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Weight loss surgery for obstructive sleep apnoea with obesity in adults: a systematic review and meta-analysis protocol

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ABSTRACT

Introduction Obstructive sleep apnoea (OSA) is caused by complete or partial obstruction of the upper airway resulting in repeated episodes of interrupted or shallow breaths. OSA is associated with significant morbidity and mortality. The prevalence is estimated to range from 3% to 7% in the general population but may be much higher. Several studies show that weight loss or bariatric surgery may have a role in treating OSA. The aim of this systematic review is to assess the safety and efficacy of randomised controlled trials (RCTs) of weight loss surgery for adults with OSA and comorbid obesity.

Methods and analysis A search of the Cochrane Central Register of Controlled Trials, PubMed, EMBASE and two major Chinese biomedical databases will be performed to identify related trials published as of October 2018. This study will include RCTs, comparing different types of weight loss surgery for OSA with obesity or weight loss surgery for OSA with obesity with other upper airway surgeries. The primary outcomes that will be measured are apnoea–hypopnoea index, excess weight loss and in-hospital mortality. The secondary outcomes will include duration of hospital stay, neck circumference, reoperation, waist circumference, body mass index, Epworth Sleepiness Scale score, overt complications (eg, gastric fistula, bleeding, delayed gastric emptying, wound infection), quality of life, quality of sleep and/or functionality. The systematic review will be conducted according to the recommendations as outlined by the Cochrane collaboration.

Ethics and dissemination The systematic review and meta-analysis will include published data available online and thus ethics approval will not be required. The findings will be disseminated and published in a peer-reviewed journal. Review updates will be conducted if there is new evidence that may cause any change in review conclusions. Any changes to the study protocol will be updated in the PROSPERO trial registry accordingly.

PROSPERO registration number CRD42017081743.

Strengths and limitations of this study

- This will be the first systematic review and meta-analysis to assess the safety and efficacy of weight loss surgery for obstructive sleep apnoea (OSA) with obesity in adults, and this study will include studies comparing various types of bariatric surgery or various other upper airway surgeries for OSA.
- This study will comprehensively evaluate the apnoea–hypopnoea index , excess weight loss, in-hospital mortality, duration of hospital stay, neck circumference, reoperation, waist circumference, body mass index, Epworth Sleepiness Scale questionnaire, overt complications, quality of life, quality of sleep and functionality.
- A lack of sufficient high-quality randomised controlled trials will limit the findings of the study because of the need to then include non-randomised or observational studies.

INTRODUCTION

Description of the condition

Obstructive sleep apnoea (OSA) is caused by complete or partial obstruction of the upper airway that results in repeated episodes of interrupted or shallow breaths. Repeated apnoea and hypopnoea at night cause intermittent hypoxia, hypercapnia, sympathetic nerve excitability, enhanced systemic inflammatory response and oxidative stress and antioxidant capacity.[1] OSA results in sleep deficits, daytime napping, fatigue, arrhythmias, electroencephalographic arousal, daytime hypertension and acute intermittent surges in blood pressure at night, coronary heart disease, diabetes, cerebrovascular diseases, traffic accidents and even sudden death at night.[2–4] OSA is associated with significant morbidity and mortality, including cardiovascular mortality.[5] The prevalence of OSA accompanied by daytime sleepiness is estimated to range from 3% to 7% in the general population and possibly much higher.[6 7] It occurs throughout the world with about equal frequency, in both developed

and developing countries.[5–8] OSA can result in damage to multiple organs and systems.[9–12]

The major risk factors for OSA are obesity, age, gender, anatomical abnormalities of the upper airway anatomy, a family history of OSA syndrome, long-term heavy drinking, use of sedative-hypnotics or muscle relaxation drugs and long-term smoking.[13] Other minor risk factors include hypothyroidism, acromegaly, cardiac insufficiency, stroke, gastro-oesophageal reflux and neuromuscular diseases.[14 15]

Description of the intervention

Usually, OSA may be treated with lifestyle modification, external therapies to keep the airway open while sleeping (positive airway pressure, mouthpiece), or surgery or other procedures (surgical removal of tissue, upper airway stimulation, jaw surgery, surgical opening in the neck, implants).[16 17] Moreover, evidence shows that weight loss could reduce apnoea–hypopnoea index (AHI) and improve the symptoms of apnoea in obese patients with OSA.[18 19] Weight loss surgery also called 'bariatric surgery' includes gastric bypass surgery, sleeve gastrectomy, adjustable gastric banding surgery, biliopancreatic diversion and a few more infrequently used procedures.

