Major Early Complications Following Bariatric Surgery

A systematic review and meta-analysis

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# Table of Contents

- **Header** ............................................. 2
- **Abstract** .......................................... 2
- **Background** ....................................... 2
- **Objectives** ........................................ 3
- **Methods** .......................................... 3
- **Plans for Updating the Review** ...................... 7
- **Acknowledgements** ................................ 7
- **Statement Concerning Conflict of Interest** .......... 7
- **References** ........................................ 8
[Intervention Protocol]

Major Early Complications Following Bariatric Surgery: A Systematic Review and Meta-Analysis

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**ABSTRACT**

This is the protocol for a review and there is no abstract. The objectives: are to examine the major surgical complications and their related mortality resulting from different bariatric surgery procedures using up-to-date, comprehensive data and appropriate meta-analytic techniques.

**BACKGROUND**

This protocol is written following the Guidelines for Preparation of Review Protocols.\textsuperscript{1} The protocol will be posted for five months and during this time we will actively seek feedback and criticism of the methods to be employed. All feedback will be logged, publicly posted (unless privacy is requested), and addressed. In light of the feedback, the protocol may be amended upon agreement of all review authors. Any amendments to the protocol will be detailed in full along with the corresponding reasons. Feedback may be submitted via email to the corresponding author.
Description of Bariatric Surgery

As the prevalence of obesity increases globally, the demand for bariatric surgery has risen dramatically in recent years. The total number of operations performed in the United States and Canada reached 220,000 between 2008 and 2009. Bariatric surgery includes a variety of procedures, e.g., Roux-en-Y gastric bypass, biliopancreatic diversion with duodenal switch, adjustable gastric banding, vertical banded gastroplasty, and sleeve gastrectomy.

Why it is important to do this review

Leak, myocardial infarction (MI), and pulmonary embolism (PE) are three of the most feared early complications of bariatric surgery. Generally considered rare events, their seriousness and potentially deadly consequences warrant their further investigation. Moreover, the relative infrequency of these events impede reliable estimation of their rate in small samples, and as with most rare adverse events, the availability of randomized control trial studies is scant at best, further complicating attempts at meta-analysis. Although some specific post-surgical complications such as internal hernia and venous thromboembolism have been meta-analyzed, to our knowledge no comprehensive review of leak, MI, and PE and their related mortality has been attempted. Therefore, it is necessary to provide a systematic review of these complications following bariatric surgery and utilize appropriate meta-analytic techniques to estimate complication and complication-related mortality rates.

OBJECTIVES

To quantify the major risks of various bariatric surgery procedures, focusing on adult patients, by reporting the post-operative incidence of leak, MI, PE, and the mortality resulting from these major complications.

METHODS

Criteria for considering studies for this review

Types of studies

Randomized controlled trials and observational studies reporting on bariatric surgery procedures and/or bariatric surgery outcomes

Types of participants

Adult, human patients age ≥18 who underwent bariatric surgery
**Types of interventions**

Types of bariatric surgery will be grouped into four categories:

1. **Gastric bypass (GB), including**
   - a. Roux-en-Y gastric bypass (RYGB)/laparoscopic RYGB (LRYGB)
   - b. Biliopancreatic diversion with duodenal switch (BPD-DS)
   - c. BPD with RYGB (BPD-RYGB)
   - d. Mini gastric bypass (MGB)

2. **Adjustable gastric banding (AGB), including**
   - a. Laparoscopic AGB (LAGB) using LapBand (LAGB-LapBand)
   - b. LAGB using the Swedish Adjustable Band (LAGB-Swedish)

3. **Vertical banded gastroplasty (VBG)**

4. **Sleeve gastrectomy (SG)**

**Types of outcome measures**

**Primary outcomes**

- Post-surgical rates of leak, MI, and PE
- The time at which leak, MI, or PE occurred
- Post-surgical mortality attributed to leak, MI, or PE

**Secondary outcomes**

- Additional details of each study that could be used in the meta-analyses, including co-morbidities, patient characteristics, study characteristics, and study quality.

**Search methods for identification of studies**

A search strategy for studies published between January 1st, 2003 and September 12, 2014 will be created by an MLIS qualified librarian. Comprehensive searches of the literature will be performed on MEDLINE, EMBASE, SCOPUS, COCHRANE, and CLINICALTRIALS.GOV. Searches will be performed using the Firefox internet browser, and results will be imported to EndNote X7.3.1 (Thomson Reuters).

