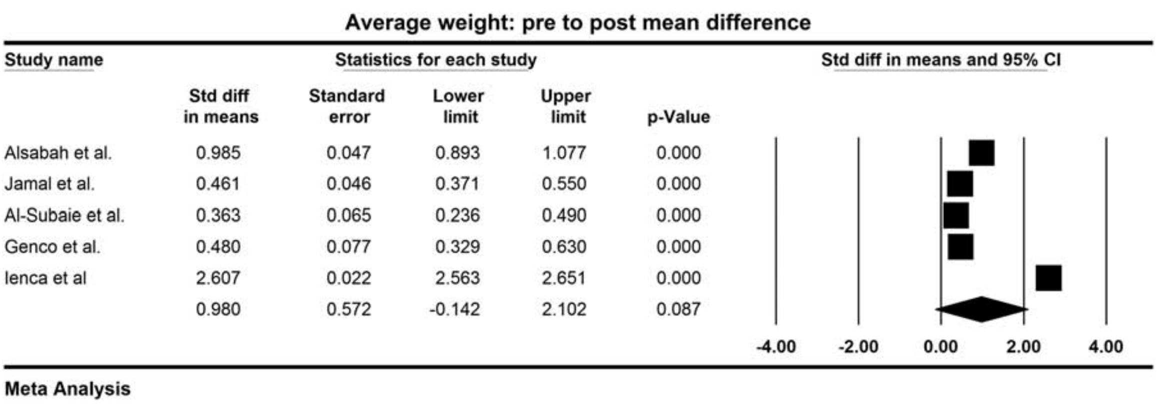

FIGURE 3. Forrest plot of weight loss. CI indicates confidence interval.

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TABLE 2. Summary of Meta-Analysis Results

Endpoints	Pooled Outcome (95% Confidence Interval); Heterogeneity (I^2%)	*P*
Body mass index	MD: 0.88 (0.58-1.18); 98	0.001
Percent total body weight loss	12.2% (10.1-14.3); 94	—
Percent excess body weight loss	49.1% (30.6-67.5); 97	—
Average weight (kg)	MD: 0.98 (-0.14-2.1); 99	0.09
Waist circumference (cm)	MD: 0.89 (0.72-1.05); 53	0.001
Triglyceride (mg/dL)	MD: 0.66 (0.21-1.1); 96	0.004

(5) Triglyceride levels.
(6) Rate of early balloon deflation.
(7) Adverse events.

Statistical Analysis

We used meta-analysis techniques to calculate the pooled estimates in each case following the methods suggested by DerSimonian and Laird using the random effects model.[9–11] We assessed heterogeneity between study-specific estimates by using Cochran *Q* statistical test for heterogeneity and the I^2 statistics.[12–15] In this, values of <30%, 30% to 60%, 61% to 75%, and >75% were suggestive of low, moderate, substantial, and considerable heterogeneity, respectively.[16,17]

Publication bias was ascertained, qualitatively, by visual inspection of funnel plot and quantitatively, by the Egger test.[18,19] $P<0.05$ was considered statistically significant for comparison of groups. Statistical analyses were conducted using STATA software, version 16.0 (StataCorp LLC, College Station, TX).

RESULTS

Search Results

From an initial total of 273 studies, 7 studies were ultimately included in the final meta-analysis.[20–26] The schematic diagram of study selection is illustrated in Figure 1.

Study Characteristics and Quality

A total of 2152 patients were included in the final analysis. Patient age ranged from 18 to 65 years. All studies were designed as prospective cohorts and reported outcomes at 3 to 4 months when the Elipse balloon was expected to deflate. Three studies[21,22,26] were multicenter while the remaining 4 studies[20,23–25] were single center. All studies originated outside the United States and Canada The Elipse balloon is not available for sale in the United States and is not currently approved by the US Food and Drug Administration (FDA) Additional details of study characteristics with patient demographics and location are summarized in Table 1. A detailed assessment of study quality is given in Supplementary Table 1 (Supplemental Digital Content 1, http://links.lww.com/JCG/A644).

