Evidence Report/Technology Assessment
Number 103

Pharmacological and Surgical Treatment of Obesity

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-Based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. This report on *Pharmacological and Surgical Treatment of Obesity* was requested and funded by the U.S. Food and Drug Administration's Office of Women's Health. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome written comments on this evidence report. They may be sent to: Director, Center for Outcomes and Evidence, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850.

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Structured Abstract

Context: Pharmacological and surgical treatments for weight loss have become both more numerous and more commonly used. This report was commissioned to review the evidence on such treatments in adults, adolescents, and children.

Objectives: To assess the efficacy and safety of the weight loss medications sibutramine, orlistat, fluoxetine, phentermine, and diethylpropion; to assess the evidence for other medications that have been used for weight loss including bupropion, zonisamide, topiramate, and sertraline; and to assess the efficacy and safety of various types of bariatric surgery.

Data Sources: We searched numerous electronic databases electronically, including MEDLINE® and EMBASE, for potentially relevant studies. We scanned the reference lists of recent extensive reviews on sibutramine, orlistat, and bariatric surgery. We also contacted experts in the field.

Study Selection: We screened 1,063 articles. We quality-reviewed 78 medication studies that reported on sertraline (1 article), zonisamide (1 article), orlistat (49), buproprion (5), topirmate (9), and fluoxetine (13). Meta-analysis was performed for all medications except sertraline and zonisamide which are summarized in the text. We quality-reviewed 159 surgery studies reporting on weight loss and considered an additional 8 surgery studies reporting only on complications, for a total of 167 surgery studies. Of these 167 studies, 20 were duplicate publication of an already included study. Of the remaining 147 studies, 89 contributed to the weight loss analysis, 134 contributed to the mortality analysis, and 128 contributed to the complications analysis. Studies could contribute to one or more surgery analyses.

Data Extraction: We abstracted information about study design, intervention, co-interventions (diet, exercise), population, and outcomes. We also collected data on randomization, dropouts, blinding, and allocation, to assess methodological quality. We abstracted weight loss, control of comorbidities, and adverse events from controlled trials of medication, controlled trials of surgery, and surgery case series.

Data Synthesis: A recent meta-analysis of sibutramine efficacy reported a mean difference in weight loss (compared to placebo) of 3.43 kg at 6 months. At 12 months, the difference was 4.45 kg. Treatment with sibutramine was associated with modest increases in heart rate and blood pressure, very small improvements in glycemic control among diabetics, and (based on the longest-duration and best-quality studies) small improvements in HDL cholesterol and triglycerides.

In our own meta-analysis on orlistat, the pooled random-effects estimate of the mean weight loss for orlistat-treated patients, compared to placebo-treated patients, was 2.51 kg at 6 months; at 12 months, it was 2.75 kg. We found an increase in diarrhea, flatulence, and bloating/ abdominal pain/dyspepsia in orlistat-treated patients compared to placebo, with relative risks (RR) of 3.4, 3.1, and 1.5, respectively.

We identified a published review on phentermine and diethylpropion for weight loss. Our literature review identified no new RCTs of these drugs since publication. Compared to placebo, subjects treated with phentermine lost on average 3.6 additional kg of weight at 6 months**,** while subjects treated with diethylpropion lost on average 3.0 additional kg of weight (but this

difference had only borderline statistical significance). This review did not report side effects or adverse-event data.

Our meta-analysis of fluoxetine studies showed a mean weight loss, compared to placebo-treated patients, of 4.74 kg at 6 months and 3.05 kg at 12 months. There was an increase in nervousness/sweating/tremors, nausea/vomiting, fatigue/asthenia/ hypersomnia/somnolence, insomnia, and diarrhea in fluoxetine-treated patients compared to placebo, with RR of 6.4, 2.7, 2.4, 2.0, and 1.7, respectively.

We identified three studies of bupropion for weight loss that were suitable for meta-analysis. The pooled result at 6 to12 months, compared to placebo treated patients, was 2.8 kg. Bupropion causes dry mouth (RR = 2.99) and insomnia.

We identified six studies (all available only as abstracts) of topiramate for weight loss that were suitable for meta-analysis. The pooled result at 6 months, compared to placebo-treated patients, was an additional 6.5 percent of pretreatment weight lost. Parasthesias (RR = 4.9) and taste perversion (RR = 9.2) are the most commonly reported side effects attributable to topiramate.

We found single studies for each of the following: zonisamide and sertraline.

We identified one large matched cohort analysis that established that surgery results in greater weight loss than does medical treatment in obese individuals with a BMI of 40 kg/m^2 or greater. Surgery resulted in a 20 to 30 kg weight loss, maintained up to 8 years and accompanied by significant improvements in several comorbidities. For patients with a BMI between 35 and 40 kg/m^2, the data strongly support the superiority of surgical therapy but cannot yet be considered conclusive. Bariatric surgical procedures in current use have been performed with an overall postoperative mortality rate of less than 1 percent. The average postoperative mortality rate is probably twice this number. Laparoscopic procedures result in fewer wound complications or incisional hernias than open procedures.

Conclusions: Sibutramine, orlistat, phentermine, diethylpropion (probably), bupropion, fluoxetine, and topiramate all promote weight loss when given along with recommendations for diet. Sibutramine and orlistat are the two most-studied drugs. The amount of extra weight loss attributable to these medications is modest (less than 5 kg at one year), but this amount still may be clinically significant. No evidence indicates that any particular drug promotes more weight loss than another drug. All of these drugs have side effects. The choice of drug may be made on an individual basis, based on tolerance to the expected side effects.

Surgical treatment is more effective than nonsurgical treatment for weight loss and the control of some comorbidities in patients with a body mass index of 40 kg/m^2 or greater. More data are needed to confirm or refute the relative efficacy of surgery for less severely obese persons. Perioperative mortality rates of less than 1 percent have been achieved by some surgeons and surgical centers. The perioperative mortality rates in other settings may be higher. Surgical treatment is associated with a substantial number of complications and adverse events, although most of these are minor.

The existing literature is almost bereft of data regarding either pharmaceutical or surgical treatment of adolescent and pediatric patients. To the extent that existing data on adults are judged to be inapplicable to adolescents or children, new studies will need to be performed.

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Note: Appendixes and Evidence Tables are provided electronically at http://www.ahrq.gov/clinic/epcindex.htm

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Pharmacological and Surgical Treatment of Obesity

Summary

Introduction

The age-adjusted prevalence of obesity in the United States was 30.5 percent in 1999-2000.[1] Although obtaining a precise estimate of the change in the prevalence of obesity over time is difficult because of changing definitions, nearly all clinical authorities agree that obesity is reaching epidemic proportions.[1-12] In response, pharmacological and surgical treatments for weight loss have become both more numerous and more commonly used. This report reviews the evidence on such treatments in adults, adolescents, and children.

We assess the efficacy and safety of the following medications used for weight loss: sibutramine, orlistat, fluoxetine, phentermine, diethylpropion, bupropion, zonisamide, topiramate, and sertraline. We also assess the efficacy and safety of various types of bariatric surgery for obesity.

Most of the medications discussed work by suppressing the appetite. Orlistat is a lipase inhibitor that aids weight loss by reversibly binding to the active center of the enzyme lipase, preventing the digestion and absorption of some dietary fats.

Surgical procedures result in weight loss by restricting the size of the stomach or by bypassing a portion of the intestines. Restricting the size of the stomach limits the quantity of food a patient can consume at a single meal. Malabsorptive (bypass) procedures decrease the proportion of nutrients that are absorbed from a meal. Gastric banding achieves weight loss by creating gastric restriction. The uppermost portion of the stomach is encircled by a band to create a gastric pouch. Vertical banded gastroplasty (VBG) and other gastroplasty procedures use the strategy of mechanical restriction to cause weight loss. The upper part of the stomach is stapled to create a narrow gastric inlet or pouch that remains connected with the remainder of the stomach. Roux-en-Y Gastric bypass (RYGB) achieves weight loss through a combination of gastric restriction and malabsorption. Reduction of the stomach to a small gastric pouch results in feelings of satiety following even small meals. In addition, because this small pouch is connected to a segment of the jejunum (which is downstream), thus bypassing the duodenum and very proximal small intestine, absorptive function is reduced.

Methods

Each evidence report requested by the Agency for Healthcare Research and Quality (AHRQ) is guided by a Technical Expert Panel (TEP). We invited a distinguished group of scientists and clinicians, including individuals with expertise in obesity, human nutrition, surgery, pediatrics, and pharmacology, to participate in the TEP for this report. TEP members suggested that our assessment of pharmacological agents include FDA-approved weight loss medications and other medications for which reports have begun to appear regarding their use as weight loss agents. The FDA-approved weight loss drugs are phentermine, sibutramine, orlistat, diethylpropion, and mazindol; however, our TEP advised us to ignore mazindol, because it is no longer used. Our TEP instructed us to include only studies with treatment durations of 6 months or longer.

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We searched MEDLINE® (which encompasses information from *Index Medicus*, the Index to Dental Literature, and the Cumulative Index to Nursing and Allied Health Literature) and the Cochrane Controlled Clinical Trials Register Database.

To be accepted for our analysis, the study had to be a randomized controlled trial (RCT) or controlled clinical trial (CCT). For the analysis of surgical studies, we broadened these inclusion criteria to encompass cohort studies and case series, since our TEP and a brief scan of the literature suggested that RCTs and CCTs would be few in number. While acknowledging that inferences about efficacy could not be easily made from case series, we did judge that such studies provided useful information in the absence of trial data, and, furthermore, would be useful to assess complications and adverse events of surgery. To avoid reviewing potentially numerous case reports, we set a threshold of 10 or more patients for inclusion in our review.

We abstracted data from the articles onto a specialized form, containing questions about the study design, the number of patients and comorbidities, dosage, adverse events, the types of outcome measures, and the time from intervention until outcome measurement.

The outcome of interest specified by our sponsor was weight loss. However, excess weight is associated with other health outcomes, such as diabetes mellitus, hypertension, sleep apnea, osteoarthrititis, and so on. Because weight loss achieves its health benefits primarily by reducing the incidence or severity of weight-related comorbidities like diabetes, we also endeavored to assess treatments by comparing their efficacy on these outcomes. Very few of the pharmaceutical studies reported these outcomes, making it not feasible to make across-study comparisons addressing the control of comorbidities. We did find surgical studies that made within-study comparisons of the control of comorbidities, and summarize their findings in this report. We also assessed the case series reports of obesity surgery for the control of selected comorbidities and compared these results to those reported in studies containing within-group comparisons.

Of the medications we assessed, three had up-to-date existing meta-analyses (sibutramine, phentermine, and diethylpropion), and others had a sufficient number of new studies to justify a new meta-analysis (orlistat, topiramate, fluoxetine, and bupropion). In order for a trial to be included in analysis, the associated publication(s) had to report on weight loss, one control or placebo group, provide data prior to the crossover point if the trial was a crossover design, and contain sufficient statistical information for the calculation of a mean difference at 6 months and/or 1 year followup as defined below.

We extracted the followup mean weight loss for the control group, the followup mean weight loss for the medication group, and the standard deviation for each group. For studies that included measures for both a 6-month and 1-year followup, we collected those measures separately. If a study did not report a followup mean, or a followup mean could not be calculated from the given data, the study was excluded from analysis. We extracted weight loss as a positive, i.e., greater than zero, quantity. For studies that did not report a standard deviation or for which a standard deviation could not be calculated from the given data, we imputed the standard deviation by using those studies and groups that did report a standard deviation and weighting all groups equally.

We converted all means and standard deviations to kilograms. We then calculated a mean difference for each study, which was the difference between the control group followup mean weight loss and the medication group followup mean weight loss. A negative mean difference indicates that the medication group experienced more weight loss at followup than did the control group. The mean difference is readily interpretable, as it is measured in kilograms.

For the 6-month and 1-year analyses respectively, we conducted a meta-analysis, estimating a pooled random-effects estimate[13] of the overall mean difference and its associated 95 percent confidence interval. The individual trial mean differences are weighted by both within-study variation and between-study variation in this synthesis. We constructed a forest plot and reported the chi-squared test of heterogeneity p-value based on Cochran's Q.[14] We conducted sensitivity analyses on four study dimensions: Jadad quality score, year of publication, completion rate, and dosage. We assessed the possibility of publication bias by evaluating a funnel plot of the trial mean differences for asymmetry, which can result from the nonpublication of small trials with negative results. Because graphical evaluation can be subjective, we also conducted an adjusted rank correlation test[15] and a regression asymmetry test[16] as formal statistical tests for publication bias.

Each trial included in the weight loss analysis was examined to determine whether it reported data on adverse events. We abstracted either the number of events or the number of people, depending on how the trial chose to report events. The majority of trials recorded the number of events, rather than the number of unique people who experienced the event. Each event was counted as if it represented a unique individual. Because a single individual might have experienced more than one event, this assumption may have overestimated the number of people having an adverse event. After abstracting the data, we identified mutually exclusive subgroups of similar events, based on clinical expertise. For example, one subgroup was "gallbladder problems," consisting of all adverse events

concerning this body system. When we subgrouped events, we again treated all observed events as having occurred in unique individuals. For each adverse event subgroup, we report the number of trials that provided data for any event in the subgroup. We also report the total number of individuals in the medication groups in the relevant trials who were observed to have experienced the event and the total number of patients in the medication groups in those trials. We then report the analogous counts for the control groups in the relevant trials.

For subgroups of events that had two or more trials, at least one event in the medication group, and at least one event in the control group, we performed a meta-analysis to estimate the pooled odds ratio and its associated 95 percent confidence interval. For interpretability, for any significant pooled odds ratio greater than one, which indicates the odds of the adverse event associated with medication is larger than the odds associated with being in the control group, we calculated the relative risk and number needed to harm (NNH). We also conducted a power calculation to determine the lowest adverse-event rate that the medication trials we identified had at least 80 percent power to detect.

For the surgery studies, we conducted several analyses. First, we note that some studies (controlled trials) had control groups, whereas others did not (case series [CS]). Depending on the analysis, these two general study types may have been handled differently. For all surgical studies, we extracted the mean weight loss and its standard deviation for each study group, generally defined by surgery procedure, at 12 months post-operative and at the maximum followup time greater than or equal to 36 months as available. For randomized controlled trials that reported a within-study comparison of two procedures of interest, a mean difference was calculated (mean weight loss in procedure "1" group minus mean weight loss in procedure "2" group). A positive mean difference indicates that patients in the procedure 1 group lost more weight on average than patients in the procedure 2 group. A negative mean difference indicates that patients in the procedure 1 group lost less weight on average than patients in the procedure 2 group. These mean differences were pooled using a random effects model and a 95 percent confidence interval was estimated. For all studies, randomized or not, a pooled mean weight loss for each procedure group was estimated using a random effects model and an associated 95 percent confidence interval was constructed.

Data for diabetes, hypertension, sleep apnea, and lipids were also extracted. A crude proportion across studies was calculated for those who resolved or improved (e.g., the number of people who resolved or improved divided by the number of people with the condition at baseline).

For each group in each study, we recorded the number of deaths observed and the total number of patients in the group. If the study self-identified the deaths as "early" or "postoperative" or if it identified the deaths as within 30 days of the surgery, we termed these "early deaths." If the deaths were self-identified as "late" or if they were identified as after 30 days, we termed these "late deaths." If the study was unclear as to the timing of the recorded deaths, we termed these "unclear deaths." If a study did not report data on death for a group, we recorded zero unclear deaths for that group. That is, we imputed zero for missing data, under the assumption that had there been a death, the authors would have reported it. We calculated the crude death rate. That is, we divided the total number of deaths observed by the total number of patients in the relevant study groups. This calculation treats all patients from all studies equally and does not take into account any variation across studies in mortality rates, but given the small number of observed deaths, this statistic is simple and easily interpretable.

Each surgery study (RCT/CCT or CS) was examined to determine whether it reported data on adverse events other than death. The extraction of data for the surgery adverse event analysis was the same as that described above for the medication trials. After abstracting the data, we identified mutually exclusive subgroups of similar events based on clinical expertise. For selected surgery comparisons (one type of surgery versus another type of surgery) for which there were RCT/CCT data available, we estimated a pooled odds ratio and its associated 95 percent confidence interval using exact methods as described above for the medication adverse events meta-analysis. We also report the crude adverse event rate for each RCT/CCT surgery group (total number of affected patients divided by total number of patients at risk). In addition, we report the crude adverse event rate for each surgery group across all studies (RCT/CCT/CS) combined.

Results

A recent meta-analysis on sibutramine efficacy reported a mean difference in weight loss (compared to placebo) of 3.43 kg at 6 months. At 12 months, the difference was 4.45 kg. Treatment with sibutramine was associated with modest increases in heart rate and blood pressure, very small improvements in glycemic control among diabetics, and (based on the longest duration and best quality studies) small improvements in HDL cholesterol and triglycerides.

In our own meta-analysis on orlistat, mean weight loss for orlistat-treated patients, compared to placebo-treated patients, was 2.51 kg at 6 months; at 12 months, it was 2.75 kg. We found an increase in diarrhea, flatulence, and bloating/

abdominal pain/dyspepsia in orlistat-treated patients, compared to placebo, with relative risks of 3.4, 3.1, and 1.5, respectively.

We identified a published review on phentermine and diethylpropion for weight loss. (Our literature review identified no new RCTs of these drugs since publication.) Compared to placebo, subjects treated with phentermine lost on average 3.6 additional kg of weight at 6 months compared to placebo, while subjects treated with diethylpropion lost on average 3.01 kg of weight, but this difference had only borderline statistical significance. This review did not report side effects or adverse event data.

Our own meta-analysis of fluoxetine studies showed a mean weight loss, compared to placebo-treated patients, of 4.74 kg at 6 months and 3.05 kg at 12 months. There was an increase in nervousness/sweating/tremors, nausea/vomiting, fatigue/asthenia/ hypersomnia/somnolence, insomnia, and diarrhea in fluoxetine-treated patients compared to placebo, with relative risks of 6.4, 2.7, 2.4, 2.0, and 1.7, respectively.

We identified three studies of bupropion for weight loss that were suitable for meta-analysis; two studies reported results at 6 months, the other at 12. The pooled result, compared to placebo treated patients, was 2.8 kg. Bupropion causes dry mouth (RR = 2.99) and insomnia.

We identified six studies (all but one available only as abstracts) of topiramate for weight loss that were suitable for meta-analysis. The pooled result at 6 months, compared to placebo-treated patients, was an additional 6.5 percent of pre-treatment weight lost. Parasthesias (RR = 4.9) and taste perversion (RR = 9.2) were the most commonly reported side effects attributable to topiramate.

Our literature search identified one eligible study that assessed the efficacy of the drug zonisamide for weight loss.[17] Patients were followed for 16 weeks in the double-blind portion of the study, with an additional 16-week single blind extension available. The researchers reported that patients in the zonisamide group lost an average of 6.0 percent of baseline body weight, compared to 1.0 percent for placebo patients ($p < .001$).

We identified no direct comparisons of weight loss medications. Our summary of the results for each drug (compared to placebo) does not support a hypothesis that any one drug is more effective than the others.

We identified numerous reports on obesity surgery. Two RCTs of surgery compared to nonsurgical treatment were considered to be of limited relevance because they used surgical procedures that are considered obsolete. An observational study, the Swedish Obese Subjects (SOS) study,[18-25] matched subjects on 18 variables, including gender, age, height, and weight. At 8 years of followup, among 251 surgically treated patients, the average weight loss was 20 kg (or 16 percent of body weight), whereas among 232 medically treated patients, the average weight did not change. We consider this study as providing conclusive evidence of the superiority of surgical treatment for the patients that were enrolled (middle-aged adults with a BMI of about 41 kg/m^2). The strength of this study is the extended duration of followup, documenting sustained weight loss and improved health up to 10 years following treatment. A series of reports from the SOS study support the superiority of obesity surgery compared to medical therapy in ameliorating or preventing the morbidities due to obesity such as hypertension, diabetes, and lipid abnormalities. At 24 months after surgery, among 845 surgically treated patients and 845 matched controls (two-thirds women, average age of 48, average BMI about 41), the incidence of hypertension, diabetes, and lipid abnormalities was markedly lower in the surgically treated patients (adjusted odds ratios of 0.02 to 0.38, depending on condition).[25] At 8 years of followup, the effect of surgery on the reduction in diabetes risk was still dramatic (odds ratio = 0.16), whereas the effect on reduction in risk for hypertension did not persist (odds ratio = 1.01).[19] However, significant decreases in both systolic (8.3 mm Hg) and diastolic (6.7 mm Hg) blood pressure persisted in the small (6 percent) subset of patients who underwent a gastric bypass and lost significantly more weight than the 94 percent of patients who underwent a vertical banded gastroplasty or gastric banding.[18] Additional reports from the SOS study support a substantial benefit of surgery in reducing sleep apnea,[20] symptoms of dyspnea and chest pain,[20] and improving quality of life.[23] The SOS study is the only one we identified that compares the effect on comorbidities between surgically treated patients and a concurrent control group receiving non-surgical treatment.

Weight loss outcomes were reported in a large number of RCTs comparing various surgical procedures and case series of specific surgical procedures. For patients with a BMI between 35-40 kg/m^2, the data strongly support the superiority of surgical therapy, but cannot be considered conclusive yet, in the absence of a study with a concurrent comparison group. These studies support the conclusion that gastric bypass produces superior weight loss compared to gastroplasty procedures. The weight loss reported in surgical studies is an order of magnitude greater than weight loss reported in pharmaceutical or diet studies of obesity (weight losses of 20 to 40 kg at 1 or 2 years in surgical studies versus 2 to 5 kg in pharmaceutical studies), although direct comparisons cannot be made across studies.

There is no clear pattern of differential mortality between the various procedures, and there is no clear pattern in terms of higher or lower early death rates in randomized trials compared with case series. In these reports early mortality following bariatric surgery is less than 1 percent. Existing reports of post-

operative mortality in unselected populations are twice this value (about 2 percent). Adverse events other than mortality are reported with great variability between the studies. None of the comparisons of complications between various surgical procedures show statistically significant differences. The absolute rates of some complications are substantial, although many may be minor in their degree of severity. For example, the proportion of subjects receiving vertical banded gastroplasty who have gastrointestinal complications is 15.2 percent in the RCT/CCT data and 17.8 percent in the case series data, the proportion of subjects receiving RYGB who experience nutritional deficiencies is 26.8 percent in the case series data (many of these nutritional deficiencies were mild); and the proportion of subjects receiving a banding procedure who require re-operation is 7.3 percent in the case series data. The proportion of patients with adverse events or complications may be on the order of 10 percent to 20 percent, although the majority of these may be mild and respond to conservative treatment. The data also support a reduced occurrence of wound and incisional hernia complications in patients treated laparoscopically compared to open procedures; data are insufficient to reach conclusions about differences in other complications.

As part of our literature search and appraisal process, we attempted to identify studies that reported data specific to adolescent and pediatric populations. Too few studies were identified to permit quantitative analysis. We identified three controlled trials of medication that reported data specific to adolescents. One study (in two reports) assessed mazindol, which was not an included drug for this review.[26,27] A second study assessed the use of a caffeine/ephedrine mixture, which was also not an included drug for this review.[28] The other trial studied sibutramine. At six months, subjects treated with the drug lost a mean of 7.8 kg, which was equal to an 8.5 percent reduction in initial BMI, whereas placebo-treated patients had a significantly smaller 3.2 kg weight loss, which was equal to a 5.4 percent reduction in BMI.

There have been a handful of case reports of bariatric surgery in adolescents, which in total report on 172 subjects. These reports document both benefits in terms of weight loss and resolution of complications and harms in terms of complications. There are no studies comparing these benefits and harms to similar patients receiving alternative therapies, such as diet or medication.

Conclusions

Sibutramine, orlistat, phentermine, diethylpropion (probably), bupropion, fluoxetine, and topiramate all promote weight loss when given along with recommendations for diet. Sibutramine and orlistat are the two most studied drugs. The amount of extra weight loss attributable to these medications is modest (less than 5 kg at 1 year), but this amount still may be clinically significant. No evidence indicates that any particular drug promotes more weight loss than another drug. All of these drugs have side effects. The choice of drug may be made on an individual basis, based on tolerance to the expected side effects.

Surgical treatment is more effective than nonsurgical treatment for weight loss and the control of some comorbidities in patients with a body mass index of 40 kg/m^2 or greater. More data are needed to confirm or refute the relative efficacy of surgery for less severely obese persons. Perioperative mortality rates of less than 1 percent have been achieved by some surgeons and surgical centers. The perioperative mortality rates in other settings may be higher. Surgical treatment is associated with a substantial number of complications and adverse events, although most of these are minor.

The existing literature is almost bereft of data regarding either pharmaceutical or surgical treatment of adolescent and pediatric patients. To the extent that existing data on adults are judged to be inapplicable to adolescents or children, new studies will need to be performed.

Availability of the Full Report

The full evidence report from which this summary was taken was prepared for the Agency for Healthcare Research and Quality (AHRQ) by the Southern California–RAND Evidence-based Practice Center, under Contract No. 290-02-0003. It is expected to be available in July 2004. At that time, printed copies may be obtained free of charge from the AHRQ Publications Clearinghouse by calling 800-358-9295. Requesters should ask for Evidence Report/Technology Assessment No. 103, *Pharmacological and Surgical Treatment of Obesity*. In addition, Internet users will be able to access the report and this summary online through AHRQ's Web site at www.ahrq.gov.

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Evidence Report

Chapter 1. Introduction

Obesity has been defined as excess body fat relative to lean body mass,[1] and in humans is the result of interactions of the environment with multiple genes. While humans are well-adapted to starvation, they are poorly adapted to over-nutrition. In fact, only for the past 100 years have humans have had a continuous surplus of food. The modern high-fat, high-calorie diet combined with physical inactivity has resulted in an epidemic of obesity and overweight.

The age-adjusted prevalence of obesity was 30.5 percent in 1999-2000.[2] While a precise estimate of the change in the prevalence of obesity over time is difficult because of changing definitions, nearly all clinical authorities agree that obesity is reaching epidemic proportions.[2-13] Obesity is currently defined as a body mass index (BMI) of 30 or greater: BMI is obtained by dividing body weight (in kilograms) by the height (in meters) squared. Those individuals whose BMI falls between 25 and 29.9 are termed "overweight." According to the most recent results of the National Health and Nutrition Examination Survey (NHANES), 15.5 percent of adolescents are currently overweight[14] and are displaying increasing rates of obesity-related chronic diseases not previously seen in children,[6] such as Type II diabetes. Moreover, efforts to stem this increase have failed thus far: Attempts to meet the body weight goal of the Healthy People 2000 Initiative[7] – to reduce the prevalence of overweight among adults to less than 20 percent of the population – did not succeed.

The United States is not alone in facing rising rates of obesity. In Canada, between 1985 and 1998, the overall prevalence of obesity increased in adults from 5.6 percent to 14.8 percent, and from 1981 to 1996, it tripled in children.[8, 9] The World Health Organization reports that there are more than 300 million obese people in the world, and the rising rate of obesity is no longer solely a problem of industrialized countries but is rapidly appearing in developing countries as well.[10, 11]

The health consequences of obesity include some of the most common chronic diseases in our society. Obesity is an independent risk factor for heart disease,[15] the most common killer disease in most developed countries. Type II diabetes, hypertension and stroke, hyperlipidemia, osteoarthritis, and sleep apnea are all more common in obese individuals.[16-18] A recent prospective study involving 900,000 U.S. adults reported that increased body weight was associated with increased death rates for all cancers combined and for cancers at multiple specific sites.[19] Adult weight gain is associated with increased risk of breast cancer in postmenopausal women.[20] Weight loss of 5 to 10 percent can be associated with marked reductions in the risk of these chronic diseases [21]. In the Diabetes Prevention Program, a weight loss of about 5 to 6 percent among persons with a BMI of 34 kg/m^2, along with increased physical activity, resulted in a 58 percent reduction in the incidence of diabetes.[22]

In response to the increase in obesity, treatments for obesity have become both more numerous and more commonly used. This Evidence Report was commissioned to review the evidence on pharmacologic and surgical treatments of obesity in adults, adolescents, and children.

Prescription Weight Loss Medications

Drugs prescribed for weight loss can be divided into two categories, based on their putative mechanisms of action: appetite suppressants and lipase inhibitors. Appetite suppressants can be

further subdivided, based on the neurotransmitters on which they are believed to exert their effects.

Appetite Suppressants

Medications have been prescribed for their ability to suppress appetite for over half a century. The first prescription appetite suppressants were the sympathomimetic amphetamine derivatives, so described because they exert their effects by stimulating the sympathetic nervous system. Some of the newer appetite suppressants exert their effects by mimicking the sympathetic nervous system.

Sibutramine is a combined norepinephrine and serotonin reuptake inhibitor. Its putative effect on weight loss is attributed to appetite suppression and increased thermogenesis, secondary to stimulation of brown adipose tissue. Sibutramine was approved for use in conjunction with a low calorie diet as an aid to weight loss in 1998.[23]

Fluoxetine is a selective serotonin reuptake inhibitor (SSRI) that was originally approved to treat depression. The original manufacturer submitted an New Drug Application for use of fluoxetine as a weight loss drug in the early 1990s; however, approval was not given, and the application was eventually withdrawn.[24]

Sertraline, like fluoxetine, is a SSRI. In the early 1990s, it was noted that sertraline administered to laboratory animals resulted in weight loss.[25,26]

Phentermine is a sympathomimetic amine of the β-phenethylamine family. It was approved for use by the FDA in 1959 as a short term aid to weight loss in conjunction with a low calorie diet and exercise. Unlike use of sibutramine, use of phentermine leads to the development of tolerance.[27]

Diethylpropion, like phentermine, is a sympathomimetic agent prescribed for short-term weight loss when used in conjunction with diet and exercise. Diethylpropion is similar in chemical structure to bupropion, which is approved as an antidepressant and as a smoking cessation aid and has also been tested as a weight loss aid.[28]

Zonisamide was approved by the FDA in 2000 for the treatment of partial (focal) seizures in adults with epilepsy, in conjunction with other anticonvulsants. Although the precise mechanism of action is unknown, it may exert its effects by acting as a sodium or calcium channel blocker. Because one of zonisamide's side effects is appetite suppression, its use as a weight loss drug has been tested.[29]

Topiramate is also an anticonvulsant, approved in the mid 1990s for the treatment of refractory seizures in conjunction with other anticonvulsants. In the process of testing topiramate for treatment of mood disorders, it was discovered that the agent might mitigate the weight gain often observed with antidepressant treatment[30], and a dose-ranging study established it does so in a dose-dependent manner.[31,32]

Lipase Inhibitors

Lipase inhibitors putatively aid weight loss by reversibly binding to the active center of the enzyme lipase, preventing the digestion and absorption of some dietary fats. Orlistat was approved in the late 1990s and is currently the only lipase inhibitor approved for weight loss. Orlistat inhibits approximately 30 percent of fat absorption, including the absorption of fat-soluble vitamins.[33]

Bariatric Surgical Procedures

A variety of surgical procedures have been used to induce weight loss for obese patients. These procedures result in weight loss via of one of two mechanisms: mechanically restricting the size of the stomach or bypassing a portion of the intestines; however, several procedures exert their effects by both mechanisms. Restricting the size of the stomach limits the quantity of food a patient can consume at a single meal. Malabsorptive (bypass) procedures decrease the proportion of nutrients that are absorbed from a meal. Details of selected bariatric procedures (i.e., those performed frequently now and in the past) are provided below.

Restrictive Procedures

Gastric banding. Gastric banding achieves weight loss by creating gastric restriction. The uppermost portion of the stomach is encircled by a band to create a gastric pouch with a capacity of approximately 15 to 30 cc. The band consists of an inflatable doughnut-shaped balloon whose diameter can be adjusted in the clinic by adding or removing saline via a reservoir port that is positioned beneath the skin. When the procedure was introduced, the bands were of a fixed size. However, the bands used today are adjustable, which allows the size of the gastric outlet to be modified as needed, depending on the rate of a patient's weight loss. Gastric banding does not produce malabsorption. Currently, almost all of the banding procedures are performed laparoscopically. While it is technically possible to remove the band (e.g., for failed weight loss or complications), doing so will expose the patient to potential risks associated with a second operation and, of course, will necessitate identifying an alternative method for weight loss.

Vertical Banded Gastroplasty (VBG) and other gastroplasty procedures. VBG uses the strategy of mechanical restriction to cause weight loss. The upper part of the stomach is stapled to create a narrow gastric inlet or pouch that remains connected with the remainder of the stomach. In addition, a non-adjustable band is placed around this new inlet in an attempt to prevent future enlargement of the stoma. As a result, patients experience a sense of fullness after eating small meals. Weight loss from this procedure results entirely from eating less: There is no component of malabsorption. VBG was one of the more common surgical procedures for weight loss in the late 1980s and early 19990s but has been superseded since 1995 by adjustable band procedures and procedures that combine mechanical restriction with bypass (see below).

Variations of gastroplasty procedures include horizontal gastroplasty and gastric partitioning without a band. These procedures are no longer performed because they had a high failure rate; thus, they are only of historic interest.

Bypass Procedures

Jejunoileal bypass. Jejunoileal bypass was one of the earliest procedures performed for weight loss. This procedure connected the proximal small intestine to a segment of distal small intestine (located a short distance upstream from the ileocecal junction), which bypassed the majority of the absorptive capacity of the small intestine. Although this procedure produced significant weight loss, patients developed complications such as severe malnutrition, chronic diarrhea, and liver failure. Thus, the procedure was abandoned about 25 years ago and is generally of only historical interest.

Combination Procedures

Roux-en-Y Gastric Bypass (RYGB). RYGB achieves weight loss through a combination of gastric restriction and malabsorption. Reduction of the stomach to a small gastric pouch (30 cc) results in feelings of satiety following even small meals. In addition, because this small pouch is connected to a segment of the jejunum (which is downstream), thus bypassing the duodenum and very proximal small intestine, absorptive function is reduced. The resultant "dumping" of sugar may also aid weight loss via the production of some unpleasant gastrointestinal symptoms following ingestion of high-density carbohydrate-containing foods. Typical symptoms include abdominal pain, cramping, and diarrhea.

The RYGB procedure has been performed regularly since the early 1980s; it was first performed laparoscopically in the early 1990s. RYGB is one of the most common types of weight loss procedures in current use, with almost 50,000 cases performed in 2001.

Biliopancreatic diversion (BPD). BPD, like RYGB, combines both the restrictive and malabsorptive strategies of obtaining weight loss. The stomach is partially resected, but the remaining capacity is generous compared to that achieved with the RYGB. As such, patients eat relatively normal-sized meals and do not need to restrict intake severely. Because the most proximal areas of the small intestine (i.e., the duodenum and jejunum) are bypassed, substantial malabsorption occurs. Although this procedure is not as commonly performed as either banding procedures or RYGB, the approach is strongly favored by some bariatric surgery specialists. The partial biliopancreatic diversion with duodenal switch is a variant of the BPD procedure that, until recently, was performed mostly in Italy and only rarely performed in the United States. Recently, a number of centers in the United States and Canada have begun to perform this procedure, which involves resection of the greater curvature of the stomach, preservation of the pyloric sphincter, and transection of the duodenum above the ampulla of Vater with a duodeno-ileal anastomosis and a lower ileo-ileal anastomosis.

Chapter 2. Methods

Original Proposed Key Questions

The American College of Physicians-American Society of Internal Medicine (ACP/ASIM) and the American Academy of Pediatrics (AAP) nominated the topic of this report. Other interested groups include the American Academy of Family Physicians (AAFP) and the National Heart, Lung, and Blood Institute (NHLBI). These groups provided us this initial list of questions.

1. *What is the evidence that pharmacotherapy is effective in weight loss and maintenance of weight loss?*

2. *Are certain agents more effective than others?*

3. *Do certain populations (e.g., gender- or age-related, racial/ethnic populations) benefit more from different agents?*

4. *What is the optimum amount of time to treat, and what is the optimum level of weight loss to target? Do optimum amount of time to treat and optimum levels of weight loss differ according to a patient's age? Gender? Racial/ethnic population?*

5. *What are the most effective non-pharmacological, non-surgical treatment approaches (e.g., individual vs. group; specific dietary regimens in conjunction with other therapies; alternative medicine)?*

6. *What is the safety and efficacy of surgical therapies, such as stomach stapling and bypass surgeries, as interventions for children and adolescents with morbid obesity?*

Technical Expert Panel

Each AHRQ evidence report is guided by a Technical Expert Panel (TEP). We invited a distinguished group of scientists and clinicians, including individuals with expertise in obesity, human nutrition, surgery, pediatrics, and pharmacology, to participate in the TEP for this report. A list of members is included in Appendix D. Our TEP conference call was held on January 28, 2003. The subjects discussed were the following: identification of pharmacological agents to include in review; limitation of the scope of question 5 (regarding nonpharmacologic and alternative treatments); and broadening the scope of question 6 to include adults.

