INPLASY

Effect of Gastric Pouch Size on Weight Loss, Metabolic, and Surgical Outcomes After Roux-en-Y Gastric Bypass: A Systematic Review and Meta-analysis

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Bananis, K; Khan, S; Mor, R; Gandhi, R; Obale, E; Voros, C; Ramar, S.

Corresponding author:
Kyriakos Bananis

kyriakos.bananis@nhs.net

Author Affiliation:
King's College Hospital NHS Trust.

ADMINISTRATIVE INFORMATION

Support - No support.

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

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202670018

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 7 July 2026 and was last updated on 7 July 2026.

INTRODUCTION

Review question / Objective The aim of this systematic review and meta-analysis is to determine whether gastric pouch size during primary Roux-en-Y gastric bypass (RYGB) influences postoperative weight loss, metabolic outcomes, and surgical complications, with a view to informing surgical standardisation.

PICO question: In adult patients undergoing primary RYGB (Population), does construction of a smaller gastric pouch compared with a larger gastric pouch result in different outcomes for weight loss (%EWL, %TWL), metabolic parameters (T2DM remission, HbA1c, fasting plasma glucose, HOMA-IR), and complications including marginal ulcer, weight regain, and need for revision.

Rationale Roux-en-Y gastric bypass (RYGB) remains the reference operation for severe obesity with metabolic comorbidities, accounting for approximately 32% of primary bariatric procedures globally. Despite five decades of refinement, the gastric pouch component is not standardised: pouches range from 15 mL to over 100 mL across published series, with corresponding variation in length, geometry, and calibration technique. Whether this variation translates to clinically meaningful differences in patient outcomes has remained contested.

Three mechanisms predict that pouch size should influence outcomes: (1) restriction of meal volume reduces caloric intake; (2) reduced parietal cell mass lowers acid load at the gastrojejunal anastomosis and may reduce marginal ulcer risk; and (3) altered gastric emptying rate shapes the postprandial gut-hormone response (GLP-1, PYY) that drives sustained weight loss and metabolic benefit. Each mechanism is supported by physiological data, but their net effect on clinical outcomes has not been quantified.

The most recent qualitative systematic review on this question (Mahawar 2020) included 14 studies, only two of which were randomised, and concluded that quantitative synthesis was not

feasible with the available evidence. Six years have since produced an additional 11 studies, including two further randomised controlled trials, a 14,168-patient national registry analysis, three-dimensional CT volumetric studies, and a 9-year follow-up of an existing trial. This expanded evidence base now permits the first quantitative meta-analysis of pouch-size effects after RYGB. This protocol describes that synthesis.

Condition being studied Severe obesity (BMI ≥ 30 kg/m²) treated by Roux-en-Y gastric bypass. The review examines surgical anatomical determinants (gastric pouch size, defined by volume, length, or calibration technique) and their effects on:

1. Weight loss trajectories (%EWL, %TWL, MIL)
2. Type 2 diabetes mellitus remission and glycaemic control (HbA1c, fasting plasma glucose, HOMA-IR)
3. Surgical complications, particularly marginal ulcer (anastomotic ulceration at the gastrojejunostomy), weight regain, and need for revisional bariatric surgery.

METHODS

Search strategy Databases searched:
- PubMed/MEDLINE (inception to 22 April 2026)
- Cochrane Central Register of Controlled Trials (CENTRAL) (inception to 23 April 2026)
- Cochrane Database of Systematic Reviews (inception to 23 April 2026)

Search strategy: The search combined terms for the intervention with pouch-related terms. The following terms were used with Boolean operators OR within concept blocks and AND between blocks:

Intervention concept: ("gastric bypass" OR "Roux-en-Y" OR "RYGB")

AND

Pouch concept: ("gastric pouch" OR "stomach pouch" OR "pouch size" OR "pouch volume" OR "pouch length" OR "pouch dilation" OR "pouch enlargement" OR "small pouch" OR "large pouch" OR "extended pouch" OR "standard pouch" OR "pouch calibration")

No date or language restrictions were applied at the search stage. Records were deduplicated using a reference management tool before screening.

Search yields:
- PubMed: 441 records
- Cochrane CENTRAL: 2,820 records
- Cochrane Reviews: 9 records
- Total after deduplication: 3,252 records entered screening.

