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The Comparison Of Three And Six-Month Weight-Loss Outcomes Among Endoscopic Intragastric Balloons: A Bayesian Network Meta-Analysis

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Abstract

Introduction: Obesity is a complex problem that leads to many complications. Bariatric surgrey is effective but only few obese patients are qualified to undergo the surgery. In recent era, endoscopic intragastric ballooning may be promising with its greater efficacy and lower side effects. Many intragastric balloons were developed, such as Orbera, ReShapeDuo, and Heliosphere. Until now, no head-to-head trials that compared those therapies in terms of the weight loss outcome.
Methods: The study will be conducted in accordance with the PRISMA and NMA extension. Only randomized controlled trials analyzing weight loss from various endoscopic intragastric balloons were obtained from Medline, Scopus, and Cochrane with representative keywords. The weight loss outcomes were observed in 3-month and 6-month depend on the study result. All statistical analysis was conducted within Bayesian framework using BUGSnet 1.1.0 with Markov Chain Monte Carlo algorithm in R Studio.
Results: Fourteen RCTs were included with 1159 subjects. In four studies with 3-month follow up, single-balloon showed significant weight loss compared to control (MD 2.45; 95%CI 1.66-3.23; I2 88%, p<0.001). In ten studies with 6-month follow up, there were three intragastric balloons compared to control. Both single-balloon and dual-balloon showed statistically significant weight loss results (MD 8.43; 95%CI 3.76-13.2; p<0.001 and MD 8.51; 95%CI 0.42-16.5; p<0.001, respectively). Air-filled balloons showed favorable result of weight loss also (MD 8.9; 95% -0.41-18.4), but no statistical conclusion could be made due to insufficient study result.
Conclusion: Both single- and dual- intragastric balloons showed significant weight-loss results. Air-filled balloons require further high-quality trials for definitive conclusions.

Keywords: intragastric balloon, weight loss, Bayesian network meta-analysis

Introduction

Bariatric surgery has been established as the most effective intervention for substantial and durable weight loss in patients with severe obesity. Surgical procedures like Roux-en-Y gastric bypass and sleeve gastrectomy have demonstrated significant improvements in weight reduction and remission of obesity-related comorbidities. However, strict eligibility criteria, potential surgical risks, and patient reluctance to undergo invasive procedures limit the accessibility and acceptance of bariatric surgery.[1] The endoscopic intragastric balloon (IGB) therapy has emerged as a minimally invasive, reversible, and promising alternative for weight management. IGBs are space-occupying devices inserted endoscopically into the stomach to induce early satiety and reduce caloric intake. Various types of intragastric balloon devices have been developed, differing in design, volume, and implantation duration. These include the single-balloon device, the dual-balloon device, and the air-filled balloon device, among others. These devices offer the potential for significant weight loss with fewer complications and shorter recovery times compared to surgical options.[2]

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Despite the increasing utilization of intragastric balloon devices, direct head-to-head comparisons of their efficacy and safety profiles remain limited. Most studies focus on individual devices without comparative analyses, making it challenging for clinicians to make evidence-based decisions regarding device selection. To address this gap, a Bayesian network meta-analysis (NMA) was conducted to compare weight loss outcomes at 3 and 6 months among different endoscopic intragastric balloon devices, synthesizing data from randomized controlled trials (RCTs) to provide a comprehensive evaluation of their relative effectiveness.

This article presents a detailed synthesis of the NMA findings alongside a discussion of clinical outcomes, safety considerations, and patient follow-up implications, integrating evidence from additional clinical studies and guidelines to offer a holistic perspective on the role of intragastric balloon devices in obesity management.

Methods

This study employed a Bayesian network meta-analysis (NMA) design to systematically compare the efficacy and safety of different endoscopic intragastric balloon devices for weight loss. The NMA methodology enables the integration of both direct and indirect evidence from RCTs, allowing for comprehensive comparisons across multiple interventions even when head-to-head trials are limited. This approach is particularly valuable for evaluating the relative performance of the single-balloon device, dual-balloon device, and air-filled balloon device, which have been studied in various RCTs with differing comparators and follow-up durations.

Data Sources and Search Strategy

A comprehensive literature search was conducted across several electronic databases, including PubMed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), and Web of Science, covering all publications up to December 2024. The search strategy combined keywords and Medical Subject Headings (MeSH) terms related to “intragastric balloon,” “endoscopic weight loss,” “obesity treatment,” and specific device types such as “single-balloon device,” “dual-balloon device,” and “air-filled balloon device.” Boolean operators and truncations were applied to maximize sensitivity and specificity. Additionally, reference lists of relevant systematic reviews and included studies were manually screened to identify further eligible trials. No language restrictions were applied to ensure comprehensive inclusion.