Meta-Analysis Outcomes

(1) BMI: the pooled mean difference (MD) in BMI was 0.88 [confidence interval (CI): 0.58-1.18, $P=0.001$, $I^2=98\%$] (Fig. 2).
(2) %TBWL: %TBWL was 12.2% (CI: 10.1-14.3, $I^2=94\%$) (Fig. 3).
(3) %EBWL: %EBWL was 49.1% (CI: 30.6-67.5, $I^2=97\%$) (Table 2).
(4) Waist circumference: the MD in waist circumference was 0.89 (CI: 0.72-1.05, $I^2=53\%$) (Fig. 4).
(5) Triglyceride levels: MD in triglyceride level was 0.66 (CI: 0.21-1.1, $I^2=96\%$) (Fig. 5).
(6) Rate of early balloon deflation: the pooled overall rate of early deflation was 1.8% (CI: 0.6-5.1, $I^2=74\%$) (Supplementary Figure 1, Supplemental Digital Content 2, http://links.lww.com/JCG/A645).
(7) Pooled adverse events: abdominal pain (37.5%), vomiting (29.6%), diarrhea (15.4%), and small bowel obstruction (0.5%) (Supplementary Figures 2–5, Supplemental Digital Contents 3–6, http://links.lww.com/JCG/A646, http://links.lww.com/JCG/A647, http://links.lww.com/JCG/A648, http://links.lww.com/JCG/A649).

VALIDATION OF META-ANALYSIS RESULTS

Heterogeneity and Publication Bias Assessment

We assessed dispersion of the calculated rates using I^2 percentage values. I^2 tell us what proportion of the dispersion is true versus chance. We found significant heterogeneity in reported outcomes (Table 2). A publication bias analysis was not done, as the total number of studies included in the analysis was <10.

DISCUSSION

Our study is the largest to evaluate the EIGB as an alternative to bariatric surgery and endoscopic bariatric

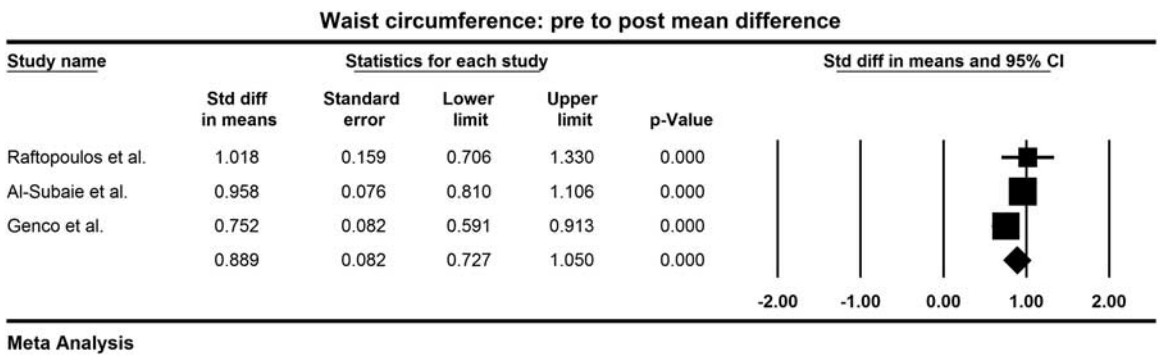
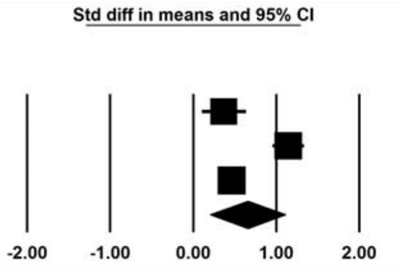


FIGURE 4. Forrest plot of waist circumference. CI indicates confidence interval.