Participant or population Inclusion criteria for participants:
- Adult patients (≥18 years)
- Underwent primary laparoscopic or open Roux-en-Y gastric bypass for severe obesity
- Both type 2 diabetic and non-diabetic patients eligible
- No restriction on baseline BMI, sex, or ethnicity

Exclusion criteria for participants:
- Paediatric patients (< 18 years)
- Revisional-only populations (patients operated primarily for failure of prior bariatric surgery)
- Patients undergoing one-anastomosis gastric bypass (OAGB / mini-gastric bypass) or other non-RYGB procedures
- Patients with current or prior gastric malignancy

Mixed populations: studies enrolling both eligible and ineligible patients were included only if outcome data were reported separately for the eligible subgroup; otherwise excluded.

Intervention The intervention of interest is construction of a smaller gastric pouch during primary RYGB. Pouch size is characterised across included studies by:

- Volume measurement: intra-operative measurement, upper GI contrast study, or three-dimensional CT volumetry. Typical "smaller" definitions span 10–30 mL.

- Length measurement: intra-operative measurement or imaging. Typical "smaller" length is 5 cm.

- Surgical construction proxy: stapler count (e.g., 2 staplers), use of bougie calibration (e.g., 40-Fr), or anatomic landmarks.

The review accepts both dichotomous-exposure designs (smaller vs larger pouch with study-specific cutoffs) and continuous-exposure designs (pouch size as a numerical predictor).

Comparator For dichotomous-exposure studies, the comparator is the larger pouch group defined within each study. Study-specific "larger" definitions include:

- Volume: 25–35 mL, ≥50 mL, 80 cc, or unrestricted
- Length: standard 5 cm (where compared against 10 cm extended)
- Calibration: non-calibrated construction
- Stapler count: 3-stapler construction

For continuous-exposure studies, there is no separate comparator; the exposure-outcome relationship is modelled across the full observed range of pouch size.

Study designs to be included All original peer-reviewed research articles and complete conference abstracts in English reporting eligible PICO and outcomes will be included, regardless of design hierarchy. Eligible designs are:- Randomised controlled trials- Prospective cohort studies- Retrospective cohort studies- Matched cohort studies (including propensity-score-matched)- Case-control studies- Within-patient pre-post studies (where pouch size is changed within the same patient by revision)- Registry-based observational studiesExcluded designs: case reports, case series of <10 patients, editorials, commentaries.

Eligibility criteria Inclusion criteria:

1. Adult patients (≥18 years) undergoing primary RYGB
2. Comparison of smaller versus larger gastric pouch (dichotomous designs) OR correlation of pouch size with outcomes (continuous-exposure designs)
3. At least one of the following outcomes reported: weight loss (%EWL, %TWL, or MIL); metabolic outcomes (T2DM remission, HbA1c, FPG, HOMA-IR); complications (marginal ulcer, weight regain, revision)
4. Original peer-reviewed research article OR complete conference abstract
5. English language

Exclusion criteria:

1. One-anastomosis gastric bypass (OAGB) or other non-RYGB procedures
2. Paediatric populations (< 18 years)
3. Revisional-only populations
4. Mechanism-only physiology studies (e.g., pouch motility, hormone response) without clinical outcome data
5. Editorial, commentary, case report, or narrative review articles
6. Studies in languages other than English (resource limitation)

No time-frame restriction was applied; studies from inception of indexing to 23 April 2026 were eligible.

No restriction on publication status; both peer-reviewed full texts and complete conference abstracts are eligible.

Information sources Primary electronic databases:
- PubMed/MEDLINE (via the PubMed interface)
- Cochrane Central Register of Controlled Trials (CENTRAL, via the Cochrane Library)
- Cochrane Database of Systematic Reviews (via the Cochrane Library)

Additional sources:
- Manual checking of reference lists of included studies and the Mahawar 2020 prior systematic review for potentially missed studies
- Citation tracking of key included trials using PubMed's "Cited By" feature

No grey literature databases, dissertation databases, or trial registries were searched as primary sources; this is acknowledged as a methodological limitation. The Embase database was not searched, which is acknowledged in the manuscript's limitations section.

Main outcome(s) Primary outcomes (weight loss):

1. Percentage excess weight loss (%EWL) at the longest reported follow-up per study. Defined as ([Initial weight – Current weight] / [Initial weight – Ideal weight]) × 100, where ideal weight is typically calculated for BMI 25 kg/m².

2. Percentage total weight loss (%TWL or %TBWL) at the longest reported follow-up per study. Defined as ([Initial weight – Current weight] / Initial weight) × 100.

Measurement timing: longest available follow-up per study is used. Heterogeneity in follow-up duration is reported and accounted for in the analysis and limitations.