TEP members suggested that our assessment of pharmacological agents include FDA-approved weight loss medications and other medications for which reports have begun to appear regarding their use as weight loss agents. The FDA-approved weight loss drugs are phentermine, sibutramine, orlistat, diethylpropion, and mazindol; however, our TEP advised us to disregard mazindol because it is no longer used. Drugs for which reports have begun to appear regarding weight loss, but that are not currently FDA approved for weight loss, included the antidepressants fluoxetine and bupropion, and topiramate, a drug indicated for seizure control.

Note: Appendixes and Evidence Tables cited in this report are provided electronically at http://www.ahrq.gov/clinic/epcindex.htm.

Our TEP also instructed us to include only studies that had treatment durations of six months or longer, considering shorter durations of treatment to be less informative about effectiveness.

RAND staff suggested that the panel narrow the focus of question 5, above, because the list of nonpharmacological and alternative medicine therapies is potentially infinite. The TEP agreed that diet was the most important therapy to focus on. At a subsequent conference call with AHRQ and ACP/ASIM, the topic of diet was dropped from further review because the number of studies and their heterogeneity made it impossible to synthesize the data satisfactorily within the resources of the project. On this phone call, we agreed that the subject of this report would be the efficacy of drug therapy and surgical therapy.

Finally, regarding question 6, RAND staff expressed curiosity as to why the scope of this question was restricted to adolescent and pediatric populations, since most of the data on these procedures would derive from studies of adult populations only. The TEP agreed that we should examine data on bariatric surgery with patients of all ages in mind. In fact, we broadened our search of all interventions to include adolescent and pediatric populations.

Literature Search

Our search for controlled human studies of pharmacological and surgical treatments of obesity began with an electronic search of MEDLINE® on October 16, 2002. Appendix A shows our specific search strategies. MEDLINE®, which is maintained by the U.S. National Library of Medicine, is widely recognized as the premier source for bibliographic coverage of biomedical literature. It encompasses information from *Index Medicus*, the Index to Dental Literature, and the Cumulative Index to Nursing and Allied Health Literature ([CINAHL]; allied health includes occupational therapy, speech therapy, and rehabilitation), as well as other sources of coverage in the areas of health care organization, biological and physical sciences, humanities, and information science as they relate to medicine and health care. Subsequently, our librarian conducted "current awareness" search updates on May 22, June 2, June 12, and July 3, 2003.

We also searched the Cochrane Controlled Clinical Trials Register Database. The Cochrane Collaboration is an international organization that helps people make well-informed decisions about health care by preparing, maintaining, and promoting the accessibility of systematic reviews on the effects of heath care interventions.

Additional Sources of Evidence

U.K. University of Aberdeen report. Broom and colleagues prepared a systematic review of the long-term outcomes of treatments for obesity, the implications for health improvement, and the economic consequences, for the National Health Service of the United Kingdom.[34] Members of the project team kindly shared with us the draft report October 2002. We ordered all studies referenced therein; using their search terms, we conducted an update of their library search. Search terms are provided in Appendix A. The final report has since been released.

Orlistat review. In 2001, O'Meara and colleagues published a rapid and systematic review of the clinical effectiveness and cost-effectiveness of orlistat in the management of obesity.[35] The review was published as a Health Technology Assessment by the United Kingdom National Health Service (NHS). We ordered all studies referenced therein.

Note: Appendixes and Evidence Tables cited in this report are provided electronically at http://www.ahrq.gov/clinic/epcindex.htm.

Sibutramine review. We identified a high-quality meta-analysis on the effects of sibutramine that was "in press" at the time of our search.[36] The first author of this review agreed to allow us to incorporate their results into our evidence report. The authors of that review did not restrict their literature search by language and made extensive efforts to identify unpublished and ongoing trials, including contacting representatives of the pharmaceutical industry.

NICE surgery review. In July 2002, the United Kingdom's National Institute for Clinical Excellence (NICE) published an assessment report[37] on the clinical and cost effectiveness of surgery for morbidly obese patients, authored by Clegg and colleagues at the University of Southampton. We ordered all studies referenced therein.

Cochrane surgery review. Our literature search also identified a Cochrane review[38] on surgery for morbid obesity, published by the team that authored the NICE surgery review. The Cochrane review was updated in February 2003 during our literature search process. The authors included both randomized controlled trials (RCTs) and non-randomized controlled trials comparing surgery with nonsurgical management for morbid obesity and assessed RCTs comparing different surgical procedures. The review was restricted to adults age 18 years or older with morbid obesity defined as a BMI greater than 40 or a BMI index greater than 35 with serious comorbid disease. In addition to summarizing their results, we obtained copies of studies referenced therein and conducted an update of their library search.

Article Review

We reviewed the articles retrieved from the various sources against our exclusion criteria to determine whether to include them in the evidence synthesis. A one-page screening review form (checklist) that contains a series of categorization questions was created to track the articles (see Appendix B). After being evaluated against this checklist, each article was either accepted for further review or rejected. Three reviewers, each trained in the critical analysis of scientific literature, independently reviewed the studies, abstracted data, and resolved disagreements by consensus (each study was reviewed by two reviewers: One reviewer assessed all the studies and worked as a team with the other two reviewers, each of whom reviewed half the studies.) The principal investigator resolved any disagreements that remained unresolved after discussions among the reviewers. Project staff entered data from the forms into an electronic database that was used to track all studies through the screening process.

To be accepted for analysis, studies of drug therapy had to be controlled clinical trials according to the following definitions:

Randomized controlled trial (RCT). A trial in which the participants (or other units) are definitely assigned prospectively to one of two (or more) alternative forms of health care, using a process of random allocation (e.g., random number generation, coin flips).

Controlled clinical trial (CCT). A trial in which participants (or other units) are either

(a) definitely assigned prospectively to one of two (or more) alternative forms of health care using a quasi-random allocation method (e.g., alternation, date of birth, patient identifier)

OR

Note: Appendixes and Evidence Tables cited in this report are provided electronically at http://www.ahrq.gov/clinic/epcindex.htm.

(b) possibly assigned prospectively to one of two (or more) alternative forms of health care using a process of random or quasi-random allocation.

For the analysis of surgical studies, we broadened these inclusion criteria to encompass case series, since our TEP suggested, and a brief scan of the literature confirmed, that RCTs would be few in number. While acknowledging that inferences about efficacy cannot easily be made from case series, we did judge that such studies provided useful information in the absence of RCT data and, furthermore, would be useful to assess complications and adverse events of surgery. To avoid reviewing potentially numerous case reports, we set a threshold of ten or more patients per series for inclusion in our review.

Extraction of Study-Level Variables and Results

We abstracted data from the articles that passed our screening criteria onto a specialized Quality Review Form (See Appendix B). The form contains questions about the study design, the number of patients and comorbidities, dosage, adverse events, the types of outcome measures, and the time from intervention until outcome measurement. With input from the project's TEP, we selected the variables for abstraction. Three reviewers, working in groups of two, extracted data from the same articles and resolved disagreements by consensus. A senior physician resolved any disagreements not resolved by consensus.

To evaluate the quality of the studies, we collected information on the study design, withdrawal/dropout rate, method of random assignment (and blinding), and method for concealment of allocation (the attempt to prevent selection bias by concealing the assignment sequence prior to allocation). We also calculated the percentage of attrition by dividing the number of persons who dropped out of the trial (i.e., the number of people who entered the trial minus the number who completed the trial) by the number of persons entering the trial. The elements of design and execution (randomization, blinding, and withdrawals) have been aggregated into a summary score developed by Jadad.[39] The Jadad score rates studies on a 0 to 5 scale, based on the answer to three questions:

1. Was the study randomized?

2. Was the study described as double-blind?

3. Was there a description of withdrawals and dropouts?

One point is awarded for each "yes" answer, and no points are given for a "no" answer. Additional points are awarded if the randomization method and method of blinding were described and were appropriate. A point is deducted if the method is described but is not appropriate. Empirical evidence has shown that studies scoring 2 or fewer points show larger apparent differences between treatment groups than do studies scoring 3 or more.[40]

Choice of Outcomes

The outcome of interest specified by our sponsor was weight loss. Excess weight is associated with other negative health outcomes, such as diabetes mellitus, hypertension, sleep

apnea, and osteoarthritis. A loss of 5 percent to 10 percent of body weight by an obese person, followed by long-term weight maintenance, is associated with improved health outcomes.[16]

Weight loss can be measured in several ways, most commonly kilograms of weight lost, "excess" weight loss, or percentage of excess weight loss. Excess weight is defined as that above a patient's "ideal body weight" based on height and weight tables. Among these, the most commonly reported outcome, by far, is kilograms (or pounds) of weight lost. Among 111 surgical studies reporting weight loss that we reviewed, 43 reported weight loss only in terms of kilograms or pounds, 17 reported only excess weight loss or some variant, 46 reported both of these outcomes, and 5 reported neither of these. Among the 76 pharmaceutical studies that we assessed, none reported excess weight loss. Therefore, we chose weight loss (in kilograms or pounds) as the principal outcome measure, since this choice allowed us to include the maximum number of studies in our analysis and afforded us the only way of comparing the effectiveness of surgical and pharmaceutical therapies across studies.

Because weight loss achieves health benefits primarily by reducing the incidence or severity of weight-related comorbidities like diabetes, we also endeavored to assess treatments by comparing their effects on these outcomes. Very few of the pharmaceutical studies reported these outcomes; thus, it was not feasible to make cross-study comparisons to address the control of comorbidities. We did search for studies that made within-study comparisons of the control of comorbidities, and we summarize their findings in this report. We also assessed the case series reports of obesity surgery for the control of selected comorbidities and compared these results to those reported in studies containing within-group comparisons.

Meta-Analyses of Weight Loss Medications

Of the medications we assessed, three had up-to-date existing meta-analyses (sibutramine, phentermine, and diethylpropion) and three others had a sufficient number of new studies to justify a new meta-analysis (orlistat, topiramate, and fluoxetine). Our meta-analytic methods are the same for the orlistat and fluoxetine weight loss meta-analyses, so we discuss the approach for both medications simultaneously. We conducted all analyses and drew all graphs using the statistical package Stata.[41]

Selection of Trials for Meta-Analysis

The outcome of interest was weight loss between baseline and followup. Based on clinical considerations, we focused on weight loss measured at six months or later. To make our analyses comparable, we stratified the analysis in the same manner as the "in press" meta-analysis on sibutramine.[36] Thus, we defined data collected at "six months" to be data collected at any point between 16 and 24 weeks; likewise, "one year" followup data were collected at any point between 44 and 54 weeks. If a study presented data for two or more time points in an interval, e.g., at 16 and 18 weeks, we chose the longest followup measurement for our analysis.

For some trials, several publications presented the same outcome data. In these cases, we picked the more informative of the duplicates; for example, if one publication was a conference abstract with preliminary data and the second was a full journal article, we chose the latter. The publications dropped for duplicate data do not appear in the evidence table but are noted in the text. We note that multiple citations of the same article were removed at the title screening stage of the project.

For a trial to be included for further analysis, the associated publication(s) had to report on weight loss, provide data prior to the crossover point if the trial was a crossover design, and contain sufficient statistical information for the calculation of a mean difference at six months and/or one year followup as defined below.

Mean Difference

Each trial contained one control or placebo group, which is referred to below simply as the control group. Some trials contained more than one medication group, e.g., at different dose levels. In order not to double-count patients for each trial, we chose the most clinically relevant medication group for our analysis, or in some cases, we combined medication groups. In the discussion below, we assume that a single medication group per study has been determined by choice or defined by combination.

For each trial, we extracted the followup mean weight loss for the control group, the followup mean weight loss for the medication group, and the standard deviation for each group. For studies that included measures for both a six-month and a 12-month followup, we collected those measures separately. If a study did not report a followup mean or if a followup mean could not be calculated from the given data, the study was excluded from analysis. We extracted weight loss as a positive quantity—i.e., greater than zero. For studies that did not report a standard deviation or for which a standard deviation could not be calculated from the given data, we imputed the standard deviation by using those studies and groups that did report a standard deviation and weighting all groups equally.

We converted all means and standard deviations to kilograms. The vast majority of studies measured weight loss in pounds or kilograms. For the few that measured weight loss in terms of BMI, we converted BMI to kilograms by assuming an average height of 5 feet 4 inches. (Past experience has shown that our results—efficacy of weight loss therapies—vary little if any height between 5 feet and 6 feet is chosen to convert BMI to weight.) We then calculated a mean difference for each study, which was the difference between the control group followup mean weight loss and the medication group followup mean weight loss:

$$\text{mean difference} = \text{control followup mean} - \text{medication followup mean}$$

We also estimated the standard deviation for that mean difference.[42] A negative mean difference indicates that the medication group experienced more weight loss at followup than did the control group. For example, if the medication group lost 3 kg on average and the control group lost 1 kg, the mean difference is –2 kg. The mean difference is readily interpretable because it is measured in kilograms.

Sensitivity Analyses

We conducted sensitivity analyses on four study dimensions: Jadad quality score (less than or equal to 2 versus greater than or equal to 3); year of publication (1998 or earlier versus 1999 or later); completion rate (less than 80 percent versus 80 percent or greater; and less than 70 percent versus 70 percent or greater); and dosage (for the study[43] of bupropion, the 300 mg arm was used rather than the 400 mg arm; for the fluoxetine analysis, the study[44] with the 20 mg dose was

excluded because all other studies used a 60 mg dose; for the topiramate analysis, the 96 mg study arms were analyzed separately from the 192 mg study arms). We tested for differences between subgroups—e.g., the high-quality versus lower-quality studies—by conducting a meta-regression analysis using a single dichotomous variable to indicate subgroup membership.

Performance of Meta-Analysis

For the 6-month and 12-month analyses, respectively, we estimated a pooled random-effects estimate[45] of the overall mean difference. The individual trial mean differences are weighted by both within-study variation and between-study variation in this synthesis. We also report the chi-squared test of heterogeneity p-value based on Cochran's Q.[46] We constructed a forest plot in which each individual trial mean difference is shown as a box whose area is inversely proportional to the estimated variance of the mean difference in that trial. The trial's confidence interval is shown as a horizontal line through the box. The pooled "weighted mean difference" and its confidence interval are shown as a diamond at the bottom of the plot with a dotted vertical line indicating the pooled estimate value. A vertical solid line at zero indicates no effect of medication on weight loss.

Publication Bias

We assessed the possibility of publication bias by evaluating a funnel plot of the trial mean differences for asymmetry, which can result from the nonpublication of small trials with negative results. These funnel plots include a horizontal line at the pooled fixed-effects estimate and pseudo-95% confidence limits.[47] If bias due to nonpublication exists, the distribution is asymmetric or skewed. Because graphical evaluation can be subjective, we also conducted an adjusted rank correlation test[48] and a regression asymmetry test[47] as formal statistical tests for publication bias. The correlation approach tests whether the correlation between the mean differences and their variances is significant, and the regression approach tests whether the intercept of a regression of the mean differences on their precision differs from zero; that is, both approaches formally test for asymmetry in the funnel plot. We acknowledge that other factors, such as differences in trial quality or true study heterogeneity, could produce asymmetry in funnel plots.

Medication Adverse-Events Meta-Analysis

As we described for the meta-analysis of weight loss, our methods for the adverse-event analysis are the same for all medications.

Extraction of Adverse-Event Data

Each trial included in the weight loss analysis was examined to determine whether it reported data on adverse events. Adverse events were recorded onto a spreadsheet that identified each trial group, the description of the adverse event as listed in the original article, and the number of subjects in each group. We then abstracted either the number of events or the number of people, depending on how the trial chose to report events. The majority of trials recorded the number of

events, rather than the number of unique people who experienced the event. Each event was counted as if it represented a unique individual. Because a single individual might have experienced more than one event, this assumption may have overestimated the number of people having an adverse event. In fact, for some adverse events in a few trials, the number of events reported in a group was greater than the number of individuals in that group. In those cases, we assumed that all individuals in the group experienced the adverse event when we calculated the risk of the event in that group, as described below.

If a report of a trial mentioned a particular type of adverse event in the discussion but did not report data on that adverse event, we did not include that trial in that particular event's analysis. In other words, we did not assume zero events occurred unless the trial report specifically stated that zero events were observed. By taking this approach, we may have overestimated the number of patients for whom a particular adverse event was observed.

After abstracting the data, we identified mutually exclusive subgroups of similar events, based on clinical expertise. For example, one subgroup was "gallbladder problems," consisting of all adverse events concerning this body system. When we subgrouped events, we again treated all observed events as having occurred in unique individuals. For example, we considered bloating, abdominal pain, and dyspepsia as a single subgroup: For a trial that reported abdominal pain events and dyspepsia events separately, we assumed the events that occurred in each category were unique and occurred in different individuals. The number of individuals who were at risk of being affected is the total number of patients in the trial's relevant group (medication or control). Tables 1 and 2 present the categories of adverse events for which we considered a pooled analysis, and the exact descriptions used in the original articles that we aggregated into each category.

For each adverse-event subgroup, we report the number of trials that provided data for any event in the subgroup. We also report the total number of individuals in the medication groups in the relevant trials who were observed to have experienced the event and the total number of patients in the medication groups in those trials. We then report the analogous counts for the control groups in the relevant trials.

Meta-Analysis

For subgroups of events that occurred in two or more trials and occurred at least once in the medication group and at least once in the control group, we performed a meta-analysis to estimate the pooled odds ratio and its associated 95% confidence interval. Given that many of the events were rare, we used exact conditional inference to perform the pooling rather than applying the usual asymptotic methods that assume normality. Asymptotic methods require corrections if zero events are observed; generally, half an event is added to all cells in the outcome-by-treatment (two-by-two) table in order to allow estimation, because these methods are based on assuming continuity. Such corrections can have a major impact on the results when the outcome event is rare. Exact methods do not require such corrections. We conducted the meta-analysis using the statistical software package StatXact.[49]

For interpretability, for any significant pooled odds ratio greater than one (which indicates that the odds of the adverse event being associated with medication is larger than the odds of the event associated with being in the control group), we calculated the RR and number needed to harm (NNH). To perform these calculations, we assume that the expected rate of the adverse

event in an untreated population was equal to the observed crude rate among all control patients (the total number of adverse events observed across all control groups divided by the total number of control patients). The number needed to harm is the number of patients who would have to be treated with medication to produce one adverse event, on average, and is clinically more interpretable than the odds ratio. We calculated the risk ratio by making the same assumption about the expected rate among untreated patients.

Power Calculation

We also conducted a power calculation to determine the lowest adverse-event rate that the included medication trials had at least 80 percent power to detect. First, we assumed a sample size equal to the total number of patients receiving each medication across all trials for which we had sample size data, either reported directly in trials we reviewed or from sample size data reported in other systematic reviews. We then determined the lowest detectable adverse-event rate based on a two-sided test of level 0.05. This calculation was performed to assess the statistical power we actually had available to detect adverse events if few or none were observed. Even if no adverse events were observed, we cannot necessarily conclude that the rate is zero, because the available sample size may have been too small to detect a rare event.

Surgery Analyses

Because the surgery studies included both controlled trials and case series (which do not include controls), we conducted several types of analysis. The way that studies were handled depended on their design and the type of analysis to which they could be subjected. Duplicate publications on surgery studies were treated as described above for the medication publications.

The vast number of types of surgery reported on in the literature required that we aggregate clinically similar surgeries and also identify the key comparisons between different types of surgeries that were of most interest to the clinical audience. Based on discussions with three expert bariatric surgeons, we categorized obesity surgery procedures by (1) procedure type, (2) whether the procedure was performed laparoscopically or open, and (3) more specific surgical details such as length of Roux limb or whether the band was adjustable or nonadjustable. To allow for comparisons in our analysis, we found it necessary to combine certain procedures that were judged clinically similar. Table 3 shows the categories used for the analysis. Vertical banded gastroplasty (VBG) is the only "gastroplasty" procedure that is performed currently. Thus, the other "gastroplasty" procedures were placed into a separate, single category, to be used for historic comparisons as needed.

Analysis of the Efficacy of Surgical Weight Loss

We first summarized the Cochrane review[38] on surgical studies of weight loss. For all surgical studies that we found, we also extracted the mean weight loss and its standard deviation for each study group, generally defined by surgery procedure, at 12 postoperative months and at the maximum followup time greater than or equal to 36 months, as available. We followed the same procedures regarding imputation, conversion to kilograms, and conversion of BMI measurements as we did for the medication meta-analysis.

For randomized controlled trials that reported a within-study comparison of two procedures of interest, a mean difference was calculated (mean weight loss in procedure "1" group minus mean weight loss in procedure "2" group). A positive mean difference indicates that patients in the procedure 1 group lost more weight on average than patients in the procedure 2 group. A negative mean difference indicates that patients in the procedure 1 group lost less weight on average than patients in the procedure 2 group. These mean differences were pooled using a random effects model, and a 95% confidence interval was estimated. For all studies, randomized or not, a pooled mean weight loss for each procedure group was estimated using a random effects model, and an associated 95% confidence interval was constructed.

Analysis of Surgery Mortality

For each group in each study, we recorded the number of deaths observed and the total number of patients in the group. If the study self-identified the deaths as “early” or “postoperative” or if it identified the deaths as within 30 days of the surgery, we termed these “early deaths.” If the deaths were self-identified as “late” or if they were identified as after 30 days, we termed these “late deaths.” If the study was unclear as to the timing of the recorded deaths, we termed these “unclear deaths.” If a study did not report data on death for a group, we recorded zero unclear deaths for that group. That is, we imputed zero for missing data, under the assumption that the authors would have reported a death if there had been one.

For each group of similar procedures (described above in our discussion of the surgery categorization), we conducted analysis for four separate combinations of death definition and type of study: late deaths for RCTs/CCTs; late deaths for CSs; early or unclear deaths for RCTs/CCTs; and early or unclear deaths for CSs. In each setting, we calculated the crude death rate. That is, we divided the total number of deaths observed by the total number of patients in the relevant study groups. This calculation treats all patients from all studies equally and does not take into account any variation across studies in mortality rates, but given the small number of observed deaths, this statistic is simple and easily interpretable.

We were also interested in examining the variation in mortality rates across studies. Thus, for any study with one or more observed deaths, we determined the probability that we would observe as many deaths or more in a sample the size of the study sample, if the population mortality rate is equal to the observed crude death rate. We identified in our results any studies that have a probability less than or equal to 0.05 and, in this way, identified studies with outlying mortality rates compared with the those of the majority of studies. We made this identification by conducting an exact binomial test.

Analysis of Surgery Comorbidity

Three clinicians extracted comorbidity data for all case series studies. Data for diabetes, hypertension, sleep apnea, and lipids were extracted. For each condition, we collected data on the number of people who had the condition at the start of the study. We then collected data on the number of those people whose condition resolved, improved, or was unchanged. A crude proportion was calculated across studies for those who resolved or improved (e.g., the number of people who resolved or improved divided by the number of people with the condition at baseline).

Analysis of Surgery Adverse Events

Each surgery study (RCT/CCT or CS) was examined to determine whether it reported data on adverse events (other than death). The extraction of data for the surgery adverse-event analysis was the same as that described above for the medication trials. After abstracting the data, we identified mutually exclusive subgroups of similar events based on clinical expertise. The actual terms used in the articles that were aggregated into the adverse-event categories are listed in Table 3.

For selected surgery comparisons (one type of surgery versus another type of surgery) for which RCT/CCT data were available, we estimated a pooled odds ratio and its associated 95% confidence interval using exact methods as described above for the medication adverse-events meta-analysis. We also report the crude adverse-event rate for each RCT/CCT surgery group (total number of affected patients divided by total number of patients at risk). In addition, we report the crude adverse-event rate for each surgery group across all studies (RCT/CCT/CS) combined.

Rating the Body of Evidence

We rated the body of evidence on each topic in terms of quality, quantity, and consistency. The quality of the evidence is the aggregate of the quality of the individual studies and is influenced by study design, execution, and analysis of the results. In terms of study design, our minimum criterion for conclusive evidence for the efficacy of a treatment for a chronic disease is that a study have concurrent comparison groups, i.e., conclusive evidence cannot derive solely from case series or studies with historical controls. Empirical evidence shows that studies without a concurrent comparison group report estimates of effect that are inflated when compared with estimates from studies with a concurrent comparison group.[50] Numerous examples of interventions—both medical and surgical—can be cited that reported benefits in case series, only to be shown to be less effective or even ineffective when subjected to a study with a concurrent comparison group.[51,52] Consequently, in order to judge a treatment as having conclusive evidence of effect, we required statistically and clinically significant within-study comparisons of outcomes. In order to have confidence in making cause-and-effect conclusions between the treatment and outcome when assessing a difference in outcome between two groups receiving different treatments, we need to be confident that the groups were sufficiently similar before the treatment. Random assignment of a large number of patients is the best way to obtain similar groups, but that does not mean that conclusive evidence can come only from randomized trials. Rather, when drawing conclusions, we judge the size of the difference in outcome compared to the possibility that there were pretreatment differences between groups that might explain the outcome differences. If a large number of patients are randomly assigned to groups, the two groups are very likely to be similar at baseline, and we are more confident in drawing conclusions about cause-and-effect relationships, even if the difference in outcome is small. However, even when patients are not assigned randomly to groups, we can still draw conclusions about cause-and-effect if the differences in outcome are very large, so large that we judge it unlikely that measured or unmeasured differences in groups could account for the outcome differences.

The quantity of evidence refers to the number of studies, the sample sizes of the studies, and the sizes of the study effects. In the absence of a single very large study, then the number of studies, their sizes, and the sizes of the effects are taken into consideration when assessing the quantity of evidence.

Peer Review

A draft of this report was prepared in October 2003 and sent to the peer reviewers listed in Appendix D. The comments we received from peer review were used to prepare the final report. Service as a reviewer of this report should not in any way be construed as agreeing with or endorsing the contect of the report.

Note: Appendixes and Evidence Tables cited in this report are provided electronically at http://www.ahrq.gov/clinic/epcindex.htm.

Chapter 3. Results

Results of the Literature Search

Our search identified 1,102 articles. Of these 1,102 articles, 291 were references from Broom and colleagues' draft evidence report on obesity treatment ("NHS Report"); 415 were references from the other reviews described in the methods section; our library search identified another 325 articles; and our experts sent an additional 71 articles. Figure 1 displays the flow of the literature review.

We were unable to obtain 11 of the1,102 articles, which were mostly non-English language or very old articles. Our physician obesity specialist rejected another 20 as irrelevant. Eight articles were not received by the cutoff date. This left 1,063 articles to screen.

Of the 1,063 articles screened, 235 articles were either controlled trials of weight loss medication, controlled trials of surgery, or surgery case reports/case series. These articles went on to quality review to assess the applicability for data pooling or narrative synthesis. The other articles were rejected for the following reasons: 113 did not study weight loss; 204 studied diet; 255 others studied an intervention other than weight loss medication or surgery; 30 studied the weight loss drug mazindol, which is rarely used today; 39 studied sibutramine, phentermine, or diethylproprion (for which recent previous meta-analyses of efficacy are summarized in this report); 103 were medication trials with less than six months of followup; 66 were rejected because of study design (descriptive articles, background, reviews, etc.); three were animal studies; three were duplicate articles ordered accidentally; and four articles were published in eastern European languages for which we could not find translators. Ten surgery articles did not include weight loss outcomes but were considered for analysis of adverse events. Two articles compared surgery to diethylproprion and are counted tice in these numbers.

We quality-reviewed 78 medication studies that reported on sertraline (1 article), zonisamide (1 article), orlistat (49), buproprion (5), topirmate (9), and fluoxetine (13). Meta-analysis was performed for all medications except sertraline and zonisamide which are summarized in the text. We quality-reviewed 159 surgery studies reporting on weight loss and considered an additional 8 surgery studies reporting only on complications, for a total of 167 surgery studies. Of these 167 studies, 20 were duplicate publication of an already included study. Of the remaining 147 studies, 89 contributed to the weight loss analysis, 134 contributed to the mortality analysis, and 128 contributed to the complications analysis. Studies could contribute to one or more surgery analyses.

We found no direct comparisons of weight loss medications (key question 2). In addition, we found no RCT evidence regarding the "optimum amount of time to treat" (key question 3). Consequently, our results focused on the efficacy of medications relative to placebo.

Efficacy of Medications

Sibutramine

Our literature search identified a high-quality meta-analysis that was "in press" at the time of our search and has since been published [53]. The authors of this paper agreed to let us incorporate

their results into our evidence report. In their literature search, the authors did not restrict their search to English-language publications and made extensive efforts to identify unpublished and ongoing trials, including contacting representatives of the pharmaceutical industry. Inclusion criteria for the review were that the study was a RCT that assessed sibutramine (10 or 20 mg daily), enrolled adults 18 years of age or older who had a BMI of 25 or more, assessed weight loss, and had a treatment duration of at least eight weeks. The primary outcome was mean change in body weight, and data on blood pressure, heart rate, cholesterol, fasting glucose, and glycosylated hemoglobin were abstracted if reported. Studies were analyzed in three strata, based on duration of the trial: 8 to12 weeks, 16 to 24 weeks, and 44 to 54 weeks. Of 1,245 potentially relevant citations, 432 manuscripts and abstracts were reviewed in more detail, which resulted in 44 trials that were considered for inclusion in their analysis. Ten authors provided additional, unpublished data. The meta-analysis authors identified seven trials of 8 to 12 weeks duration that included a total of 546 participants; 12 trials of 16 to 24 weeks duration that included a total of 1,179 participants; and five trials of 44 to 54 weeks duration that included 2,188 participants. The mean age of enrolled patients ranged from 34 to 54 years of age. Adults with known cardiovascular disease were generally excluded from most primary studies. Dietary interventions were a co-intervention in nearly all primary studies, and exercise and behavior modification were each interventions in about one quarter of the studies. Ultimately, twenty-nine studies met all the authors' criteria for inclusion in the analysis. Of these, 23 (79 percent) had a Jadad score of 3 or greater.

The summary result for weight loss for the seven studies reporting results at 8 to 12 weeks was a mean difference in weight loss (sibutramine compared to placebo) of 2.78 kg (Figure 2). The authors reported that this result changed little in sensitivity analyses that excluded small trials, those with low-quality scores, those reporting data only for subjects who completed the study, or unpublished data.

Among the 12 trials reporting results at 16 to 24 weeks, the authors reported statistical heterogeneity among trials and therefore analyzed the data in three subgroups. Subgroup A included those studies with a greater than 70 percent followup and used the "last observation carried forward" method to impute missing observations (the most recent previous observation is used). This subgroup of studies had a pooled result of 3.43 kg favoring treatment with sibutramine. Studies in subgroup B, which analyzed only participants who completed the entire study, had a summary result of 6.03 kg favoring sibutramine treatment. Studies in subgroup C also used the "last observation carried forward" analysis, had less than 70 percent followup, and had a summary mean difference in weight loss of 6.04 kg in favor of sibutramine treatment. The authors detected statistical evidence of publication bias in these trials (Figure 3).

Among the five studies that assessed outcomes at 44 to 54 weeks duration, the summary mean difference in weight loss was 4.45 kg favoring sibutramine (Figure 4). This result was changed little by the authors' sensitivity analysis, and no evidence of publication bias was detected.

In a dose-ranging study not included in the meta-analysis, 1,047 patients were given instructions on diet, physical activity, and lifestyle changes and then randomized to received placebo or sibutramine at 1 mg, 5 mg, 10 mg, 15 mg, 20 mg, or 30 mg a day. Weight loss at 24 weeks was dose-dependent, with a mean weight loss above placebo equal to 4.9 percent, 6.2 percent, 7.6 percent, and 8.2 percent for the 10 mg, 15 mg, 20 mg, and 30 mg doses,

respectively. Side effects such as dry mouth, insomnia, and nausea also increased in a dose-dependent manner.[54] Of note, sibutramine was not FDA approved in the 20 mg and 30 mg doses.

Regarding other assessed outcomes, the authors did not identify any evidence that sibutramine reduces mortality or morbidity from obesity-associated diseases. Systolic and diastolic blood pressure outcomes were variable, with some studies reporting small decreases and other studies reporting small increases. Fasting blood glucose and hemoglobin A1c fell slightly in sibutramine-treated patients, but no consistent effect was observed on cholesterol or lipid outcomes. Adverse-event analysis identified no studies in which participants died. The analysis showed that in patients who took sibutramine, heart rate was consistently increased by about four beats per minute.

The conclusions of this systematic review and meta-analysis were that sibutramine with lifestyle modification was more effective than placebo with lifestyle modification in promoting weight loss in overweight and obese adults at all time points that were assessed, with an average of 4.5 kg greater weight loss at one year and a 20 to 30 percent greater likelihood of achieving a weight loss of 5 percent or more (compared to placebo). The authors also concluded that treatment with sibutramine is associated with modest increases in heart rate and blood pressure, very small improvements in glycemic control among diabetics, and (based on the longest-duration and best-quality studies) small improvements in HDL cholesterol and triglycerides. Efficacy and safety beyond two years of treatment are unknown. We calculated that, in aggregate, the RCTs of sibutramine contained sufficient numbers of patients to evaluate adverse outcomes that occurred at a rate of 8 per 10,000 or higher; the existence of outcomes at lower rates is untested.

Orlistat

Our literature search identified 28 studies of orlistat eligible for inclusion in a meta-analysis.[55-82] The average age of patients enrolled in these studies was 48 years old; 73 percent were women; and the average BMI was 36.7. In all 28 studies, diet was a co-intervention in all experimental arms; 39 percent of studies included educational, behavioral, or psychosocial co-interventions; and 18 percent of studies included exercise co-interventions. Consistent with the meta-analysis of sibutramine, we stratified the data according to treatment duration for analysis.

We identified 11 studies[56, 63, 65-68, 70, 72, 78, 81, 82] that reported six-month treatment outcomes. The weight loss for individual studies is presented in Table 4 and shown graphically in Figure 5. The pooled random-effects estimate of the mean weight loss for orlistat-treated patients over placebo-treated patients, was 2.51 kg (95% CI, 1.63, 3.4). The total weight lost in the orlistat-treated patients was 5.35 kg. Significant heterogeneity was found among studies ($p = 0.00$). In a sensitivity analysis by study quality, five studies with a Jadad score of 3 or more showed a pooled random-effects estimate of mean weight loss of 2.32 kg (95% CI, 1.0, 3.6) over placebo. No effect of quality score on outcome was detected by meta-regression. No effect of year of publication on outcome was detected. No sensitivity analysis by dose was possible. All studies had followup rates of 80 percent or more, so no sensitivity analysis by followup was performed. No evidence of publication bias was found.

We identified 21 studies[55-58, 60-63, 69-71, 73-77, 79, 80, 82-84] that reported data with 12-month outcomes. The weight loss for individual studies is presented in Table 5 and shown graphically in Figure 6. The pooled random-effects estimate of the mean weight loss for orlistat-treated patients,

compared to placebo-treated patients, was 2.75 kg (95% CI, 2.2, 3.3). The total weight lost in the orlistat-treated patients was 8.10 kg. Significant heterogeneity was observed between studies (p = 0.00). In a sensitivity analysis by study quality, 15 studies with a Jadad score of 3 or more had a pooled random-effects estimate of mean weight loss of 2.58 kg (95% CI, 1.9, 3.3). No effect of quality score on outcome was detected by meta-regression. No effect of year of publication on outcome was detected. No sensitivity analysis by dose was possible. In a sensitivity analysis by followup rate, the pooled random-effects estimate of 15 studies with followup rates of 70 percent or more was a mean weight loss of 2.83 kg (95% CI, 2.0, 3.6) over placebo; using 80 percent as the threshold for successful followup, no effect of completeness of followup on outcome was detected by meta-regression. One test of publication bias was statistically significant (Egger's test p = 0.006), whereas the other test was not (Begg's test p = 0.695).

Table 6 presents the results of our adverse-event analysis for orlistat. In this analysis, all 28 studies were considered for inclusion. Our results indicate an increase in diarrhea, flatulence, and bloating/abdominal pain/dyspepsia in orlistat-treated patients compared to placebo, with RR of 3.4, 3.1, and 1.5, respectively. As described in Chapter 2, adverse-event data are typically reported as the number of adverse events, rather than per patient. Thus, our results may overestimate the number of individuals who reported the adverse events, because we cannot distinguish between one person who reported diarrhea twice and two people who each reported diarrhea once. Five trials reported more incidents of diarrhea than the number of enrolled subjects; for these five (out of 13 trials reporting this complication), we assumed all patients reported this event. Hence, we may overestimate the true risk of diarrhea. Nevertheless, our data suggest significant gastrointestinal side effects from orlistat. We attempted to determine if the proportion of persons reporting adverse events decreased over time, but since our search strategy eliminated studies with a duration of less than 6 months we could assess only whether adverse-event reports differed between 6 and 12 months. No difference was detected. We calculated that in aggregate, the RCTs of orlistat contained a sufficient number of patients to evaluate outcomes occurring at a rate of 2 per 10,000 or higher; the existence of outcomes at lower rates is untested.

