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Leaks After Sleeve Gastrectomy: An Umbrella Review of Systematic Reviews and Meta-Analyses

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We use this protocol and it's working

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Keywords: leaks after sleeve gastrectomy, following sleeve gastrectomy, sleeve gastrectomy, vertical sleeve gastrectomy, gastric leak, gastrectomy in adult patient, bariatric surgery, performed bariatric procedure, gastrectomy, bariatric procedure, overview of systematic review, examining leak incidence, anastomotic leak, leak incidence, examined leak rate, umbrella review of systematic review, leak incidence rate, systematic review, leak, pooled leak incidence rate, existing systematic review, leak rate, characterization of leak, multiple systematic review, pooled leak rate, complication, level evidence on leak, leak rates by geographic region, surgical approach, staple line leak, surgical technique optimization

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Athanasios Pantelis

Abstract

Background: Sleeve gastrectomy has become one of the most commonly performed bariatric procedures worldwide. Despite its popularity, staple line leaks remain a serious and potentially life-threatening complication. Multiple systematic reviews and meta-analyses have examined leak rates, risk factors, and management strategies, but findings vary across reviews. A comprehensive synthesis of this high-level evidence is needed to guide clinical practice and identify research gaps.

Objective: To systematically identify, critically appraise, and synthesize all existing systematic reviews and meta-analyses examining leak incidence, risk factors, timing, and management outcomes following sleeve gastrectomy.

Methods: This umbrella review will follow the PRISMA 2020 guidelines. We will conduct comprehensive searches in PubMed and Google Scholar from inception to present. Two independent reviewers will screen titles, abstracts, and full-text articles using predefined eligibility criteria. Eligible studies will include systematic reviews (with or without meta-analysis) that report leak rates following sleeve gastrectomy in adult patients. We will extract data on review characteristics, search methodology, leak incidence, timing, risk factors, and management outcomes. Methodological quality will be assessed using AMSTAR-2 (A MeaSurement Tool to Assess systematic Reviews). Primary study overlap will be quantified using the GROOVE (Graphical Representation of Overlap for OVErviews) and presented in a citation matrix. If appropriate, we will conduct umbrella meta-analysis using random-effects models to estimate pooled leak rates with 95% confidence intervals. Subgroup analyses will examine leak rates by geographic region, timing (early vs. late), surgical approach, and temporal trends. Sensitivity analyses will assess the robustness of findings by excluding low-quality reviews and high-overlap studies. The certainty of evidence will be assessed using the GRADE approach for key outcomes.

Expected Outcomes: This umbrella review will provide a comprehensive synthesis of the highest-level evidence on leaks following sleeve gastrectomy, including pooled leak incidence rates, identification of key risk factors, characterization of leak timing patterns, and evaluation of management strategies. We will assess the methodological quality of existing systematic reviews, quantify the degree of primary study overlap, and identify gaps in the current evidence base.

Clinical and Research Implications: The findings will inform clinical decision-making regarding patient selection, surgical technique optimization, and early detection strategies. By identifying methodological limitations and evidence gaps, this review will guide the design of future primary studies and systematic reviews. The assessment of primary study overlap will help prevent double-counting in future evidence syntheses and meta-analyses.

Protocol Registration: This protocol will be registered with protocols.io prior to commencing the systematic search.

Keywords: Sleeve gastrectomy; vertical sleeve gastrectomy; gastric leak; staple line leak; anastomotic leak; umbrella review; overview of systematic reviews; bariatric surgery; complications; meta-analysis.

TITLE

1 **Leak Diagnosis and Management After Sleeve Gastrectomy: An Umbrella Review of Systematic Reviews and Meta-Analyses.**

1. PROTOCOL METADATA

2 **Protocol Type:** Umbrella Review / Overview of Reviews
Protocol Version: 1.0
Protocol Date: February 11, 2026
Review Stage: Pre-registration (Prior to literature search)
Anticipated Completion: August 2026 (6-7 months)

2. AUTHORS AND AFFILIATIONS

3 Principal investigator
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Co-investigators
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3. BACKGROUND AND RATIONALE

4 **3.1 Background**
Sleeve gastrectomy (SG), also known as vertical sleeve gastrectomy (VSG) or laparoscopic sleeve gastrectomy (LSG), has become one of the most commonly performed bariatric surgical procedures worldwide. The procedure involves the removal of approximately 80% of the stomach along the greater curvature, creating a tubular gastric remnant.