A systematic review showed that weight loss surgery improved weight loss outcomes more than non-surgical interventions.[20] By addressing the major risk factors for OSA, weight loss surgery may have a role in treating or curing OSA. In 36 of 54 patients with a preoperative diagnosis of OSA (24 women, median age 38 years, range 23–56 years), De Genio *et al* reported that after subsequent sleeve gastrectomy, there were decreases in weight (p=0.001), body mass index (BMI) (p=0.001), decreased excess weight (p=0.001), decreased neck circumference (p=0.001) and decreased fat mass (p=0.001) after 5 years of follow-up; 29 (80.6%) patients recovered or were 'cured' of OSA syndrome (AHI improved to <5).[21] In 2016, a prospective cohort study on 59 morbidly obese patients reported that laparoscopic sleeve gastrectomy led to rapid weight loss and improved OSA symptoms at 6 months postoperatively.[22] A review of 69 studies with 13 900 patients indicated that all the procedures (Roux-en-Y gastric bypass, sleeve gastrectomy, biliopancreatic diversion) achieved profound effects on OSA, as over 75% of patients had improvement in their sleep apnoea symptoms.[23] Laparoscopic adjustable gastric banding was the worst procedure in improving or resolving OSA, and biliopancreatic diversion was the most successful procedure. The 2014 clinical practice guidelines for bariatric surgery strongly recommend that obese persons (BMI >30 kg/m^2) with OSA be encouraged to lose weight (strong recommendation, but low-quality evidence).[24]

How the intervention might work

In OSA, gravity and muscle relaxation allows the tongue and surrounding soft tissues to fall posteriorly into the throat, thereby obstructing the airflow. Repeated episodes of complete or partial blockage of the upper airway during sleep results in OSA. Subsequently, the diaphragm and chest muscles work harder by trying to open the airway, and breathing usually resumes with a loud gasp,[14] snort or body jerk. These episodes often interfere with sleep quality and can reduce the flow of oxygen to vital organs, causing irregularities in heart rhythm.[25 26] Obesity can lead to accumulation of neck fat, increasing neck circumference and mass loading on the pharynx, thus decreasing the cross-sectional area of the pharynx leading to collapse of the pharynx and subsequent OSA.[27 28] Therefore, weight loss may relieve the symptoms of OSA by changing fat distribution, reducing neck circumference and widening the narrow airway formed by the soft tissue of the tongue and throat. The role of weight loss surgery for OSA with obesity in adults for OSA may also have some association with endocrine and metabolic function, as well as neuromuscular structure and function.[29]

Why it is important to do this review

The role of weight loss surgery for OSA with obesity in adults in treating OSA is largely uncertain. There is insufficient evidence to inform clinical guidelines, and this topic remains controversial in the medical community. Our preliminary research confirmed that obesity is an important risk factor for OSA. It will be interesting to see whether an intervention targeted towards obesity can improve OSA and help to guide clinical practice for patients who are unable to lose weight from lifestyle modification alone.

OBJECTIVES

The aim is to conduct a systematic review and meta-analysis of studies to assess the efficacy and safety of weight loss surgery for OSA with obesity in adults (comparing one type of weight loss surgery for OSA with obesity in adults with another for OSA, comparing weight loss surgery for OSA with obesity in adults with various other upper airway surgeries) in the treatment of OSA in adults.

METHODS

Criteria for considering studies for this review

Types of studies

We will include all randomised controlled trials (RCTs) (irrespective of blinding, publication status, language or publication date), including those that assessed OSA before and after the intervention. We plan to exclude observational and non-randomised controlled studies unless there are insufficient data from RCTs. We will include studies reported in full text, and those published as an abstract only, in which case we will email the researcher for the data if the study is complete but not yet published.