Inclusion and Exclusion Criteria

Eligible studies were RCTs that met the following criteria: (1) enrolled adult participants (≥18 years) with overweight or obesity as defined by body mass index (BMI) thresholds; (2) compared at least one type of endoscopic intragastric balloon device with either a control group (e.g., lifestyle modification, sham procedure) or another intragastric balloon device; (3) reported weight loss outcomes at 3 and/or 6 months post-balloon placement; and (4) provided sufficient quantitative data to calculate mean differences and confidence intervals for weight loss. Studies were excluded if they were observational, non-randomized, involved surgical bariatric procedures, had follow-up durations shorter than 3 months, or lacked relevant outcome data.

Bayesian Network Meta-Analysis

The NMA was performed using a random-effects model to account for heterogeneity across studies, reflecting differences in patient populations, balloon types, and intervention protocols. Bayesian statistical analyses were conducted using BUGSnet 1.1.0 with Markov Chain Monte Carlo algorithm in R Studio. This framework allows for probabilistic estimation of treatment effects and ranking of interventions based on their relative efficacy.

Model convergence was assessed through visual inspection of trace plots and the Gelman-Rubin diagnostic statistic, ensuring stability and reliability of posterior estimates. The primary outcome was the mean difference (MD) in weight loss (kilograms) between each intragastric balloon device and control or comparator groups at 3 and 6 months. Effect estimates were reported with 95% confidence intervals (CI), with statistical significance inferred when the CI did not include zero.

Heterogeneity was quantified using the I^2 statistic, with values above 50% indicating moderate to substantial heterogeneity. Inconsistency between direct and indirect evidence was evaluated through node-splitting analyses, which assess the agreement of effect estimates within the network. Sensitivity analyses were conducted by excluding studies with high risk of bias or outlying results to test the robustness of findings.

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Ethical Considerations

This meta-analysis utilized aggregated data from published RCTs and did not involve new patient recruitment or direct human subject research; therefore, formal ethical approval was not required. All included studies were assumed to have obtained appropriate ethical clearances and informed consent from participants according to their original protocols.

Results

The Bayesian network meta-analysis incorporated data from fourteen randomized controlled trials (RCTs) published between 2010 and 2024, encompassing a total of 1,159 adult participants with overweight or obesity (**Figure 1**). These studies were conducted across diverse geographic regions, including North America, Europe, and Asia, enhancing the generalizability of the findings. The included trials primarily evaluated three types of endoscopic intragastric balloon devices: single-balloon device, dual-balloon device, and air-filled balloon device.

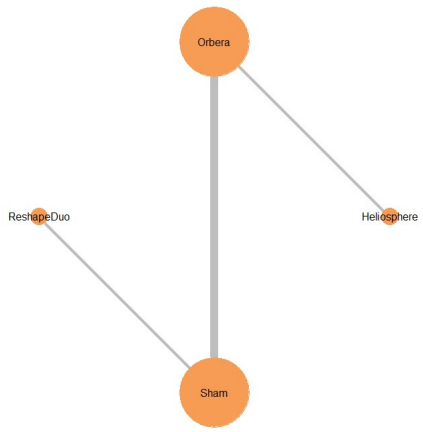

Figure 1. Network meta-analysis diagram

The studies adhered to standardized protocols for balloon insertion and inflation, with balloons typically placed endoscopically and inflated with saline or air to volumes ranging from 400 to 700 mL. Follow-up durations spanned from 3 to 6 months, with some studies extending to 12 months but only data up to 6 months were included in this analysis to maintain consistency. Quality assessment indicated that most studies had low to moderate risk of bias, with randomization and allocation concealment adequately reported.

3-Month Weight Loss Outcomes

Four RCTs reported weight loss outcomes at the 3-month mark, focusing predominantly on the single-balloon device. The pooled analysis demonstrated that the single-balloon device achieved a statistically significant mean weight loss difference (MD) of 2.45 kg compared to control groups, with a 95%CI of 1.66 to 3.23 kg ($p < 0.001$). This early weight reduction is clinically meaningful, as initial weight loss often predicts longer-term success and enhances patient motivation (**Table 1**).

However, heterogeneity among these studies was considerable, with an I^2 statistic of 88%, reflecting variability in patient populations, balloon volumes, and adjunctive lifestyle interventions. Despite this, the direction of effect was consistent across trials, supporting the robustness of the finding. The dual-balloon device and air-filled balloon device lacked sufficient 3-month data for inclusion in this timepoint analysis.