Additional outcome(s) Metabolic outcomes:
- Type 2 diabetes mellitus (T2DM) remission (complete or partial, as defined by each study)
- HbA1c change from baseline
- Fasting plasma glucose change from baseline
- HOMA-IR change from baseline

Complication outcomes:
- Marginal ulcer (anastomotic ulceration at the gastrojejunostomy)

- Weight regain (≥10% or ≥15% from nadir, as defined by each study)
- Need for revisional bariatric surgery for weight regain
- Anastomotic stenosis
- Gastrointestinal reflux disease (de novo)
- Food tolerance / dumping / vomiting

Additional weight-loss outcome:
- Percentage excess BMI loss (MIL), where reported.

Data management Two reviewers independently screened all titles and abstracts against the eligibility criteria. Potentially eligible reports were retrieved in full text and assessed independently by both reviewers. Disagreements were resolved by discussion; no third reviewer was required. Inter-reviewer agreement was quantified using Cohen's kappa for both the title-abstract stage and the full-text stage.

Data extraction followed a structured template capturing: study identifiers, design, country, setting and enrolment period, population characteristics (n, age, sex, baseline BMI), intervention and comparator definitions, follow-up duration, and all reported outcomes. Both reviewers extracted independently and values were reconciled in a single verified workbook. Standard deviations not directly reported were reconstructed from 95% confidence intervals using SD = (CI half-width / 1.96) × $\sqrt{n}$, or from standard errors of the mean using SD = SEM × $\sqrt{n}$, with each transformation documented per study.

Reference management: a standard reference manager was used to import, deduplicate, and track records throughout the screening process.

Data storage and analysis: extracted data were stored in a structured Excel workbook with a verification tier per study (V1-FT = full-text verified; V1-AB = verified against complete abstract only). Statistical analysis was implemented in Python 3 using numpy and scipy from first principles, without reliance on meta-analysis packages. Source code is deposited on the Open Science Framework.

Quality assessment / Risk of bias analysis Randomised controlled trials: appraised using the Cochrane Risk of Bias 2.0 (RoB 2) tool across five domains — randomisation process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result.

Observational cohort studies: appraised using the Newcastle–Ottawa Scale (NOS), assessing selection of study groups, comparability of groups on the basis of design or analysis, and ascertainment of outcomes/exposures.

Each study was independently assessed by two reviewers and scores were reconciled. Risk of bias was incorporated as a GRADE domain rather than as an exclusion criterion.

Certainty of evidence: rated for each pooled outcome using the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework, considering five domains — risk of bias, inconsistency, indirectness, imprecision, and publication bias.

Strategy of data synthesis Quantitative synthesis approach:

Effect measures: Mean difference (MD) for continuous outcomes reported on the same scale; risk ratio (RR) for binary outcomes.

Pooling method: Random-effects meta-analysis using the DerSimonian–Laird estimator with inverse-variance weighting for continuous outcomes; Mantel–Haenszel methods with continuity correction (0.5 added per cell) for binary outcomes with arms reporting zero events.

Heterogeneity assessment: quantified using Cochran's Q (χ^2-distributed statistic with chi-square p-value), I^2 with 95% confidence interval calculated using the Higgins–Thompson method, and τ^2 (between-study variance estimate).

Prediction intervals: calculated and reported where $k \geq 3$ using the t-distribution with $df = k - 2$ (Higgins 2009).

Fixed-effect model: presented alongside random-effects model for sensitivity comparison when between-study heterogeneity is low ($I^2 < 25\%$).

Narrative synthesis: applied to studies with continuous-exposure designs (correlation/regression against pouch size as a numerical variable), within-patient pre-post designs, and single-arm studies. Pattern of effect across narrow vs wide exposure ranges is examined as a structured component of the narrative synthesis.

Software: all analyses implemented in Python 3 using numpy and scipy, from first principles. Source code is publicly available on the Open Science Framework.

Subgroup analysis Pre-specified subgroup analyses for the primary %EWL pool:

1. By geographic origin (Asian centres vs European/American centres)
2. By study design (RCTs vs observational)
3. By follow-up duration (< 24 months vs ≥ 24 months)
4. By baseline BMI category (< 35 kg/m² vs ≥ 35 kg/m²), where data permit

Subgroup analyses for marginal ulcer:

1. By continuous vs dichotomous pouch-size exposure
2. By follow-up duration (minimum 12 months for adequate ulcer ascertainment)

We acknowledge that subgroup analyses with small numbers of contributing studies are exploratory and interpreted as hypothesis-generating, not confirmatory.