Despite its popularity and generally favorable outcomes, sleeve gastrectomy is associated with several potential complications, with staple line leak being one of the most serious and potentially life-threatening. Gastric leaks typically occur along the staple line, most commonly near the gastroesophageal junction or the incisura angularis. The reported incidence of leaks varies widely across studies, ranging from less than 1% to over 5%, depending on surgical technique, patient characteristics, and institutional

experience.

Multiple systematic reviews and meta-analyses have been published examining leak rates, risk factors, timing, and management strategies following sleeve gastrectomy. However, the findings across these reviews vary, and there has been no comprehensive umbrella review synthesizing this body of evidence.

5 **3.2 Rationale for Umbrella Review**

An umbrella review (also called an overview of systematic reviews) is warranted for the following reasons:

1. Multiple systematic reviews exist on this topic with potentially conflicting findings.

2. Decision-makers and clinicians need a comprehensive synthesis of the highest-level evidence.

3. Assessment of methodological quality across existing reviews is needed.

4. Identification of gaps in the evidence base can guide future primary research.

5. Quantification of primary study overlap across reviews is essential to avoid double-counting.

This umbrella review will provide a comprehensive, high-level synthesis of all systematic reviews examining leaks after sleeve gastrectomy, assess their methodological quality, quantify overlap, and provide recommendations for clinical practice and future research.

4. RESEARCH QUESTION

6 **4.1 Primary Research Question**

What is the pooled incidence of leaks following sleeve gastrectomy based on existing systematic reviews and meta-analyses, and what are the risk factors, timing, and management outcomes?

7 **4.2 Secondary Research Questions**

- What is the methodological quality of existing systematic reviews on this topic?
- What is the degree of overlap of primary studies across included systematic reviews?
- What are the identified risk factors for leak development?
- What is the timing distribution of leak occurrence (early vs. late)?
- What are the outcomes of different leak management strategies?
- What are the mortality rates associated with gastric leaks?
- What are the gaps in the current evidence base?

5. PICO FRAMEWORK

8 **Population:** Adult patients (≥18 years) undergoing sleeve gastrectomy for obesity or metabolic disease.
Intervention: Sleeve gastrectomy (vertical sleeve gastrectomy, laparoscopic sleeve gastrectomy).
Comparison: Not applicable (descriptive synthesis of leak incidence and outcomes).
Outcomes:
- Primary: Leak incidence rate.
- Secondary: Leak timing, risk factors, management strategies, mortality, morbidity.

6. ELIGIBILITY CRITERIA

9 **6.1 Inclusion Criteria**
Study Design:
- Systematic reviews with or without meta-analysis.
- Must include explicit search strategy.
- Must include quality assessment of primary studies.

Published in peer-reviewed journals or high-quality grey literature.

Population:
- Adult patients (≥18 years old).
- Undergoing primary sleeve gastrectomy.
- Any indication (obesity, metabolic disease, pre-transplant).

Outcomes:
- Must report leak rate or leak incidence as primary or secondary outcome.
- Leak defined clinically, radiologically, or surgically.

Language:
- English language publications only.

10 **6.2 Exclusion Criteria**
- Narrative reviews without systematic methodology.
- Conference abstracts without full-text availability.
- Systematic reviews focusing on mixed bariatric procedures without separate data for sleeve gastrectomy.
- Systematic reviews that do not report leak rates or leak-related outcomes.
- Duplicate publications (we will include the most recent/comprehensive version).

7. SEARCH STRATEGY

11 **7.1 Databases to be Searched**

- PubMed/MEDLINE.
- Google Scholar (first 1000 results).

12 **7.2 PubMed Search Strategy**

("Gastrectomy"[Mesh] OR "sleeve gastrectomy"[tiab] OR "gastric sleeve"[tiab] OR "vertical sleeve gastrectomy"[tiab] OR "VSG"[tiab] OR "laparoscopic sleeve gastrectomy"[tiab] OR "LSG"[tiab])

AND

("Anastomotic Leak"[Mesh] OR "leak"[tiab] OR "leaks"[tiab] OR "leakage"[tiab] OR "fistula"[tiab] OR "staple line leak"[tiab] OR "gastric leak"[tiab])

AND

("Meta-Analysis as Topic"[Mesh] OR "Meta-Analysis"[Publication Type] OR "Systematic Review"[Publication Type] OR "systematic review"[tiab] OR "meta-analysis"[tiab] OR "metaanalysis"[tiab] OR "meta analysis"[tiab] OR "pooled analysis"[tiab])

Search strategies will be adapted appropriately for other databases using equivalent subject headings and keywords.