Triglyceride: pre to post mean difference

Study name	Std diff in means	Standard error	Lower limit	Upper limit	p-Value
Raftopoulos et al.	0.368	0.133	0.107	0.630	0.006
Genco et al.	1.144	0.093	0.961	1.327	0.000
Ienca et al	0.462	0.011	0.440	0.484	0.000
	0.660	0.232	0.206	1.114	0.004



Meta Analysis

FIGURE 5. Forrest plot of triglyceride levels. CI indicates confidence interval.

approaches. Our study reported a pooled MD in BMI of 0.88 (CI: 0.58-1.18, $P=0.001$, $I^2=98\%$). In addition, we found that there was a %TBWL of 12% (CI: 10.1-14.3, $I^2=94\%$) and %EBWL of 49.1% (CI: 30.6-67.5, $I^2=97\%$).

Currently the most used IGBs are the Orbera, Obalon, and ReShape Duo of which all 3 are FDA approved.[27,28] Previous studies with IGBs have shown a %TBWL of 7.6 ± 5.5% in contrast to patients who received lifestyle modifications with a % TBWL of 3.6% ± 6.3%.[8,29] One IGB has shown a %TBWL of 13.2% and 11.3% at 6 and 12 months, respectively.[30]

Our study revealed adverse events associated with the Elipse balloon including early deflation (1.8%), abdominal pain (37.5%), vomiting (29.6%), diarrhea (15.4%), and small bowel obstruction (0.5%). Previous studies have demonstrated that the ReShape Duo and Orbera balloons are associated with higher rates of vomiting, 86.7% and 86.8%, respectively, possibly because of the size or shape of the balloons used.[31] In addition, ReShape Duo and Orbera were also associated with higher rates of abdominal pain, 54.5% and 57.5%, respectively, possibly because of overinflation.[31,32]

Our meta-analysis analyzed the effect of the Elipse procedureless IGB on waist circumference. Pooled analysis revealed that the Elipse balloon effectively reduced waist circumference by about 11 cm (MD: 0.89, CI: 0.72-1.05, $I^2=53\%$). In addition, the MD in triglyceride level was 0.66 (CI: 0.21-1.1, $I^2=96\%$). A study that examined the Orbera IGB showed a reduction in triglyceride levels from 174.5 ± 157 to 129.8 ± 87 ($P=0.02$).[33] Another study of the Obera balloon showed that 18 of 48 (37.5%) patients had normal triglyceride levels after 4 months without concomitant medical therapy.[34] Studies involving the Obalon balloon showed a reduction in waist circumference from 109 ± 12.3 to 99 ± 10.5 cm ($P<0.05$).[35] Our study suggests that the Elipse balloon may also be effective in reducing triglyceride levels and waist circumference. Studies comparing the metabolic profile and waist circumference of different IGBs are sparse, however, our study provides the best estimate of the Elipse balloon.

The strengths of our review are as follows: systematic literature search with well-defined inclusion criteria, careful exclusion of redundant studies, inclusion of good quality studies with detailed extraction of data, rigorous evaluation of study quality, and statistics to establish and/or refute the validity of the results of our meta-analysis. There were also several limitations to this study, most of which are inherent to any meta-analysis. Our meta-analysis did not explore modifiable risk factors for obesity such as nutritional status or other metabolic parameters. Long-term effects (beyond 4 months) of the Elipse balloon remains unclear. In addition, of the 7 papers meeting eligibility for meta-analysis, only 1 paper reported all parameters (including BMI, %TBWL, %EBWL, waist circumference, triglyceride levels, etc.). The other 6 papers included for meta-analysis did not report on all parameters. Lastly, all studies originated outside the United States which may hinder its applicability in a Western population. However, we believe this analysis to be the most comprehensive review.

In conclusion, our systematic review and meta-analysis shows that the EIGB is an effective alternative to surgery for obesity and weight loss. In addition, our study showed that the Elipse balloon reduces waist circumference and triglyceride levels and associated with less adverse events when compared with other IGBs.

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