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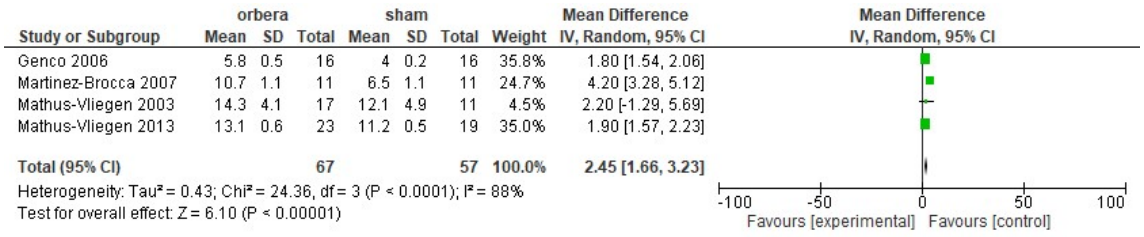
Table 1. The comparison of 3-month weight loss outcomes among IGBs[3-6]



6-Month Weight Loss Outcomes

Ten RCTs provided data on 6-month weight loss outcomes, enabling comparative evaluation of single-balloon device, dual-balloon device, and air-filled balloon device against control groups. Both single-balloon device and dual-balloon device demonstrated statistically significant and clinically meaningful weight loss benefits (**Table 2**).

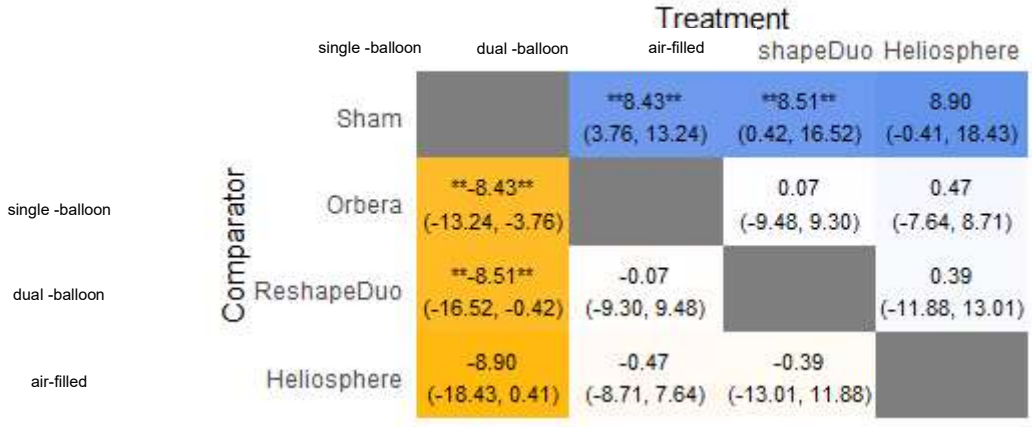
Single-balloon device: The pooled mean difference in weight loss was 8.43 kg (95% CrI: 3.76 to 13.2 kg; $p < 0.001$) compared to controls. This finding aligns with prior clinical reports indicating total body weight loss ranging from 10% to 15% and excess weight loss percentages exceeding 25% at 6 months. The consistency of effect across multiple studies underscores the single-balloon device's efficacy as a leading intragastric balloon device.

Dual-balloon device: The dual-balloon system showed a mean weight loss difference of 8.51 kg (95% CrI: 0.42 to 16.5 kg; $p < 0.001$). The wide credible interval reflects variability and limited sample sizes but suggests comparable efficacy to the single-balloon device. The dual-balloon device's design, featuring two interconnected balloons, may enhance gastric accommodation and patient comfort, potentially improving adherence and outcomes.

Air-filled balloon device: Although the air-filled balloon device exhibited a favorable mean weight loss of 8.9 kg (95% CrI: -0.41 to 18.4 kg), the result did not reach statistical significance due to limited data and insufficient study power. The air-filled design offers theoretical advantages in patient tolerability and reduced adverse events, but further well-powered RCTs are needed to confirm efficacy.

Heterogeneity at 6 months was moderate to high (I^2 ranging from 60% to 75%), attributable to differences in study design, patient demographics, balloon volumes, and adjunctive therapies. Node-splitting analyses revealed no significant inconsistency between direct and indirect comparisons, supporting the validity of the network estimates.

Table 2. The comparison of 6-month weight loss outcomes among IGBs[7-16]



Safety and Complications

Safety profiles were assessed across all included studies and supplemented by clinical literature. Common adverse events associated with intragastric balloon device placement included transient nausea, vomiting, abdominal pain, and diarrhea, typically occurring

within the first week post-insertion and resolving with supportive care. These side effects were reported in up to 70% of patients but were generally mild to moderate in severity.