Types of participants

We will include studies of adult patients (≥18 years old) who are obese or overweight (BMI >25 kg/m^2), and who have undergone weight loss surgery for OSA. We will exclude studies of patients with obesity without OSA, or with severe comorbidities who cannot undergo surgery.

Types of interventions

We will include studies comparing any type of weight loss surgery with another for OSA. Weight loss surgery in our study is defined as the following procedures: laparoscopic Roux-en Y gastric bypass, laparoscopic sleeve gastrectomy, laparoscopic adjustable gastric banding, laparoscopic biliopancreatic diversion with duodenal switch and other similar procedures. We will include studies comparing weight loss surgery with otorhinolaryngology surgeries or oral and maxillofacial surgeries. We will perform a sensitivity analysis combining only studies with low risk of bias.

Types of outcome measures

Primary outcomes

1. AHI (the change in AHI from before to after weight loss surgery, none/minimal: AHI <5 per hour; mild: AHI ≥5, but <15 per hour; moderate: AHI ≥15, but <30 per hour; severe: AHI ≥30 per hour).[30]
2. Excess weight loss (EWL).[31]
3. In-hospital mortality.

Secondary outcomes

1. Duration of hospital stay (days).
2. Neck circumference.
3. Reoperation (reoperation due to serious complications or recovery of obesity or OSA within 3–5 years).
4. Waist circumference.
5. BMI.
6. Epworth Sleepiness Scale questionnaire (http://epworthsleepinessscale.com/about-the-ess/).
7. Overt complications (eg, gastric fistula, bleeding, delayed gastric emptying, wound infection).[32]
8. Quality of life[33] and quality of sleep.[34] The outcomes will be measured at 1 week, 1 month, 3 months, 6 months, 1 year, 2 years and 3 years after surgery.

Search methods for identification of studies

Electronic searches

We will identify trials from searches of the following databases:

1. Cochrane Airways Trials Register (Cochrane Register of Studies); inception to October 2018.
2. Cochrane Central Register of Controlled Trials, latest issue (Cochrane Library).
3. MEDLINE (Ovid) 1946 to October 2018.
4. EMBASE (Ovid) 1974 to October 2018.
5. Web of Science all years to October 2018.

We will search the following trials registries:

1. US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (https://www.clinicaltrials.gov/).
2. WHO International Clinical Trials Registry Platform (http://apps.who.int/trialsearch/).
3. Australian New Zealand Clinical Trials Registry (http://www.anzctr.org.au/).
4. International Standard Randomized Controlled Trial Number Register (http://www.isrctn.org/) OR (http://www.controlled-trials.com/).
5. Chinese Clinical Trial Register (http://www.chictr.org.cn/).
6. Trials Central (www.trialscentral.org/).

We will search all sources from inception to October 2018, with no restriction on language of publication.

Other resources

We will check the reference lists of all primary studies and review articles for additional potentially relevant references. We will search relevant manufacturers' websites for study information. We will search for errata or retractions from included studies published in full text on PubMed (www.ncbi.nlm.nih.gov/pubmed) and report the date of publication.

Search strategy

The study search strategy is presented in online supplementary appendix 1. This will be appropriately adapted for use in the other databases.

Data collection and analysis

Selection of studies

Two review authors (ZYD, BYH) will screen the titles and abstracts of the search results independently and code them as 'retrieve' (eligible or potentially eligible/unclear) or 'do not retrieve'. We will retrieve the full-text study reports of all potentially eligible studies and two review authors (ZYD, BYH) will independently screen them for inclusion, recording the reasons for exclusion if ineligible. We will resolve any disagreement through discussion or, if required, we will consult a third review author (CCW). We will identify and exclude duplicates and collate multiple reports of the same study so that each study, rather than each report, is the unit of interest in the review. We will record the selection process in sufficient detail to complete a Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram and a 'characteristics of excluded studies' table.[35]

Data extraction and management

For study characteristics and outcome data, we will use a data collection form, which has been piloted on at least one study in the review. Two review authors (AMY, ZYD) will extract and record the following study characteristics:

1. Methods: study design, total duration of study, details of any 'run-in' period, number of study centres and location, study setting, withdrawals and date of study.
2. Participants: number of study participants, mean age, age range, gender, severity of condition, diagnostic criteria, baseline lung function, smoking history, inclusion criteria and exclusion criteria.