Phentermine

Our literature search identified a recent meta-analysis[85] that assessed RCTs of the use of phentermine for weight loss in obese individuals. This review identified nine studies published between 1975 and 1999. Our literature review identified no new RCTs of phentermine since this time; consequently, we rely on the existing meta-analysis for our evidence regarding efficacy of phentermine. In this review, six placebo-controlled RCTs contributed data to the pooled analysis. The duration of treatment with phentermine varied from 2 to 24 weeks. More than 80 percent of enrolled individuals were female, and more than 80 percent of participants also received lifestyle modification treatments as co-interventions. The dose of phentermine ranged from 15 to 30 mg a day. In the authors' pooled analysis, subjects treated with phentermine lost an average of 3.6 additional kg of weight compared to placebo, (95% CI, 0.6 to 6.0). In an analysis assessing the effect on maintenance of weight loss, the authors reported that patients treated with phentermine maintained a "fairly large" weight loss compared to placebo (2.43 kg) after discontinuation of the drug. The authors concluded that phentermine use, in addition to lifestyle interventions, resulted in a statistically significant, but modest, increase in weight loss. In this review, no side-effect or adverse-event data were reported. We identified no systematic reports of adverse events

with phentermine. However, since phentermine is a sympathomimetic amine, side effects consistent with this class of drugs can be expected, e.g. palpitations, tachycardia, elevation of blood pressure, central nervous system effects, and gastrointestinal effects. Case reports of stroke in persons taking phentermine for weight loss have been reported,[86,87] but as with all case-report analyses, a causal relationship cannot be established or assumed. We calculated that in aggregate, the RCTs of phentermine contained sufficient numbers of patients to evaluate outcomes occurring at a rate of 8 per 1,000 or higher; the existence of outcomes at lower rates is untested.

Diethylpropion

Our literature search identified a recent meta-analysis[85] that assessed RCTs of the use of diethylpropion for weight loss in obese individuals. This review identified 13 studies published between 1965 and 1983. Our literature review identified no new RCTs of diethylpropion since this time; consequently, we rely on the existing meta-analysis for our evidence regarding efficacy of diethylpropion. In this review, nine placebo-controlled RCTs contributed data to the pooled analysis. The duration of treatment with diethylpropion varied from 6 to 52 weeks. More than 80 percent of enrolled individuals were female, and 100 percent of participants received lifestyle modification treatments as co-interventions. The dose of diethylpropion was 75 mg a day. In the authors' pooled analysis, subjects treated with diethylpropion lost an average of 3.0 additional kg of weight over placebo (95% CI, -1.6, 11.5). The authors concluded that diethylpropion use, in combination with lifestyle interventions, was associated with a modest increase in weight loss of borderline statistical significance. In this review, no side-effect or adverse-event data were reported. We calculated that, in aggregate, the RCTs of diethylpropion contained sufficient numbers of patients to evaluate outcomes occurring at a rate of 8 per 1,000 or higher; the existence of outcomes at lower rates is untested.

Fluoxetine

Our literature search identified nine studies of fluoxetine treatment that reported weight loss outcomes (fluoxetine is usually indicated for treatment of depression, obsessive compulsive disorder, and bulimia).[44,88-95] Of note is that the doses used for weight loss were higher (60 mg) than those used for depression (20 mg). The average age of patients enrolled in these studies was 48 years old; 69 percent were women; and the average BMI was 35.5. In 78 percent of the studies (7 of 9), diet was a co-intervention; 33 percent of studies included an educational, behavioral, or psychosocial co-intervention; and 12 percent of the studies included exercise as a co-intervention. Consistent with the analyses of sibutramine and orlistat, we stratified the data according to treatment duration for analysis.

We identified seven studies of fluoxetine that reported weight loss outcomes at 6 months. The individual weight loss values for each study are listed in Table 7 and shown graphically in Figure 7. The pooled random-effects estimate of the weight loss in fluoxetine-treated patients, compared to placebo-treated patients, was 4.74 kg (95% CI, 2.8, 6.7). The total weight lost in the fluoxetine-treated patients was 5.81 kg. Significant heterogeneity was found among studies ($p = 0.00$). In sensitivity analyses of study quality, the pooled random-effects estimate for four studies with Jadad scores of 3 or more found a mean weight loss of 5.27 kg (95% CI, 3.0, 7.5). No effect

of quality score on outcome was detected by meta-regression. No effect of year of publication on outcome was detected. In a sensitivity analysis that dropped the one study that used only 20 mg/day of fluoxetine, the pooled estimate of increased weight loss in the remaining six studies was 5.36 kg (95% CI 3.7, 7.0). In a sensitivity analysis by followup rate, four studies with a followup rate of 70 percent or more had a pooled random-effects estimate for mean weight loss of 3.96 kg (95% CI, 1.4, 6.5). Using 80 percent as the threshold for successful followup, no effect of completeness of followup on outcome was detected by meta-regression. We did not detect any evidence of publication bias.

We identified six studies of fluoxetine that reported weight loss outcomes at 12 months.[44,88-92] The individual results for studies are listed in Table 8 and shown graphically in Figure 8. The pooled random-effects estimate of weight loss in fluoxetine-treated patients over placebo-treated patients was 3.15 kg (95% CI, 0.5, 5.8). The total weight lost in the fluoxetine-treated patients was 4.70 kg. There was significant heterogeneity among studies (p = 0.00). In sensitivity analyses by study quality, the pooled random-effects estimate for four studies with Jadad scores of 3 or more was a mean weight loss of 3.28 kg (95% CI, 0.6, 7.2) over placebo. No effect of quality score on outcome was detected by meta-regression. No effect of year of publication on outcome was detected. In a sensitivity analysis that dropped the one study that used only 20 mg/day of fluoxetine, the pooled estimate of increased weight loss in the remaining five studies was 3.9 kg (95% CI 0.9, 6.9) In a sensitivity analysis by followup rate, the pooled random-effects estimate of effect for three studies with followup rates of 70 percent or more was a mean weight loss of 2.60 kg (95% CI, -2.0, 7.2) over placebo. Using 80 percent as the threshold for successful followup, no effect of completeness of followup on outcome was detected by meta-regression. We did not detect any evidence of publication bias.

Table 9 presents the results of our adverse-event analysis, which included all nine studies. Our results indicate an increase in nervousness/sweating/tremors, nausea/vomiting, fatigue/asthenia/ hypersomnia/somnolence, insomnia, and diarrhea in fluoxetine-treated patients compared to placebo-treated patients, RR 6.4, 2.7, 2.4, 2.0, and 1.7, respectively). Our results may overestimate the risk of side effects, because we cannot distinguish between one person who reported nervousness twice, and two people who each reported nervousness once. Nevertheless, the results indicate that certain central nervous system and gastrointestinal adverse events are common with fluoxetine treatment. The literature on the use of fluoxetine for other indications is large, and the results of our analysis are comparable with the adverse events reported in those studies.

Sertraline

Our literature search identified one study of sertraline.[96] This study assessed the effect of sertraline in maintaining weight loss in 53 women (out of a total of 68) who had completed a 26-week weight reduction program that combined a very low calorie diet and behavior therapy. To be eligible for inclusion in the sertraline trial, subjects had to have lost at least 10 percent of their initial weight; they were then randomly assigned to receive sertraline beginning at 50 mg per day, titrating upwards to 200 mg per day, or placebo. All patients also attended a 54-week relapse prevention program that addressed skills required to maintain weight loss. Patients had a mean age of 42 years and a mean BMI of 30, having lost approximately 23 kg in the prior six-month study. At the end of the 54-week period of evaluation, sertraline-treated patients had

regained an average of 17.7 kg, while placebo-treated patients had regained an average of 11.8 kg, a difference the authors did not report as statistically significant. However, in the first 10 weeks of the study, sertraline-treated patients regained significantly less weight than did the placebo-treated patients.

More sertraline-treated patients than placebo-treated patients reported fatigue, nausea, difficulty concentrating, and problems urinating. Three sertraline-treated subjects discontinued the study because of adverse events, compared with no adverse events were associated with the placebo. Of note is that insomnia, headache, nausea, and fatigue were reported by approximately half of all sertraline-treated patients.

Bupropion

Our literature search identified five articles assessing the efficacy of bupropion for weight loss. Of the five, one article[97] was an abstract that reported the same data as a subsequent full report,[43] so only four articles reported on unique studies. One of those studies was dropped because the duration of treatment and followup was only 8 weeks, which left three studies available for a pooled analysis. In these three studies, the average age of enrolled patients was 42.7; 81 percent were female; and the average weight was 94.3 kg. Patients in one study[98] had major depression and in another[99] had depressive symptoms. Two studies reported results at 6 months,[43,99] and one study reported results at 12 months.[98] Hence, we were unable to do separate analyses by 6-month and 12-month outcomes, and readers should keep in mind that our pooled result for bupropion is a mix of 6- and 12-month outcomes. Two of the three studies included diet as a co-intervention, and one study included exercise. One study reported results for both 300 mg/day and 400 mg/day of bupropion; the other two studies assessed only the 400 mg/day dose. In this analysis, we present results only for 400 mg/day of bupropion compared to placebo. The individual weight loss values for each study are presented in Table 10 and shown graphically in Figure 9. The pooled random-effects estimate of the weight loss in bupropion-treated patients compared to placebo-treated patients was 2.77 kg (95% CI 1.0, 4.5). The total weight loss in the bupropion-treated patients was 4.14 kg. There was significant heterogeneity among studies ($p = 0.000$). There were too few studies to support sensitivity analyses based on study quality, year of publication, or dose. We did not detect any evidence of publication bias.

Table 11 presents the results of our adverse event analysis. Our results indicate an increase in dry mouth (pooled odds ratio = 3.26, RR = 2.99), and nonsignificant increases in diarrhea and constipation. The research literature on the use of bupropion for depression and smoking cessation is extensive: In addition to dry mouth, insomnia is a commonly reported side effect in these studies.

Topiramate

Our literature search identified nine studies that assessed the efficacy of the drug topiramate for weight loss. One study,[100] which did not include a placebo group, is excluded from review. One study[101] was dropped because it duplicated data in another included study.[31] Two articles reported data on the same trial;[102,103] however, one had a larger sample size, so only it was included, leaving six studies for analysis. [31,103-107] These six were judged sufficiently clinically similar to support a pooled analysis. All but one of these studies were published only as abstracts at the time of our

analysis. Of note, all these studies reported their data only as percent weight loss, so the outcome for this analysis was percent weight loss. Many of the studies assessed multiple doses, the most common being 96 mg/day and 192 mg/day. We determined that the higher dose produced significantly more weight loss than the lower dose (by 1.75 percent) over the duration of the study, so we present data only on the higher dose. In these studies, the average age of subjects was 47; 68 percent were female, and the baseline weight was 102 kg. Four of the six studies had as co-interventions diet, exercise, education, and behavioral theraphies.

The individual percent weight loss values for the six studies reporting 6-month weight loss outcomes are listed in Table 12 and graphically in Figure 10. The pooled random-effects estimate of the percent weight loss in topiramate-treated patients, compared to placebo-treated patients, was 6.5 percent (95% CI 4.8 percent to 8.3 percent). The total percent weight lost in the topiramate-treated patients was 8 percent. In a sensitivity analysis of study quality, only one study had a Jadad score of 3 or greater (as studies were assessed based on data in abstracts, this finding may have been the result of the incomplete nature of the report), and its exclusion did not materially alter the pooled result. All studies were recent, so no sensitivity analysis by year of publication could be performed. As previously mentioned, in our dose analysis, we determined that a daily dose of 192 mg/day produces more weight loss than a daily dose of 96 mg/day. Only one study reported a followup rate of less than 80 percent and its exclusion did not materially alter the pooled result. We did not detect any evidence of publication bias.

Table 13 present the results of our adverse event analysis. Paraesthesia and taste perversion were reported much more commonly in topiramate-treated patients than in placebo-treated patients (pooled odds ratios of 20 and 11, respectively; RR of 4.9 and 9.2). Other central nervous system effects and gastrointestinal effects were also reported more commonly in topiramate-treated subjects. Adverse events were more common in patients treated with 192 mg/day of topiramate compared to 96 mg/day. We calculated that, in aggregate, the topiramate studies had enough patients to evaluate outcomes occurring at a rate of 3.2 per 1,000; the existence of outcomes at lower rates is untested.

Zonisamide

Our literature search identified one eligible study that assessed the efficacy of the drug zonisamide for weight loss.[108] This study was a double-blind, RCT that enrolled 60 patients with a mean age of 37 years. Approximately 90 percent were women, and their mean BMI was 36. Patients were randomized to begin receiving placebo or zonisamide at 100 mg per day; daily doses were increased to a maximum of 600 mg per day, based on response. Patients in both groups were also instructed to follow an individualized diet that was devised to reduce their daily energy intakes to 500 kilocalories per day below maintenance level. Increased physical activity was also encouraged for participants in both groups. Patients were followed for 16 weeks in the double-blind portion of the study, with an additional 16-week single-blind extension available. Of the 60 patients, 51 (85 percent) completed the 16-week phase. Using a “last observation carried forward” analysis for dropouts, the researchers found that patients in the zonisamide group lost an average of 6.0 percent of baseline body weight, compared to 1.0 percent for placebo patients ($p < .001$). In the extension phase of the study, 37 patients (20 in the zonisamide group, 17 in the placebo group) continued, and 36 completed the study at week 32. Ten of the 19 zonisamide patients who completed the study had lost at least 10 percent of initial body weight at

week 32 (compared with none of the placebo patients) ($p < .001$). Heart rate decreased by an average of approximately two beats per minute in the overall sample, and there were no differences between groups. The authors reported that systolic and diastolic blood pressure readings did not change over time. The authors also reported that the total numbers of adverse effects over the study period were 2.1 and 1.6, for those assigned to zonisamide and placebo, respectively, a difference that did not reach statistical significance. Among individual adverse effects, the only statistically significant differences observed were in fatigue: ten patients in the zonisamide group reported fatigue, compared with one in the placebo group ($p < .006$ by the Fisher exact test). The mean serum creatinine increased from 0.79 milligrams per deciliter to 0.92 milligrams per deciliter for zonisamide-treated patients and from 0.76 milligrams to 0.79 milligrams per deciliter in placebo-treated patients ($p < .001$).

Summary of Medication Studies

Table 14 presents a short summary of our findings regarding medications. As previously stated, we identified no direct comparisons of weight loss medications. Our summary of the results for each drug (compared to placebo) does not support a hypothesis that any one drug is more effective than the others, as the difference among drugs in placebo-corrected mean weight loss at one year is only about 1 to 2 kg. A further observation is that none of these medications appears to support large weight loss: The mean placebo-corrected weight loss for all drugs was less than 5 kg at one year. Total weight loss at one year was higher, up to 8.0 kg. However, as noted in the introduction, even moderate weight loss (5 percent of body weight) can significantly influence obesity-associated risk factors for poor health outcome (Type II diabetes, hypertension, etc.).

Efficacy of Surgery for Weight Loss

Our literature search identified a Cochrane review of the literature on surgery for obesity,[38] current as of February 2003. Inclusion criteria for the review were randomized controlled trials (RCTs) and non-randomized controlled trials comparing surgery with nonsurgical management for morbid obesity, and RCTs comparing alternative surgical procedures. The review was restricted to adults age 18 years or older with morbid obesity, defined as BMI greater than 40 or BMI greater than 35 with serious comorbid disease. Studies had to report at least 12 months duration of followup. Because of heterogeneity, the authors did not feel that meta-analysis was justified and summarized their data narratively. The authors identified 2,707 citations, of which they retrieved 99 for detailed examination. Eighteen trials (reported in 33 publications) met their inclusion criteria. The results of their review are summarized in Table 15. The authors concluded that there is limited evidence supporting greater long-term weight loss (maintained at least to eight years) with surgery than with conventional treatments for severe obesity, but that surgery is associated with adverse effects and the possibility of postoperative mortality. In addition, they reported that the data are too limited to draw any conclusions regarding differences in efficacy or safety among surgical procedures. However, the Cochrane review's conclusions were based primarily upon the reports of Andersen and colleagues that compared diet alone to a horizontal, unbanded gastroplasty, which has subsequently been shown to be an ineffective surgical procedure for weight loss and has not been frequently used for over 20 years.

In our review, we went beyond the Cochrane report by including case series articles (those reporting on at least ten cases) in addition to RCTs and also by assessing benefits in terms of weight loss and improvement in comorbidities and risks in terms of adverse events. A total of 142 studies were considered for our analysis. One, a Swedish Obese Subjects (SOS) study,[109-116] was an observational study and will be discussed individually below. We identified 28 RCT/CCTs of surgery[117-148] (all but two of which compared one surgical procedure with another) and 113 case series.[109-116,149-226]

Benefits

Weight loss and maintenance. We identified two RCTs that compared bariatric surgery to a nonsurgically treated control group. The first is the RCT that compared horizontal gastroplasty and diet to diet alone[120,134] and was analyzed in the Cochrane Review. This RCT generated two articles that reported net weight loss at 6 months[121] and 24 months[120] followup. At 6 months, weight loss was not different between the two groups, but at 24 months followup, the net weight change from baseline greatly favored surgical therapy (net weight change of 30.5 kg versus 8.0 kg for surgical and nonsurgical therapy, respectively), although only about half the original patients contributed data at 24 months. We also identified another randomized trial that compared jejunoileal bypass to "medical treatment" (not otherwise specified) in 186 patients. Again at 24 months followup, the mean difference in weight loss greatly favored surgical therapy (mean difference = 37 kg). Of note, these studies were conducted more than 20 years ago, and the surgical procedures assessed are not considered relevant to modern bariatric surgery, in that improvements in procedures and technique have been associated with significantly greater long-term weight loss, as compared to horizontal gastroplasty, and fewer major complications as compared to the jejunoileal bypass.

In addition to the two RCTs, we identified numerous reports from an observational study, the Swedish Obese Subjects (SOS) study.[109-116] In the intervention portion of this study (a cross-sectional registry portion was also included), obese adults (BMI ≥ 34 for men and ≥ 38 for women) were assessed in two groups: those who voluntarily underwent bariatric surgery (most of whom were treated with vertical banded gastroplasty) and a group of matched controls treated medically. Matching was done on 18 variables, including gender, age, height, and weight. The average age of enrolled subjects was 47, about two-thirds were women, and average BMI at baseline was about 41. At eight years of followup, among 251 surgically treated patients, the average weight loss was 20 kg (or 16 percent of body weight), whereas among 232 medically treated patients, the average weight did not change. Patients treated with RYGB lost more weight than those treated with vertical banded gastroplasty or banding procedures.[110] Based on this latter finding and on RCT evidence summarized in the text to follow, had all patients in the SOS trial been treated with RYGB the difference in weight loss between surgical and medical therapy would likely have been even greater—probably on the order of 10 kg more. Even though the SOS study was not randomized, patients were well matched in both groups, and the magnitude of the observed differences is so large that it is very unlikely that unmeasured variables could account for these differences. Thus, we believe this study provides conclusive evidence of the superiority of surgical treatment for the patients enrolled in the study (middle-aged adults with a BMI of about 41). Also contributing to the strength of this study is the extended duration of followup, documenting sustained weight loss and improved health up to eight years after

treatment. The SOS study recently reported sustained improvements in weight loss at 10 years followup, compared to controls (J. Torgerson, presentation at the 2003 annual meeting of the American Society for Bariatric Surgery).

Comorbidities. As mentioned, bariatric surgery is recommended to help control the morbidities associated with excess weight. A series of reports from the SOS study support the superiority of obesity surgery compared to medical therapy in ameliorating or preventing the comorbidities of obesity. At 24 months after surgery, among 845 surgically treated patients and 845 matched controls (two-thirds women, average age of 48, average BMI about 41), the incidence of hypertension, diabetes, and lipid abnormalities was markedly lower in the surgically treated patients (adjusted odds ratios of 0.02 to 0.38, depending on condition).[116] At eight years of followup, the effect of surgery on the reduction in diabetes risk was still dramatic (odds ratio = 0.16), while the effect on reduction in risk for hypertension did not persist (odds ratio = 1.01).[110] However, significant decreases in both systolic (8.3 mm Hg) and diastolic (6.7 mm Hg) blood pressure persisted in the small (6 percent) subset of patients who underwent a gastric bypass and lost significantly more weight than the 94 percent of patients who underwent a vertical banded gastroplasty or gastric banding.[72] Additional reports from the SOS study support a substantial benefit of surgery in reducing sleep apnea,[111] symptoms of dyspnea and chest pain,[111] and improving quality of life.[114] The latter study assessed health-related quality of life in four domains: health perception, mental well being/mood disorders, psychosocial functioning, and self-assessment of eating behavior. The researchers matched 487 surgically-treated patients to an equivalent number of control patients; at two years followup, data were available for 98 percent of surgical patients and 82 percent of control patients. Improvements in all domains in surgical patients compared to control patients were greatest at 6 months after surgery and diminished slightly at 24 months. Differences between groups were substantial in nearly all domains: in general, one-half to two-thirds of an effect size. The differences were related to the degree of weight loss, meaning that patients who lost a greater amount of weight had greater improvements in quality of life. The SOS study is the only one we identified that compares comorbidities between surgically treated patients and a concurrent control group receiving nonsurgical treatment.

We assessed reports of surgery case series for data on the control of four comorbidities: diabetes, hypertension, sleep apnea, and hyperlipidemia. Of the 114 case series publications, 21 papers reported quantitative information on the control of diabetes. The proportion of patients with preoperative diabetes who showed improvement or resolution of their diabetes after surgery ranged from 69 percent to 100 percent, with a median reported value of 100 percent. For control of hypertension, 18 papers reported results that ranged from 25 percent to 100 percent of patients showing improvement or resolution of hypertension following surgery and a median reported improvement of 89 percent. Fourteen studies reported results for sleep apnea: the range of improvement was 95 percent to 100 percent of patients, with a median of 100 percent of patients reporting improvement or resolution of sleep apnea. Ten studies reported on hyperlipidemia following surgery, with 60 percent to 100 percent of patients reporting improvement or resolution of hyperlipidemia following surgery with a median of 88 percent. These reported improvements in comorbidities are substantial and suggest that bariatric surgery is helping to relieve the burden of these comorbidities in severely obese individuals. However, a cause-and-effect relationship cannot be conclusively proven from case series data alone. Still, these results are consistent with the statistically significant improvement reported by the SOS study for

diabetes, hypertension (in the RYGB subset), and sleep apnea, although the magnitude of benefit reported in SOS was smaller than that reported in the case series.

Although not assessed in this report, improvements in cardiac dysfunction,[152,227-231] gastroesophageal reflux,[232-239] pseudotumor cerebri,[240,241] polycystic ovary syndrome,[242] complications of pregnancy,[243-247] stress urinary incontinence,[248] degenerative joint disease,[249-252] nonalcoholic steatohepatitis,[253] severe venous stasis disease,[254-257] and overall quality of life[137, 180, 216,258-267] have been reported in some case series of obesity surgery. As mentioned above, a cause-and-effect relationship cannot be conclusively proven from case series data alone.

Comparing methods. We also identified a large number of RCTs as well as case series that compared weight loss outcomes between or among surgical procedures. Results at 12 months of followup are summarized in Table 16, and results at 36 months (or longer) are summarized in Table 17.

Five RCTs were identified that compared surgical procedures and reported data sufficient for pooling; that is, the studies compared similar surgical procedures and reported weight loss data in sufficient detail. In two studies comparing RYGB procedures to VBG,[128,129] including 231 patients in total, pooled weight loss outcomes for both procedures were substantial (at least 30 kg at 36 months for both) and favored RYGB at both 12 and 36 months (8-9 kg more weight loss from RYGB). These results are supported by the pooled results from all studies combined (both RCTs and case series), which report data on approximately 2,000 patients for each procedure. These combined data show that RYGB patients reported about 10 kg more weight loss than patients treated with VBG, at both 12 and 36 months.

Several additional randomized trials compared RYGB and other gastric bypass procedures with VBG or other gastric partitioning procedures,[125,130,131,140-142] but the results could not be included in our pooled analysis because either they did not report their results in terms of kilograms of weight lost or they did not report the results in sufficient statistical detail. Nevertheless, the results of all these studies support the conclusion that gastric bypass produces superior weight loss to gastroplasty procedures

In two RCTs, the weight lost using VGB, compared to laparoscopic adjustable gastric banding, was 14 kg more at 12 months followup but only about 3 kg more at 36 months followup. No difference in net weight loss was seen in the pooled results from all studies combined.

Finally, one RCT compared open RYGB with that performed laparoscopically.[139] Again, the weight loss for both approaches was substantial, but no significant differences between the two were found (greater than 30 kg for both at 12 months); a result that was supported by the "all studies" pooled analysis at both 12 months and out to 36 months. Because the final anatomic reconfiguration is the same for laparoscopic and open RYGB, weight loss and comorbidity outcomes should be identical. However, these procedures involve very different technical approaches that result in different types and rates of complications.

Summary of Benefit Data

The data we identified support that surgical treatment results in greater weight loss than does medical treatment in obese individuals (BMI ≥ 40), resulting in 20 to 30 kg of weight loss, maintained up to eight years, that is accompanied by significant improvements in several comorbidities. For patients with a BMI between 35 and 40, the data strongly support the

superiority of surgical therapy but cannot be considered conclusive in the absence of a study with a concurrent comparison group. Similarly, the evidence supports but does not prove an effect of surgical treatment for obesity on improvement in a large number of weight-related comorbidities for this population.

Further supporting the superiority of surgical therapy in patients with a BMI of 40 or greater is the observation that the weight loss reported in surgical studies is an order of magnitude greater than weight loss reported in pharmaceutical or diet studies of obesity (weight losses of 20-40 kg at one or two years in surgical studies versus 2 to5 kg in pharmaceutical studies), although direct comparisons cannot be made across studies because the patient populations are clearly different: The surgical studies enrolled only patients who are severely obese, whereas the average BMI in the medical weight loss studies was about 33. Additionally, many surgical studies report sustained weight loss (i.e. at 24 months or longer), whereas studies of medical weight loss therapies that report data beyond 12 months are rare, and those that do tend to report regain of most initial weight loss.

Both RCT data and observational data demonstrate clearly that RYGB results in greater weight loss than vertical banded gastroplasty. All three procedures for which we found data—RYGB; VBG; and laparoscopic adjustable band procedures—report substantial long-term weight loss.

Risks

We divided the risks of surgery or adverse events associated with it, into mortality and morbidity and further divided morbidity risks into four primary and six secondary categories, based on research findings. Our analyses were stratified by study design: Randomized trials have strong internal validity but are frequently of small sample size and limited generalizability; case series frequently contain data on many more patients, but comparisons of outcomes across procedures in different publications may not be warranted. Randomized and controlled clinical trials (CCTs) were considered to have sufficient internal validity for statistical comparisons of outcomes between groups within individual studies to be made, and—where the number of studies comparing the same surgical procedures was sufficient (two or more)—we pooled the results. Data from case series were used (along with data from RCTs/CCTs) to calculate the simple proportion of outcomes by procedure, but no statistical comparisons were made between proportions across different procedures, as we did not judge these comparisons to have sufficient internal validity to justify such comparisons: Patient selection and other factors may vary greatly across studies. Nevertheless, we present these findings alongside our findings from RCTs and CCTs, to allow the reader to compare and contrast the findings from the two study designs.

Our findings for mortality are presented in Table 18. Surgical procedures are divided into four categories: RYGB, biliopancreatic diversion (BPD), adjustable band procedures, and VBG. “Early” deaths were those occurring 30 days or less after the procedure or those self-defined as “early” in the original report. “Late” deaths were those occurring more than 30 days from the procedure or self-defined as “late” in the original report. We included “postoperative” deaths as “early” deaths when the time was not specified. Three observations are worth making from Table 18. First, no clear pattern of differential mortality between the various procedures emerges; second, no clear pattern emerges in terms of higher or lower early death rates in randomized

trials compared with case series. Third, in these reports, early mortality following bariatric surgery is less than 1 percent.

These data on mortality came from selected patient populations, that is, a specific clinic or surgeon performing the procedures on patients enrolled in a research study. The first assessment of 30-day mortality in unselected patients was reported by Dr. David Flum at the 2003 Clinical Congress of the American College of Surgeons.[268] Among more than 62,000 procedures performed in the state of Washington between 1987 and 2001, the 30-day mortality as assessed using administrative data was 1.9 percent. Furthermore, a strong association was observed between a surgeon's experience and mortality: Surgeons who had performed 20 or fewer procedures during the period of the study had an almost 5 percent rate of 30-day mortality.

With regard to adverse events other than mortality, reports vary among the studies. We aggregated these reports by using clinical judgment to create the categories in Tables 3, as described in Chapter 2. Table 19 presents the comparisons among three different procedures: RYGB versus VBG; RYGB versus banding procedures; and VBG versus banding procedures. Data are summarized from RCTs/CCTs (and pooled results calculated, as appropriate) and for case series plus single arms from RCTs/CCTs ("All Studies"). We caution readers when drawing conclusions from these data: *In our judgment, these data support but do not prove any hypothesis.* Still, a few observations are worth noting.

First, we note that most of the RCT/CCT data cells include at most one study. Only four trials were identified, and three of these trials compared RYGB to VBG. In most cases, only a few hundred patients have been studied in each comparison. Second, none of the comparisons of complications between these surgical procedures show statistically significant differences, and the 95% confidence intervals are very wide, that is, we can neither conclude nor exclude that clinically important differences exist. For example, the proportion of patients with reported anastomotic or stomal stenosis was about 5 percent higher (absolute percentage) in the VBG group than in the RYGB group, but these differences are not significant. Third, the absolute rates of some complications are substantial, although many may be minor in their degree of severity. For example, the proportion of subjects receiving VBG who have gastrointestinal complications is 15.2 percent in the RCT/CCT data and 17.8 percent in the case series data; the proportion of subjects receiving RYGB who experience nutritional deficiencies is 26.8 percent in the case series data (many of these nutritional deficiencies were mild); and the proportion of subjects receiving a banding procedure who require reoperation is 7.3 percent in the case series data. Fourth, some differences between procedures in the proportions of subjects with different complications or adverse events are compatible with the anatomic changes caused by the procedure. Thus, for example, gastrointestinal symptoms are reported by almost 18 percent of patients treated with VBG but reported by fewer than half that number of patients treated with banding procedures, although this difference was not statistically significant. At a minimum, these data indicate that the proportion of patients with adverse events or complications may be on the order of 10 percent to 20 percent (although the majority of these may be mild and respond to conservative treatment) and that the occurrence of these complications may differ among procedures in ways that are clinically important.

Table 20 presents our comparisons of adverse events and complications for all bariatric procedures performed with either an open or laparoscopic approach. Again, data are summarized separately for controlled trials and for all studies. While more controlled trials are shown in Table 20 than in Table 19, we note that the number of controlled trials is still relatively small.

Thus, similar caveats apply to the interpretation of these data as applied to the interpretation of the data in Table 20. In contrast to the data presented in Table 19, Table 20 includes several comparisons of RCT/CCT data that have a statistically significant or prima facie difference between procedures: the complications of wound, all; wound infection, major; wound infection, minor; and incisional hernia. Interestingly, for some complications, such as respiratory complications, no data were found to support the beliefs regarding a lower occurrence in laparoscopically treated patients. In summary, the data support a reduced occurrence of wound and incisional hernia complications in patients treated laparoscopically compared to open procedures; however, data are insufficient to reach conclusions about differences in other complications.

Use of Obesity Medication and Bariatric Surgery in the Adolescent and Pediatric Population

As part of our literature search and appraisal process, we attempted to identify studies that reported data specific to adolescent (defined by our technical expert panel as ages 13 to 17) and pediatric (defined by our technical expert panel as age 12 and under) populations. Too few studies were identified to permit quantitative analysis. The following represents a narrative summary of our findings regarding adolescents.

Efficacy and Safety of Weight Loss Medication

We identified three controlled trials of medication that reported data specific to adolescents. One study (described in two reports) assessed mazindol, which was not an included drug for this review.[269,270] A second study assessed the use of a caffeine/ephedrine mixture, which was also not an included drug for this review.[271] Elimination of that study left one study for our review.[272] This study, which examined the efficacy of sibutramine, was conducted in two six-month phases. Phase I was a double-blind RCT; in Phase II, all participants received the drug. The study enrolled boys and girls ages 13 to 17 years who had a BMI of 32 to 44. Subjects were randomized to receive sibutramine (beginning at 5 mg per day and increasing to 15 mg per day) or matched placebo. All participants received the same comprehensive family-based behavioral weight loss program, which included regular group sessions led by dieticians and psychologists or psychiatrists. Participants in both groups were instructed to consume a 1200- to 1500 Kcal-per-day diet of conventional foods with approximately 30 percent of calories from fat, 15 percent from protein, and the remainder from carbohydrate. Exercise of approximately 120 minutes per week or more was also prescribed. Overall, 82 subjects were enrolled, with a mean age of 14 and a mean BMI of 38. Approximately two-thirds of subjects were female. At 6 months, subjects treated with sibutramine lost a mean of 7.8 kg, which was equal to an 8.5 percent reduction in initial BMI, whereas placebo-treated patients had a significantly smaller, 3.2 kg, weight loss, which was equal to a 5.4 percent reduction in BMI. More than twice as many sibutramine-treated patients achieved a 5 percent to 10 percent reduction in initial BMI than did placebo-treated patients. During Phase II, the patients who had switched from placebo treatment to sibutramine lost an additional 1.3 kg of weight, while those who continued on sibutramine gained 0.8 kg.

Sibutramine-treated subjects had an average increase in heart rate of five to six beats per minute compared to placebo-treated subjects, whereas blood pressure changed minimally between groups. With respect to other adverse events, three of the patients treated with sibutramine experienced a "marked and sustained" increase in blood pressure of greater than or equal to 10mm Hg, which required discontinuation of the medication; no such events were reported in the placebo group. No other differences in adverse events were reported between groups.

Efficacy of Bariatric Surgery

Our literature search identified twelve papers that reported weight loss after bariatric surgery in adolescents. Three of these papers[196-198] reported results following jejunoileal bypass and will not be considered here. Two papers[273,274] reported case series results from the same institution; only the latter paper is included to avoid potentially double counting patients.

The first study was a case series of ten adolescents who underwent RYGB surgery.[275] These patients ranged in age from 15 to 17 years, 7 of the 10 were female, and their BMIs ranged from 41.4 to 70.5. Most patients had comorbidities, including sleep apnea, hypertension, and vertebral compression fractures. The authors reported no early postoperative complications. Weight loss in excess of 30 kg was observed in 9 of the 10 patients at postsurgical followup times of 8 months to 156 months. The "most serious complication" reported was protein calorie malnutrition and micronutrient deficiency, which developed in one patient approximately one year after the bypass. This patient's recovery was "uneventful" after total parental nutrition was instituted. Two other patients had symptomatic cholelithiasis that required cholecystectomy. A fourth patient experienced small bowel obstruction ten years after gastric bypass surgery, and a fifth patient required repair of an incisional hernia. Iron deficiency anemia occurred in five of the seven girls, and transient folic acid deficiency occurred in three patients.

The second study reviewed the 20-year experience of one bariatric surgery center with adolescents ages 13 to 17.[276] Thirty-three subjects received surgery between 1981 and 2001. Of these 33, 19 were female and 14 were male. The mean preoperative BMI was 52, and the mean age was 16 years. Preoperative comorbid illnesses included one case of Type II diabetes, 10 cases of hypertension, 6 cases of sleep apnea, 5 cases of gastroesophageal reflux, and 10 cases of degenerative joint disease. One patient underwent horizontal gastroplasty, two had vertical banded gastroplasties, 17 had standard gastric bypass procedures, 10 had long limb gastric bypass, and three had distal gastric bypass. The authors reported no operative deaths or anastomotic leaks. They reported one case of pulmonary embolism, one major wound infection, four minor wound infections, three stomal stenoses treated with laparoscopic dilation, and four marginal ulcers treated medically. The authors report initial weight loss in all patients, but five patients had regained all or most of their lost weight at five or ten years after surgery. For the other 28 patients, the authors report an average of 77 percent of excess weight lost and a BMI of 29 at five postoperative years, with slight increases over longer durations (to a BMI of 30 and 31 at ten years and 14 years, respectively). Two late deaths were judged unrelated to surgery. Comorbid conditions were resolved in all but two patients with hypertension, two patients with gastroesophageal reflux disease, and 7 patients with joint pain.

The third study[277] reported the results of one surgeon's experience performing the procedures on 22 severely obese children between 1983 and 1995 (9 males and 13 females; 3 patients were

under the age of 12). During the first 5 years of the study period, VBG was performed; then the procedure was changed to RYGB and BPD. The author stratified his analysis by the diagnosis of preoperative sleep apnea. Among patients without the diagnosis, the BMI fell postoperatively from 56.4 to 35.5, whereas among those with the diagnosis, the BMI fell from 70.3 to 46.5. Of the nine sleep apnea patients who had long-term followup, all had resolution of their sleep apnea. Postoperative complications included one case each of vitamin A and D deficiency, folic acid deficiency, gallstone development, kidney stone, laryngeal edema, and incisional hernia, and three cases of protein deficiency. One patient was found to have a brain stem tumor at the time of operation and subsequently died. The author reported two late deaths, the one just mentioned and one in an eighteen-year-old female who was found dead at home 3.5 years postoperatively.