13 **7.3 Additional Search Methods**

- Reference list screening of included systematic reviews.
- Citation tracking (forward citation searching) of included reviews.
- Hand searching of key bariatric surgery journals.
- Contact with content experts to identify unpublished or ongoing reviews.

14 **7.4 Search Date Range**

Inception to present (no date restrictions).
Search date: [To be specified at time of search execution].

8. STUDY SELECTION PROCESS

15 **8.1 Screening Procedure**

Step 1 - Duplicate Removal:
All retrieved citations will be imported into reference management software (EndNote/Zotero/Covidence) and duplicates will be removed using automated and manual methods.

Step 2 - Title and Abstract Screening:
Two independent reviewers will screen titles and abstracts against eligibility criteria.

Studies marked as "potentially eligible" by either reviewer will advance to full-text review.

Step 3 - Full-Text Review:
Two independent reviewers will assess full-text articles against all eligibility criteria. Disagreements will be resolved through discussion or consultation with a third reviewer.

Step 4 - Documentation:
Reasons for exclusion at full-text stage will be documented and reported in the PRISMA flowchart.

16 **8.2 Inter-Rater Reliability**
Cohen's kappa will be calculated to assess agreement between reviewers at the title/abstract screening stage. A kappa value >0.60 will be considered acceptable.

9. DATA EXTRACTION

17 **9.1 Data Extraction Process**
Two independent reviewers will extract data using a standardized, piloted data extraction form. Discrepancies will be resolved through discussion or consultation with a third reviewer.

18 **9.2 Data Items to be Extracted**
Review Characteristics:

- First author, year of publication.
- Journal.
- DOI number.
- Country/geographic region.
- Review objectives/research questions.

Search Methodology:

- Databases searched.
- Search date range.
- Language restrictions.
- Grey literature inclusion.
- Number of reviewers for screening and data extraction.

Inclusion/Exclusion Criteria:

- Population characteristics.
- Study designs included.
- Surgical technique specifications.
- Outcome definitions.

Study Characteristics:

- Number of primary studies included.

- Total number of patients.
- Study designs of primary studies.
- Geographic distribution.
- Follow-up duration.

Leak Definition and Classification:

- Clinical criteria for leak diagnosis.
- Radiological criteria.
- Timing classification (early/late cutoffs).
- Severity grading systems used

Primary Outcomes:

- Overall leak rate with 95% confidence intervals.
- Leak rates by subgroups (if reported).
- Heterogeneity measures (I^2, τ^2).
- Publication bias assessment

Secondary Outcomes:

- Early leak rate (≤7 days).
- Late leak rate (>7 days).
- Leak location (GE junction, body, incisura).
- Risk factors identified.
- Management strategies employed.
- Time to leak detection.
- Leak-related mortality.
- Length of hospital stay.
- Reoperation rates.

Quality Assessment:

- Risk of bias tool used.
- Summary of quality assessment results.
- GRADE assessment (if performed).

10. METHODOLOGICAL QUALITY ASSESSMENT

19 **10.1 AMSTAR-2 Assessment**

All included systematic reviews will be independently assessed by two reviewers using AMSTAR-2 (A MeaSurement Tool to Assess systematic Reviews, version 2, Shea et al., BMJ 2017;358:j4008, doi: https://doi.org/10.1136/bmj.j4008). AMSTAR-2 evaluates 16 domains:

1. PICO components in research question

2. Protocol registration before search

3. Study design selection and justification

4. Comprehensive literature search

5. Study selection in duplicate

6. Data extraction in duplicate

7. List of excluded studies with justification

8. Adequate description of included studies

9. Satisfactory risk of bias assessment

10. Reporting of funding sources

11. Appropriate meta-analysis methods (if applicable)

12. Impact of risk of bias on results

13. Risk of bias consideration in interpretation

14. Explanation of heterogeneity

15. Publication bias investigation

16. Conflict of interest reporting

Reviews will be rated as: High quality, Moderate quality, Low quality, or Critically low quality.

20 **10.2 Handling Low-Quality Reviews**
Sensitivity analyses will be performed excluding low-quality reviews.

11. PRIMARY STUDY OVERLAP ASSESSMENT

21 **11.1 Citation Matrix**
A citation matrix will be created with primary studies as rows and systematic reviews as columns. Each cell will be marked if a primary study is included in a particular systematic review.