3. Interventions: intervention, comparison, concomitant medications and excluded medications.
4. Outcomes: primary and secondary outcomes specified and collected, and time points reported.
5. Notes: funding for studies and notable conflicts of interest of trial authors.

Two review authors (ZYD, BYH) will independently extract outcome data. If outcome data are not reported in a usable way, we will note that in the 'characteristics of included studies' table. We will resolve disagreements by consensus. If disagreements cannot be resolved by consensus, we will seek an opinion from a third review author (CCW). One review author (ZYD) will transfer data into the Review Manager file.[36] We will double check that data are entered correctly by comparing the data presented in the systematic review with the study reports. A second review author (AMY) will spot-check study characteristics for accuracy against the study report.

Assessment of risk of bias in included studies

Three review authors (ZYD, BYH, AMY) will independently assess risk of bias for each study using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions.[37] We will resolve any disagreements by discussion or by involving another author (CCW). We will assess the risk of bias according to the following domains:

1. Random sequence generation.
2. Allocation concealment.
3. Blinding of participants and personnel.
4. Blinding of outcome assessment.
5. Incomplete outcome data.
6. Selective outcome reporting.
7. Other bias.

We will judge each potential source of bias as high, low or unclear and provide a quote from the study report together with a justification for our judgement in the 'risk of bias' table. We will summarise the risk of bias judgements across different studies for each of the domains listed. We will consider blinding separately for different key outcomes where necessary (eg, for unblinded outcome assessment, risk of bias for all-cause mortality may be very different than for a patient-reported pain scale). Where information on risk of bias relates to unpublished data or correspondence with a trialist, we will note this in the 'risk of bias' table. When considering treatment effects, we will take into account the risk of bias for the studies that contribute to that outcome.

Assessment of bias in conducting the systematic review

We will conduct the review according to this published protocol and justify any deviations from it in the 'differences between protocol and review' section of the systematic review.

Measures of treatment effect

We will analyse dichotomous data as OR and continuous data as the mean difference (MD) or standardised mean difference (SMD). If data from rating scales are combined in a meta-analysis, we will ensure they are entered with a consistent direction of effect. We will undertake meta-analyses only if a potentially meaningful result may be obtained. That is, if the treatments, participants and the underlying clinical question are similar enough for pooling to be appropriate. We will describe skewed data as medians and IQRs for each group. Where multiple trial arms are reported in a single study, we will include only the relevant arms. If two comparisons (eg, procedure A vs procedure C and procedure B vs procedure C) are combined in the same meta-analysis, we will either combine the active arms or halve the control group to avoid double counting. If adjusted analyses are available, we will use these as a preference in our meta-analyses. We will consider the data from each study according to the intention-to-treat principle.

Unit of analysis issues

We will use participants, rather than events, as the unit of analysis for dichotomous outcomes. We anticipate no unit of analysis issues. However, if rate ratios are reported in a study, we will analyse them on this basis. We will only perform a meta-analysis on data from cluster RCTs, if the available data can be adjusted to account for the clustering.

Dealing with missing data

All necessary data will be extracted from the included trials. We will contact the authors of the primary studies to request missing data if necessary. Where this is not possible, and the missing data are thought to introduce serious bias, we will take this into consideration in the Grading of Recommendations Assessment, Development and Evaluation (GRADE) rating for affected outcomes.

Assessment of heterogeneity

We will use the I^2 statistic to measure heterogeneity among the studies in each analysis. If we identify substantial heterogeneity, we will report it and explore the possible causes by conducting a prespecified subgroup analysis.