The fourth study[274] reports the results of gastric bypass surgery in 41 children and adolescents, including 11 with Prader-Willi syndrome (a type of developmental disability that is characterized in part by insatiable appetite and resultant weight gain), who were all under age 20 years. Most patients underwent gastric bypass; however, eight patients had gastroplasty. Results reported here are for the 30 patients without Prader-Willi syndrome only. The average preoperative weight was 238 percent of ideal body weight. At three years post-op, average weight decreased to 171 percent of ideal body weight, and at five years post-op, it was 187 percent of ideal body weight. Eleven major complications occurred in the early postoperative period : three wound infections, two of which occurred in conjunction with dehiscence; two cases of stomal obstruction (one which required revision); three cases of atelectasis; two cases of pneumonia; and one case of subphrenic abscess. Two deaths occurred. One death occurred on the third postoperative day, ostensibly due to a suture line leak and overwhelming sepsis or massive pulmonary embolus, although no postmortem was performed. The second death was sudden and unexpected at 36 months postoperatively. Four of the patients ultimately underwent revisions for failure to lose weight satisfactorily.

Two studies reported results for patients who were treated with laparoscopic gastric banding. The first of these[278] studies reported on 17 patients under the age of 20 who were operated on by a single surgeon; of these patients, 7 were between the ages of 12 and 17. Among the larger group of 17 patients, the median preoperative BMI was 44.7 which fell postoperatively to 36.1 at 6 months, 32.6 at 12 months, and 30.2 at 24 months. The authors reported no effect on growth or development at followup in patients who underwent the procedure. They also reported complications in two patients, one with band slippage at 11 months, which was corrected laparoscopically, and another that required replacement of a leaking port. The second study[279] reported on 11 patients between the ages of 11 and 17 years (8 girls), all of whom received laparoscopic adjustable gastric bands. The mean preoperative BMI was 46.6. One patient had heart failure and pulmonary hypertension, two patients had amenorrhea, and another had gallstones. The author reported no perioperative complications and no late complications. After a mean of 23 months of followup, the mean BMI had fallen to 32.1 with improvement in all comorbid conditions.

The last two studies involved surveys of patients who had undergone bariatric surgery as adolescents. The first of these contacted 14 of 18 patients who had been less than 21 years of age at the time of surgery (performed between 1982 and 1994). These patients (11 females and 3 males) had all undergone VBG. The preoperative BMIs were 45 and 59, respectively, which fell postoperatively, and at the time of the interview were 33 and 35, respectively. The authors reported that one male patient with preoperative sleep apnea had “complete clinical resolution”

following weight loss. The second study consisted of an interview of 34 out of 39 patients who had undergone RYGB or VBG between 1979 and 1990. The patients (27 females and 7 males) were all between the ages of 11 and 19 at the time of the surgery. Preoperative BMI averaged 47 and at followup was 32. Complications included a staple line failure in one patient, which was also "suspected in other patients with large weight regains." The authors reported no major postoperative complications. Five revision procedures and four subsequent cholecystectomy procedures were scheduled or performed.

In summary, a handful of case reports of bariatric surgery in adolescents have appeared, reporting on a total of 172 subjects. These reports document benefits in terms of weight loss and resolution of complications as well as harms in terms of surgical complications. No studies have compared these benefits and harms to those of similar patients who received nonsurgical therapies such as diet or medication.

Chapter 4. Discussion

In this chapter, we describe the limitations of our review and meta-analysis and then present our conclusions. We also discuss the implications of our findings for future research.

Limitations

Publication Bias

Our literature search procedures were extensive and included canvassing experts regarding studies we may have missed. However, we tested for evidence of publication bias only in the medication meta-analysis and found such evidence in one case (orlistat at 12-month followup). We made explicit assumptions about the lack of reporting of mortality and other adverse events and discussed the possible bias that might result. We acknowledge that publication bias may still exist despite our best efforts to conduct a comprehensive search and the lack of statistical evidence for the existence of bias. Publication bias may occur for a variety of reasons, including investigators' loss of interest in the study if "negative" results are obtained or if results are contrary to the interest of the sponsor or investigator.

Study Quality

An important limitation common to systematic reviews is the quality of the original studies. Recent efforts to identify elements of study design and execution that may be associated with bias have, in many cases, been unable to distinguish biased studies or provided results that were not reproducible. Therefore, the current state of the science is to avoid rejecting studies or using quality criteria to adjust the results of meta-analysis. Thus, we made no attempt to assign greater importance to some studies based on "quality." Because empirical evidence is lacking regarding the relationship of other study characteristics to bias, we did not attempt to use other criteria. Most of the studies of orlistat and fluoxetine had Jadad scores of 3 or greater, a threshold that in other settings has been shown to be associated with less bias. Our sensitivity analyses on these higher-quality RCTs upheld our main result. Also, to be as inclusive as possible for purposes of assessing safety, we did consider nonrandomized and noncontrolled studies in our surgery analysis while noting the limited inferences that can be drawn from such designs.

Heterogeneity

Evidence of heterogeneity was observed for all the medication meta-analyses. We used a pooled random-effects approach to attempt to incorporate any heterogeneity and assessed the results of sensitivity analyses using variables that might account for heterogeneity (quality, completeness of followup, dose, year of publication). However, we were unable to explain most of the heterogeneity. Our pooled results should be interpreted in light of the observed heterogeneity.

Followup Times

For medication studies, we were able to perform meta-analysis only on 6-month and 12-month followup results for medication studies. For the surgical studies, the wide variation in followup times should be kept in mind when considering our pooled results.

Applicability of Findings

The results of the studies we synthesized are directly applicable only to the persons included in those studies. In some cases, enrollment was highly selective to avoid certain comorbidities. Whether the results are applicable to more representative populations is unknown.

Conclusions

With the above limitations in mind, we reached the following conclusions:

- RCT data are sufficient to allow us to conclude that sibutramine, orlistat, phentermine, diethylpropion (probably), fluoxetine, bupropion, and topiramate all promote weight loss for at least six months when given along with recommendations for diet (and possibly other behavioral and exercise interventions). The amount of extra weight loss attributable to these medications is modest (less than 5 kg at one year) but still may be clinically significant. The most well-studied medications are sibutramine and orlistat; thus, our conclusions for these medications are stronger than for the others.

- One RCT supports the efficacy of zonisamide for weight loss. Stronger conclusions cannot be drawn without additional studies.

- All these drugs have side effects. The side-effect profile varies by drug. Sibutramine causes modest increases in heart rate and blood pressure; gastrointestinal symptoms predominate in the use of orlistat; phentermine causes cardiovascular and gastrointestinal side effects; fluoxetine causes agitation and nervousness in addition to gastrointestinal side effects; bupropion causes paresthesia, insomnia, and central nervous system effects; topiramate causes paresthesia, and changes in taste. The choice of medications for weight loss probably rests on individual tolerance to the side effect profile.

- In general, these drugs have not been studied sufficiently to evaluate the risk of rare (less than one per 1,000) side effects.

- No data exist to allow the relative efficacy of these drugs to be compared. Based on placebo-controlled studies, no drug appears to be substantially more effective than any other. The lack of published, pharmaceutical company-sponsored head-to-head trials of weight loss medications is itself illuminating.

- No experimental data address the optimal duration of treatment with medication or how the optimal duration may vary by age, gender, or race.

- Bariatric surgical treatment results in greater sustained weight loss than nonsurgical treatments in very obese individuals (BMI ≥ 40), resulting in improved health outcomes (reduction in diabetes and sleep apnea, improved quality of life). While not conclusive, the data suggest greater sustained weight loss for bariatric surgical treatment than for nonsurgical treatment in patients with BMI between 35 and 40.

- RYGB, VBG, and adjustable banding procedures all result in substantial weight loss.

- RYGB results in greater weight loss than VBG in severely obese individuals.

- Postoperative mortality rates of less than 1 percent have been achieved by a number of surgeons and bariatric surgical centers. The postoperative mortality rate in other settings may be higher.

- Few clinical trials have compared outcomes among different bariatric surgical procedures. The existing data suggest the possibility of clinically important differences in the proportion of patients reporting various complications and adverse events among those treated with RYGB, VBG, and adjustable banding procedures.

- Laparoscopic procedures result in fewer wound complications or incisional hernias than open procedures.

- The actual proportions of patients who experience some complications of bariatric surgery may be quite substantial, greater than 20 percent (although most are minor in severity).

- The existing literature is almost bereft of data regarding either pharmaceutical or surgical treatment of adolescent and pediatric patients. To the extent that existing data on adults are judged to be inapplicable to adolescents or children, new studies will need to be performed.

Future Research

Medications

A number of RCTs of weight loss medications have been conducted; nevertheless, significant unanswered questions remain regarding the medications assessed in this report. One of our key questions concerned relative efficacy, a question that cannot be conclusively answered without head-to-head RCTs that compare the different agents. However, the placebo-controlled trial data we reviewed suggest that if any statistically significant differences are seen, they are likely to be clinically small (a difference of a few kilograms at 12 months). Whether it is worth trying to detect such differences is a matter for policymakers. A more relevant question regarding efficacy may be whether combinations of agents promote greater weight loss than individual agents. One study that combined orlistat and sibutramine reported no increase in weight loss over sibutramine alone. Another relevant question is whether use of any of those drugs combined with more aggressive behavioral interventions and diet therapies would be more

effective than the results seen in the RCTs to date, where many of the dietary interventions were modest.

Another of our key questions concerned the optimal duration of treatment and whether it varies by age, gender, or race. We found no RCT data to answer this question; therefore, new clinical trials would need to be performed. Some physicians have expressed the opinion that they expect their overweight patients will always need to take diet medications, in essence treating overweight as a chronic disease like hypertension. Given that possibility, information about long-term (i.e., much longer than 12 months) effectiveness and safety is needed.

The question of side effects, particularly the possibility of rare adverse events, remains unanswered for most of these drugs.

Surgery

For patients with BMI ≥ 40, we regard the data as conclusive concerning the superiority of surgical therapy compared to existing pharmaceutical and diet therapy. Significant advances will need to occur in the medical control of obesity or its complications for new comparative studies to be warranted. For patients with a BMI between 35 and 40, we do not regard the existing published data as conclusive, because the data are derived from case series without a concurrent comparison group. Although randomized clinical trials would be welcome, given the widespread adoption of bariatric surgery in adults, it might be difficult to mount a trial comparing surgical and nonsurgical weight loss methods. If RCTs cannot be performed, conclusive data could be obtained from well-conducted observational studies, such as a population-based matched cohort study similar to the SOS study, that would assess the effectiveness of bariatric surgery compared to nonsurgical therapy. Nonsurgical therapies to be evaluated should include high-intensity behavioral interventions in addition to pharmacotherapy. Such a study should address the balance between benefits (in terms of weight loss and comorbidities) and risks in relevant patient subgroups and should consider costs. The criteria used to identify subgroups should be those clinical factors that may be related to increased or decreased benefits or risks of surgery. For example, patient age, weight, and severity of comorbidity all may influence the net benefit of surgery compared to nonsurgical therapy. In this example, patient subgroups might be identified based on BMI; age might be stratified as below or above 55 years old; and comorbidities such as diabetes could be stratified by measures such as hemoglobin A1c or the presence of end organ damage. Only by conducting such a study can it be determined whether the net benefits of surgical therapy compared to nonsurgical therapy apply equally to all patient subgroups. Surprisingly few patients would need to be studied to assess whether or not bariatric surgery provides greatly superior outcomes compared to nonsurgical therapy. We calculate that as few as 215 patients would need to be included in each group to provide 80 percent power to detect an effect of bariatric surgery on reducing diabetes equal to only half that reported in the SOS trial. Given that more than 100,000 bariatric operations are performed yearly, attempting to enroll 0.2 percent of these patients in a clinical study seems feasible.

If the eligibility criteria for bariatric surgery were relaxed (such as allowing inclusion of people with a BMI of 30 to 32), then it becomes more justifiable to require an RCT to assess the relative health benefits and risks of surgical versus nonsurgical treatment prior to widespread

adoption of surgery in this patient population. Precedent exists for mounting such studies, even when the surgical therapy is already disseminated in the community. The studies comparing medical and surgical therapy for carotid artery stenosis are good examples.

RCTs would also be useful to compare the effectiveness and safety of various surgical procedures (e.g. adjustable band procedures versus RYGB).

Last, given the increasing rate of obesity in adolescent and pediatric populations, the need is urgent for more data about the relative efficacy of treatments. In our opinion, conducting a randomized trial of bariatric surgery in the adolescent population is still feasible. Such a study would go a long way toward establishing the role of surgery in this patient population.

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Table 1. Adverse events in medication studies

Adverse-event category	Descriptives aggregated into this category	Orlistat	Fluoxetine	Bupropion	Topiramate
Anorexia	Anorexia				x
Nausea/ vomiting	Nausea	X	X		
	Nausea/ vomiting	X	X		
	Vomiting	X			
	Nausea and vomiting		X		
	Nausea/ vomiting/ diarrhea/ vomiting		X		
Back pain	Back pain	X	X		
Bloating/ abdominal pain/ dyspepsia	Abdominal distention	X			
	Abdominal pain	X	X		
	Dyspepsia	X	X		
	Dyspepsia/ hiatal hernia/ esophagitis	X			
	Gastritis	X			
Central nervous system effects	Anxiety			X	X
	Concentration/attention difficulty				X
	Concentration difficulty				X
	Decreased concentration			X	
	Depression				X
	Difficulty with concentration				X
	Difficulty with concentration/attention				X
	Difficulty with memory				X
	Dizziness			X	X
	Insomnia			X	X
	Memory difficulty				X
	Mood problems				X
	Nervousness				X
	Somnolence				X
Constipation	Constipation			X	X
Decreased libido/ sexual dysfunction	Decreased libido/ sexual dysfunction		X		
Depression/ mood change	Depression	X	X		
	Mood change		X		
	Suicide attempt	X			
Diarrhea	Diarrhea	X	X	X	X
	Discolored feces	X			
	Fatty/ oily stool	X			
	Fecal incontinence	X			
	Fecal urgency	X			
	Increased defecation	X			
	Liquid stools	X			
	Loose stools	X			
	Oily evacuation	X			
	Oily spotting	X			
	Soft stools	X			
	Stool fat	X			
	Uncontrolled oily discharge	X			
Dry mouth	Dry mouth			X	X
Fatigue/ asthenia/ hypersomnia/ somnolence	Asthenia		X		
	Fatigue		X		X
	Hypersomnia		X		
	Somnolence		X		
Flatulence	Flatulence	X			
	Flatus with discharge	X			

Adverse-event category	Descriptives aggregated into this category	Orlistat	Fluoxetine	Bupropion	Topiramate
Gallbladder problems	Cholecystectomy	X			
	Cholelithiasis	X			
	Gallbladder abnormalities	X			
	Gallstones	X			
Headache	Headache	X	X	X	X
Hepatic abnormalities	Elevated transaminases	X			
	Hepatocellular damage	X			
	Liver disorders	X			
Hypertension	Hypertension			X	
Increased hepatic enzymes	Increased hepatic enzymes				X
Insomnia	Insomnia		X		
Nervousness/ sweating/ tremors	Nervousness		X		
	Sweating		X		
	Tremor		X		
Paresthesia	Paresthesia				X
Rhinitis	Rhinitis	X			
	Upper respiratory tract infection		X		
Seizure	Seizure			X	
Taste perversion	Taste perversion				X
Upper abdominal symptoms	Abdominal pain				X
	Dyspepsia				X
	Nausea			X	X
	Nausea or vomiting			X	
	Vomiting				x
Upper respiratory problems	Flu-like symptoms			X	
	Other respiratory complaints			X	
	Pharyngitis			X	
	Rhinitis			X	x
	Upper respiratory complaints			X	
	Viral infection			X	
	Upper respiratory tract infection				X
Urticaria/ pruritis/ rash	Pruritis		X		
	Rash		X		
	Skin rashes		X		
	Urticaria		X		
Vertigo	Vertigo				X

Table 2. Adverse events in surgery studies

Adverse-event category	Descriptives used in studies aggregated into this category
Anastomic or gastric outlet stenosis	Anas stenosis, Anastomotic stenosis, Anastomotic stricture, Gastric outlet stenosis, Gastric outlet obstruction, Gastric pouch outlet obstruction, Gastrojejunal anastomotic stenosis, Gastrojejunostomy anastomotic stricture, Narrowing of the communication lumen of 2 parts of stomach, Neostoma stenosis with porch enlargement, Outlet obstruction, Outlet stenoses, Pouch outlet obstruction, Stenosis, Stenosis at gastrojejunostomy, Stenosis of anastomosis, Stenosis of gastroplasty orifice, Stenosis of GJ, Stoma stenosis, Stomal stenosis, Stomal stenosis with endoscopy, Stomal stenosis with reoperation, Stomal stricture, Stricture
Anastomotic, gastric pouch or duodenal leak	Anastomotic failure, Anastomotic leak, Anastomotic leakage, Duodenal leak, Duodenal stomal obstruction, Gastric leak, GJ leak, Leak, Leak (asymptomatic/ contained), Leakage, Leakage/perforation, Loose suture in anastomosis, Surgical leak
Bleeding, all	Bleeding, Bleeding from suture line, Bleeding requiring reoperation or transfusion, Bleeding trocar site, Bleeding unstable BP, Endoluminal bleeding, Gastrointestinal hemorrhage, Gastric bleeding, Gastrointestinal bleeding, GI bleed, GI bleeding, GI hemorrhage, Hematemesis, Hematoma, Hemoperitoneum, Hemorrhage, Intra-abdominal bleeding, Intra-abdominal hemorrhage, Intraperitoneal bleeding, Interoperative hemorrhage, Mesenteric bleeding, Postoperative bleeding surgery required, Pouch hemorrhage, Significant bleeding, Staple line bleed, Staple line hemorrhage, Transfusion stable BP, Upper gastrointestinal bleed, Upper GI hemorrhage
Deep vein thrombosis / pulmonary embolism	Deep vein thrombosis, Deep venous thrombosis, DVT, DVT and PE, DVT/PE, Major pulmonary embolus, Nonfatal pulmonary embolism, Nonfatal pulmonary embolus, PE, Popliteal vein thrombosis, Pulmonary embolism, Thrombosis/ lung embolism
Gastrointestinal symptoms, all	Abdominal pain, Acute cholecystitis, Anorexia, Bypass enteritis, Cholecystectomy, Cholecystolithiasis, Cholelithiasis, Cirrhosis, Colitis, Constipation, Dairy food intolerance, Diarrhea, Difficulty in eating red meat, Dumping, Dumping syndrome, Dysmotility of esophagus, Dyspepsia, Dysphagia, Epigastric pain, Erosive esophatitis, Esophageal dilation, Esophagitis, Food intolerance, Frequent vomiting, Gallstones, Gastritis, Gastritis by endoscopy, Gastritis, esophagitis, Gastroesophageal reflux, GERD, Heartburn, Hepatic failure, Ileus, Intolerable malodorous gas, Involuntary vomiting, Lap cholecystectomy, Liver disease, Liver function abnormal, Lower GI hemorrhage, Mild dumping, Nausea, Nausea and vomiting, Obstipation, Obstructive ileus, Perianal abscess, Postanesthetic jaundice, Prolonged ileus, Prolonged nausea/vomiting, Readmit vomiting, Recurrent vomiting, Reflux esophagitis, Refuse du systeme, Ructus, Severe vomiting, Sigmoiditis, Symptomatic cholelithiasis, Total food intolerance, Transient hepatic dysfunction, Vomiting, Vomiting one or more per week, Vomiting with stapleline intact
Gastrointestinal symptoms, reflux	Dyspepsia, Erosive esophatitis, Esophagitis, Gastritis, esophagitis, Gastroesophageal reflux, GERD, Heartburn, Reflux esophagitis, Refuse du systeme

Adverse-event category	Descriptives used in studies aggregated into this category
Gastrointestinal symptoms, vomiting	Frequent vomiting, Involuntary vomiting, Nausea and vomiting, Prolonged nausea/ vomiting, Readmit vomiting, Recurrent vomiting, Severe vomiting, Vomiting, Vomiting one or more per week, Vomiting with stapleline intact
Medical (cardiac, stroke, severe hypertension)	A fib, Angina, Arrhythmia, Cardiac, Cardiovascular complications, CHF, CVA, MI, Severe hypertension, Severe tachycardia
Nutritional and electrolyte abnormalities	Anemia, B12 deficiency, Calcium, Electrolyte imbalance, Electrolytes abnormality, Folate deficiency, Folic acid, Iron deficiency, Iron deficient, Malnutrition, Nutritional deficiencies, Other vitamin deficiencies, Protein calorie malnutrition, Protein-calorie malnutrition, Temporary electrolytes imbalance, Vitamin B12, Vitamin and mineral deficiencies
Reoperations	Adhesiolysis, Band extraction, Band removal or revision, Bleeding requiring reoperation or transfusion, Conversion to duodenal switch, Normal but clinical failure, Open revision, Operation reversed, Patient request, Post-op exploratory laparotomy, Postoperative bleeding surgery required, Reoperation, Reanastomosis, Removal, Removal of band, Reop bowel obstruction, Reoperation for failure of reservoir, Reoperation revision, Reoperation, Reoperation due to malnutrition, Reoperation to reposition band, Revision, Same admission reoperation, Stomal stenosis with reoperation, Take downs, Stroke, Uncontrolled hypertension
Respiratory complications, all	ARDS, Atelectasis, Atelectasis/pneumonitis, Atelectesis/pneumonia, Bronchopneumonia, Chest infections, Effusion, Hemothorax, Hydrothorax, Massive subcutaneous emphysema, Other pulmonary complications, Pleura injury, Pleural effusion, Pneumonia, Pneumothorax, Post-op pneumonia, Postoperative respiratory distress, Prolonged apnea, Pulmonary problems, Pulmonary complications, Resp chest infection, Resp distress, Resp failure, Resp insufficiency, Resp rest, Respiratory, Respiratory complications, Respiratory failure, Respiratory insufficiency, Severe bronchospasm
Respiratory complications, pneumonia	Atelectesis/pneumonia, Bronchopneumonia, Pneumonia, Post op pneumonia, Dehiscence
Surgical, all	Abdominal or pulmonary collections, Abscess, Access port complications, Access port problems, Accidental band perforation, Acute obstruction, Adhesiolysis, Anas stenosis, Anastomotic failure, Anastomotic leak, Anastomotic leakage, Anastomotic stenosis, Anastomotic stricture, Anastomotic ulcers, Aneurysmal deformity of the balloon, Asymptomatic stomach erosions, Band dislocations, Band dislodgement or pouch dilation, Band disruption, Band erosion, Band extraction, Band infection, Band leakage, Band migration, Band penetration, Band rupturing, Band removal or revision, Band rupture, Band slippage, Band slipped out, Bleeding, Bleeding at port, Bleeding from suture line, Bleeding requiring reoperation or transfusion, Bleeding trocar site, Bleeding unstable BP, Bowel obstruction, C dificile colitis, Cervical esophageal mucosal tear from EEA anvil, Conversion, Conversion to duodenal switch, Conversion to open, Convert to open from bleeding, Convert to open gastric perforation, Converted to open, Dehiscence, Dehiscence of the vertical stapleline, Delayed pouch emptying, Dilated proximal pouch, Dilation or slippage, Disconnection, Disconnection of sc port, Distal Roux en Y leak, Duodenal leak, Duodenal stomal obstruction, Early band

Adverse-event category	Descriptives used in studies aggregated into this category
	repositioning, Early pouch dilatation, Efferent limb obstruction,
Surgical, all (continued)	Endoluminal bleeding, Enlarged orifice, Enlarged porch, Enlarged pouch with obstructive angulation, Enteric fistula, Enterocutaneous fistular, Erosion, Erosion into stomach, Evisceration, Fascia dehiscence and retrogastric abscess, Fistula, Food impaction, Food obstruction of stoma, Gallbladder puncture, Gastric outlet stenosis, Gastrointestional hemorrhage, Gastric bleeding, Gastric erosion at ring, Gastric fistula, Gastric herniation through band, Gastric leak, Gastric outlet obstruction, Gastric perforation, Gastric pouch outlet obstruction, Gastric slippage, Gastric wall perforation, Gastric wall slippage, Gastric perforation, Gastrogastric fistula, Gastrointestinal bleeding, Gastrointestinal ulcer, Gastrojejunal anastomotic stenosis, Gastrojejunostomy anastomotic stricture, Gastrotomy during lesser curve dissection, GI bleed, GI bleed from erosion, GI bleeding, GI hemorrhage, GJ leak, Hematemesis, Hematoma, Hemoperitoneum, Hemorrhage, Hernia, Hernia/ small bowel obstruction with reoperation, Herniation of band, Herniation of stomach through the band causing obstruction, Hypopharyngeal perforation, Incarcerated hernia, Incisional hernia, Incomplete division of stomach, Infected hematoma, Infected splenic hematoma, Infection around the port, Infection at reservoir, Infected reservoirs, Infection wound major, Internal hernia, Intestinal obstruction, Intestinal obstruction JJ, Intestinal obstruction after 1 year, Intra-abdominal abscess, Intraabdominal bleeding, Intra-abdominal hemorrhage, Intra-abdominal sepsis, Intractable ulcer, Intragastric band migration, Intraoperation perforation of stomach, Intraoperative complications, Intraperitoneal abscess, Intraperitoneal bleeding, Intraoperative hemorrhage, Intususception of gastric wall, J-J obstruction, Jejunujejunostomy obstruction, Laceration of liver/spleen, Laceration of reservoir, Lap band balloon leak, Large bowel perforation, Late band repositioning, Late pouch dilatation, Leak, Leak (asympt/ contained), Leak of reservoir, Leakage, Leakage of port from needle perforation 1, Leakage of ring, Leakage/ perforation, Leaking band, Leaking port, Leaks, LGI bleed, Liver hematoma, Liver injury, Loose suture anastomosis, Major infection, Major wound infection, Major wound problems, Marginal ulcer, Marginal ulcers NSAID induced, Mesenteric bleeding, Migration band, Minor dehiscence, Minor infection, Minor splenic injury, Minor wound infection, Minor wound problems, Miscellaneous, Narrowing of the communication lumen of 2 parts of stomach, Neostoma stenosis with porch enlargement, Normal but clinical failure, Obstruction at jejunojejunostomy, Obstruction at roux, Obstructive aneurysmal deformity, Open revision, Operation reversed, Other sepsis, Other wound infections, Outlet obstruction, Outlet stenoses, Pain in left shoulder, Painful port site, Pancreatitis, Partial obstruction, Patient request, Pelviperitonitis, Perforated stress ulcer, Perforation, Perforation of stomach, Perforation of stomach remnant, Perforation or erosion, Perforation pouch, Perioperative complications, Peritonitis, Plugging, Port, Port disconnection, Port infection, Port leakage, Port migration, Port problem, Port-site infection, Postoperative complications, Posterior herniation, Post-op exploratory laparotomy, Postoperative bleeding surgery required, Postoperative comp, Pouch dilation, Pouch hemorrhage, Pouch herniation, Pouch outlet obstruction, Prolapse of

Adverse-event category	Descriptives used in studies aggregated into this category
	stomach, Reoperation, Reanastomosis, Removal, Removal of band, Reop bowel obstruction, Reop for failure of reservoir, Reop revision, Reoperation due to malnutrition, Reoperation to reposition band,
Surgical, all (continued)	Repair hiatal hernia, Repair spleen, Repair umbilical hernia, Reservoir infection, Reservoir flipped over, Reservoir infections, Reservoir leak, Reservoir/ tubing breaks, Resp infection, Retained foreign body, Retained sponge, Revision, Rupture of tubing, Same admission reoperation, Small bowel obstruction JJ, Separation of catheter and reservoir, Sepsis, Septicemia, Seroma, Seroma with necrotic fat, Severe wound infection, Significant bleeding, Silicone band migration, Slippage, Slippage of band, Slippage or dilation, Slipping, Small bowel necrosis, Small bowel obstruction, Splenectomy, Splenic artery rupture, Splenic capsule tear, Splenic injury, Splenic laceration, Stable line disruption, Staple breakdown, Staple disruption, Staple line bleed, Staple line disruption, Staple line failure, Staple line fistula, Staple line hemorrhage, Staple line failure, Stapler malfunction, Stapling of nasogastric tube, Stenosis, Stenosis at gastrojejunostomy, Stenosis at mesocolon, Stenosis of anastomosis, Stenosis of gastroplasty orifice, Stenosis of GJ, Stoma dilation, Stoma stenosis, Stoma widening, Stomach injury, Stomach perforation, Stomach slippage, Stomal stenosis, Stomal stenosis with endoscopy, Stomal stenosis with reoperation, Stomal stricture, Stomal ulcer, Stricture, Subhepatic abscess, Subphrenic abscess, Subphrenic abscess, Subphrenic collection, Superficial wound infection, Surgical leak, Surgical wound infection, Symptomatic ulcer disease, Take downs, Technical band problems, Transfusion stable BP, Trocar hernia, Trocar site hernia, Tube dropped off the injection port, UGI bleed, Ulcer, Umbilical hernia, Upper GI hemorrhage, Ventral hernia, Violation of integrity of stomach, Vomiting with stapleline disruption, Wound abscess, Wound dehiscence, Wound hematomas, Wound hernia, Wound infection minor, Wound infection, Wound infection (pus or erythema), Wound infection erythema, Wound infection major, Wound infection minor, Wound infection or dehiscence, Wound infection port, Wound infection pus, Wound infections major, Wound minor, Wound necrotic fat, Wound or port infection, Wound seroma
Surgical: incisional hernia	Hernia, Incarcerated hernia, Incisional hernia, Ventral hernia, Wound hernia
Surgical: internal hernia	Hernia/small bowel obstruction with reoperation, Internal hernia
Surgical: splenic injury	Infected splenic hematoma, Laceration of liver/ spleen, Minor splenic injury, Repair spleen, Splenectomy, Splenic artery rupture, Splenic capsule tear, Splenic injury, Splenic laceration, Deep vein thrombosis
Surgical: wound complications, all	Evisceration, Fascia dehiscence and retrogastric abscess, Hernia, Incarcerated hernia, Incisional hernia, Infection around the port, Infection at reservoir, Infected reservoirs, Infection wound major, Infection wound minor, Major infection, Major wound infection, Major wound problems, Minor dehiscence, Minor infection, Minor wound infection, Minor wound problems, Other wound infections, Port infection, Port-site infection, Reservoir infection, Resp infection, Seroma, Seroma with necrotic fat, Severe wound infection, Superficial wound infection, Surgical wound infection, Ventral hernia, Wound abscess, Wound dehiscence, Wound hematomas, Wound hernia, Wound infection minor, Wound infection, Wound infection

Adverse-event category	Descriptives used in studies aggregated into this category
	(pus or erythema), Wound infection erythema, Wound infection major, Wound infection minor, Wound infection or dehiscence, Wound infection port, Wound infection pus, Wound infections major, Wound minor, Wound necrotic fat, Wound or port infection, Wound seroma
Surgical: wound, infection major	Infection around the port, Infection at reservoir, Infected reservoirs, Infection wound major, Major infection, Major wound infection, Port infection, Port-site infection, Reservoir infection, Severe wound infection, Wound abscess, Wound infection major, Wound infection port, Wound infection pus, Wound infections major
Surgical: wound, infection minor	Infection wound minor, Major infection, Minor infection, Minor wound infection, Superficial wound infection, Wound infection minor, Wound infection erythema, Wound infection minor, Wound minor

Table 3. Surgical procedure categories

Upper-level category	Lower-level category	Subcategory
Gastroplasty^	Open Gastroplasty	NA
	Laparoscopic Gastroplasty	NA
Jejunal-ileal bypass	NA	NA
BPD/Duodenal switch	NA	NA
Gastric Bypass	Open RYGB^^	Open RYGB, standard limb Open RYGB, long limb
	Open loop gastric bypass	NA
	Laparoscopic RYGB^^	Laparoscopic RYGB, standard limb Laparoscopic RYGB, long limb
Band	Open Band	Open adjustable Band Open nonadjustable Band
	Laparoscopic Band	Laparoscopic adjustable Band Laparoscopic nonadjustable Band
VBG**	Open VBG	NA
	Laparoscopic VBG	NA

** VBG includes: Vertical Banded Gastroplasty, VBG with Marlex, VBG with Dacron, gastric restriction, 4.5 gastroplasty, 5.0 gastroplasty, and Silastic Ring Vertical Gastroplasty.

^Gastroplasty includes: Horizontal Banded Gastroplasty, Gastric Portioning, Gastrogastrostomy, Gastric Portioning.

^^ RYGB bypass includes: Roux-en-Y Gastric Bypass and RYGBs that also have ring placement (i.e., Fobi).

Table 4. Meta-analysis of weight loss in placebo-controlled trials of orlistat at 6 months

Trial	Total n	Mean Difference	95% CI
Broom[65]	137	-1.80	(-3.15, -0.45)
Deerochangawong[67]	252	-1.20	(- 2.75, 0.35)
DeRosa[82]	48	-0.90	(-1.27, -0.53)
Halpern[72]	280	-1.66	(-4.56, 1.24)
Hauptman[56]	422	-3.30	(-4.94, -1.66)
Karhunen[70]	72	-2.50	(-5.41, 0.41)
Muls[66]	290	-2.78	(-3.73, -1.83)
Micic[81]	114	-3.41	(-5.72, -1.10)
Naumov[78]	30	-4.60	(-6.58, -2.62)
Rissanen[63]	51	-4.10	(7.55, -0.65)
Shi Yi[68]	428	-3.10	(-4.37, -1.83)
Pooled random-effects estimate		-2.51[1]	(-3.40, -1.63)

[1]Chi-squared test of heterogeneity p-value < 0.001.

Table 5. Meta-analysis of weight loss in placebo-controlled trials of Orlistat at 12 months

Trial	Total n	Mean Difference	95% CI
Bakris[74]	532	-2.70	(-3.79, -1.61)
Broom[66]	347	-3.50	(-5.07, -1.93)
Davidson[55]	591	-2.95	(-4.45, -1.45)
Derosa[82]	48	-1.00	(-1.49, -0.51)
Gotfredsen[79]	30	-3.10	(-8.48, 2.28)
Hanefeld[75]	369	-1.90	(- 2.96, -0.84)
Hauptman[56]	422	-3.80	(-5.37, -2.23)
Hill[57]	234	-1.31	(-3.00, 0.38)
Hollander[58]	321	-1.88	(-3.38, -0.38)
Karhunen[70]	72	-4.50	(-7.41, -1.59)
Kelley[69]	265	-2.62	(-3.38, -1.86)
Krempf[71]	478	-2.90	(-4.71, -1.09)
Lindgarde[83]	323	-1.30	(-2.51, -0.09)
Lucas[73]	444	-3.80	(-5.06, -2.54)
Miles[76]	311	-2.90	(-3.73, -2.07)
Reaven[80]	247	-2.14	(-3.94, -0.34)
Rissanen[280]	51	-5.80	(-9.25, -2.35)
Rosenfalck[77]	12	-4.78	(-11.88, 2.32)
Rossner[60]	479	-3.00	(-4.17, -1.83)
Sjostrom[61]	544	-4.20	(-5.26, -3.14)
Vidgren[62]	75	-4.20	(-7.46, -0.94)
Pooled random-effects estimate		-2.76[1]	(-3.31, -2.20)

[1]Chi-squared test of heterogeneity p-value < 0.001.

Table 6. Meta-analysis of adverse events in RCTs of orlistat

		Data				**Synthesis**			
Adverse event	*# of studies*	*Placebo* # *adverse events*	*sample size*	*Intervention groups* # *adverse events*	*sample size*	*Pooled OR*	*95% CI*	*RR*	*Number needed to harm (OR>1)*
Diarrhea	13	892	3178	4074	4876	54.85	(44.88, 67.48)	3.40	1.48
Flatulence	11	218	2972	1020	4669	3.72	(3.16, 4.39)	3.10	6.49
Bloating/abdominal pain/ dyspepsia	8	111	1388	155	1737	1.55	(1.18, 2.06)	1.48	25.80
Headache	3	29	516	34	519	1.18	(0.68, 2.05)	NC	NC
Nausea/vomiting	3	19	311	18	306	0.95	(0.46, 1.98)	NC	NC
Gallbladder problems	5	13	712	10	1322	0.71	(0.27, 1.82)	NC	NC
Depression/mood change	3	3	153	1	154	0.33	(0.01, 4.15)	NC	NC
Back pain	1	3	114	5	114	NC	NC	NC	NC
Hepatic abnormalities	3	0	498	1	886	NC	NC	NC	NC
Rhinitis	1	6	114	7	114	NC	NC	NC	NC

OR = Odds ratio

RR = Relative risk

NC = Not Calculated
CI = Confidence interval

Note: for the diarrhea group, five trials had more adverse events in the orlistat group than actual number of people. The total number of adverse events was truncated at the total number of people for the OR calculation.