**Data collection and analysis**

**Selection of studies**

Two independent reviewers will screen the titles and the abstracts based on the following exclusion criteria:

1. Publication of abstracts only, case reports, letters, comments, reviews, or meta-analyses
2. Animal studies
3. Languages other than English
4. Duplicate studies
5. No surgical intervention
6. Not including at least one outcome of interest (leak, MI, or PE rate)
7. Not population of interest
8. Not a study conducted in the United States

After removing excluded abstracts, full articles will be obtained and studies will be screened again more thoroughly using the same exclusion criteria and with the following additional exclusion criteria:

9. Not having a clearly defined time frame for each complication occurrence
10. Not a study in which complications was a primary study outcome

Excluded articles and the corresponding reason for exclusion will be carefully documented. Any disagreement between the two reviewers will be resolved by a third party. Reviewers assessing study eligibility will not be blinded to the names of the authors, journals, nor other publication details.

**Data extraction and management**

A standard extraction form will be created in Microsoft Excel. Studies will be extracted independently by three reviewers and the extractions will be tested for consistency across reviewers with disagreements being resolved by consensus. If more than one surgical procedure was reported in the study, data will be extracted separately according to surgical procedure.

Data extracted will include the following:

- Study characteristics (title, author, study design, publication year, number of study arms, sample size, etc.)
- Intervention details (surgical procedures performed, descriptions of the surgical procedures, number of patients receiving each intervention, follow up times, etc.)
- Patient characteristics (age, race, sex, pre-surgical BMI, pre-surgical weight, pre-surgical comorbid conditions)
- Primary outcomes (number of patients with each complication, complication definitions, number of deaths resulting from each complication of interest, etc.)

**Assessment of methodological quality in included studies**

All studies will be evaluated by three independent reviewers for quality using a four category system. The categories will be: (1) prospective or retrospective study, (2) main outcomes to be measured clearly defined, (3) clearly described the criteria and or/method of diagnosis for the complication, and (4) both occurrence and non-occurrence of a complication are determinable. For (2), studies will be categorized into four groups as follows: (a) the primary outcome of the study is related to leak, MI, and/or PE; (b) the primary outcome of the study is a specific complication or cluster of complications but not leak, MI, or PE; (c) the primary outcome of the study is complications in general; (d) complication reporting is not a primary outcome but is addressed in the methods section.
Measures of complication rates and complication-related mortality

The rates of leak, MI, and PE will be analyzed separately for occurrences within 30 days of surgery and occurrences at any reported time point. Mortality related to leak, MI, or PE will be analyzed. Deaths due to unspecified causes will not be included in any mortality analyses.

Unit of analysis issues

Conversion of units to maintain data consistency will be performed when necessary.

Dealing with missing data and duplicate studies

No attempts will be made to impute missing values. Duplicate studies will not be included, and only one article for each study will be used.

Assessment of heterogeneity

The Higgins I² index, which measures the percentage of variation across studies that is due to heterogeneity rather than random chance, will be computed to quantify the degree of heterogeneity. We will also fit two Bayesian random effects (RE) models, one standard model and one with an additional hierarchy for heterogeneity. Sensitivity analyses will be conducted between these two models to further assess heterogeneity.

Assessment of reporting biases

Publication bias will be evaluated using funnel plots and Egger's test.

Data synthesis

After data extraction is complete, the amount and types of data extracted will be reviewed and specific outcomes in which meta-analysis is possible will be analyzed. Bhaumik estimates and the numerical solutions of the standard errors will be obtained using MATLAB R2015a (MathWorks Inc, Natick, MA) and Bayesian RE meta-analysis will be conducted using R (2.14.0; R Development Core Team) to avoid the statistical problems associated with zero incidence or rare events. We will report the means and 95% confidence/credible intervals. Summary statistics for patient and study characteristics will be reported. Sensitivity analyses will be conducted to assess model fit with respect to modeled heterogeneity.
**Subgroup analysis and investigation of heterogeneity**

If there is sufficient data, statistical heterogeneity will be explored using subgroup analyses. Subgroups will be divided by surgical procedures, outcomes of interest, time points, or study designs.

**PLANS FOR UPDATING THE REVIEW**

Once the review is completed, Chang S-H will be responsible for updating the review. Updates will be performed annually when necessary.

**ACKNOWLEDGEMENTS**

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**STATEMENTS CONCERNING CONFLICT OF INTEREST**

None.
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