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Huang, PF; Yang, CW.

Corresponding author:
Pofeng Huang

td00125732@gmail.com

Author Affiliation:
tri-service general hospital.

ADMINISTRATIVE INFORMATION

Support - N/A.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 7 August 2025 and was last updated on 9 August 2025.

INTRODUCTION

Review question / Objective To compare the efficacy of ESG and IGB in achieving total body weight loss (%TBWL) across varying follow-up periods.

Rationale Despite the growing popularity of endoscopic bariatric therapies (EBTs), the comparative effectiveness of endoscopic sleeve gastroplasty (ESG) versus intragastric balloon (IGB) remains unclear due to heterogeneous study designs, varying follow-up durations, and inconsistent outcome reporting. While ESG is hypothesized to provide more durable anatomical and hormonal changes, IGB remains widely used for its simplicity and short-term efficacy. Current evidence lacks a comprehensive synthesis that evaluates how the benefits of ESG and IGB evolve over time and across different patient profiles, particularly with regard to baseline body mass index (BMI). Moreover, previous meta-analyses have rarely explored the influence of follow-up duration or baseline BMI differences as potential

moderators of treatment outcomes. Therefore, a meta-regression-based comparative analysis is warranted to clarify the temporal and individual-level factors that may influence the relative efficacy and safety of these two interventions. By addressing these gaps, our study aims to provide clinicians and policymakers with more personalized, evidence-based insights into the optimal use of ESG and IGB for obesity management.

Condition being studied

Population (P):
Adults with obesity undergoing endoscopic bariatric therapy. Participants were enrolled in comparative cohort studies across multiple international centers.

Intervention (I):
Endoscopic Sleeve Gastroplasty (ESG) — a minimally invasive, endoluminal procedure using full-thickness endoscopic suturing to reduce gastric volume and induce weight loss.

Comparison (C):

Intragastric Balloon (IGB) — a temporary space-occupying device placed endoscopically within the stomach to promote early satiety and short-term weight loss.

Outcomes (O):

Primary Outcome: Percentage of total body weight loss (%TBWL) at the longest available follow-up.

METHODS

Search strategy A comprehensive literature search was conducted in accordance with the PRISMA 2020 guidelines. Two independent reviewers (P.-F.H. and C.-W.Y.) systematically searched the following electronic databases from inception to June 30, 2025:

PubMed

Embase

Cochrane CENTRAL

Web of Science

ClinicalKey

ProQuest

ScienceDirect

Additionally, to capture gray literature and unpublished trials, a supplementary search was performed using ClinicalTrials.gov.

The search combined Medical Subject Headings (MeSH) and free-text terms related to the intervention, comparator, outcome, and population. The primary keywords and Boolean operators used were:

("Endoscopic sleeve gastropasty" OR "ESG") AND ("Intragastric balloon" OR "IGB") AND ("Body mass index" OR "BMI") AND ("Duration" OR "Follow-up time") AND ("Weight loss" OR "Efficacy" OR "Treatment outcome")

No language restrictions were applied. Reference lists of included studies and relevant review articles were manually screened to identify additional eligible studies. Titles and abstracts were independently screened by two reviewers, followed by full-text assessment. Disagreements were resolved through discussion with a third reviewer (T.-Y.H.).

Participant or population Human participants.

Intervention Endoscopic Sleeve Gastropasty (ESG).

Comparator Intragastric balloon (IGB).

Study designs to be included Comparative cohort studies.

Eligibility criteria Studies were included if they met all of the following criteria:

Population: Adults (≥ 18 years) with obesity undergoing endoscopic bariatric therapy.

Intervention: Endoscopic sleeve gastropasty (ESG).

Comparison: Intragastric balloon (IGB).

Study Design: Randomized controlled trials (RCTs), prospective or retrospective comparative cohort studies.

Outcomes: Studies reporting quantitative data on weight-related outcomes (e.g., percentage of total body weight loss [%TBWL], BMI change), with or without data on adverse events.

Follow-up: Studies reporting post-intervention outcomes at any follow-up duration.

Information sources A comprehensive search of the literature was performed using the following electronic databases:

PubMed

Embase

Cochrane Central Register of Controlled Trials (CENTRAL)

Web of Science

ClinicalKey

ProQuest

ScienceDirect

In addition, ClinicalTrials.gov was searched to identify relevant ongoing or unpublished trials and gray literature.

All databases were searched from inception to June 30, 2025, without language or publication

status restrictions. The reference lists of included studies and relevant review articles were manually screened to identify additional eligible studies.

Main outcome(s) The primary outcome of this meta-analysis was the percentage of total body weight loss (%TBWL) comparing endoscopic sleeve gastropasty (ESG) and intragastric balloon (IGB). For each included study, the %TBWL was extracted at the longest available follow-up to reflect the overall treatment effect.