Table 7. Meta-analysis of weight loss in placebo-controlled trials of fluoxetine at 6 months

Trial	Total n	Mean Difference	95% CI
Connolly[93]	24	-3.90	(-4.83, -2.97)
Goldstein[89]	303	-2.70	(-4.09, -1.31)
Gray[95]	36	-7.40	(-9.13, -5.67)
Marcus[90]	31	-9.10	(-13.32, -4.88)
Mendoza[94]	60	-4.57	(-6.58, -2.56)
Michelson[44]	192	-0.90	(-1.87, 0.07)
O'Kane[92]	18	-6.50	(-7.35, -5.65)
Pooled random-effects estimate		-4.75[1]	(-6.72, -2.77)

[1]Chi-squared test of heterogeneity p-value < 0.001.

Table 8. Meta-analysis of weight loss in placebo-controlled trials of fluoxetine at 12 months

Trial	Total n	Mean difference	95% CI
Breum[88]	29	-0.70	(-8.53, 7.13)
Darga[91]	30	-3.60	(-4.87, -2.33)
Goldstein[89]	212	0.40	(-1.70, 2.50)
Marcus[90]	21	-14.50	(-22.62, -6.38)
Michelson[44]	78	-0.20	(-2.59, 2.19)
O'Kane[92]	16	-5.80	(-7.57, -4.03)
Pooled random-effects estimate		-3.15[1]	(-5.82, -0.48)

[1]Chi-squared test of heterogeneity p-value < 0.00.

Table 9. Meta-analysis of adverse events in RCTs of fluoxetine for obesity

		Data				**Synthesis**			
Adverse event		*Placebo*		*Intervention groups*					
	# of studies	*# adverse events*	*sample size*	*# adverse events*	*sample size*	*Pooled OR*	*95% CI*	*RR*	*Number needed to harm (OR>1)*
Nervousness/sweating/ tremors	4	10	294	63	297	7.85	(3.87,17.63)	6.37	5.48
Nausea/vomiting	6	31	322	82	349	3.27	(1.94, 5.67)	2.68	6.17
Fatigue/asthenia/hypersomnia/ somnolence	6	37	336	87	363	2.83	(1.82, 4.45)	2.36	6.70
Insomnia	3	14	270	31	296	2.19	(1.10, 4.58)	2.06	18.15
Diarrhea	6	26	336	46	363	1.86	(1.10, 3.23)	1.74	17.37
Urticaria/pruritis/rash	4	7	74	11	76	1.67	(0.53, 5.65)	NC	NC
Headache	5	61	314	79	340	1.35	(0.91, 2.03)	NC	NC
Rhinitis	4	72	294	77	297	1.08	(0.73, 1.60)	NC	NC
Depression/mood change	3	6	68	6	70	0.96	(0.24, 3.82)	NC	NC
Back pain	2	5	46	6	47	NC	NC	NC	NC
Bloating/abdominal pain/dyspepsia	2	4	46	5	47	NC	NC	NC	NC
Decreased libido/sexual dysfunction	2	1	46	4	47	NC	NC	NC	NC

OR = Odds ratio

RR = Relative risk

NC = Not Calculated
CI = Confidence interval

Note: for the nausea/vomiting group, one trial had more adverse events in the fluoxetine group than actual number of people. The total number of adverse events was truncated at the total number of people for the OR calculation.

Table 10. Meta-analysis of weight loss in placebo controlled trials of bupropion at 6-12 months

Trial	Total n	Mean Difference	95% CI
Anderson [43]	217	-4.91	(-6.78, -3.05)
Croft [98]	423	-1.17	(-2.25, -0.09)
Jain [99]	384	-2.70	(-3.57, -1.83)
Pooled random-effects estimate		-2.77[1]	(-4.50, -1.05)

[1]Chi-squared test of heterogeneity p-value < 0.001.

Table 11. Meta-analysis of adverse events in RCTs of bupropion

		Data				**Synthesis**			
Adverse event		*Placebo*		*Bupropion*					
	# of trials	*# adverse events*	*sample size*	*# adverse events*	*sample size*	*Pooled OR*	*95% CI*	*RR*	*Number needed to harm (OR> 1)*
Dry mouth	2	13	321	58	428	3.26	(1.71, 6.64)	2.99	12.43
Diarrhea	1	7	112	18	215	1.37	(0.52, 4.01)	1.34	47.19
Constipation	2	20	321	39	428	1.31	(0.72, 2.44)	1.29	56.28
Upper respiratory problems	2	104	321	171	428	1.22	(0.88, 1.69)	1.14	22.23
Headaches	2	42	321	66	428	0.99	(0.63, 1.57)	NC	NC
Central nervous system effects	2	31	321	41	428	0.98	(0.58, 1.66)	NC	NC
Upper abdominal symptoms	2	24	321	30	428	0.81	(0.44, 1.50)	NC	NC
Hypertension	1	0	112	1	215	NC	NC	NC	NC
Seizure	1	0	209	1	213	NC	NC	NC	NC

NC = Not Calculated.

Table 12. Meta-analysis of weight loss in placebo controlled trials of topiramate at 6 months

Trial	Total n	Mean Difference	95% CI
Bray [31]	151	-3.70	(-5.23, -2.17)
Caterson [107]	195	-8.20	(-9.55, -6.85)
Prud' homme[105]	46	-6.00	(-9.19, -2.81)
Rissanen [104]	226	-9.10	(-10.36, -7.84)
Stenlof [103]	272	-7.00	(-8.14, -5.86)
Tonstad [106]	109	-4.60	(-6.40, -2.80)
Pooled random-effects estimate		-6.51[1]	(-8.25, -4.77)

[1]Chi-squared test of heterogeneity p-value < 0.001.

Table 13. Meta-analysis of adverse events in RCTs of topiramate

		Data				**Synthesis**			
Adverse event		*Placebo*		*Topiramate 192 mg*					
	# of trials	*# adverse events*	*sample size*	*# adverse events*	*sample size*	*Pooled OR*	*95% CI*	*RR*	*Number needed to harm (OR>1)*
Parasthesia	6	101	624	524	643	20.18	(13.99, 29.67)	4.92	1.58
Taste perversion	5	11	527	100	545	11.14	(5.80, 23.57)	9.19	5.85
Central nervous system effects	6	194	624	376	643	3.97	(2.90, 5.49)	2.06	3.02
Constipation	2	9	212	31	211	3.96	(1.77, 9.77)	3.52	9.36
Dry mouth	3	13	349	37	346	3.13	(1.59, 6.55)	2.90	14.13
Upper abdominal symptoms	5	73	589	123	610	1.76	(1.27, 2.47)	1.61	13.26
Fatigue	6	160	624	204	643	1.36	(1.03, 1.80)	1.25	15.91
Upper respiratory problems	5	184	487	199	508	1.32	(0.87, 1.99)	1.18	14.90
Diarrhea	3	47	275	55	297	1.08	(0.68, 1.71)	1.07	89.42
Vertigo	1	4	137	5	135	NC	NC	NC	NC
Headaches	1	16	177	20	178	NC	NC	NC	NC
Increased hepatic enzymes	1	0	75	0	76	NC	NC	NC	NC

NC = Not Calculated

Note: For the central nervous system effects and upper respiratory problems groups, one trial in each had more adverse events in the topiramate group than actual number of people.

For the paresthesia group, two trials had more adverse events in the topiramate group than actual number of people.

The total number of adverse events was truncated at the total number of people for the OR calculation.

Table 14. Summary of findings regarding medications for weight loss

Medication	Source of data	Weight loss assessed at:	Mean weight loss in treated patients compared to placebo (95% CI)
Sibutramine	Existing meta-analysis of 24 RCTs	52 weeks	-4.45 kg (-5.29, -3.62)
Orlistat	Our meta-analysis of 23 RCTs	52 weeks	-2.76 kg (-3.31, -2.20)
Fluoxetine	Our meta-analysis of 9 RCTs	52 weeks	-3.15 kg (-5.82, -0.48)
Phentermine	Existing meta-analysis of 9 RCTs	2 to 24 weeks	-3.6 kg (-6.0, -0.6)
Diethylpropion	Existing meta-analysis of 13 RCTs	6 to 52 weeks	-3.0 kg (-11.5, 1.6)
Bupropion	Our meta-analysis of 3 RCTs	24 to 52 weeks	-2.77 kg (-4.5, -1.0)
Zonisamide	1 RCT	16 weeks	Additional 5% of pre-treatment weight loss
Topiramate	Our meta-analysis of 6 RCTS	24 weeks	Additional 6.5% of pre-treatment weight loss (95% CI 4.8%, 8.2%)

Table 15. Summary of results of Cochrane review of surgery for morbid obesity*

Comparison	Results of literature search and synthesis
Surgery versus nonsurgical interventions RCT comparing diet and unbanded horizontal gastroplasty vs. very low calorie diet and diethylpropion in 60 patients	At 2 years, maximal weight loss did not differ between groups (26.1 kg vs. 22.0 kg), but differential regain in weight made the net weight loss favor surgically treated patients. At 5 years, 30% of surgical patients and 17% of diet patients had 10 kg or greater weight loss (p=n.s.), although 16% of surgically treated patients maintained at least 10 kg of net weight loss compared with 3% of diet-treated patients (p,0.05). Heartburn, pain projected to the left shoulder, and vomiting were more common in surgically treated patients, irritability and low spirits were more common in diet-only treated patients.
Cohort study comparing gastric surgery** vs. conventional treatment	At 8 years, surgical patients had lost 16% and conventional patients had lost 1% of weight (p<0.001)
RYGB versus unbanded horizontal gastroplasty	2/5 RCTs reported greater weight loss for patients treated with gastric bypass
VBG versus unbanded horizontal gastroplasty	1 RCT reported greater weight loss for patients treated with VBG
VBG versus adjustable gastric banding	1 RCT reported greater weight loss for patients treated with VBG

* Adapted from: Colquitt J, Clegg A, Sidhu M, Royle P. Surgery for Morbid Obesity[38]
** 94% purely gastric restrictive (VBG, gastric banding), 6% gastric bypass

Table 16. Weight loss following bariatric surgery by procedure (at 12 months followup), pooled results by study type

Controlled trials (includes controlled trials comparing one procedure to another)			**All studies (includes all controlled trials and case series)**		
Procedure	*Weight loss (kg) at 12 months*	*# trials # patients*	*Procedure*	*Weight Loss (kg) at 12 months (95% CI)*	*# Studies/Patients*
RYGB (all) versus VBG (all)	δ 42.43 kg δ 34.45 kg Mean difference = 7.97 kg CI (2.99, 12.96)	2 trials) n=114 n=117	RYGB (all) versus VBG (all)	Δ 43.46 kg (41.24, 43.46) Δ 32.16 kg (29.92, 34.41)	l=32 / n=2937 l=21 / n=2080
RYGB (all) versus Adj Band (all)	Not reported	(0 trials)	RYGB (all) versus Adj Band (all)	Δ 43.46 kg (41.24, 45.68) Δ 30.19 kg (27.95, 32.42)	l=32 / n=2937 l=27 / n=5562
RYGB (open) versus RYGB (lap)	δ 34.35 kg δ 37.00 kg Mean difference = -2.64 kg CI (-11.28, 6.00)	(1 trial) n=21 n=30	RYGB (open) versus RYGB (lap)	Δ 43.89 kg (41.09, 46.69) Δ 42.17 kg (38.95, 45.38)	l=25 / n=2074 l=10 / n=863
VBG (all) versus Adj Band (all)	δ 38.58 kg δ 24.20 kg Mean difference = 14.41 kg CI (9.39, 19.42)	(2 trials) n=71 n=76	VBG (all) versus Adj Band (all)	Δ 32.16 kg (29.92, 34.41) Δ 30.19 kg (27.95, 32.42)	l=21 / n=2080 l=27 / n=5562
RYGB (all) versus BPD (all)	Not reported	(0 Trials)	RYGB (all) versus BPD (all)	Δ 43.46 kg (41.24, 45.68) Δ 51.93 kg (45.10, 58.75)	l=32 / n=2937 l=3 / n=735

Table 17. Weight loss following bariatric surgery by procedure (at ≥ 36 months followup), pooled results by study type

Controlled trials (includes controlled trials comparing one procedure to another)			**All studies (includes all controlled trials and case series)**		
Procedure	*Weight loss (kg) at ≥ 36 months followup (95% CI)*	*# Trials # Patients*	*Procedure*	*Weight loss (kg) at ≥ 36 months followup (95% CI)*	*# Studies/patients*
RYGB (all) versus VBG (all)	Δ 39.73 kg Δ 30.65 kg Mean difference = 9.29 kg CI (1.61, 16.96)	(2 trials) n=103 n=96	RYGB (all) versus VBG(all)	Δ 41.46 kg (37.36, 45.56) Δ 32.03 kg (27.67, 36.38)	l=21 / n=1281 l=18 / n=1877
RYGB (all) versus Adj Band (all)	Not reported	(0 trials)	RYGB (all) versus Adj Band (all)	Δ 41.46 kg (37.36, 45.56) Δ 34.77 kg (29.47, 40.07)	l=21 / n=1281 l=17 / n=3076
RYGB (open) versus RYGB (lap)	Not reported	(0 trials)	RYGB (open) versus RYGB (lap)	Δ 41.58 kg (37.38, 45.78) Δ 38.32 kg (28.04, 48.60)	l=20 / n=1266 l=1 / n=15
VBG (all) versus Adj Band (all)	Δ 35.51 kg Δ 32.97 kg Mean difference = 2.79 kg CI (-16.63, 22.21)	(2 trials) n=64 n=60	VBG (all) versus Adj Band (all)	Δ 32.03 kg (27.67, 36.38) Δ 34.77 kg (29.47, 40.07)	l=18 / n=1877 l=17 / n=3076
RYGB (all) versus BPD (all)	Not reported	(0 trials)	RYGB (all) versus BPD (all)	Δ 41.46 kg (37.36, 45.56) Δ 53.10 kg (47.36, 58.84)	l=21 / n=1281 l=1 / n=50

Table 18. Mortality analysis, surgical procedures

	Early or time unspecified deaths				**Late deaths**			
Procedure	*Controlled trials*		*Case series*		*Controlled trials*		*Case series*	
RYGB	1.0% (0.5, 1.9)	I=15/ n=907	0.3% (0.2, 0.4)	I=50/ n=11290	1.1% (0.4, 2.5)	I=9/ n=524	0.6% (0.4, 0.8)	I=24/ n=5411
BPD	Not Reported	I=0/ n=0	0.9% (0.5, 1.3)	I=7/ n=2808	Not Reported	I=0/ n=0	0.3% (0.01, 0.6)	I=4/ n=2362
Band	0.4% (0.01, 2.1)	I=6/ n=268	0.02% (0, 0.78)	I=35/ n=9222	Not Reported	I=0/ n=0	0.1% (0.02, 0.2)	I=11/ n=3975
VBG	0.2% (0, 1.4)	I=11/ n=401	0.3% (0.1, 0.5)	I=33/ n=4091	0.0% (0, 16.8)*	I=1/ n=20	0.6% (0.4, 1.0)	I=20/ n=2638

* one-sided, 97.5% confidence interval

Early = ≤ 30 days from procedure, or designated “early” in the original report.
Late = > 30 days from procedure, or designated “late” in the original report

Table 19. Postoperative adverse events by bariatric procedure (RYGB versus VBG, Band, or BPD), results pooled by study type

	Controlled trials (includes controlled trials comparing one procedure to another)		**All studies (includes all controlled trials and case series)**	
Category of adverse event	*Adverse event (%) by procedure*	*(#trials) # patients*	*Adverse event (%) by procedure*	*# Studies/patients*
1. Gastrointestinal symptoms (including reflux, vomiting, dysphagia, dumping syndrome, etc.)	RYGB = 18.3% versus VBG = 15.2% OR=1.29 (0.70, 2.42)	(3 trials) n=169 n=178	RYGB = 16.9% versus VBG = 17.5%	l=34 / n=7374 l=21 / n=1692
	RYGB versus Band Not reported	(0 trials)	RYGB = 16.9% versus Band = 7.0%	l=34 / n=7374 l=17 / n=3400
	RYGB versus BPD Not reported	(0 trials)	RYGB = 16.9% versus BPD = 37.7%	l=34 / n=7374 l=1 / n=305
1a. Reflux	RYGB versus VBG Not reported	(0 trials)	RYGB = 10.9% versus VBG = 2.2%	l=3 / n=727 l=7 / n=823
	RYGB versus Band Not reported	(0 trials)	RYGB = 10.9% versus Band = 4.7%	l=3 / n=727 l=4 / n=485
	RYGB versus BPD Not reported	0 trials)	RYGB = 10.9% versus BPD = NR	l=3 / n=727 l=0 / n=0

trials considered for analysis by procedure
RYGB – 70 trials
VBG – 48 trials
BAND – 41 trials
BPD – 7 trials

Table 19. Postoperative adverse events by bariatric procedure (RYGB versus VBG, band, or BPD), results pooled by study type (cont.)

	Controlled trials (includes controlled trials comparing one procedure to another)		**All studies (includes all controlled trials and case series)**	
Category of adverse event	*Adverse event (%) by procedure*	*(#trials) # patients*	*Adverse event (%) by procedure*	*# Studies/patients*
1. Gastrointestinal symptoms (cont) 1b. Vomiting	RYGB versus VBG Not reported	(0 trials)	RYGB = 15.7% versus VBG = 18.4%	I=8 / n=1324 I=10 / n=1177
	RYGB versus Band Not reported	(0 trials)	RYGB = 15.7% versus Band = 2.5%	I=8 / n=1324 I=4 / n=562
	RYGB versus BPD Not reported	(0 trials)	RYGB = 15.7% versus BPD = 5.9%	I=8 / n=1324 I=1 / n=305
2. Nutritional and electrolyte abnormalities (including mineral, vitamin, protein deficiencies, etc.)	RYGB versus VBG Not reported	(0 trials)	RYGB = 16.9% versus VBG = 2.5%	I=10 / n=2088 I=4 / n=397
	RYGB versus Band Not reported	(0 trials)	RYGB = 16.9% versus Band = Not Reported	I=10 / n=2088 I=0 / n=0
	RYGB versus BPD Not reported	(0 trials)	RYGB = 16.9% versus BPD = Not Reported	I=9 / n=2088 I= 0 / n=0

trials considered for analysis by procedure

- RYGB – 70 trials
- VBG – 48 trials
- BAND – 41 trials
- BPD – 7 trials

Table 19. Postoperative adverse events by bariatric procedure (RYGB versus VBG, Band, or BPD), results pooled by study type (cont.)

	Controlled trials (includes controlled trials comparing one procedure to another)		**All studies (includes all controlled trials and case series)**	
Category of adverse event	*Adverse event (%) by procedure*	*(#Trials) # patients*	*Adverse event (%) by procedure*	*# Studies/patients*
3. Surgical, preventable and not preventable issues (including anastomotic or stoma-related, bleeding, reoperations, wound, etc.)	RYGB = 20.3% versus VBG = 15.1% OR=1.48 (0.88, 2.49)	(5 trials) n=241 n=252	RYGB = 18.7% versus VBG = 23.7%	I=49 / n=10088 I=34 / n=3247
	RYGB versus Band Not reported	(0 trials)	RYGB = 18.7% versus Band = 13.2%	I=49 / n=10088 I=34 / n=8846
	RYGB versus BPD Not reported	(0 trials)	RYGB = 18.7% versus BPD = 5.9%	I=49 / n=10088 I=5 / n=2663
3a. Anastomotic, gastric pouch or duodenal leak	RYGB = 1.4% versus VBG = 2.8% OR=0.49 (0.01, 9.74)	(2 trials) n=70 n=72	RYGB = 2.2% versus VBG = 1.0%	I=30 / n=5645 I=14 / n=1456
	RYGB versus Band Not reported	(0 trials)	RYGB = 2.2% versus Band = 3.3%	I=30 / n=5645 I=2 / n=180
	RYGB versus BPD Not reported	(0 trials)	RYGB = 2.2% versus BPD = 1.8%	I= 30/ n=5645 I=4 / n=2358

trials considered for analysis by procedure

- RYGB – 70 trials
- VBG – 48 trials
- BAND – 41 trials
- BPD – 7 trials

Table 19. Postoperative adverse events by bariatric procedure (RYGB versus VBG, Band, or BPD), results pooled by study type (cont.)

	Controlled trials (includes controlled trials comparing one procedure to another)		**All studies (includes all controlled trials and case series)**	
Category of adverse event	*Adverse event (%) by procedure*	*(#trials) # patients*	*Category of adverse event*	*Adverse event (%) by procedure*
3. Surgical, preventable and not preventable issues (cont.) 3b. Anastomotic or stomal stenosis	RYGB = 6.9 versus VBG = 14.9 OR=0.51 (0.13, 1.72)	(2 trials) n=72 n=74	RYGB = 4.6% versus VBG = 6.0%	l=27 / n=6078 l=16 / n=1696
	RYGB versus Band Not reported	(0 trials)	RYGB = 4.6% versus Band = Not reported	l=27 / n=6078 l=0 / n=0
	RYGB versus BPD Not reported	(0 trials)	RYGB = 4.6% versus BPD = Not reported	l=27/ n=6078 l=0 / n=0
3c. Bleeding	RYGB = 1.0% versus VBG = 0.0% OR = Not estimable	(1 trial) n= 99 n= 106	RYGB = 2.0% versus VBG = 0.7%	l=19 / n=5026 l=6 / n=1027
	RYGB versus Band Not reported	(0 trials)	RYGB = 2.0% versus Band = 0.3%	l=19 / n=5026 l=6 / n=2844
	RYGB versus BPD Not reported	(0 trials)	RYGB = 2.0% versus BPD = 0.2%	l=19 / n=5026 l=2 / n=1617

trials considered for analysis by procedure

- RYGB – 70 trials
- VBG – 48 trials
- BAND – 41 trials
- BPD – 7 trials

Table 19. Postoperative adverse events by bariatric procedure (RYGB versus VBG, Band, or BPD), results pooled by study type (cont.)

	Controlled trials (includes controlled trials comparing one procedure to another)		**All studies (includes all controlled trials and case series)**	
Category of adverse event	*Adverse event (%) by procedure*	*(#trials) # patients*	*Category of adverse event*	*Adverse event (%) by procedure*
3d. Reoperations (including those related to anastomosis, band, bleeding, revisions, etc.)	RYGB = 0% versus VBG = 3.7% OR=0 (0, 5.73)	(1 trial) n= 52 n= 54	RYGB = 1.6% versus VBG = 11.3%	I=9 / n=4356 I=7 / n=520
	RYGB versus Band Not reported	(0 trials)	RYGB = 1.6% versus Band = 7.7%	I=9 / n=4536 I=11 / n=2140
	RYGB versus BPD Not reported	(0 trials)	RYGB = 1.6% versus BPD = 4.2%	I=9 / n=4536 I=2 / n=1101
4. Medical (cardiac, stroke, or severe HTN)	RYGB versus VBG Not reported	(0 trials)	RYGB = 4.8% versus VBG = 4.7%	I=5 / n=2161 I=2 / n=473
	RYGB versus Band Not reported	(0 trials)	RYGB = 4.8% versus Band = 0.7%	I=5 / n=2161 I=1 / n=150
	RYGB versus BPD Not reported	(0 trials)	RYGB = 4.8% versus BPD = Not Reported	I=5 / n=2161 I=0/ n=0

trials considered for analysis by procedure

- RYGB – 70 trials
- VBG – 48 trials
- BAND – 41 trials
- BPD – 7 trials

Table 20. Postoperative adverse events following bariatric procedures differs by operative approach (open versus laparoscopic), pooled results by study type

	Controlled trials (includes controlled trials comparing one procedure to another)		**All studies (includes all controlled trials and case series)**	
Category of adverse event	*Adverse event (%) by operative approach*	*(#trials) # patients*	*Adverse event (%) by operative approach*	*# Studies/patients*
1. Respiratory (including pneumonia, atelectasis, respiratory insufficiency, etc.)	Open = 3.0% Lap = 1.9% OR=1.54 (0.17, 19.42)	(2 trials) N=101 N=104	Open = 2.4% Lap = 1.5%	l=26 / n=5317 l=18 / n=5437
1a. Pneumonia	Not reported	(0 trials)	Open = 0.9% Lap = 0.8%	l=11 / n=3555 l=7 / n=2064
2. Medical (cardiac, stroke, severe HTN)	Not reported	(0 trials)	Open = 6.0% Lap = 3.1%	l=5 / n=1360 l=5/ n=1463
3. Surgical, preventable and not preventable issues (including wound, hernia, splenic injury, reoperations, anastomotic, etc.)	Open = 31.1% Lap = 26.1% OR=1.32 (0.72, 2.43)	(3 trials) N=122 N=134	Open = 22.1% Lap = 12.4%	l=68 / n=11094 l=47 / n=13752
3a. Wound, all	Open = 13.1% Lap = 0.0% OR=Not estimable	(3 trials) N=122 N=134	Open = 11.4% Lap = 2.3%	l=47 / n=8333 l=27 / n=8320
I. Wound infection, major	Open = 3.0% Lap = 0.0% OR=Not estimable	(2 trials) N=101 N=104	Open = 4.0% Lap = 1.6%	l=8 / n=907 l=17 / n=4694

trials considered for analysis by operative approach

- Open – 98 trials
- Lap – 53 trials

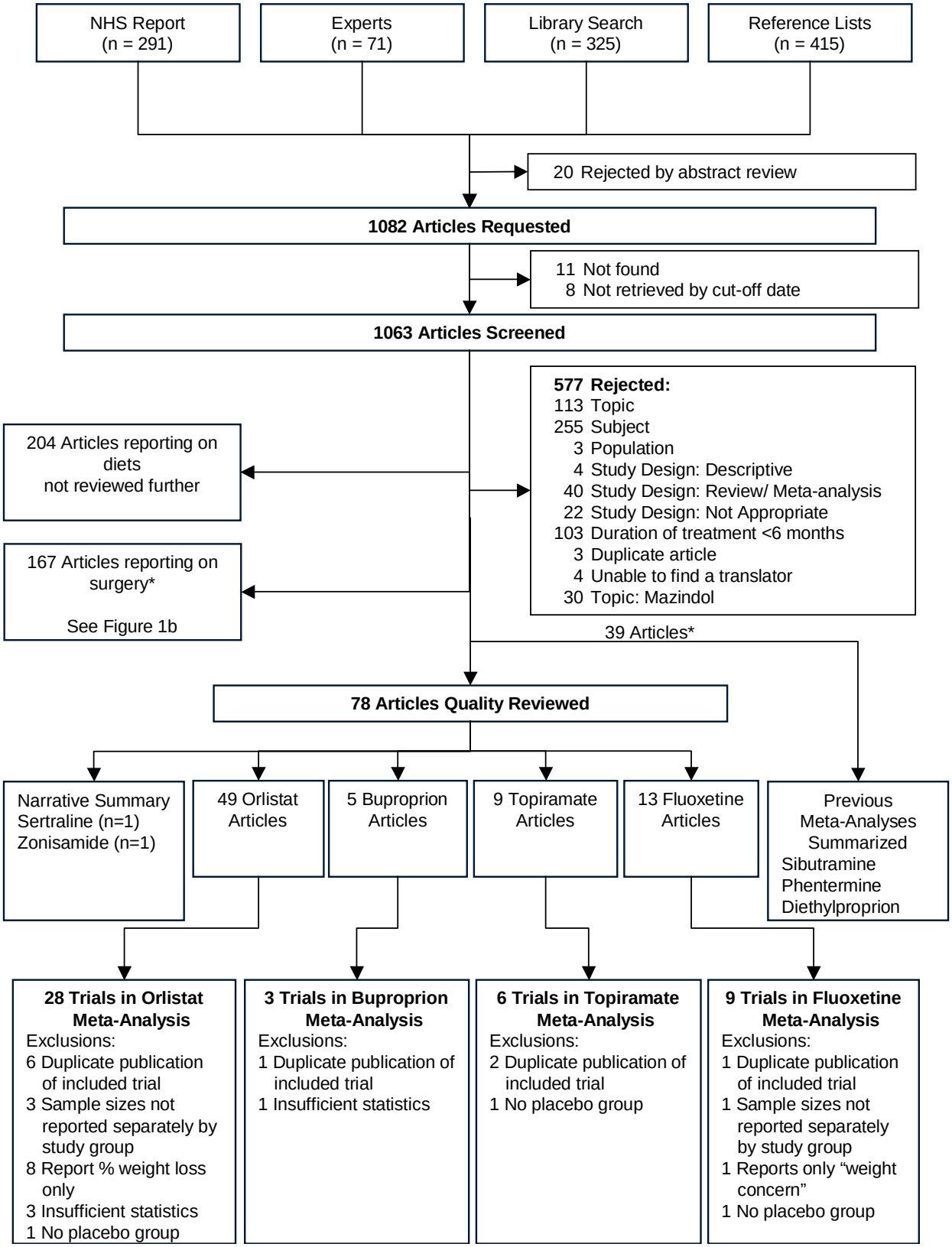
Table 20. Postoperative adverse events following bariatric procedures differs by operative approach (open versus laparoscopic), pooled results by study type (cont.)

	Controlled trials (includes controlled trials comparing one procedure to another)		**All studies (includes all controlled trials and case series)**	
Category of adverse event	*Adverse event (%) by operative approach*	*(#trials) # patients*	*Adverse event (%) by operative approach*	*# studies/patients*
3a. Wound, all (cont.) II. Wound infection, minor	Open = 14.3% Lap = 0.0% OR=Not estimable	(1 trial) n=21 n=30	Open = 10.8% Lap = 3.3%	l=9 / n=739 l=5 / n=1555
III. Incisional hernia	Open = 8.2% Lap = 0.0% OR=Note	(3 trials) n=122 n=134	Open = 11.9% Lap = 0.4%	l=29 / n=3686 l=7 / n=1075
3b. Internal hernia	Open = 0.0% Lap = 1.3% OR=0.00 (0.00, 40.40)	(1 trial) n=76 n=79	Open = 1.4% Lap = 2.9%	l=4 / n=287 l=6 / n=3422
3c. Splenic injury (including splenectomy or repair)	Not reported	(0 trials)	Open = 1.2% Lap = 0.2%	l=18 / n=5065 l=4 / n=1541
3d. Reoperations	Open = 0.0% Lap = 4.0% OR=0.00 (0.00, 38.94)	(1 trial) n=25 n=25	Open = 8.1% Lap = 2.7%	l=18 / n=3465 l=9 / n=5018
4. DVT and/or PE	Open = 1.0% Lap = 0.9% OR=1.22 (0.02, 96.69)	(2 trials) n= 97 n= 109	Open = 1.3% Lap = 0.6%	l=23 / n=4704 l=16 / n=3995

trials considered for analysis by operative approach:

- Open – 98 trials
  Lap – 53 trials.

Figure 1a. Literature flow



* Two articles report on Diethylproprion compared to surgery and are included in both counts

Figure 1b. Literature flow, continued

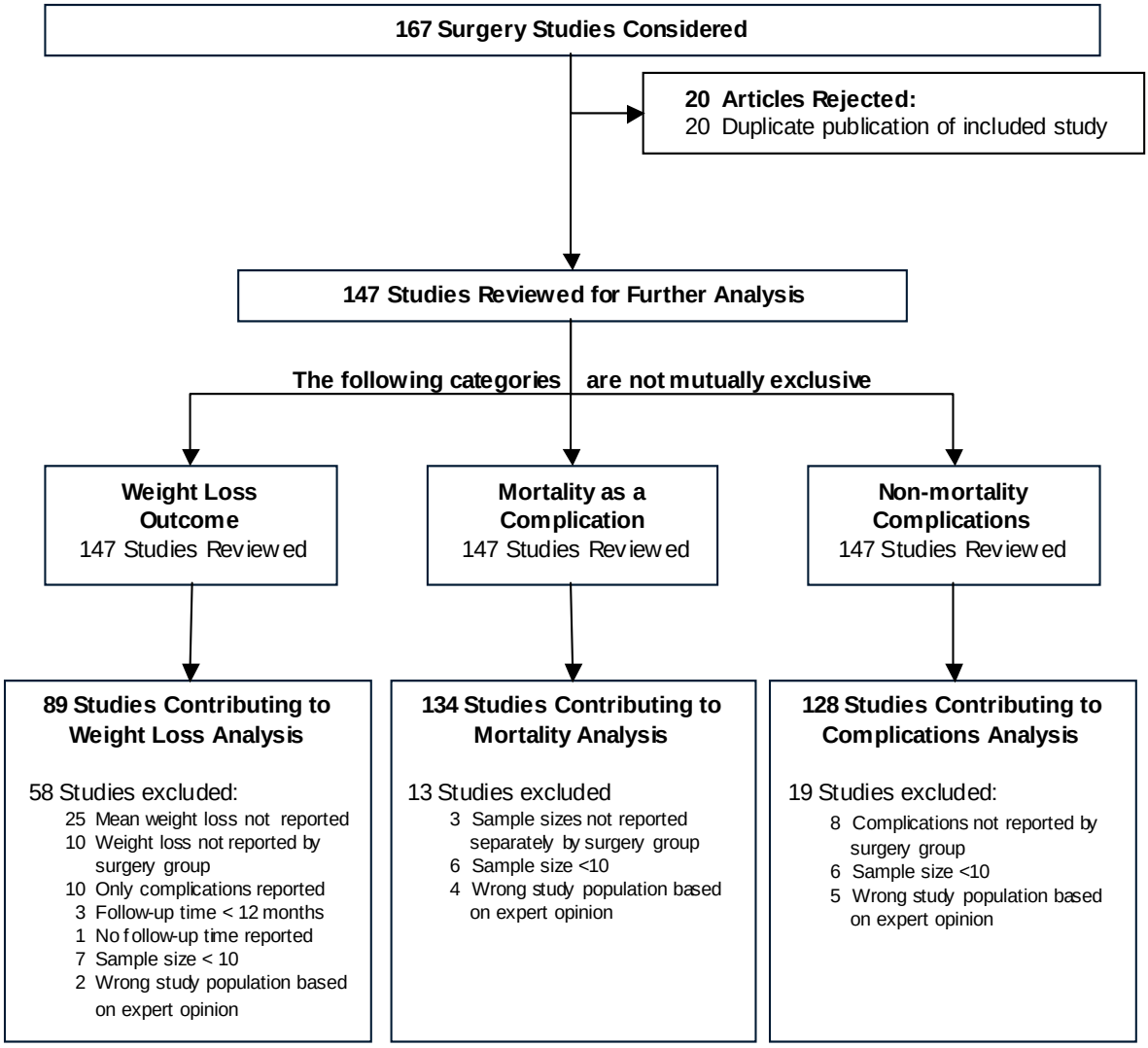
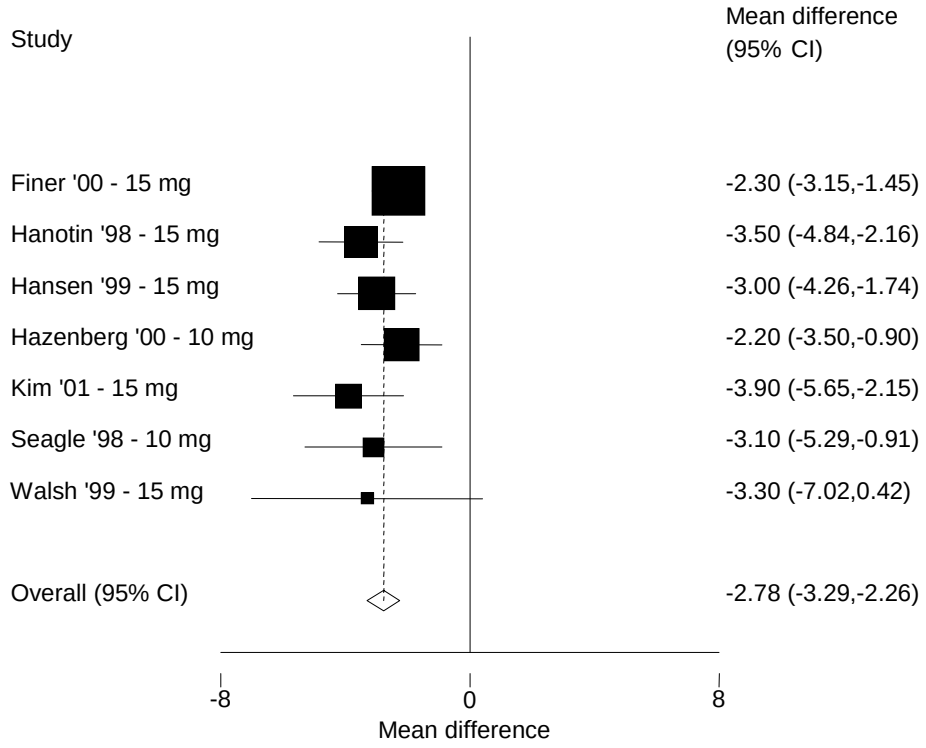
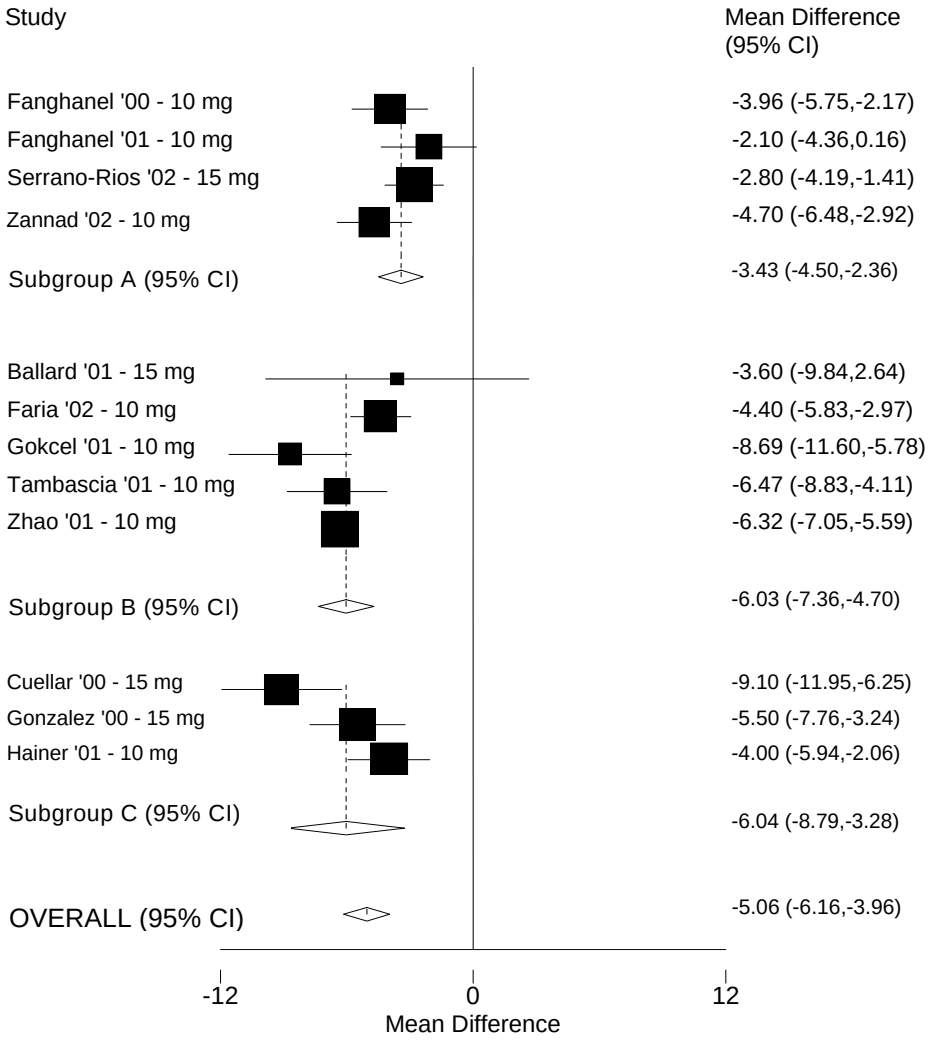