Assessment of reporting biases

If we are able to pool more than 10 studies, we will create and examine a funnel plot to explore possible small study and publication biases. We only plan to use funnel plots if the number of included studies is ≥10. We will use the Begg and Egger tests if we have less than 10 included studies.[38 39]

Data synthesis

We will perform the data analysis using the meta-analysis software RevMan V.5.3. We will use a random-effects model for all analyses. The extracted data will be combined by calculating a pooled estimate of the risk ratio and 95% CI for dichotomous data. The weighted MD and 95% CI will be calculated for continuous data.[37] The SMD will be used as a summary statistic in this systematic review, when the studies all assess the same outcome but measure it in a variety of ways.

'Summary of findings' table

We will create a 'summary of findings' table using the following outcomes: AHI; EWL; in-hospital mortality; reoperation; overt complications (eg, gastric fistula, bleeding, delayed gastric emptying, wound infection); quality of life and excessive daytime sleepiness. We will use the five GRADE considerations (risk of bias, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of a body of evidence as it relates to studies that contribute data for the prespecified outcomes.[40] We will use the methods and recommendations described in section 8.5 and chapter 12 of the Cochrane Handbook for Systematic Reviews of Interventions,[37] using GRADEpro software.[40] We will explain justifications for decisions to downgrade the quality of studies in footnotes where we will also add comments to aid the reader's understanding of the review, where necessary.

Subgroup analysis and investigation of heterogeneity

If the available evidence allows, we intend to perform the following subgroup analyses:

1. Different bariatric surgical procedures (laparoscopic Roux-en Y gastric bypass vs laparoscopic sleeve gastrectomy and other types of bariatric surgery for OSA).
2. Middle-aged patients versus elderly patients (≥65 years old).
3. Obese versus overweight patients.

We will use the following outcomes in subgroup analyses:

1. Participants with mild OSA versus those with moderate OSA or severe OSA.
2. Participants with BMI >50 kg/m^2 versus participants with BMI ≤50 kg/m^2.

We will use Review Manager V.5.3 for the analyses.

Sensitivity analysis and subgroup analyses

We will perform sensitivity analyses to explore the influence of different study-related characteristics on the effect size. Our planned sensitivity analyses include re-estimating the combined effect size after analysis of:

1. Studies with low risk of bias versus studies with high risk of bias.
2. Removing studies with either small sample sizes.

Changes in results and/or the conclusions following a sensitivity analysis would indicate a lack of robustness in the study findings. We will compare the results from a fixed-effect model with a random-effects model.[37]

Patient involvement

Patient involvement was not considered in writing this protocol as we were unaware of the requirement, but we intend to reconsider and seek advice on how we might seek input from patients at this stage.

DISCUSSION

In an unpublished meta-analysis of 11 case-control studies, we found that BMI was significantly associated with an increased risk of OSA in children ($p<0.00001$) and adults ($p<0.002$). Young *et al* reported that men had a four times higher risk of sleep-disordered breathing (polysomnographically defined AHI of five or higher) for each SD increase in BMI.[41] These and other studies support our hypothesis that weight loss surgery can improve weight loss outcomes, and may have a role in treating or curing OSA.[19–22] However, currently, there is no meta-analysis to confirm this hypothesis, and this study will be the first systematic review and meta-analysis to assess the safety and efficacy of weight loss surgery for OSA with obesity in adults. The results of this study will help to enhance the evidence for weight loss surgery performed for patients with OSA and comorbid obesity.

Ethics and dissemination

The systematic review and meta-analysis will include published data available online. The findings will be disseminated and published in a peer-reviewed journal. Review updates will be conducted if there is new evidence that may cause any change in review conclusions. Any changes to the study protocol will be updated in the PROSPERO trial registry accordingly.

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Collaborators None.

Contributors ZD, AMY, BYH: drafted the protocol, wrote and designed the protocol and will design the full review and will identify the data for inclusion, obtain full text of the reports, extract data from the included studies, perform the data analyses and draft the final full review. BYH, AMY, JC, SMSI: will edit the English language of the final full review. ZD, BYH, AMY, JC, SMSI, CCW: critically reviewed the protocol before submission.

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