22 **11.2 Calculation of Study Overlap**

The degree of study overlap will be quantified using the GROOVE tool (Perez-Bracchiglione et al., Res Synth Methods. 2022 May;13(3):381-388. doi: 10.1002/jrsm.1557, available online at https://es.cochrane.org/es/groovetool).

Interpretation:
- 0-5%: Slight overlap.
- 6-10%: Moderate overlap.
- 11-15%: High overlap.
- >15%: Very high overlap.

23 **11.3 Handling Overlap**

- CCA will be calculated and reported transparently.
- If overlap is high (>15%), sensitivity analyses will exclude overlapping reviews.
- Primary study-level synthesis may be performed if overlap is very high.
- Overlap will be discussed as a limitation.

12. DATA SYNTHESIS AND ANALYSIS

24 **12.1 Narrative Synthesis**

A narrative synthesis will be conducted for all included systematic reviews, describing study characteristics, populations, methodological approaches, and key findings. Results will be organized by outcome and presented in summary tables.

25 **12.2 Quantitative Synthesis**

If appropriate (low heterogeneity, comparable populations and definitions), an umbrella meta-analysis will be performed:

- Random-effects model (DerSimonian-Laird or REML method).
- Pooled leak rate with 95% confidence intervals.
- Forest plots for visualization.
- Heterogeneity assessment using I^2 statistic and τ^2.
- Prediction intervals (if ≥3 reviews included).
- Meta-analysis will be performed using R (metafor package).

26 **12.3 Subgroup Analyses**

If sufficient data are available, subgroup analyses will be performed for:

- Geographic region (Western vs. Eastern centers).
- Leak timing (early ≤7 days vs. late >7 days).
- Surgical approach (laparoscopic vs. robotic).
- Bougie size used.
- Publication year (temporal trends).
- Study design (RCTs vs. observational studies in primary reviews).

27 **12.4 Sensitivity Analyses**

- Excluding reviews with critically low AMSTAR-2 quality.

- Excluding reviews with very high overlap.
- Excluding outlier estimates.
- Leave-one-out analysis.
- Fixed-effects vs. random-effects models.

28 **12.5 Publication Bias Assessment**

Publication bias will be assessed using:

- Funnel plot visual inspection (if ≥10 reviews).
- Egger's regression test.
- Trim-and-fill method if bias is suspected.

13. CERTAINTY OF EVIDENCE ASSESSMENT

29 The GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach will be used to assess the certainty of evidence for key outcomes:

- Overall leak rate.
- Early vs. late leak rates.
- Leak-related mortality.
- Management outcomes.

Evidence will be rated as: High, Moderate, Low, or Very low certainty.

14. REPORTING AND DISSEMINATION

30 **14.1 Reporting Guidelines**

This umbrella review will be reported according to PRISMA 2020 (Preferred Reporting Items for Systematic Reviews and Meta-Analyses).

31 **14.2 Registration**

This protocol will be registered with protocols.io (for open-access dissemination), prior to conducting the study search.

32 **14.3 Protocol Amendments**

Any amendments to this protocol will be documented with the date, description of change, and rationale. Amended protocols will be updated in the registration databases.

33 **14.4 Dissemination Plan**

- Peer-reviewed journal publication.
- Conference presentations at major bariatric surgery meetings.
- Social media dissemination.
- Summary for patient advocacy groups.
- Policy brief for clinical guideline developers.

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	Phase	Duration	Target Completion
	Protocol finalization and registration	2 weeks	February 2026
	Literature search	2-3 weeks	March 2026
	Title/abstract screening	3 weeks	March-April 2026
	Full-text screening	2 weeks	April 2026
	Data extraction	4-5 weeks	April-May 2026
	Quality assessment (AMSTAR-2)	2-3 weeks	May 2026
	Data analysis and synthesis	3-4 weeks	June 2026
	Manuscript writing and revision	6-8 weeks	July-August 2026

16. ETHICAL CONSIDERATIONS

35 As this is a review of published systematic reviews and does not involve primary data collection from human participants, formal ethical approval is not required. However, this review will be conducted in accordance with principles of research integrity and transparent reporting.

17. FUNDING AND CONFLICTS OF INTEREST

36 **Funding:** None.

Conflicts of Interest: The authors declare no conflicts of interest.

18. KEY REFERENCES

37

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19. APPENDICES

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Appendix A: PRISMA Flowchart Template.

Appendix B: Search Strategies for All Databases

Appendix C: Excluded studies with justification.