Figure 2. Pooled analysis: 8- to 12-week trials of sibutramine, 10-15 mg daily*



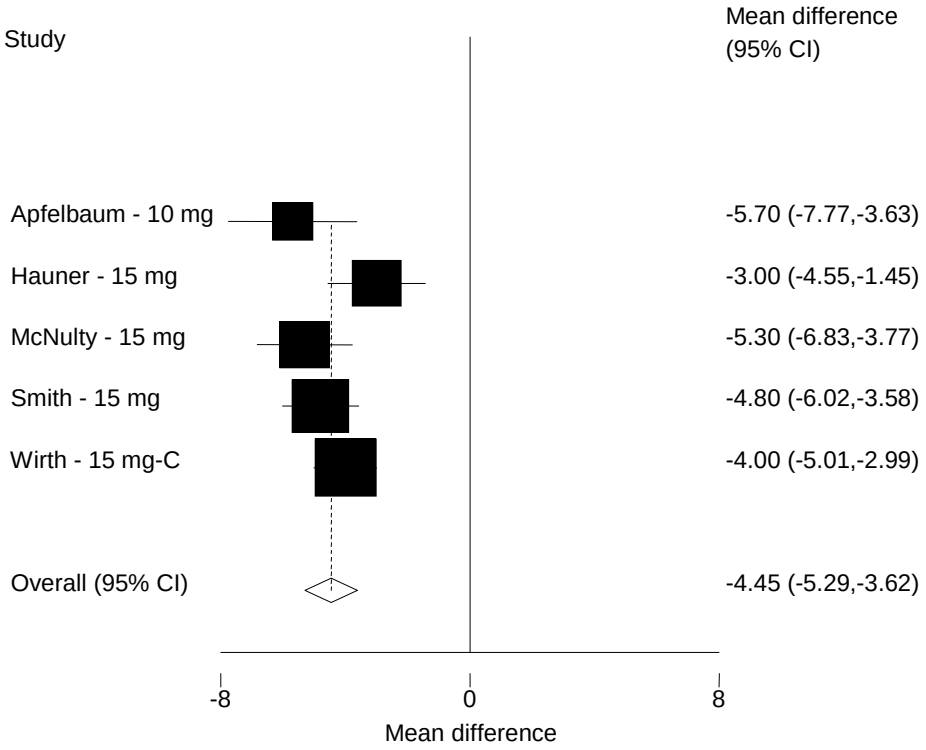
* Weighted mean difference in weight loss at 8 to 12 weeks in kilograms, sibutramine minus placebo. Arterburn DE, Crane PK, Veenstra DL. The efficacy and safety of sibutramine for weight loss: A systematic review.[53]
CI = confidence interval.

Figure 3. Pooled analysis: 16- to 24-week trials of sibutramine, 10-15 mg daily*



* Weighted mean difference in weight loss at 8 to 12 weeks in kilograms, sibutramine minus placebo. Subgroup A contains trials that used Last Observation Carried Forward (LOCF) and had greater than 70% follow-up, Subgroup B contains trials that analyzed completers only, and Subgroup C contains trials with follow-up rates less than 70%. See text for details. Arterburn DE, Crane PK, Veenstra DL. The efficacy and safety of sibutramine for weight loss: A systematic review.[53]

Figure 4. Pooled analysis: 44- to 54-week trials of sibutramine, 10-15 mg daily*



* Weighted mean difference in weight loss at 8 to 12 weeks in kilograms, sibutramine minus placebo. Arterburn DE, Crane PK, Veenstra DL. The efficacy and safety of sibutramine for weight loss: A systematic review.[281]
CI = confidence interval.

Figure 5. Pooled analysis: orlistat, 6 months

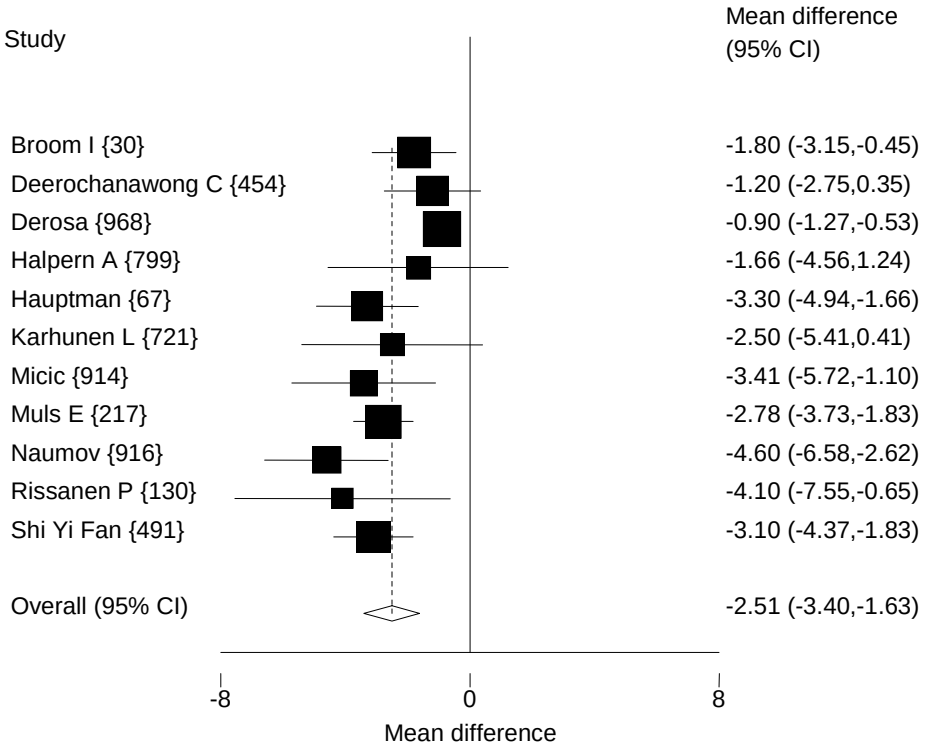


Figure 6. Pooled analysis: orlistat, 12 months

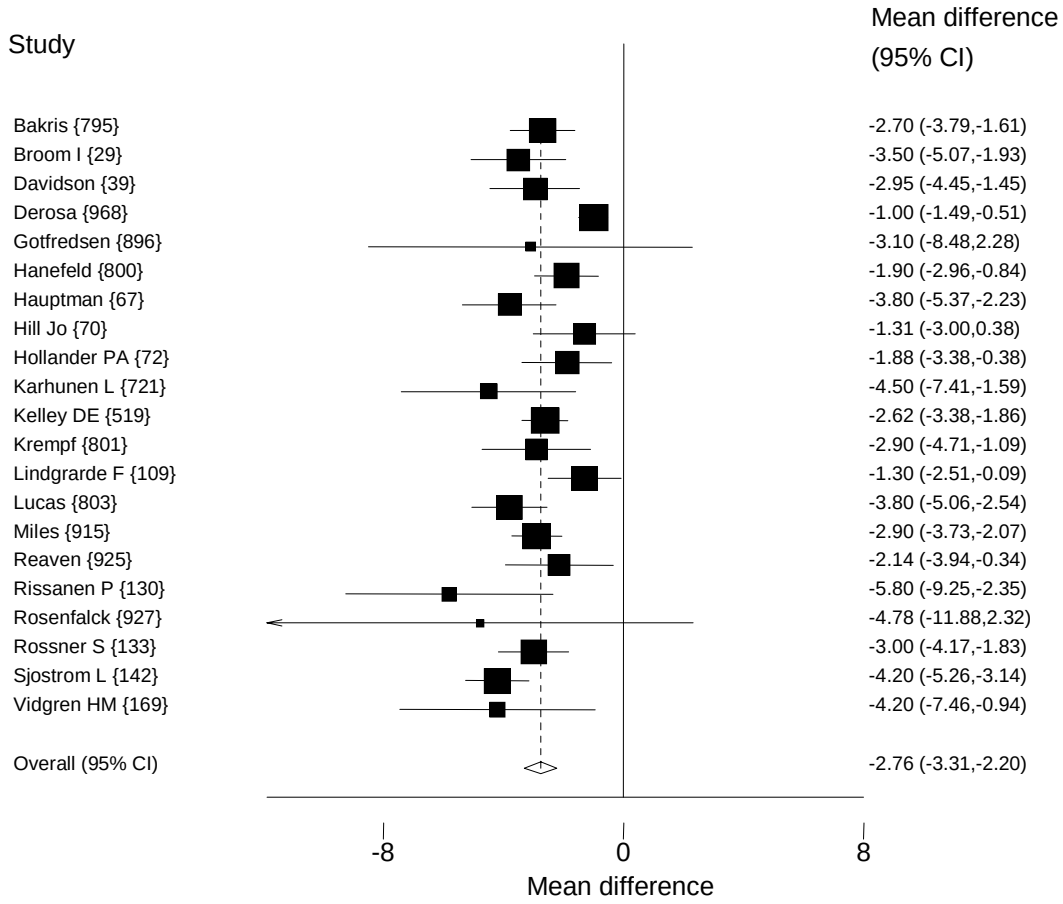


Figure 7. Pooled analysis: fluoxetine, 6 months

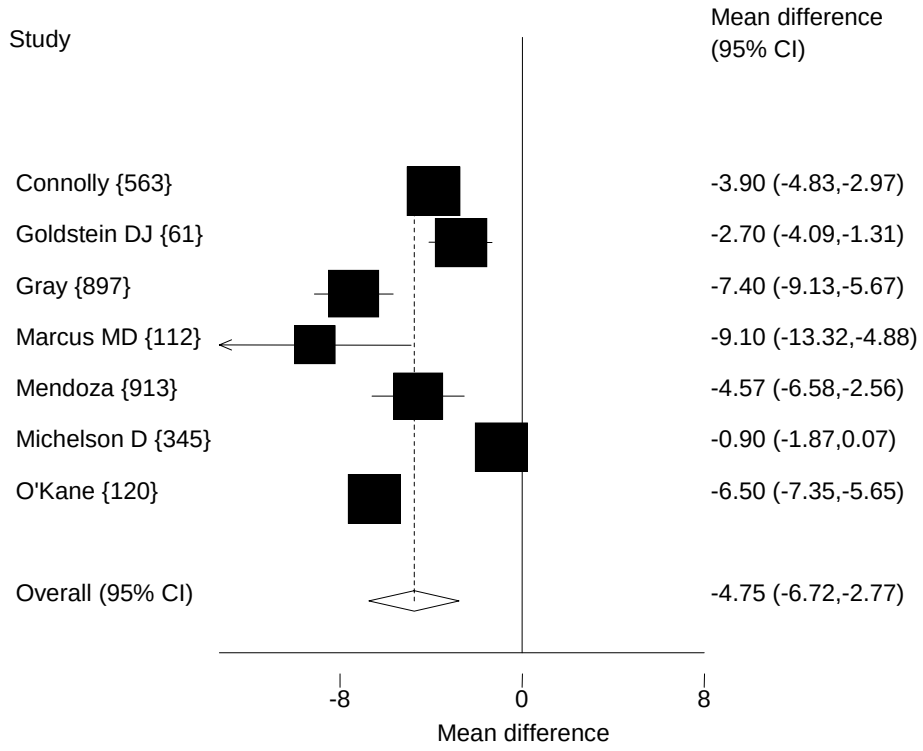


Figure 8. Pooled analysis: fluoxetine, 12 months

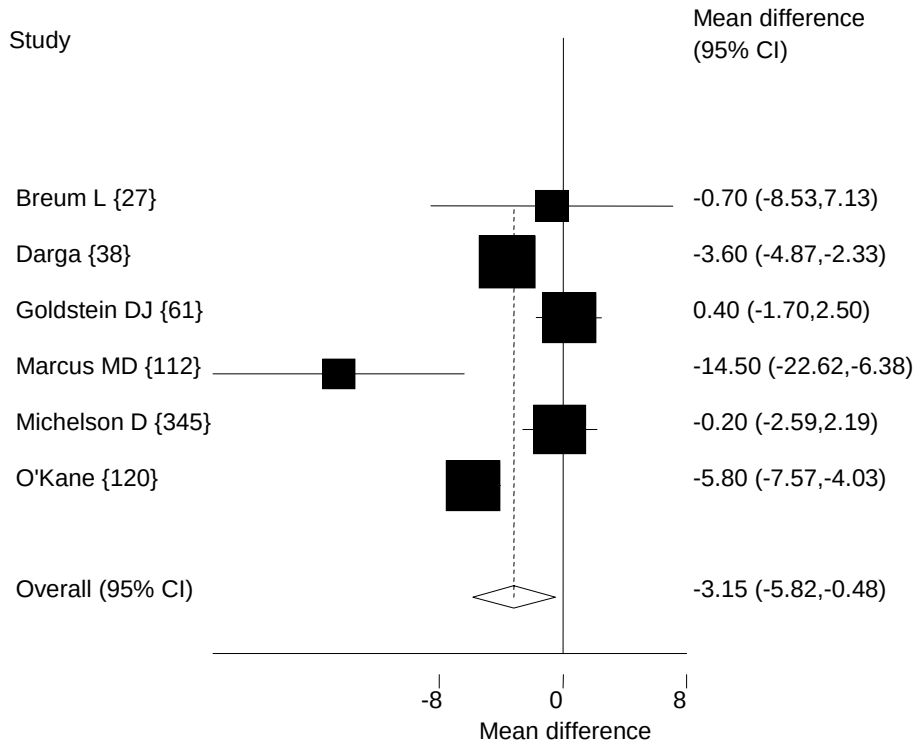


Figure 9. Pooled analysis: bupropion, 6-12 months

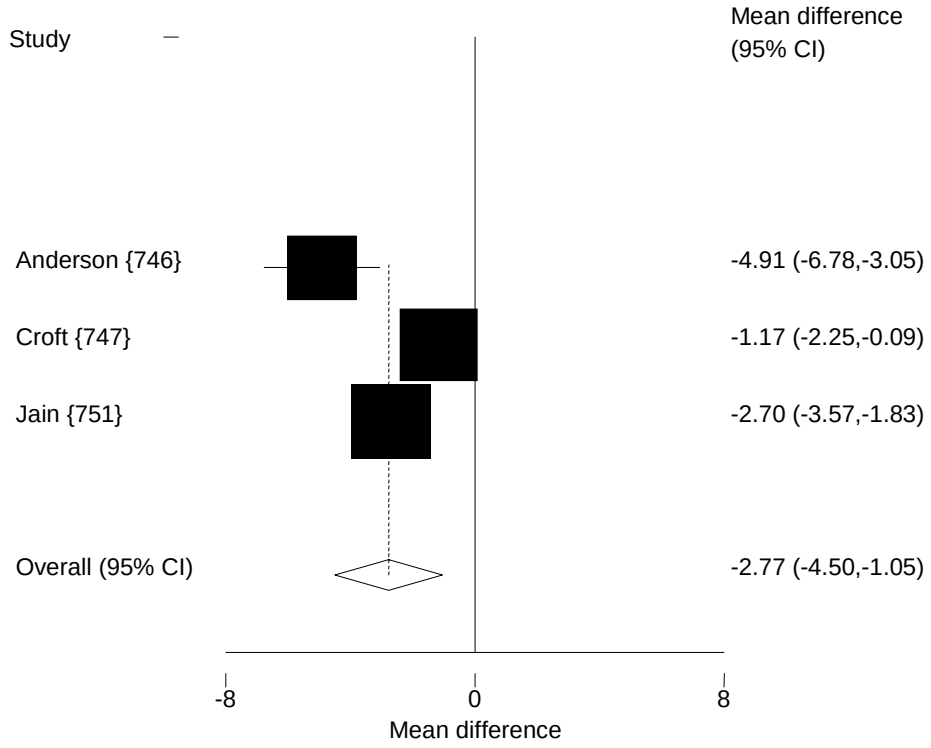
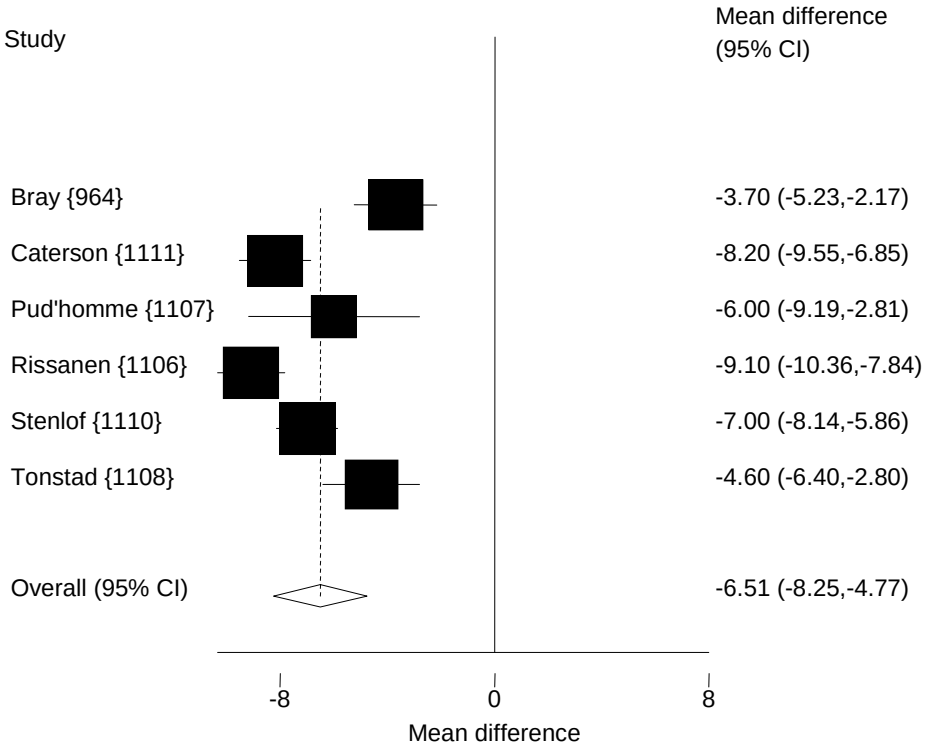


Figure 10. Pooled analysis: topiramate



SC-EPC Obesity Report

Appendix A: Preliminary Search Methodologies

Appendix B: Sample Data Abstraction Forms

Appendix C: Evidence Tables. Table 1- Medication
Table 2- Surgery

Appendix D: Technical Expert Panel (TEP) Members and Peer Reviewers

Appendix E: TEP and Peer Review Comments

Appendix F: Included Studies

Appendix G: Excluded Studies

Appendix A

PRELIMINARY SEARCH METHODOLOGIES – OBESITY

NOTE – An asterisk after a term indicates truncation

SEARCH #1 (Performed 10/16/02)

DATABASE SEARCHED AND TIME PERIOD COVERED:
PUBMED – 1966-2002/Oct.

SEARCH STRATEGY:
diethylpropion* OR mazindol* OR phentermine* OR fluoxetine* OR sibutramine* OR orlistat* OR sertaline*

AND

obesity OR obes* [ti] OR obes* [ab]

AND

random allocation OR randomi* OR randomized controlled trials OR randomized controlled trial[pt]

NUMBER OF ITEMS RETRIEVED: 192

SEARCH #2 (Performed 10/16/02)

DATABASE SEARCHED AND TIME PERIOD COVERED:
PUBMED – 1966-2002/Oct.

SEARCH STRATEGY:
diethylpropion* OR mazindol* OR phentermine* OR fluoxetine* OR sibutramine* OR orlistat* OR sertaline*

AND

obesity OR obes* [ti] OR obes* [ab]

AND

controlled clinical trials OR controlled clinical trial[pt]

NUMBER OF ITEMS RETRIEVED: 168

SEARCH #3 (Performed 10/16/02)

DATABASE SEARCHED AND TIME PERIOD COVERED:
PUBMED – 1966-2002/Oct.

SEARCH STRATEGY:
anti-obesity agents AND (therapeutic use OR adverse effects)

AND

random allocation OR randomi* OR randomized controlled trials OR randomized controlled trial[pt]

NUMBER OF ITEMS RETRIEVED: 150

SEARCH #4 (Performed 10/16/02)

DATABASE SEARCHED AND TIME PERIOD COVERED:
PUBMED – 1966-2002/Oct.

SEARCH STRATEGY:
anti-obesity agents AND (therapeutic use OR adverse effects)

AND

controlled clinical trials OR controlled clinical trial[pt]

NUMBER OF ITEMS RETRIEVED: 172

APPENDIX A

Obesity Updates to Aberdeen Searches Methodologies

NOTE – An asterisk after a term indicates truncation
An exclamation point after a term indicates that the term is exploded – ie. the term and all terms under it in the hierarchy are being searched.

SEARCH #1 (Performed 11/21/2002)

DATABASE SEARCHED:
Medline

TIME PERIOD COVERED:
2000-2001

SEARCH STRATEGY:

OBESITY! OR OBESITY IN DIABETES! OR OBESITY, MORBID OR HYPERPHAGIA! OR BULIMIA! OR OBES? OR WEIGHT LOSS OR OVERWEIGHT OR WEIGHT MAINT? OR WEIGHT REDUC? OR (LOSS OR LOST OR LOSE OR LOSING)WITHIN 2 WORDS OF WEIGHT OR DIET WITHIN 5 WORDS OF WEIGHT OR WEIGHT CONTROL

AND

RANDOMIZED CONTROLLED TRIALS OR RANDOM ALLOCATION OR CLINICAL TRIALS! OR DOCUMENT TYPE=RANDOMIZED CONTROLLED TRIAL OR DOCUMENT TYPE=CLINICAL TRIAL OR CLIN TRIAL?/TI,AB OR PLACEBOS OR PLACEBO?/TI,AB OR RANDOM?/TI,AB OR RESEARCH DESIGN)OR(SINGL? OR DOUBL? OR TREBL? OR TRIPL?)(BLIND? OR MASK?)/TI,AB)

NOT

CHILD! OR CHILD? OR INFANT? OR ADOLESCEN?

AND

HUMAN

NUMBER OF ITEMS RETRIEVED: 996

SEARCH #2 (Performed 11/21/02)

DATABASE SEARCHED:
EMBASE

TIME PERIOD COVERED: 2000-2001

SEARCH STRATEGY:

OBESITY OR DIABETIC OBESITY OR MORBID OBESITY OR HYPERPHAGIA OR BULIMIA OR OVERWEIGHT OR WEIGHT REDUC? OR WEIGHT MAINT? OR WEIGHT CONTROL?) OR OBES?) OR DIET WITHIN 5 WORKDS OF WEIGHT

AND

MULTICENTER STUDY OR RANDOMIZED CONTROLLED TRIAL OR META ANALYSIS OR CROSSOVER PROCEDURE OR DOUBLE BLIND PROCEDURE OR SINGLE BLIND PROCEDURE OR RANDOMIZATION OR PLACEBO OR DRUG COMPARISON OR CLINICAL STUDY RANDOM? OR (SINGL? OR DOUBL? OR TRIPL? OR TREBL?)WITHIN 25 WORDS OF (BLIND? OR MASK?)) OR CLIN? WITH 25 WORDS OF TRIAL OR DOCUMENT TYPE= RANDOMIZED CONTROLLED TRIAL

NOT

CHILD! OR CHILD? OR INFANT? OR ADOLESCEN?

AND

HUMAN

NUMBER OF ITEMS RETRIEVED: 1319

SEARCH #3:

DATABASE SEARCHED:
Medline

TIME PERIOD COVERED:
2000-2001

SEARCH STRATEGY:

OBESITY! OR OBESITY IN DIABETES! OR OBESITY, MORBID OR HYPERPHAGIA! OR BULIMIA! OR OBES? OR WEIGHT LOSS OR OVERWEIGHT OR WEIGHT MAINT? OR WEIGHT REDUC? OR (LOSS OR LOST OR LOSE OR LOSING)WITHIN 2 WORDS OF WEIGHT OR DIET WITHIN 5 WORDS OF WEIGHT OR WEIGHT CONTROL

AND

RANDOMIZED CONTROLLED TRIALS OR RANDOM ALLOCATION OR CLINICAL TRIALS! OR DOCUMENT TYPE=RANDOMIZED CONTROLLED TRIAL OR DOCUMENT TYPE=CLINICAL TRIAL OR CLIN TRIAL?/TI,AB OR PLACEBOS OR PLACEBO?/TI,AB OR RANDOM?/TI,AB OR RESEARCH DESIGN)OR(SINGL? OR DOUBL? OR TREBL? OR TRIPL?)(BLIND? OR MASK?)/TI,AB)

AND

CHILD! OR CHILD? OR ADOLESCEN?

AND

HUMAN

NUMBER OF ITEMS RETRIEVED: 297

SEARCH #4:

DATABASE SEARCHED:
EMBASE

TIME PERIOD COVERED: 2000-2001

SEARCH STRATEGY:

OBESITY OR DIABETIC OBESITY OR MORBID OBESITY OR HYPERPHAGIA OR BULIMIA OR OVERWEIGHT OR WEIGHT REDUC? OR WEIGHT MAINT? OR WEIGHT CONTROL?) OR OBES?) OR DIET WITHIN 5 WORKDS OF WEIGHT

AND

MULTICENTER STUDY OR RANDOMIZED CONTROLLED TRIAL OR META ANALYSIS OR CROSSOVER PROCEDURE OR DOUBLE BLIND PROCEDURE OR SINGLE BLIND PROCEDURE OR RANDOMIZATION OR PLACEBO OR DRUG COMPARISON OR CLINICAL STUDY RANDOM? OR (SINGL? OR DOUBL? OR TRIPL? OR TREBL?)WITHIN 25 WORDS OF (BLIND? OR MASK?)) OR CLIN? WITH 25 WORDS OF TRIAL OR DOCUMENT TYPE= RANDOMIZED CONTROLLED TRIAL

AND

CHILD! OR CHILD? OR ADOLESCEN?

AND

HUMAN

NUMBER OF ITEMS RETRIEVED: 265

SEARCH #5 (Performed 11/22/02)

DATABASES SEARCHED:
CAB Abstracts

TIME PERIOD COVERED:
2000-2001

SEARCH STRATEGY:

OBES? OR OVEREATING OR OVERWEIGHT OR OVERFEEDING OR WEIGHT REDUCTION OR WEIGHT HYPERGLYCAEMIA SYNDROME OR WEIGHT HYPERGLYC? OR WEIGHT LOSSES OR WEIGHT GAIN OR HYPERPHAGI? OR BULIMI? OR WEIGHT LOS? OR WEIGHT AND (MAINT? OR REDUC? OR LOS? OR DIET? OR CONTROL?)OR OBESITY HYPERGLYC? SYNDROME?

AND

RANDOM? OR TRIAL? OR PLACEBO? OR VOLUNTEER? OR (SINGL? OR DOUBL? OR TREBL? OR TRIPL?) WITHIN 25 WORDS OF (BLIND? OR MASK?)

AND

MAN

NUMBER OF ITEMS RETRIEVED: 588

SEARCH #6 (Performed 11/22/02)

DATABASES SEARCHED:
BIOSIS Previews

TIME PERIOD COVERED:
2000-2001

SEARCH STRATEGY:
OBES? OR HYPERPHAGI? OR BULIMI? OR WEIGHT()LOS? OR OVERWEIGHT OR WEIGHT AND (MAINT? OR REDUC? OR LOS? OR DIET? OR CONTROL

AND

RANDOM? OR TRIAL? OR PLACEBO?

AND

HUMAN

NUMBER OF ITEMS RETRIEVED: 1322

SEARCH #7:

DATABASE SEARCHED:
Allied & Complementary Medicine

TIME PERIOD COVERED: 2001-2003

SEARCH STRATEGY:

(OBES? OR BULIMI? OR WEIGHT()LOSS? OR OVERWEIGHT)OR (WEIGHT AND (MAINT? OR REDUC? OR LOS? OR DIET? OR CONTROL?)

AND

RANDOMIZED CONTROLLED TRIALS OR RANDOM ALLOCATION OR DOUBLE BLIND METHOD OR RESEARCH DESIGN OR CLIN?(25W)TRIAL?/TI,AB OR PLACEBO OR RANDOM?/TI,AB OR TRIAL? OR SINGL? OR DOUBL? OR TREBL? OR TRIPL?)(25W)(BLIND? OR MASK?)/TI,AB) OR CLINICAL TRIALS!

NUMBER OF ITEMS RETRIEVED: 63

SEARCH #8

DATABASES SEARCHED:
SPORTDiscus

TIME PERIOD COVERED:
2000-2001

SEARCH STRATEGY:

OBES? OR HYPERPHAGI? OR BULIMI? OR WEIGHT()LOS? OR OVERWEIGHT OR WEIGHT (MAINT? OR REDUC? OR CONTROL) OR LOS?(2W)WEIGHT OR DIET?(5W)WEIGHT

AND

DOUBLE BLIND METHOD OR PROSPECTIVE STUDY OR COMPARATIVE STUDY OR RESEARCH DESIGN OR PLACEBO OR CLIN?(25W)TRIAL?/TI,AB OR PLACEBO?/TI,AB OR RANDOM?/TI,AB OR (SINGL? OR DOUBL? OR TREBL? OR TRIPL?)(25W)(BLIND? OR MASK?)/TI,AB

NUMBER OF ITEMS RETRIEVED: 110

SEARCH #9 (Performed 12/9/02)

DATABASE SEARCHED:
PsycINFO

TIME PERIOD COVERED:
2000-2001

SEARCH STRATEGY:

OBES? OR HYPERPHAGIA? OR BINGE-EATING OR BULIMI? NON-PURG? OR OVERWEIGHT OR WEIGHT (LOS? OR MAINT? OR REDUC? OR CONTROL) OR DIET?(5W)WEIGHT

AND

CLIN?(25N)TRIAL? OR PLACEBO? OR RANDOM? OR CONTROL? OR (SING? OR DOUBL? OR TREBL? OR TRIPL?)(25N)(BLIND? OR MASK?)

AND

HUMAN

NUMBER OF ITEMS RETRIEVED: 407

SEARCH #10 (Performed 12/9/02)

DATABASE SEARCHED:
SciSearch (Science Citation Index)

TIME PERIOD COVERED:
2000-2001

SEARCH STRATEGY:

OBES? OR OVERWEIGHT

AND

(TRIAL? OR STUD?) AND RANDOM?

NOT

RAT? ? OR MICE OR MOUSE OR HAMSTER? OR PORCINE OR MURINE

NUMBER OF ITEMS RETRIEVED: 520

SEARCH #11 (Performed 12/5/02)

DATABASE SEARCHED:
CINAHL

TIME PERIOD COVERED:
2000-2001

SEARCH STRATEGY:

hyperphagia or bulimia or obese or (weight and loss) or overweight

and

clinical and trial? or random or randomized or placeb? or volunteer?