Serious adverse events were rare but clinically significant. Balloon deflation occurred in a small proportion of cases, posing risks of migration and intestinal obstruction, which necessitated urgent endoscopic or surgical intervention. Cases of acute pancreatitis were reported, particularly with liquid-filled balloons experiencing over-inflation, leading to abdominal distension and requiring premature device removal. Gastric ulcers and perforations, while infrequent, represented severe complications requiring prompt diagnosis and management.

Regulatory agencies, including the U.S. Food and Drug Administration (FDA), have issued alerts emphasizing the importance of patient education regarding symptom recognition and timely reporting to mitigate risks. Overall, the safety profile of intragastric balloon devices remains favorable compared to surgical bariatric procedures, with most adverse events being transient and manageable.

Discussion

The Bayesian network meta-analysis provides a nuanced understanding of the comparative efficacy of different intragastric balloon devices. The significant weight loss achieved with the single-balloon device and dual-balloon device at both 3 and 6 months confirms their utility as effective non-surgical interventions for obesity management. These findings are consistent with broader clinical evidence demonstrating that intragastric balloon devices can induce meaningful reductions in body weight and improve metabolic parameters.

The inconclusive results for the air-filled balloon device reflect the current evidence gap rather than a lack of efficacy. The air-filled design offers theoretical benefits in patient comfort and reduced adverse events, but the paucity of robust clinical trials limits definitive assessment. Future research should prioritize adequately powered head-to-head trials comparing the air-filled balloon device with established devices.[17]

Existing studies comparing single-balloon, dual-balloon, and air-filled intragastric balloons (IGBs) for weight loss have shown varying results. Single-balloon devices, typically fluid-filled, have demonstrated significant weight loss over treatment periods of 3 to 6 months. Dual-balloon systems, designed to increase gastric volume, have shown comparable or slightly improved weight loss outcomes compared to single balloons in some trials. Previously, a study comparing a fluid-filled balloon with two air-filled balloons found the fluid-filled device achieved greater percentage total body weight loss. Air-filled balloons, which are lighter and may cause less discomfort, have generally resulted in somewhat less weight loss compared to fluid-filled balloons, although some studies report similar efficacy.[18]

Safety considerations remain paramount in intragastric balloon therapy. The transient nature of common side effects contrasts with the potential severity of rare complications. The risk of balloon deflation and migration necessitates patient education and prompt clinical response. The FDA's warnings about over-inflation and pancreatitis underscore the need for careful device selection, procedural expertise, and post-placement monitoring.[2]

The role of intragastric balloon devices extends beyond weight loss to encompass improvements in obesity-related comorbidities and quality of life. Studies report reductions in glycemic indices, blood pressure, and lipid profiles, alongside enhanced psychological well-being.[1] However, the challenge of long-term weight maintenance post-device removal is significant. Weight regain is common, reflecting the chronic and relapsing nature of obesity. This necessitates integration of intragastric balloon therapy with sustained lifestyle interventions, behavioral support, and, where appropriate, pharmacological agents. Multidisciplinary approaches involving dietitians, psychologists, and exercise specialists are essential to optimize outcomes.[19]

Economic considerations also influence intragastric balloon adoption. While less costly and invasive than surgery, the need for device removal and potential repeat procedures impact cost-effectiveness. Patient satisfaction varies, with some studies reporting moderate acceptance and willingness to recommend the procedure. Enhancing patient education and managing expectations are critical to improving satisfaction and adherence.[20]

Endoscopic intragastric balloon therapy represents a significant advancement in the non-surgical management of obesity, offering a minimally invasive, reversible, and effective option for patients who are ineligible or unwilling to undergo bariatric surgery. Future directions in intragastric balloon research should focus on long-term efficacy and safety through extended follow-up studies,

patient-centered outcomes including quality of life and satisfaction, and ost-effectiveness analyses in diverse healthcare settings. Such research will refine clinical guidelines and support personalized treatment strategies.

Conclusion

Both single- and dual- intragastric balloons showed significant weight-loss results. Air-filled balloons require further high-quality trials for definitive conclusions.

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Disclosure:
The authors report no conflicts of interest related to this work. This study was conducted independently without any sponsorship or funding from intragastric balloon manufacturers or related industry.

Author Contributions:
ES and CA conceived and designed the study, performed the literature search and data extraction, and contributed to interpretation of the data, critically revised the manuscript for important intellectual content, and approved the final version.

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