Additional outcome(s) Adverse events analysis: The incidence and types of adverse events reported in each study were extracted and categorized. A pooled odds ratio (OR) comparing ESG and IGB was calculated using a random-effects model. Specific events of interest included intolerance-related symptoms (e.g., nausea, vomiting), early device removal, and serious complications (e.g., bleeding, fluid collection).

Data management Data from eligible studies were extracted using a standardized, pre-piloted data extraction form developed by the review team. Two independent reviewers (P.-F.H. and C.-W.Y.) extracted data in duplicate to ensure accuracy and minimize bias. Extracted data included:

Study characteristics (author, year, country, study design)

Participant demographics (age, sex distribution, baseline BMI)

Intervention details (type and duration of ESG or IGB)

Follow-up duration

All extracted data were entered into a secure spreadsheet (e.g., Microsoft Excel), which was cross-validated for consistency. Any discrepancies were resolved by discussion or consultation with a third reviewer (T.-Y.H.).

For meta-regression and pooled analyses, data were imported into Comprehensive Meta-Analysis (CMA) software, version 4.0. Effect size calculations and data conversions (e.g., from standard errors to standard deviations) followed Cochrane Handbook recommendations. When required, authors of included studies were contacted for missing or clarifying information.

Quality assessment / Risk of bias analysis The methodological quality and risk of bias of each included study were assessed using the

Newcastle–Ottawa Scale (NOS), a validated tool for evaluating non-randomized studies in meta-analyses. The NOS evaluates three key domains:

Selection of study groups (maximum 4 points)

Comparability of groups (maximum 2 points)

Outcome assessment (maximum 3 points)

Two independent reviewers (P.-F.H. and C.-W.Y.) assessed each study, with disagreements resolved by discussion or consultation with a third reviewer (T.-Y.H.). Each domain was further categorized as low, some, or high risk based on predefined point thresholds:

Low risk: $\geq 75\%$ of maximum points

Some risk: 50–74% of maximum points

High risk: $< 50\%$ of maximum points

Studies receiving a total NOS score of ≥ 7 were considered high-quality and at low overall risk of bias. Those scoring 5–6 were considered moderate risk, and those scoring < 5 were rated as high risk.

Strategy of data synthesis A random-effects meta-analysis model (DerSimonian–Laird method) was used to synthesize data, accounting for anticipated heterogeneity among studies. For continuous outcomes such as percentage of total body weight loss (%TBWL), pooled mean differences (MDs) and 95% confidence intervals (CIs) were calculated. For dichotomous outcomes (e.g., incidence of adverse events), pooled odds ratios (ORs) with 95% CIs were computed.

Statistical heterogeneity was assessed using:

Cochran's Q test ($p < 0.10$ considered significant), and

I^2 statistic, with values interpreted as:

25% = low heterogeneity

50% = moderate heterogeneity

75% = high heterogeneity

To explore sources of heterogeneity and effect modifiers, meta-regression analyses were performed using:

Follow-up duration (in months) as a continuous moderator

Baseline BMI difference between ESG and IGB groups as a covariate

Additional stratified subgroup analyses were conducted at predefined follow-up intervals (1, 3, 6, and 12 months), as well as for studies with follow-up durations ≤ 3 months versus > 3 months.

Sensitivity analyses were performed by sequentially removing one study at a time (leave-one-out analysis) to test the robustness of pooled estimates.

Subgroup analysis To explore potential sources of heterogeneity and time-dependent treatment effects, subgroup analyses were conducted based on follow-up duration:

Duration-based subgroup analysis

Studies were stratified into two subgroups based on follow-up length:

Short-term: ≤ 3 months

Mid- to long-term: > 3 months

This allowed evaluation of the temporal inflection point in treatment efficacy between ESG and IGB.

Timepoint-specific subgroup analysis

Pooled %TBWL differences were analyzed at predefined post-procedure timepoints:

1 month

3 months

6 months

12 months

These subgroup analyses aimed to assess the trajectory of weight loss outcomes over time and identify at which points ESG begins to demonstrate superior efficacy compared to IGB.

Sensitivity analysis To assess the robustness and stability of the pooled estimates, a leave-one-out sensitivity analysis was conducted for the primary outcome (%TBWL). In this approach, the meta-analysis was repeated iteratively with one study removed at a time to evaluate the influence of each individual study on the overall effect size.

If the direction and significance of the effect remained consistent across all iterations, the

results were considered robust and not unduly influenced by any single study.

The findings of the sensitivity analysis are graphically presented in Supplementary Figure S1, which demonstrated that exclusion of any individual study did not materially alter the pooled effect size. This supports the internal validity and reliability of the primary meta-analytic findings.

Language restriction No language limit.

Country(ies) involved Taiwan.

Keywords endoscopic sleeve gastropasty, intragastric balloon, obesity, weight loss.

Contributions of each author

Author 1 - Po-Feng Huang.

Email: td00125732@gmail.com

Author 2 - Chi-Wei Yang.

Email: youngwayleon@gmail.com