Sensitivity analysis Pre-specified sensitivity analyses:

1. each primary pool is recomputed with one study omitted at a time, to verify that no single study disproportionately drives the pooled estimate.

2. Boerboom 2019 reinterpretation: this RCT compared a 10 cm extended pouch with a 5 cm standard pouch and reported greater weight loss with the longer pouch. We re-included this study in a sensitivity analysis under the authors' length-based interpretation (Laplace's law: longer narrow pouch resists dilation; Poiseuille's law: longer pouch has slower emptying), in which the extended pouch represents the functionally "smaller" geometry.

3. studies using pouch calibration as a proxy for size (Reiber 2018) were excluded to test whether the primary finding depends on this measurement approach.

4. Fixed-effect vs random-effects comparison: where heterogeneity is low (I^2 < 25%), fixed-effect estimates are presented alongside random-effects estimates.

Language restriction English only. Studies published in languages other than English were excluded, and this is acknowledged as a methodological limitation in the manuscript. Search strategies were entered in English.

Country(ies) involved United Kingdom and Greece.

Other relevant information This systematic review extends the previous qualitative review by Mahawar et al. (2020) which included 14 studies on pouch and/or stoma size after RYGB and called for quantitative synthesis as the evidence base matured. The present review includes 19 reports representing 18 unique trials plus one long-term follow-up paper, enabling the first formal meta-analysis of this question.

Reporting: this review will be reported in accordance with the PRISMA 2020 statement (Page MJ et al., BMJ 2021;372:n71).

The authors note that this protocol is being registered retrospectively (see Item 4 for justification). All methods described above were pre-specified before formal data extraction. The completed extraction workbook, analysis scripts, risk-of-bias assessments, and forest plot generation code are publicly available on the Open Science Framework, allowing reviewers to independently verify that the methods described in this protocol match the analyses performed.

Keywords Roux-en-Y gastric bypass; gastric pouch; pouch size; bariatric surgery; weight loss; marginal ulcer; type 2 diabetes remission; meta-analysis.

Dissemination plans This systematic review extends the previous qualitative review by Mahawar et al. (2020) which included 14 studies on pouch and/or stoma size after RYGB and called for quantitative synthesis as the evidence base matured. The present review includes 19 reports representing 18 unique trials plus one long-term follow-up paper, enabling the first formal meta-analysis of this question.

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Contributions of each author

Author 1 - Kyriakos Bananis - Conceived and designed the review; developed the search strategy; performed title-abstract screening; performed full-text assessment; performed data extraction; performed risk-of-bias assessment; performed statistical analysis; interpreted the data; drafted the manuscript; coordinated the review team.
Email: kyriakos.bananis@nhs.net
Author 2 - Shaan Khan - Performed title-abstract screening independently as the second reviewer; performed full-text eligibility assessment independently as the second reviewer; performed data extraction independently and reconciled with the lead reviewer; performed risk-of-bias assessment independently; contributed to interpretation of data; contributed to manuscript drafting; contributed to manuscript revision.
Email: shaan.khan3@nhs.net
Author 3 - Rahul Mor - Contributed to the development and testing of the search strategy; assisted with title-abstract screening; contributed to the interpretation of data; critically reviewed the manuscript for important intellectual content; approved the final version for submission.
Email: rahul.mor1@nhs.net
Author 4 - Rahi Gandhi - Contributed to the statistical analysis plan and methodological review; assisted with the interpretation of quantitative results; contributed to the drafting of the methods and results sections; critically reviewed the manuscript for important intellectual content; approved the final version for submission.
Email: rahi.gandhi@nhs.net
Author 5 - Emmanuel Obale - Contributed to the framing of the review question and clinical interpretation of findings; critically reviewed the manuscript for important intellectual content; provided supervisory input; approved the final version for submission.
Email: emmanuel.obale@nhs.net
Author 6 - Charalampos Voros - Contributed to data extraction and verification of extracted values against source documents; assisted with the risk-of-bias assessment; contributed to the interpretation of data; critically reviewed the manuscript for important intellectual content; approved the final version for submission.
Email: charalamposvoros@hotmail.com
Author 7 - Sasindran Ramar - Provided overall supervision and guidance for the review; conceived the research question in collaboration with the first author; provided methodological oversight throughout all stages of the review; provided senior clinical expertise on Roux-en-Y gastric bypass surgical technique and outcome interpretation; critically reviewed and revised the manuscript for important intellectual content.
Email: sasindran.ramar@nhs.net