NUMBER OF ITEMS RETRIEVED: 80

SEARCH #12

DATABASE SEARCHED:
Cochrane Library

TIME PERIOD COVERED:
2000-2001

SEARCH STRATEGY:

OBESITY-IN-DIABETES OR OBESITY OR OBESITY-MORBID OR ((HYPERPHAGIA OR BULIMIA OR WEIGHT-LOSS OR OBES* OR OVERWEIGHT)) OR (WEIGHT AND (LOSS or MAINT* or DIET* OR CONTROL OR REDUC* OR LOS*)

NOT

NEOPLASMS*

NUMBER OF ITEMS RETRIEVED: 1443

Appendix B

Figure 1. Screening form for literature

1. Article ID: _____

2. First Author: _____
   (Last name of first author)

3. Reviewer: _____

4. Research topic: **(circle one)**
   - Weight loss primary outcome 1
   - Weight loss secondary outcome..... 2
   - Weight loss not an outcome, but adverse events are reported 3
   - Unclear..... 8
   - None of the above..... 9 **(STOP)**

5. Subject of article: **(check all that apply)**
   - Medication ..... ❒
   - Diet (calories or composition: protein/ carbs/ fat) ..... ❒
   - Surgery..... ❒
   - Alternative medicine..... ❒
   - Other (specify:_____) .... ❒ **(STOP)**

6. Study population: **(check all that apply)**
   - Human: Adults, age 18 and over..... ❒
   - Human: Adolescents, age 13-17 ..... ❒
   - Human: Children, age 12 and under ..... ❒
   - Animal ..... ❒ **(STOP)**
   - Other (specify:_____) .... ❒ **(STOP)**

7. Study design: **(circle one)**
   - Descriptive (historical, editorial, etc.)..... 1 **(STOP)**
   - Review/ meta-analysis ..... 2 **(STOP)**
   - Randomized clinical trial 3
   - Controlled clinical trial 4
   - Case series <10 subjects..... 5
   - Case series ≥ 10 subjects..... 6
   - Case Report..... 7
   - Other (specify:_____) ..... 8 **(STOP)**

8. If RCT or CCT, duration of treatment: **(circle one)**
   - ≤ 3 months 1
   - >3 months to ≤ 6 months 2
   - >6 months to ≤12 months 3
   - > than 12 months..... 4
   - Unclear..... 8

9. If RCT or CCT, maximum follow-up time from baseline: **(circle one)**
   - ≤ 3 months..... 1
   - >3 months to ≤ 6 months..... 2
   - >6 months to ≤12 months..... 3
   - > than 12 months..... 4
   - Unclear..... 8

10. If RCT or CCT, BMI or weight measurements: **(circle one)**
    - Is BMI ≥ 27..... 1
    - Or weight ≥ 160 lbs..... 2
    - Or weight ≥ 72.7 kg 3
    - None of the above 9

11. Language of article: **(circle one)**
    - English 1
    - German..... 2
    - French 3
    - Danish 4
    - Other (specify:_____)..... 7

Notes:

Figure 2. QRF

Article ID:_____ Reviewer:_____

First Author: _____
(Last Name Only)

Study Number: ___of____Description:_____
(Enter '1of 1' if only one) (if more than one study)

1. Subject: **(check all that apply)**
   - Medication ❒
   - Diet ❒
   - Surgery ❒
   - None of the above ❒ **(STOP)**
2. Design: **(circle one)**
   - RCT 1 **(GO TO Q3)**
   - CCT 2 **(GO TO Q3)**
   - Case Report/ Series (surgery only) 3 **(GO TO Q10)**
   - CBA (school –based diet only 4 **(GO TO Q10)**
   - Other designs 5 **(STOP)**

   (If Other, change study design on cover sheet and STOP)
3. Is the study described as randomized? **(circle one)**
   - Yes 1
   - No 2
4. If the study was randomized, was method of randomization appropriate? **(circle one)**
   - Yes 1
   - No 2
   - Method not described 8
   - Not applicable 9
5. Is the study described as: **(circle one)**
   - Double blind 1
   - Single blind, patient 2
   - Single blind, outcome assessment 3
   - Open 4
   - Blinding not described 8
   - Not applicable 9
6. If reported, was the method of double blinding appropriate? **(circle one)**
   - Yes 1
   - No 2
   - Double blinding method not described 8
   - Not applicable 9
7. If study was randomized, did the method of randomization provide for concealment of allocation? **(circle one)**
   - Yes 1
   - No 2
   - Concealment not described 8
   - Not applicable 9
8. Are withdrawals (W) and dropouts (D) described? **(circle one)**
   - Yes, reason described for all W and D 1
   - Yes, reason described for some W and D 2
   - Not described 8
   - Not applicable 9
9. Is this a cross-over study design? **(circle one)**
   - Yes 1
   - No 2
   - Not described 8
10. Are outcome data reported separately for or primarily on over 75% of any of the following populations? **(check all that apply)**

    Race:
    - African-Americans ❒
    - Hispanic ❒
    - Asian ❒

    Gender:
    - Male ❒
    - Female ❒

    Age:
    - Adolescents (13-17) ❒
    - Children (0-12) ❒

    Other:

    (Enter code: ____ ____, ____ ____, ____ ___, ____ ____)

    None of the above ❒

11. What types of co-morbidities are described in the groups?

(check all that apply)

Morbid Obesity (BMI 35-39.9 with co-morbidities, or ≥40).. ❑
Diabetes ..... ❑
Hypertension ..... ❑
Other cardiovascular disease ..... ❑
Sleep apnea ..... ❑
Cancer ..... ❑
Gallbladder disease and gallstones ..... ❑
Degenerative arthritis ..... ❑
Hyperlipidemia ..... ❑
Other (specify):
Enter code: ____ ____, ____ ____, ____ ____, ____ ____
Not described ..... ❑
Not applicable ..... ❑

Interventions

12. Enter sample size and interventions for each arm beginning with placebo or control, then in order of first mention:

Arm		Medication Intervention		Diet Intervention		Surgery	Co-intervention(s)
1	N entering (enter #)	Drug (code)		Diet Name (code)		Name (code)	(codes)
	N completing (enter #)	Dose (enter #)	Units (code)	Diet Type (code)			
	(CIRCLE ONE) Placebo .....1 Active.....3 Control.....2 Active (NA).....4 Enter Code _____	Duration (enter #)	Units (code)	Duration (enter #)	Units (code)		
2	N entering	Drug		Diet Name		Name	
	N completing	Dose	Units	Diet Type			
	(CIRCLE ONE) Placebo .....1 Active.....3 Control.....2 Active (NA).....4 Enter Code _____	Duration	Units	Duration	Units		
3	N entering	Drug		Diet Name		Name	
	N completing	Dose	Units	Diet Type			
	(CIRCLE ONE) Placebo .....1 Active.....3 Control.....2 Active (NA).....4 Enter Code _____	Duration	Units	Duration	Units		
4	N entering	Drug		Diet Name		Name	
	N completing	Dose	Units	Diet Type			
	(CIRCLE ONE) Placebo .....1 Active.....3 Control.....2 Active (NA).....4 Enter Code _____	Duration	Units	Duration	Units		

Dose Units:
1. mg
2. mcg or µg
3. IU
8. ND
9. NA

Duration Units:
1. hour
2. day
3. week
4. month
5. year
8. ND
9. NA

Other Codes:
997. Variable
998. ND
999. NA

Interventions (continued)

12. Enter sample size and interventions for each arm beginning with placebo or control, then in order of first mention:

Arm		Medication Intervention		Diet Intervention		Surgery	Co-intervention(s)
1	N entering (enter #)	Drug (code)		Diet Name (code)		Name (code)	(codes)
	N completing (enter #)	Dose (enter #)	Units (code)	Diet Type (code)			
	(CIRCLE ONE) Placebo .....1 Active.....3 Control.....2 Active (NA).....4 Enter Code _____	Duration (enter #)	Units (code)	Duration (enter #)	Units (code)		
2	N entering	Drug		Diet Name		Name	
	N completing	Dose	Units	Diet Type			
	(CIRCLE ONE) Placebo .....1 Active.....3 Control.....2 Active (NA).....4 Enter Code _____	Duration	Units	Duration	Units		
3	N entering	Drug		Diet Name		Name	
	N completing	Dose	Units	Diet Type			
	(CIRCLE ONE) Placebo .....1 Active.....3 Control.....2 Active (NA).....4 Enter Code _____	Duration	Units	Duration	Units		
4	N entering	Drug		Diet Name		Name	
	N completing	Dose	Units	Diet Type			
	(CIRCLE ONE) Placebo .....1 Active.....3 Control.....2 Active (NA).....4 Enter Code _____	Duration	Units	Duration	Units		

Dose Units:
1. mg
2. mcg or µg
3. IU
8. ND
9. NA

Duration Units:
1. hour
2. day
3. week
4. month
5. year
8. ND
9. NA

Other Codes:
997. Variable
998. ND
999. NA

Outcomes

13. Type of outcomes measured:

Enter the code for each outcome measured:
____ ____
____ ____
____ ____
____ ____
____ ____
____ ____
____ ____
____ ____
____ ____
____ ____
____ ____
____ ____

Evaluation

14a. What is the duration of follow-up (defined as the period of time from the start of treatment until the last reported outcome)? **(Circle One)**

Same as duration of treatment ..... 1 (GO TO 14B)
Longer than duration of treatment ..... 2 (GO TO 14B)
Not described 8
Not applicable 9

14b.

DURATION	UNITS	TYPE
Enter # or 999	1. Day 2. Week 3. Month 4. Year 8. ND 9. NA	1. Maximum 2. Mean 3. Median

Appendix C

Evidence Table-Medication

First author Year	Medication type Study design and Quality Population	Arm	Intervention	Sample size	Meta-analysis data
Anderson 2001	Buproprion RCT Jadad 3 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 112 N completing ND	Excluded from meta-analysis because of insufficient statistics.
		2	Bupropion Variable dose for 24 dy	N entering 110 N completing ND	
		3	Bupropion Variable dose for 24 dy	N entering 105 N completing ND	
Anderson 2002	Buproprion RCT Jadad 3 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 112 N completing 80	Included in meta-analysis of buproprion. Average weight loss at 6 months in kg
		2	Bupropion Variable dose for 48 dy	N entering 110 N completing 67	Arm 1 = -5.2 (6.6) Arm 3 = -10.1 (7.4)
		3	Bupropion Variable dose for 48 dy	N entering 105 N completing 57	Arm 2 was dropped from analysis because it was a lower dose of the same medication.
Croft 2002	Buproprion RCT Jadad 2 Population Adults	1	Placebo Dosage/Duration NR	N entering 213 N completing 43	Included in meta-analysis of buproprion. Average weight loss at 13 months in kg
		2	Bupropion 300 mg for 44 dy	N entering 210 N completing 60	Arm 1 = 0.02 (5.7) Arm 2 = -1.2 (5.7)
Gadde 2001	Buproprion RCT Jadad 5 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 25 N completing 1	Excluded from meta-analysis because of insufficient statistics.
		2	Bupropion Variable dose for 2 yr	N entering 25 N completing 12	
Jain 2002	Buproprion RCT Jadad 3 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 209 N completing 191	Included in meta-analysis of buproprion. Average weight loss at 6 months in kg
		2	Bupropion Variable dose for 24 dy	N entering 213 N completing 195	Arm 1 = -1.7 (4.3) Arm 2 = -4.4 (4.4)
Andersen 1984	Diethylpropion RCT Jadad 2 Population Adults, Females	1	Diethylpropion 12 mg for 18 dy	N entering 30 N completing 29	Excluded from meta-analysis because drug has existing meta-analysis.
		2	Open VBG Dosage/Duration NR	N entering 30 N completing 26	
Andersen 1988	Diethylpropion RCT Jadad 2 Population Adults, Females	1	Open VBG Dosage/Duration NR	N entering 30 N completing 26	Excluded from meta-analysis because drug has existing meta-analysis.
		2	Diethylpropion 12 mg for 18 dy	N entering 30 N completing 30	

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C

Evidence Table-Medication

First author Year	Medication type Study design and Quality Population	Arm	Intervention	Sample size	Meta-analysis data
McKay 1973	Diethylpropion RCT Jadad 3 Population Adults	1	Placebo Dosage/Duration NR	N entering ND N completing 18	Excluded from meta-analysis because drug has existing meta-analysis.
		2	Diethylpropion 75 mg for 24 dy	N entering ND N completing 20	
Breum 1995	Fluoxetine RCT Jadad 3 Population Adults	1	Placebo Dosage/Duration NR	N entering 20 N completing 14	Included in meta-analysis of fluoxetine. Average weight loss at 12 months in kg
		2	Fluoxetine 60 mg for 52 dy	N entering 20 N completing 15	Arm 1 = -9.4 (11.5) Arm 2 = -10.1 (10.0)
Chiasson 1989	Fluoxetine RCT Jadad 2 Population Adults	1	Placebo Dosage/Duration NR	N entering ND N completing ND	Excluded from meta-analysis because of insufficient statistics.
		2	Fluoxetine 60 mg for 36 dy	N entering ND N completing ND	
Connolly 1995	Fluoxetine RCT Jadad 3 Population Adults	1	Placebo Dosage/Duration NR	N entering 15 N completing 13	Included in meta-analysis of fluoxetine. Average weight loss at 6 months in kg
		2	Fluoxetine 60 mg for 6 mo	N entering 15 N completing 11	Arm 1 = 0.0 (0.5) Arm 2 = -3.9 (1.5)
Darga 1991	Fluoxetine RCT Jadad 3 Population Adults	1	Placebo Dosage/Duration NR	N entering 22 N completing 16	Included in meta-analysis of fluoxetine. Average weight loss at 12 months in kg
		2	Fluoxetine 60 mg for 52 dy	N entering 23 N completing 14	Arm 1 = -4.6 (1.1) Arm 2 = -8.2 (2.2)
Goldstein 1994	Fluoxetine RCT Jadad 4 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 184 N completing ND	Included in meta-analysis of fluoxetine. Average weight loss at 5 months in kg
		2	Placebo Dosage/Duration NR	N entering 22 N completing ND	Arm 1 = -2.4 (5.4) Arm 4 = -5.1 (6.9)
		3	Placebo Dosage/Duration NR	N entering 22 N completing ND	Average weight loss at 12 months in kg
		4	Fluoxetine 60 mg for 52 dy	N entering 182 N completing ND	Arm 1 = -2.1 (6.8) Arm 4 = -1.7 (8.7) Arms 1, 2, and 3 were collapsed.
Gray 1992	Fluoxetine RCT Jadad 3 Population Adults	1	Placebo Dosage/Duration NR	N entering 24 N completing 24	Excluded from meta-analysis because study reported data on another study already included in analysis (Gray, 1992).
		2	Fluoxetine 60 mg for 24 dy	N entering 24 N completing 24	

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C

Evidence Table-Medication

First author Year	Medication type Study design and Quality Population	Arm	Intervention	Sample size	Meta-analysis data
Gray 1992	Fluoxetine RCT Jadad 4 Population Adults	1	Placebo Dosage/Duration NR	N entering 24 N completing 20	Included in meta-analysis of fluoxetine. Average weight loss at 6 months in kg
		2	Fluoxetine 60 mg for 6 mo	N entering 24 N completing 16	Arm 1 = -1.9 (2.9) Arm 2 = -9.3 (2.4)
Marcus 1990	Fluoxetine RCT Jadad 4 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 22 N completing 11	Included in meta-analysis of fluoxetine. Average weight loss at 5 months in kg
		2	Fluoxetine 60 mg for 52 dy	N entering 23 N completing 13	Arm 1 = -2.1 (6.1) Arm 2 = -11.2 (5.8) Average weight loss at 9 months in kg Arm 1 = -0.7 (6.2) Arm 2 = -12.3 (9.8) Average weight loss at 12 months in kg Arm 1 = 0.6 (5.0) Arm 2 = -13.9 (12.7)
Mendoza 1995	Fluoxetine RCT Jadad 1 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 30 N completing 19	Included in meta-analysis of fluoxetine. Average weight loss at 6 months in kg
		2	Fluoxetine 180 mg for 6 mo	N entering ND N completing ND	Arm 1 = -7.7 (4.0) Arm 2 = -12.3 (4.0)
Michelson 1999	Fluoxetine RCT Jadad 1 Population Adults	1	Placebo Dosage/Duration NR	N entering 96 N completing ND	Included in meta-analysis of fluoxetine. Average weight loss at 6.5 months in kg
		2	Fluoxetine 20 mg for 14 dy	N entering 97 N completing ND	Arm 1 = 1.9 (2.3) Arm 2 = 1.0 (2.4)
		3	Fluoxetine 20 mg for 38 dy	N entering 100 N completing ND	Average weight loss at 11.5 months in kg
		4	Fluoxetine 20 mg for 50 dy	N entering 102 N completing ND	Arm 1 = 3.2 (4.3) Arm 4 = 3.0 (4.0) For 6.5 month analysis, arms 3 and 4 were combined and arm 2 was excluded because it has less than 6 month follow-up. For 11.5 month analysis, arms 2 and 3 were excluded because they had less than 11.5 month follow-up.

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C

Evidence Table-Medication

First author Year	Medication type Study design and Quality Population	Arm	Intervention	Sample size	Meta-analysis data
O'Kane 1994	Fluoxetine RCT Jadad 2 Population Adults	1	Placebo Dosage/Duration NR	N entering 10 N completing 9	Included in meta-analysis of fluoxetine. Average weight loss at 6 months in kg Arm 1 = 0.2 (1.1) Arm 2 = -6.3 (0.8) Average weight loss at 12 months in kg Arm 1 = 1.5 (1.7) Arm 2 = -4.3 (1.9)
		2	Fluoxetine 60 mg for 12 mo	N entering 10 N completing 7	
Pedrinola 1996	Fluoxetine RCT Jadad 3 Population Adults	1	Fluoxetine 40 mg for 8 mo	N entering 20 N completing 13	Excluded from meta-analysis because study had no placebo group.
		2	Fluoxetine 40 mg for 8 mo	N entering 20 N completing 20	
Ricca 2001	Fluoxetine RCT Jadad 1 Population Adults	1	Active n/s Cognitive-behavioral Dosage/Duration NR	N entering 20 N completing 17	Excluded from meta-analysis because study did not report weight loss as an outcome.
		2	Fluoxetine Variable dose for 24 dy	N entering 22 N completing 16	
		3	Cognitive-behavioral + fluvoxamine Dosage/Duration NR	N entering 23 N completing 18	
		4	Fluoxetine Variable dose for 24 dy	N entering 21 N completing 16	
		5	Fluvoxamine Dosage/Duration NR	N entering 22 N completing 16	
Anderson 1997	Orlistat RCT Jadad 2 Population Adults	1	Placebo Dosage/Duration NR	N entering ND N completing ND	Excluded from meta-analysis because of insufficient statistics.
		2	Orlistat 90 mg for 1 yr	N entering ND N completing ND	
		3	Orlistat 180 mg for 1 yr	N entering ND N completing ND	
		4	Orlistat 360 mg for 1 yr	N entering ND N completing ND	
Bakris 2002	Orlistat RCT Jadad 3 Population Adults	1	Placebo Dosage/Duration NR	N entering 276 N completing 108	Included in meta-analysis of orlistat. Average weight loss at 12 months in kg Arm 1 = -2.7 (6.4) Arm 2 = -5.4 (6.4)
		2	Orlistat 360 mg for 52 dy	N entering 278 N completing 162	

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C

Evidence Table-Medication

First author Year	Medication type Study design and Quality Population	Arm	Intervention	Sample size	Meta-analysis data
Broom 2001	Orlistat RCT Jadad 2 Population Adults	1	Placebo Dosage/Duration NR	N entering 266 N completing ND	Excluded from meta-analysis because study reported data on another study already included in analysis (Broom, 2001).
		2	Orlistat 360 mg for 1 yr	N entering 265 N completing ND	
Broom 2002	Orlistat RCT Jadad 3 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 261 N completing 161	Included in meta-analysis of orlistat. Average weight loss at 12 months in kg Arm 1 = -2.3 (6.4)
		2	Orlistat 360 mg for 52 dy	N entering 265 N completing 186	Arm 2 = -5.8 (8.5)
Broom 2001	Orlistat RCT Jadad 2 Population Adults	1	Placebo Dosage/Duration NR	N entering 71 N completing 60	Included in meta-analysis of orlistat. Average weight loss at 6 months in kg Arm 1 = -2.6 (3.9)
		2	Orlistat 360 mg for 52 dy	N entering 71 N completing 34	Arm 2 = -4.4 (4.1)
Davidson 1999	Orlistat RCT Jadad 3 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 224 N completing 133	Included in meta-analysis of orlistat. Average weight loss at 12 months in kg Arm 1 = -5.8 (7.7)
		2	Orlistat 360 mg for 52 dy	N entering 668 N completing 458	Arm 2 = -8.8 (7.9)
Deerochanawong 2001	Orlistat RCT Jadad 2 Population Adults	1	Placebo Dosage/Duration NR	N entering 126 N completing ND	Included in meta-analysis of orlistat. Average weight loss at 6 months in kg Arm 1 = -1.4 (6.3)
		2	Orlistat 360 mg for 24 dy	N entering 126 N completing ND	Arm 2 = -2.6 (6.3)
Derosa 2003	Orlistat RCT Jadad 3 Population Adults	1	Placebo Dosage/Duration NR	N entering 23 N completing 23	Included in meta-analysis of orlistat. Average weight loss at 6 months in kg Arm 1 = -4.2 (0.6)
		2	Orlistat 360 mg for 1 yr	N entering 27 N completing 25	Arm 2 = -5.1 (0.7)
		3	Fluvastatin Dosage/Duration NR	N entering 24 N completing 24	Average weight loss at 12 months in kg Arm 1 = -7.6 (0.7)
		4	Orlistat + fluvastatin 360 mg for 1 yr	N entering 25 N completing 24	Arm 2 = -8.6 (1.1) Arms 3 and 4 were excluded because they are different medications.

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C

Evidence Table-Medication

First author Year	Medication type Study design and Quality Population	Arm	Intervention	Sample size	Meta-analysis data
Derosa 2002	Orlistat RCT Jadad 3 Population Adults	1	Orlistat 360 mg for 1 yr	N entering 31 N completing 28	Excluded from meta-analysis because study had no placebo group.
		2	Active n/a Simvastatin (Zocor) Dosage/Duration NR	N entering 29 N completing 29	
		3	Orlistat 360 mg for 1 yr	N entering 27 N completing 26	
Farrell 1997	Orlistat RCT Jadad 2 Population Adults	1	Placebo Dosage/Duration NR	N entering ND N completing ND	Excluded from meta-analysis because of insufficient statistics.
		2	Orlistat 180 mg for 2 yr	N entering ND N completing ND	
		3	Orlistat 360 mg for 2 yr	N entering ND N completing ND	
Finer 2000	Orlistat RCT Jadad 4 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 114 N completing 61	Excluded from meta-analysis because study did not report weight loss as an outcome.
		2	Orlistat 360 mg for 12 mo	N entering 114 N completing 59	
Foreyt 1997	Orlistat RCT Jadad 3 Population Adults	1	Placebo Dosage/Duration NR	N entering 224 N completing 133	Excluded from meta-analysis because study reported data on another study already included in analysis (Davidson, 1999).
		2	Orlistat 360 mg for 52 dy	N entering 668 N completing 458	
Franson 2000	Orlistat RCT Jadad 2 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering ND N completing 14	Excluded from meta-analysis because of insufficient statistics.
		2	Orlistat Dosage data not collected for 52 dy	N entering ND N completing 20	
Gotfredsen 2001	Orlistat RCT Jadad 3 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 14 N completing ND	Included in meta-analysis of orlistat. Average weight loss at 12 months in kg
		2	Orlistat 360 mg for 1 yr	N entering 16 N completing ND	Arm 1 = -8.1 (7.5) Arm 2 = -11.2 (7.5)

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C

Evidence Table-Medication

First author Year	Medication type Study design and Quality Population	Arm	Intervention	Sample size	Meta-analysis data
Halpern 2003	Orlistat RCT Jadad 4 Population Adults	1	Placebo Dosage/Duration NR	N entering 174 N completing 141	Included in meta-analysis of orlistat. Average weight loss at 6 months in kg Arm 1 = -2.58 (17.3) Arm 2 = -4.24 (2.7)
		2	Orlistat 360 mg for 6 mo	N entering 169 N completing 139	
Halpern 2001	Orlistat RCT Jadad 4 Population Adults	1	Placebo Dosage/Duration NR	N entering 174 N completing 141	Excluded from meta-analysis because study did not report weight loss as an outcome.
		2	Orlistat 360 mg for 6 mo	N entering 164 N completing 139	
Hanefeld 2002	Orlistat RCT Jadad 2 Population Adults	1	Placebo Dosage/Duration NR	N entering 188 N completing 180	Included in meta-analysis of orlistat. Average weight loss at 12 months in kg Arm 1 = -3.4 (5.3) Arm 2 = -5.3 (5.1)
		2	Orlistat 360 mg for 48 dy	N entering 195 N completing 189	
Hanefeld 2001	Orlistat RCT Jadad 2 Population Adults	1	Placebo Dosage/Duration NR	N entering ND N completing 180	Excluded from meta-analysis because study did not report weight loss as an outcome.
		2	Orlistat 360 mg for 48 dy	N entering ND N completing 189	
Hauptman 2000	Orlistat RCT Jadad 3 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 212 N completing 91	Included in meta-analysis of orlistat. Average weight loss at 6 months in kg Arm 1 = -4.7 (8.7) Arm 3 = -8 (8.4) Average weight loss at 12 months in kg Arm 1 = -4.1 (8.2) Arm 3 = -7.9 (8.3) Arm 2 was excluded because it is low dosage.
		2	Orlistat 180 mg for 2 yr	N entering 213 N completing 120	
		3	Orlistat 360 mg for 2 yr	N entering 210 N completing 117	
Hill 1999	Orlistat RCT Jadad 3 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 188 N completing 138	Included in meta-analysis of orlistat. Average weight loss at 12 months in kg Arm 1 = -5.9 (7.6) Arm 4 = -7.2 (5.5) Arms 2 and 3 were excluded because they are low dosage.
		2	Orlistat 90 mg for 52 dy	N entering 187 N completing 140	
		3	Orlistat 180 mg for 52 dy	N entering 173 N completing 133	
		4	Orlistat 360 mg for 52 dy	N entering 181 N completing 126	

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C

Evidence Table-Medication

First author Year	Medication type Study design and Quality Population	Arm	Intervention	Sample size	Meta-analysis data
Hollander 1998	Orlistat RCT Jadad 3 Population Adults	1	Placebo Dosage/Duration NR	N entering 159 N completing 115	Included in meta-analysis of orlistat. Average weight loss at 12 months in kg Arm 1 = -4.3 (7.2) Arm 2 = -6.2 (6.5)
		2	Orlistat 360 mg for 52 dy	N entering 163 N completing 139	
James 1997	Orlistat RCT Jadad 2 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 23 N completing 12	Excluded from meta-analysis because study did not report weight loss as an outcome.
		2	Orlistat 360 mg for 52 dy	N entering 23 N completing 14	
Karhunen 2000	Orlistat RCT Jadad 2 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 36 N completing 19	Included in meta-analysis of orlistat. Average weight loss at 6 months in kg Arm 1 = -8.7 (6.3) Arm 2 = -11.2 (6.3) Average weight loss at 12 months in kg Arm 1 = -8.6 (6.3) Arm 2 = -13.1 (6.3)
		2	Orlistat 360 mg for 104 dy	N entering 36 N completing 19	
Kelley 1997	Orlistat RCT Jadad 2 Population Adults	1	Placebo Dosage/Duration NR	N entering 159 N completing ND	Excluded from meta-analysis because study reported data on another study already included in analysis (Hollander, 1998).
		2	Orlistat 360 mg for 52 dy	N entering 163 N completing ND	
Kelley 2002	Orlistat RCT Jadad 3 Population Adults	1	Placebo Dosage/Duration NR	N entering 276 N completing 128	Included in meta-analysis of orlistat. Average weight loss at 12 months in kg Arm 1 = -1.3 (3.2) Arm 2 = -3.9 (3.2)
		2	Orlistat 360 mg for 1 yr	N entering 274 N completing 137	
Krempf 2003	Orlistat RCT Jadad 2 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 350 N completing 350	Included in meta-analysis of orlistat. Average weight loss at 12 months in kg Arm 1 = -4.4 (10.4) Arm 2 = -7.3 (9.6)
		2	Orlistat 360 mg for 18 mo	N entering 346 N completing 346	
Krempf 2001	Orlistat RCT Jadad 2 Population Adults	1	Placebo Dosage/Duration NR	N entering ND N completing ND	Excluded from meta-analysis because of insufficient statistics.
		2	Orlistat 360 mg for 18 mo	N entering ND N completing ND	

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C

Evidence Table-Medication

First author Year	Medication type Study design and Quality Population	Arm	Intervention	Sample size	Meta-analysis data
Lindgarde 1999	Orlistat RCT Jadad 1 Population Adults	1 2	Placebo Dosage/Duration NR Orlistat 120 mg for 1 yr	N entering 185 N completing ND N entering 188 N completing ND	Excluded from meta-analysis because study reported data on another study already included in analysis (Lindgarde, 2000).
Lindgarde 2000	Orlistat RCT Jadad 3 Population Adults	1 2	Placebo Dosage/Duration NR Orlistat 360 mg for 1 yr	N entering 186 N completing 164 N entering 190 N completing 159	Included in meta-analysis of orlistat. Average weight loss at 12 months in kg Arm 1 = -4.3 (5.9) Arm 2 = -5.6 (5.2)
Lucas 2003	Orlistat RCT Jadad 2 Population Adults, Females	1 2	Placebo Dosage/Duration NR Orlistat 360 mg for 1 yr	N entering 188 N completing ND N entering 256 N completing ND	Included in meta-analysis of orlistat. Average weight loss at 12 months in kg Arm 1 = -6.1 (6.9) Arm 2 = -9.9 (6.4)
Micic 1999	Orlistat RCT Jadad 3 Population Adults, Females	1 2	Placebo Dosage/Duration NR Orlistat 360 mg for 24 dy	N entering 59 N completing 49 N entering 60 N completing 50	Included in meta-analysis of orlistat. Average weight loss at 6 months in kg Arm 1 = -7.3 (6.3) Arm 2 = -10.8 (6.3)
Miles 2002	Orlistat RCT Jadad 2 Population Adults	1 2	Placebo Dosage/Duration NR Orlistat 360 mg for 1 yr	N entering 261 N completing 254 N entering 255 N completing 250	Included in meta-analysis of orlistat. Average weight loss at 12 months in kg Arm 1 = -1.8 (3.6) Arm 2 = -4.7 (3.9)
Muls 2001	Orlistat RCT Jadad 3 Population Adults, Females	1 2	Placebo Dosage/Duration NR Orlistat 360 mg for 24 dy	N entering 147 N completing 127 N entering 147 N completing 128	Included in meta-analysis of orlistat. Average weight loss at 6 months in kg Arm 1 = -1.9 (4.5) Arm 2 = -4.7 (3.8)
Naumov 2002	Orlistat RCT Jadad 1 Population Adults	1 2	Control Dosage/Duration NR Orlistat 360 mg for 6 mo	N entering 15 N completing 15 N entering 15 N completing 15	Included in meta-analysis of orlistat. Average weight loss at 6 months in kg Arm 1 = -2.9 (3.0) Arm 2 = -7.5 (2.5)
Reaven 2001	Orlistat RCT Jadad 2 Population Adults	1 2	Placebo Dosage/Duration NR Orlistat 360 mg for 1 yr	N entering 91 N completing ND N entering 156 N completing ND	Included in meta-analysis of orlistat. Average weight loss at 12 months in kg Arm 1 = -6.8 (6.4) Arm 2 = -9.0 (7.9)

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C

Evidence Table-Medication

First author Year	Medication type Study design and Quality Population	Arm	Intervention	Sample size	Meta-analysis data
Rissanen 2001	Orlistat RCT Jadad 2 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering ND N completing 26	Included in meta-analysis of orlistat. Average weight loss at 6 months in kg Arm 1 = -7.5 (6.3) Arm 2 = -11.6 (6.3) Average weight loss at 12 months in kg Arm 1 = -7.2 (6.3) Arm 2 = -13.0 (6.3)
		2	Orlistat 360 mg for 12 mo	N entering ND N completing 25	
Rosenfalck 2002	Orlistat RCT Jadad 3 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering ND N completing 1	Included in meta-analysis of orlistat. Average weight loss at 12 months in kg Arm 1 = -3.8 (4) Arm 2 = -8.6 (8.3)
		2	Orlistat 360 mg for 2 yr	N entering ND N completing 3	
Rossner 2000	Orlistat RCT Jadad 3 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 243 N completing 136	Included in meta-analysis of orlistat. Average weight loss at 12 months in kg Arm 1 = -6.4 (6.7) Arm 2 = -8.5 (7.3) Arm 3 = -9.4 (6.4)
		2	Orlistat 180 mg for 2 yr	N entering 242 N completing 140	
		3	Orlistat 360 mg for 2 yr	N entering 244 N completing 159	
Samuelsson 2003	Orlistat RCT Jadad 2 Population Adults	1	Placebo Dosage/Duration NR	N entering 186 N completing 186	Excluded from meta-analysis because study reported data on another study already included in analysis (Lindgarde, 2000).
		2	Orlistat 360 mg for 52 dy	N entering 190 N completing 190	
Scheen 2002	Orlistat RCT Jadad 2 Population Adults	1	Placebo Dosage/Duration NR	N entering ND N completing 1637	Excluded from meta-analysis because follow-up time was too long to pool.
		2	Orlistat 360 mg for 4 yr	N entering ND N completing 1640	
Serrano-Rios 2001	Orlistat RCT Jadad 2 Population Adults	1	Placebo Dosage/Duration NR	N entering 118 N completing ND	Excluded from meta-analysis because study did not report weight loss as an outcome.
		2	Orlistat 360 mg for 24 dy	N entering 119 N completing ND	

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C

Evidence Table-Medication

First author Year	Medication type Study design and Quality Population	Arm	Intervention	Sample size	Meta-analysis data
Shi Yi 2001	Orlistat RCT Jadad 2 Population Adults	1	Placebo Dosage/Duration NR	N entering ND N completing 142	Included in meta-analysis of orlistat. Average weight loss at 6 months in kg Arm 1 = -3.0 (6.3) Arm 2 = -6.1 (6.3)
		2	Orlistat 360 mg for 6 mo	N entering 986 N completing 286	
Sjostrom 1998	Orlistat RCT Jadad 3 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 343 N completing 123	Included in meta-analysis of orlistat. Average weight loss at 12 months in kg Arm 1 = -6.1 (6.0) Arm 2 = -10.3 (6.3)
		2	Orlistat 360 mg for 2 yr	N entering 345 N completing 133	
Sjostrom 2000	Orlistat RCT Jadad 3 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 343 N completing 123	Excluded from meta-analysis because study reported data on another study already included in analysis (Sjostrom, 1998).
		2	Orlistat 360 mg for 2 yr	N entering 345 N completing 133	
Toornvliet 1997	Orlistat RCT Jadad 2 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering ND N completing ND	Excluded from meta-analysis because of insufficient statistics.
		2	Orlistat 180 mg for 2 yr	N entering ND N completing ND	
		3	Orlistat 360 mg for 2 yr	N entering ND N completing ND	
Van Gaal 1998	Orlistat RCT Jadad 3 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 125 N completing 123	Excluded from meta-analysis because of insufficient statistics.
		2	Orlistat 90 mg for 6 mo	N entering 122 N completing 122	
		3	Orlistat 180 mg for 6 mo	N entering 124 N completing 123	
		4	Orlistat 360 mg for 6 mo	N entering 122 N completing 120	
		5	Orlistat 720 mg for 6 mo	N entering 120 N completing 117	
Van Gaal 1999	Orlistat RCT Jadad 2 Population Adults	1	Placebo Dosage/Duration NR	N entering 1119 N completing ND	Excluded from meta-analysis because study did not report weight loss as an outcome.
		2	Orlistat 360 mg for 1 yr	N entering 1561 N completing ND	

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C

Evidence Table-Medication

First author Year	Medication type Study design and Quality Population	Arm	Intervention	Sample size	Meta-analysis data
Vidgren 1999	Orlistat RCT Jadad 3 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 38 N completing ND	Included in meta-analysis of orlistat. Average weight loss at 12 months in kg Arm 1 = -7.8 (6.0) Arm 2 = -12 (8.2)
		2	Orlistat 360 mg for 12 mo	N entering 37 N completing ND	
Zavoral 1998	Orlistat RCT Jadad 2 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 1119 N completing 1119	Excluded from meta-analysis because study did not report weight loss as an outcome.
		2	Orlistat 360 mg for 52 dy	N entering 1561 N completing 1561	
Campbell 1977	Phentermine RCT Jadad 4 Population Adults	1	Placebo Dosage/Duration NR	N entering 37 N completing 32	Excluded from meta-analysis because drug has existing meta-analysis.
		2	Phentermine 30 mg for 6 mo	N entering 34 N completing 34	
Wadden 1995	Sertraline RCT Jadad 2 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 27 N completing 17	Excluded from meta-analysis because interventions of interest were not studied. Data summarized narratively.
		2	Sertraline Variable dose for 54 dy	N entering 26 N completing 13	
Berkowitz 2003	Sibutramine RCT Jadad 4 Population Adolescents	1	Placebo Dosage/Duration NR	N entering 39 N completing 39	Excluded from meta-analysis because drug has existing meta-analysis.
		2	Sibutramine Variable dose for 12 mo	N entering 43 N completing 43	
Cuellar 2000	Sibutramine RCT Jadad 5 Population Adults, Adolescents, Females	1	Placebo Dosage/Duration NR	N entering 35 N completing 9	Excluded from meta-analysis because drug has existing meta-analysis.
		2	Sibutramine 15 mg for 6 mo	N entering 35 N completing 22	
Fanghanel 2000	Sibutramine RCT Jadad 4 Population Adults, Adolescents, Females	1	Placebo Dosage/Duration NR	N entering 54 N completing 44	Excluded from meta-analysis because drug has existing meta-analysis.
		2	Sibutramine 10 mg for 6 mo	N entering 55 N completing 40	

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C

Evidence Table-Medication

First author Year	Medication type Study design and Quality Population	Arm	Intervention	Sample size	Meta-analysis data
James 2000	Sibutramine RCT Jadad 5 Population Adults, Adolescents, Females	1	Placebo Dosage/Duration NR	N entering 145 N completing 57	Excluded from meta-analysis because drug has existing meta-analysis.
		2	Sibutramine Variable dose for 18 mo	N entering 352 N completing 204	
Bray 2003	Topiramate RCT Jadad 4 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 75 N completing 48	Included in meta-analysis of topiramate. Average weight loss at 6 months in % weight loss Arm 1 = -2.6 (4.8) Arm 3 = -4.8 (4.8) Arm 4 = -6.3 (4.8) Arms 2 and 5 were excluded because they were of low/high dosage of the same medication.
		2	Topiramate Variable dose for 24 dy	N entering 76 N completing 53	
		3	Topiramate Variable dose for 24 dy	N entering 75 N completing 48	
		4	Topiramate Variable dose for 24 dy	N entering 76 N completing 49	
		5	Topiramate Variable dose for 24 dy	N entering 78 N completing 44	
Bray 2002	Topiramate RCT Jadad 3 Population Adults	1	Placebo Dosage/Duration NR	N entering 79 N completing 48	Excluded from meta-analysis because study reported data on another study already included in analysis (Bray, 2003).
		2	Topiramate Variable dose for 24 dy	N entering 79 N completing 57	
		3	Topiramate Variable dose for 24 dy	N entering 79 N completing 49	
		4	Topiramate Variable dose for 24 dy	N entering 79 N completing 50	
		5	Topiramate Variable dose for 1 dy	N entering 79 N completing 44	
Caterson 2003	Topiramate RCT Jadad 2 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering ND N completing 97	Included in meta-analysis of topiramate. Average weight loss at 11 months in % weight loss Arm 1 = 1.8 (4.8) Arm 2 = -5.2 (4.8) Arm 3 = -6.4 (4.8)
		2	Topiramate Variable dose for 44 dy	N entering ND N completing 93	
		3	Topiramate Variable dose for 44 dy	N entering ND N completing 98	

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C

Evidence Table-Medication

First author Year	Medication type Study design and Quality Population	Arm	Intervention	Sample size	Meta-analysis data
Gilliam 2003	Topiramate RCT Jadad 2 Population Adults, Adolescents, Children	1	Topiramate Variable dose for 758 dy	N entering 125 N completing 99	Excluded from meta-analysis because study had no placebo group.
		2	Topiramate Variable dose for 809 dy	N entering 127 N completing 93	
Pud'homme 2003	Topiramate RCT Jadad 2 Population Adults, Males	1	Placebo Dosage/Duration NR	N entering 35 N completing 29	Included in meta-analysis of topiramate. Average weight loss at 6 months in % weight loss Arm 1 = 0.2 (3.2) Arm 2 = -5.8 (6.4)
		2	Topiramate Variable dose for 24 dy	N entering 33 N completing 20	
Rissanen 2003	Topiramate RCT Jadad 2 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering ND N completing 103	Included in meta-analysis of topiramate. Average weight loss at 15 months in % weight loss Arm 1 = -2.9 (4.8) Arm 2 = -9.1 (4.8) Arm 3 = -12 (4.8) Arm 4 was excluded because it was a high dosage study.
		2	Topiramate Variable dose for 60 dy	N entering ND N completing 133	
		3	Topiramate Variable dose for 60 dy	N entering ND N completing 123	
		4	Topiramate Variable dose for 60 dy	N entering ND N completing 125	
Stenlof 2003	Topiramate RCT Jadad 2 Population Adults	1	Placebo Dosage/Duration NR	N entering ND N completing 78	Excluded from meta-analysis because study reported data on another study already included in analysis (Stenlof, 2003).
		2	Topiramate Variable dose for 40 dy	N entering ND N completing 74	
		3	Topiramate Variable dose for 40 dy	N entering ND N completing 77	
Stenlof 2003	Topiramate RCT Jadad 2 Population Adults	1	Placebo Dosage/Duration NR	N entering ND N completing 137	Included in meta-analysis of topiramate. Average weight loss at 10 months in % weight loss Arm 1 = -3.0 (4.8) Arm 2 = -8.2 (4.8) Arm 3 = -10.0 (4.8)
		2	Topiramate Variable dose for 40 dy	N entering ND N completing 127	
		3	Topiramate Variable dose for 40 dy	N entering ND N completing 135	

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C

Evidence Table-Medication

First author Year	Medication type Study design and Quality Population	Arm	Intervention	Sample size	Meta-analysis data
Tonstad 2003	Topiramate RCT Jadad 2 Population Adults	1	Placebo Dosage/Duration NR	N entering 177 N completing 56	Included in meta-analysis of topiramate. Average weight loss at 7 months in % weight loss Arm 1 = -1.9 (4.8) Arm 2 = -5.9 (4.8) Arm 3 = -6.5 (4.8)
		2	Topiramate Variable dose for 28 dy	N entering 176 N completing 49	
		3	Topiramate Variable dose for 28 dy	N entering 178 N completing 53	
Gadde 2003	Zonisamide RCT Jadad 5 Population Adults, Females	1	Placebo Dosage/Duration NR	N entering 30 N completing 17	Excluded from meta-analysis because interventions of interest were not studied. Data summarized narratively.
		2	Zonisamide Variable dose for 32 dy	N entering 30 N completing 19	

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C
Evidence Table-Medication

Reference List

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Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
Abu-Abeid 2003	Design Case Series Jadad NA Population Adolescents, Children, Females	1	LAP adjustable band	N entering 11 N completing 11	Included in meta-analysis of weight loss. Average weight loss at 23 months in bmi Arm 1 = -14.5 (7.6)
Abu-Abeid 1999	Design Case Series Jadad NA Population Adults, Adolescents, Females	1	LAP adjustable band	N entering 391 N completing 356	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi Arm 1 = -11.2 (5.9) Average weight loss at 18 months in bmi Arm 1 = -13.3 (7.6)
Aghahosseini 2001	Design Case Series Jadad NA Population Adults	1	LAP adjustable band	N entering 84 N completing 84	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -29.2 (15.5) Average weight loss at 24 months in kg Arm 1 = -34.6 (20.3)
Agren 1989	Design RCT Jadad 1 Population Adults	1 2 3	Open VBG Open loop gastric bypass Open nonadjustable band	N entering 27 N completing ND N entering 25 N completing ND N entering 25 N completing ND	Excluded from meta-analysis because study did not report mean weight loss.
Al-Jiffry. 2003	Design Case Series Jadad NA Population Adults	1 2	Control LAP adjustable band	N entering 26 N completing 26 N entering 14 N completing 10	Excluded from meta-analysis based on expert opinion.
Alden 1977	Design Case Serie Jadad NA Population Adults, Adolescents, Females	1 2	Jejunal-ileal bypass Open loop gastric bypass	N entering 100 N completing ND N entering 100 N completing ND	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -40.6 (14.8) Arm 2 = -40.2 (11.8)
Alper 2000	Design Case Series Jadad NA Population Adults, Adolescents	1	Open VBG	N entering 450 N completing 300	Included in meta-analysis of weight loss. Average weight loss at 62 months in kg Arm 1 = -37.0 (23.2)

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
Andersen 1984	Design RCT Jadad 2 Population Adults, Females	1	Diethylpropion	N entering 30 N completing 29	Included in meta-analysis of weight loss.
		2	Open VBG	N entering 30 N completing 26	Average weight loss at 12 months in kg Arm 1 = -18.0 (15.5) Arm 2 = -22.0 (15.5) Average weight loss at 24 months in kg Arm 1 = -8.0 (20.3) Arm 2 = -30.5 (20.3)
Andersen 1982	Design RCT Jadad 1 Population Adults, Females	1	Open VBG	N entering 30 N completing 28	Included in meta-analysis of weight loss.
		2	Very low calorie diet(<1000)	N entering 30 N completing 30	Average weight loss at 6 months in kg Arm 1 = -26.6 (15.5) Arm 2 = -25.9 (15.5)
Andersen 1987	Design RCT Jadad 1 Population Adults, Females	1	Open gastroplasty	N entering 22 N completing 20	Included in meta-analysis of weight loss.
		2	Open VBG	N entering 23 N completing 21	Average weight loss at 12 months in kg Arm 1 = 1.0 (12.8) Arm 2 = -9.7 (14.2)
Andersen 1988	Design RCT Jadad 2 Population Adults, Females	1	Open VBG	N entering 30 N completing 26	Excluded from meta-analysis because study reported data on another study already included in analysis (253).
		2	Diethylpropion	N entering 30 N completing 30	
Anderson 1980	Design Case Series Jadad NA Population Adults, Adolescents, Children	1	Open RYGB, std	N entering 33 N completing ND	Excluded from meta-analysis because study did not report mean weight loss.
		2	Open VBG	N entering 8 N completing ND	
Anthone 2003	Design Case Series Jadad NA Population Adults, Females	1	BPD/Duodenal switch	N entering 701 N completing 50	Included in meta-analysis of weight loss. Average weight loss at 12 months in lbs Arm 1 = -127.0 (41.0) Average weight loss at 60 months in lbs Arm 1 = -118.0 (46.0)
Balsige 2000	Design Case Series Jadad NA Population Adults, Females	1	Open VBG	N entering 73 N completing 70	Included in meta-analysis of weight loss. Average weight loss at 120 months in kg Arm 1 = -28.0 (33.4)

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
Baltasar 1998	Design Case Series Jadad NA Population Adults, Adolescents	1 2 3	Open VBG Open VBG Open VBG	N entering 9 N completing ND N entering 81 N completing ND N entering 86 N completing ND	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 4 = -32.0 (15.5) Average weight loss at 114 months in kg Arm 4 = -32.0 (20.3) Arms 1, 2, 3 combined into single arm 4.
Belachew 1998	Design Case Series Jadad NA Population Adults, Females	1	LAP adjustable band	N entering 350 N completing ND	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi Arm 1 = -11.0 (5.9) Average weight loss at 41 months in bmi Arm 1 = -15.0 (7.6)
Belachew 2002	Design Case Series Jadad NA Population Adults, Females	1	LAP adjustable band	N entering 763 N completing 687	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi Arm 1 = -10.0 (5.9) Average weight loss at 48 months in bmi Arm 1 = -12.0 (7.6)
Bloomston 1997	Design Case Series Jadad NA Population Adults, Females	1 2	Open VBG Open RYGB, std	N entering 133 N completing ND N entering ND N completing 3	Excluded from meta-analysis because weight loss not reported by surgery type.
Breaux 1995	Design Case Series Jadad NA Population Adults, Adolescents, Children	1 2 3	Open VBG Open RYGB, std BPD/Duodenal switch	N entering 5 N completing 5 N entering 13 N completing 13 N entering 4 N completing 4	Excluded from meta-analysis because study did not report mean weight loss.
Brolin 1992	Design RCT	1	Open RYGB, std	N entering 22 N completing 22	Included in meta-analysis of weight loss.

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
	Jadad 1 Population Adults	2	Open RYGB, long	N entering 23 N completing 23	Average weight loss at 12 months in lbs Arm 1 = -118.0 (35.0) Arm 2 = -140.0 (41.0) Average weight loss at 48 months in lbs Arm 1 = -140.0 (63.0) Arm 2 = -159.0 (70.0)
Brolin 2000	Design Case Series Jadad NA Population Adults	1	Open gastroplasty	N entering 56 N completing ND	Excluded from meta-analysis because weight loss not reported by surgery type.
		2	Open VBG	N entering 30 N completing ND	
		3	Open RYGB, std	N entering 565 N completing ND	
Brolin 1994	Design Case Series Jadad NA Population Adults, Females	1	Open VBG	N entering 30 N completing ND	Included in meta-analysis of weight loss.
		2	Open RYGB, std	N entering 108 N completing ND	Average weight loss at 12 months in lbs Arm 1 = -74.0 (23.0) Arm 2 = -91.0 (34.1) Average weight loss at 48 months in lbs Arm 1 = -57.0 (44.7) Arm 2 = -90.0 (44.7)
Buckwalter 1977	Design RCT Jadad 2 Population Adults, Females	1	Jejunal-ileal bypass	N entering 19 N completing 6	Included in meta-analysis of weight loss.
		2	Open RYGB, std	N entering 19 N completing 6	Average weight loss at 12 months in kg Arm 1 = -31.5 (15.5) Arm 2 = -43.0 (15.5)
Capella 1996	Design Case Series Jadad NA Population Adults, Females	1	Open VBG	N entering 329 N completing 121	Included in meta-analysis of weight loss.
		2	Open RYGB, std	N entering 623 N completing 65	Average weight loss at 60 months in lbs Arm 1 = -66.0 (44.7) Arm 2 = -100.0 (44.7)
Choban 2002	Design RCT Jadad 2 Population Adults, Females	1	Open RYGB, std	N entering 35 N completing 33	Included in meta-analysis of weight loss.
		2	Open RYGB, std	N entering 34 N completing 34	Average weight loss at 12 months in kg Arm 1 = -44.0 (15.5) Arm 2 = -39.0 (15.5) Arm 3 = -60.0 (15.5)
		3	Open RYGB, std	N entering 33 N completing 33	

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
		4	Open RYGB, long	N entering 31 N completing 28	Arm 4 = -64.0 (15.5) Average weight loss at 36 months in kg Arm 1 = -41.0 (20.3) Arm 2 = -31.0 (20.3) Arm 3 = -59.0 (20.3)
Choban 1999	Design Case Series Jadad NA Population Adults, Females	1	Open RYGB, std	N entering 107 N completing 54	Included in meta-analysis of weight loss. Average weight loss at 23 months in kg Arm 1 = -42.0 (20.3)

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
Choi 1999	Design Case Series Jadad NA Population Adults, Females	1	Open VBG	N entering ND N completing 17	Included in meta-analysis of weight loss.
		2	Open RYGB, std	N entering ND N completing 12	Average weight loss at 12 months in kg Arm 1 = -39.3 (15.5) Arm 2 = -46.7 (15.5) Average weight loss at 19 months in kg Arm 1 = -38.4 (15.5) Arm 2 = -54.6 (15.5)
Cook 1999	Design Case Series Jadad NA Population Adults, Females	1	Open RYGB, std	N entering 100 N completing 100	Excluded from meta-analysis because weight loss not reported by surgery type.
Courcoulas 2003	Design Case Series Jadad NA Population Adults, Females	1	LAP RYGB, std	N entering 80 N completing 12	Included in meta-analysis of weight loss.
		2	Open RYGB, std	N entering 80 N completing 12	Average weight loss at 12 months in bmi Arm 1 = -15.2 (5.9) Arm 2 = -15.1 (5.9)
Crampton 1997	Design Case Series Jadad NA Population Adults, Females	1	Open RYGB, std	N entering 64 N completing 6	Included in meta-analysis of weight loss. Average weight loss at 24 months in kg Arm 1 = -48.0 (20.5)
Dargent 1999	Design Case Series Jadad NA Population Adults, Adolescents, Females	1	LAP adjustable band	N entering 500 N completing ND	Excluded from meta-analysis because study did not report mean weight loss.
Das 2003	Design Case Series Jadad NA Population Adults, Females	1	Open RYGB, std	N entering 20 N completing 20	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -44.7 (14.6)
Davila-Cervantes 2000	Design Case Series Jadad NA Population Adults, Females	1	Open VBG	N entering 20 N completing 19	Included in meta-analysis of weight loss.
		2	LAP VBG	N entering 20 N completing 20	Average weight loss at 12 months in kg Arm 1 = -31.0 (15.5) Arm 2 = -28.0 (15.5)

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
de Csepel 2001	Design Case Series Jadad NA Population Adults, Females	1	LAP RYGB, std	N entering 7 N completing 7	Excluded from meta-analysis because study sample size < 10.
De Luca 2000	Design Case Series Jadad NA Population Adults, Females	1	LAP adjustable band	N entering 22 N completing 22	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -35.1 (15.5) Arm 2 = -25.1 (15.5) Average weight loss at 36 months in kg Arm 1 = -54.9 (20.3) Arm 2 = -43.0 (20.3)
		2	Open adjustable band	N entering 47 N completing 47	
de Wit 1999	Design RCT Jadad 2 Population Adults	1	LAP adjustable band	N entering 25 N completing 25	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -35.0 (15.5) Arm 2 = -34.4 (15.5)
		2	Open adjustable band	N entering 25 N completing 24	
de Zwaan 2002	Design Case Series Jadad NA Population Adults, Adolescents, Females	1	Control	N entering 164 N completing 110	Included in meta-analysis of weight loss. Average weight loss at 168 months in bmi Arm 2 = -11.0 (6.7) Arm 1 excluded because mean weight loss not reported.
		2	Open RYGB, std	N entering 100 N completing 78	
DeMaria 2000	Design Case Series Jadad NA Population Adults	1	LAP adjustable band	N entering 300 N completing 115	Excluded from meta-analysis because study did not report mean weight loss.
DeMaria 2001	Design Case Series Jadad NA Population Adults, Females	1	LAP adjustable band	N entering 37 N completing 4	Included in meta-analysis of weight loss. Average weight loss at 12 months in lbs Arm 1 = -44.0 (34.1) Average weight loss at 36 months in lbs Arm 1 = -61.0 (44.7)

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
Doherty 2002	Design Case Series Jadad NA Population Adults	1	Open adjustable band	N entering 40 N completing 13	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg
		2	LAP adjustable band	N entering 22 N completing 13	Arm 1 = -34.0 (15.5) Arm 2 = -19.0 (15.5) Average weight loss at 72 months in kg Arm 1 = -21.0 (20.3) Arm 2 = -10.0 (20.3)
Doherty 1998	Design Case Series Jadad NA Population Adults	1	Open adjustable band	N entering 40 N completing 24	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -35.0 (15.5) Average weight loss at 48 months in kg Arm 1 = -29.0 (20.3)
Dolan 2003	Design Case Series Jadad NA Population Adults, Adolescents, Children	1	LAP adjustable band	N entering 17 N completing 17	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -30.9 (11.6) Average weight loss at 24 months in kg Arm 1 = -35.6 (11.8)
Doldi 2000	Design Case Series Jadad NA Population Adults, Females	1	Open adjustable band	N entering 64 N completing 64	Excluded from meta-analysis because study did not report mean weight loss.
		2	LAP adjustable band	N entering 109 N completing 109	
Dymek 2002	Design Case Series Jadad NA Population Adults, Females	1	Control	N entering 80 N completing 80	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi
		2	Open RYGB, std	N entering 236 N completing ND	Arm 2 = -18.3 (5.9) Arm 1 excluded because weight loss was not reported.
Feng 2002	Design Case Series Jadad NA Population Adults	1	BPD/Duodenal switch	N entering 40 N completing 40	Excluded from meta-analysis because study did not report mean weight loss.

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
Field 1992	Design Case Series Jadad NA Population Adults, Adolescents, Females	1	Open VBG	N entering 36 N completing 11	Included in meta-analysis of weight loss. Average weight loss at 120 months in bmi Arm 1 = -7.5 (7.6)
Fielding 1999	Design Case Series Jadad NA Population Adults	1	LAP adjustable band	N entering 335 N completing 308	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -37.0 (10.0) Average weight loss at 18 months in kg Arm 1 = -41.0 (18.0)
Fobi 1993	Design Case Series Jadad NA Population Adults, Females	1	Open VBG	N entering 100 N completing 43	Excluded from meta-analysis because study did not report mean weight loss.
		2	Open RYGB, std	N entering 100 N completing 46	
Fobi 2001	Design CCT Jadad 0 Population Adults, Females	1	Open RYGB, std	N entering 25 N completing 22	Included in meta-analysis of weight loss.
		2	Open RYGB, std	N entering 25 N completing 20	Average weight loss at 12 months in lbs Arm 1 = -20.6 (34.1) Arm 2 = -18.7 (34.1) Average weight loss at 72 months in lbs Arm 1 = -21.6 (44.7) Arm 2 = -21.7 (44.7)
Forestieri 1998	Design Case Series Jadad NA Population Adults, Adolescents, Females	1	Open adjustable band	N entering 52 N completing 52	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 3 = -35.6 (17.0) Average weight loss at 24 months in kg Arm 3 = -61.6 (13.7) Arms 1, 2 combined into single arm 3.
		2	LAP adjustable band	N entering 10 N completing 10	
Forsell 1999	Design Case Series Jadad NA Population Adults, Females	1	Open adjustable band	N entering 326 N completing 311	Included in meta-analysis of weight loss. Average weight loss at 28 months in kg Arm 1 = -37.0 (20.3)

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
Forsell 1997	Design Case Series Jadad NA Population Adults	1	Open adjustable band	N entering 50 N completing 46	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -42.0 (9.0) Average weight loss at 48 months in kg Arm 1 = -54.5 (8.0)
Freeman 1997	Design Case Series Jadad NA Population Adults, Adolescents, Females	1	Open RYGB, std	N entering 40 N completing 37	Included in meta-analysis of weight loss
		2	Open RYGB, long	N entering 81 N completing 69	Average weight loss at 12 months in bmi Arm 1 = -13.0 (5.9) Arm 2 = -14.0 (5.9) Average weight loss at 36 months in bmi Arm 1 = -18.0 (7.7) Arm 2 = -16.0 (7.7)
Goulding 1995	Design Case Series Jadad NA Population Adults, Adolescents, Females	1	Open VBG	N entering 200 N completing 114	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi Arm 1 = -13.2 (5.9)
Greenstein 1995	Design Case Series Jadad NA Population Adults, Adolescents, Females	1	Open VBG	N entering 14 N completing 14	Included in meta-analysis of weight loss. Average weight loss at 12 months in lbs Arm 1 = -15.8 (12.4) Average weight loss at 36 months in lbs Arm 1 = -54.9 (42.1)
Griffen 1977	Design CCT Jadad 0 Population Adults	1	Open RYGB, std	N entering 32 N completing 18	Included in meta-analysis of weight loss.
		2	Jejunal-ileal bypass	N entering 27 N completing 22	Average weight loss at 12 months in kg Arm 1 = -51.0 (21.8) Arm 2 = -57.9 (25.3)
Gustavsson 2002	Design Case Series Jadad NA Population Adults	1	LAP adjustable band	N entering 90 N completing 90	Included in meta-analysis of weight loss. Average weight loss at 60 months in bmi Arm 1 = -9.3 (7.6)

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
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Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
Hall 1990	Design RCT Jadad 3 Population Adults, Females	1	Open VBG	N entering 106 N completing 80	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -36.0 (16.3) Arm 2 = -29.0 (29.0) Arm 3 = -42.0 (18.8)
		2	Open gastroplasty	N entering 105 N completing 67	
		3	Open RYGB, std	N entering 99 N completing 85	Average weight loss at 36 months in kg Arm 1 = -33.0 (20.3) Arm 2 = -17.0 (24.0) Arm 3 = -39.0 (21.3)
Hedenbro 2002	Design Case Series Jadad NA Population Adults, Females	1	Open RYGB, std	N entering 146 N completing 15	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -47.0 (15.5) Average weight loss at 36 months in kg Arm 1 = -53.0 (20.3)
Hess 1998	Design Case Series Jadad NA Population Adults, Females	1	BPD/Duodenal switch	N entering 440 N completing ND	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -55.0 (15.5)
Hesse 2001	Design Case Series Jadad NA Population Adults, Females	1	Open adjustable band	N entering 29 N completing 29	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -24.8 (15.5) Arm 2 excluded because it only reported 6 month follow-up.
		2	Open adjustable band	N entering 41 N completing 41	
Higa 2000	Design Case Series Jadad NA Population Adults, Females	1	LAP RYGB, std	N entering 1040 N completing ND	Excluded from meta-analysis because study did not report mean weight loss.
Higa 2000	Design Case Series Jadad NA Population Adults, Adolescents, Females	1	LAP RYGB, std	N entering 400 N completing ND	Excluded from meta-analysis because study reported data on another study already included in analysis (949).

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
Horchner 1999	Design Case Series Jadad NA Population Adults, Females .	1	LAP adjustable band	N entering 42 N completing 39	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -22.4 (15.5)
Howard 1995	Design RCT Jadad 1 Population Adults, Females	1	Open RYGB, std	N entering ND N completing 6	Excluded from meta-analysis because study did not report mean weight loss.
		2	Open VBG	N entering ND N completing 6	
Kalfarentzos 1999	Design Case Series Jadad NA Population Adults, Adolescents, Females	1	Open VBG	N entering 35 N completing 9	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi Arm 1 = -13.3 (5.9) Arm 2 = -16.5 (5.9) Average weight loss at 36 months in bmi Arm 1 = -10.2 (7.6) Arm 2 = -14.0 (7.6) Arm 3 excluded from 36 month analysis because maximum follow-up time reported was 24 months.
		2	Open RYGB, std	N entering 38 N completing 7	
		3	Open RYGB, long	N entering 17 N completing 2	
Karason 1997	Design Case Series Jadad NA Population Adults	1	Control	N entering 43 N completing 43	Excluded from meta-analysis based on expert opinion.
		2	Control	N entering 35 N completing 31	
		3	Gastric surgery NOS	N entering 41 N completing 41	
Karason2000	Design Case Series Jadad NA Population Adults	1	Control	N entering 1310 N completing 1099	Excluded from meta-analysis because study reported data on another study already included in analysis (733).
		2	Gastric surgery NOS	N entering 1310 N completing 1210	
Karason 1999	Design Case Series Jadad NA Population Adults	1	Control	N entering 28 N completing 24	Excluded from meta-analysis because study reported data on another study already included in analysis (733).
		2	Gastric surgery NOS	N entering 28 N completing 28	

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NA = Not available or not applicable
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Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population		Arm	Type of surgery	Sample size		Meta-analysis data
Karason 1999	Design	Case Series	1	Control	N entering N completing	19 17	Excluded from meta-analysis because study reported data on another study already included in analysis (733).
	Jadad	NA	2	Gastric surgery NOS	N entering N completing	20 19	
	Population	Adults					
Karlsson 1998	Design	Case Series	1	Control	N entering N completing	487 487	Excluded from meta-analysis because study reported data on another study already included in analysis (733).
	Jadad	NA	2	Open VBG	N entering N completing	315 315	
	Population	Adults	3	Open adjustable band	N entering N completing	136 136	
			4	Open RYGB, std	N entering N completing	36 36	
Kim 1992	Design	Case Series	1	Open RYGB, std	N entering N completing	2 2	Excluded from meta-analysis because study sample size < 10.
	Jadad	NA					
	Population	Adults, Females					
Kothari 2002	Design	Case Series	1	LAP adjustable band	N entering N completing	36 36	Excluded from meta-analysis because study did not report mean weight loss.
	Jadad	NA					
	Population	Adults					
Laws 1981	Design	RCT	1	Open RYGB, std	N entering N completing	27 ND	Excluded from meta-analysis because study did not report mean weight loss.
	Jadad	2	2	Open gastroplasty	N entering N completing	26 ND	
	Population	Adults					
Lechner 1983	Design	CCT	1	Open gastroplasty	N entering N completing	147 16	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -28.6 (17.1) Arm 2 = -43.6 (12.1) Average weight loss at 24 months in kg Arm 1 = -28.8 (18.0) Arm 2 = -45.5 (13.3)
	Jadad	0	2	Open RYGB, std	N entering N completing	95 8	
	Population	Adults, Females					

Meta-analysis data reported as an average with its standard deviation in parentheses.
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Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
Lechner 1981	Design RCT Jadad 1 Population Adults, Females	1 2	Open VBG Open RYGB, std	N entering 50 N completing 50 N entering 50 N completing 50	Excluded from meta-analysis because study reported data on another study already included in analysis (1140).
Letiexhe 1995	Design Case Series Jadad NA Population Adults, Females	1	Open VBG	N entering 8 N completing 8	Excluded from meta-analysis because study sample size < 10.
Lujan 2002	Design Case Series Jadad NA Population Adults, Females	1	LAP RYGB, std	N entering 50 N completing 50	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi Arm 1 = -14.0 (5.9) Average weight loss at 18 months in bmi Arm 1 = -17.0 (7.6)
Lundell 1987	Design RCT Jadad 2 Population Adults, Females	1 2	Open nonadjustable band Open gastroplasty	N entering 12 N completing 12 N entering 15 N completing 15	Excluded from meta-analysis because weight loss not reported by surgery type.
Lundell 1997	Design RCT Jadad 1 Population Adults	1 2	Open VBG Open adjustable band	N entering 24 N completing ND N entering 26 N completing ND	Excluded from meta-analysis because weight loss not reported by surgery type.
MacLean 2000	Design Case Series Jadad NA Population Adults	1	Open RYGB, std	N entering 277 N completing 243	Included in meta-analysis of weight loss. Average weight loss at 60 months in bmi Arm 1 = -17.3 (7.6)
MacLean 1990	Design Case Series Jadad NA Population Adults	1	Open VBG	N entering 201 N completing 57	Excluded from meta-analysis because study did not report mean weight loss.
MacLean 1996	Design Case Series	1	Open VBG	N entering 21 N completing 21	Excluded from meta-analysis because weight loss not reported by surgery type.

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Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
	Jadad NA Population Adults	2	Open RYGB, std	N entering 57 N completing 57	
MacLean 1993	Design RCT	1	Open VBG	N entering 54 N completing 54	Excluded from meta-analysis because weight loss not reported by surgery type.
	Jadad 1 Population Adults	2	Open RYGB, std	N entering 52 N completing 52	
Marceau 1993	Design Case Series	1	BPD/Duodenal switch	N entering 149 N completing 27	Excluded from meta-analysis because study did not report mean weight loss.
	Jadad NA Population Adults, Females	2	BPD/Duodenal switch	N entering 156 N completing 10	
Mason 1998	Design Case Series	1	Open VBG	N entering 70 N completing 40	Excluded from meta-analysis because study did not report mean weight loss.
	Jadad NA Population Adults	2	Open VBG	N entering 43 N completing 23	
Mason 1982	Design Case Series Jadad NA Population Adults	1	Open VBG	N entering 42 N completing ND	Excluded from meta-analysis because follow-up time was less than 12 months.
Matthews 2000	Design Case Series Jadad NA Population Adults, Females	1	LAP RYGB, std	N entering 48 N completing 27	Included in meta-analysis of weight loss. Average weight loss at 12 months in lbs Arm 1 = -115.0 (34.1)
Melissas 1998	Design Case Series Jadad NA Population Adults, Females	1	Open VBG	N entering 62 N completing 12	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -44.0 (13.0) Average weight loss at 48 months in kg Arm 1 = -47.0 (18.0)
Miller 1999	Design Case Series Jadad NA	1	LAP adjustable band	N entering ND N completing 102	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
	Population Adults, Adolescents, Females	2	LAP adjustable band	N entering ND N completing 54	Arm 1 = -12.0 (15.5) Arm 2 = -17.0 (15.5) Average weight loss at 36 months in kg Arm 1 = -44.0 (20.3) Arm 2 = -48.0 (20.3)
Mitchell 2001	Design Case Series Jadad NA Population Adults, Females	1	Open RYGB, std	N entering 100 N completing 78	Included in meta-analysis of weight loss. Average weight loss at 180 months in kg Arm 1 = -30.1 (20.3)
Mittermair 2003	Design Case Series Jadad NA Population Adults, Females	1	LAP adjustable band	N entering 454 N completing ND	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -35.5 (15.5) Average weight loss at 36 months in kg Arm 1 = -54.0 (20.3)
Morino 2003	Design RCT Jadad 1 Population Females	1	LAP adjustable band	N entering 49 N completing 44	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi Arm 1 = -9.2 (5.9) Arm 2 = -9.0 (5.9)
		2	LAP VBG	N entering 51 N completing 49	Average weight loss at 36 months in bmi Arm 1 = -14.1 (7.7) Arm 2 = -13.5 (7.7)
Narbro 1999	Design Case Series Jadad NA Population Adults	1	Control	N entering 369 N completing 339	Excluded from meta-analysis because study reported data on another study already included in analysis (733).
		2	Gastric surgery NOS	N entering 369 N completing 339	
Naslund 1987	Design RCT Jadad 1 Population Adults, Females	1	Open loop gastric bypass	N entering 29 N completing 29	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -42.3 (10.9) Arm 2 = -29.9 (10.0) Average weight loss at 36 months in kg Arm 1 = -38.4 (13.2) Arm 2 = -24.7 (13.1)
		2	Open gastroplasty	N entering 28 N completing 28	

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
Naslund 1986	Design RCT Jadad 1 Population Adults, Females	1 2	Open loop gastric bypass Open gastroplasty	N entering 29 N completing 29 N entering 28 N completing 28	Excluded from meta-analysis because study reported data on another study already included in analysis (1078).

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
Naslund 1987	Design RCT Jadad 1 Population Adults, Females	1 2	Open gastroplasty Open loop gastric bypass	N entering 28 N completing 28 N entering 29 N completing 29	Excluded from meta-analysis because study reported data on another study already included in analysis (1078).
Naslund1988	Design RCT Jadad 1 Population Adults, Females	1 2	Open loop gastric bypass Open gastroplasty	N entering 26 N completing 26 N entering 25 N completing 25	Excluded from meta-analysis because study reported data on another study already included in analysis (1078).
Naslun 1988	Design RCT Jadad 2 Population Adults, Females	1 2	Open loop gastric bypass Open gastroplasty	N entering 26 N completing 26 N entering 25 N completing 23	Excluded from meta-analysis because study reported data on another study already included in analysis (1078).
Naslund 1986	Design RCT Jadad 1 Population Adults, Females	1 2	Open loop gastric bypass Open VBG	N entering 29 N completing 29 N entering 28 N completing 28	Excluded from meta-analysis because study reported data on another study already included in analysis (1078).
Nguyen 2001	Design CCT Jadad 1 Population Adults, Females	1 2	LAP RYGB, std Open RYGB, std	N entering 79 N completing ND N entering 76 N completing ND	Excluded from meta-analysis because study did not report mean weight loss.
Nguyen 2000	Design Case Series Jadad NA Population Adults, Females	1 2	LAP RYGB, std Open RYGB, std	N entering 35 N completing 35 N entering 69 N completing 35	Excluded from meta-analysis because weight loss not reported by surgery type.
Nilsell 2001	Design RCT Jadad 2 Population Adults, Females	1 2	Open VBG Open adjustable band	N entering 30 N completing 16 N entering 16 N completing 3	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -41.0 (15.5) Arm 2 = -24.0 (15.5) Average weight loss at 60 months in kg Arm 1 = -35.0 (19.2) Arm 2 = -43.0 (12.0)

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
Nowara 2001	Design Case Series Jadad NA Population Adults, Females	1	LAP adjustable band	N entering 34 N completing ND	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi Arm 3 = -11.7 (5.9) Average weight loss at 24 months in bmi Arm 3 = -14.6 (7.6) Arms 1, 2 combined into single arm 3.
		2	LAP adjustable band	N entering 74 N completing ND	
O'Brien 1999	Design Case Series Jadad NA Population Adults, Adolescents, Females	1	LAP adjustable band	N entering 302 N completing 289	Excluded from meta-analysis because study did not report mean weight loss.
O'Brien 2002	Design Case Series Jadad NA Population Adults, Adolescents, Females	1	LAP adjustable band	N entering 659 N completing ND	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi Arm 3 = -10.0 (5.9) Average weight loss at 72 months in bmi Arm 3 = -13.0 (7.6) Arms 1 & 2 combined into single arm 3.
		2	LAP adjustable band	N entering 50 N completing ND	
Oh 1997	Design Case Series Jadad NA Population Adults, Adolescents, Females	1	Open RYGB, std	N entering 194 N completing 14	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -47.5 (15.5) Average weight loss at 48 months in kg Arm 1 = -48.5 (20.3)
Olbers 2003	Design Case Series Jadad NA Population Adults, Females	1	LAP RYGB, std	N entering 140 N completing ND	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi Arm 3 = -15.0 (5.9) Average weight loss at 60 months in bmi Arm 3 = -14.5 (7.6) Arms 1 & 2 combined into single arm 3.
		2	LAP RYGB, std	N entering 10 N completing ND	

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
Papasavas 2002	Design Case Series Jadad NA Population Adults, Females	1	LAP RYGB, std	N entering 113 N completing ND	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi Arm 3 = -16.3 (5.9) Average weight loss at 18 months in bmi Arm 3 = -17.3 (7.6) Arms 1 & 2 combined into single arm 3.
		2	LAP RYGB, std	N entering 3 N completing ND	
Peace 1989	Design Case Series Jadad NA Population Adults, Females	1	Open gastroplasty	N entering 48 N completing 39	Included in meta-analysis of weight loss. Average weight loss at 17 months in kg Arm 1 = -42.3 (15.8)
Perugin 2003	Design Case Series Jadad NA Population Adults, Females	1	LAP RYGB, std	N entering 188 N completing 93	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -48.0 (15.5)
Pontiroli 2002	Design Case Series Jadad NA Population Adults, Females	1	Control	N entering 120 N completing ND	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi Arm 2 = -8.0 (5.9) Average weight loss at 36 months in bmi Arm 2 = -7.9 (7.6) Arm 1 excluded because no sample size was reported.
		2	LAP adjustable band	N entering 143 N completing 56	
Pories 1982	Design RCT Jadad 1 Population Adults, Females	1	Open RYGB, std	N entering 42 N completing 42	Included in meta-analysis of weight loss. Average weight loss at 12 months in lbs Arm 1 = -108.5 (34.1) Arm 2 = -68.3 (34.1) Average weight loss at 18 months in lbs Arm 1 = -113.3 (44.7) Arm 2 = -66.2 (44.7)
		2	Open gastroplasty	N entering 45 N completing 45	

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
Pories 1987	Design: Case Series Jadad: NA Population: Adults, Females	1	Open RYGB, std	N entering: 397 N completing: 26	Included in meta-analysis of weight loss. Average weight loss at 12 months in lbs Arm 1 = -106.0 (34.1) Average weight loss at 72 months in lbs Arm 1 = -85.0 (44.7)
Quaade 1979	Design: RCT Jadad: 1 Population: Adults, Females	1	Control	N entering: 66 N completing: ND	Excluded from meta-analysis because study reported data on another study already included in analysis (1140)
		2	Jejunal-ileal bypass	N entering: 130 N completing: ND	
Rand 1994	Design: Case Series Jadad: NA Population: Adults, Adolescents, Children, Females	1	Open RYGB, std	N entering: 30 N completing: 30	Excluded from meta-analysis because study did not report mean weight loss.
		2	Open VBG	N entering: 4 N completing: 4	
Randolph 1974	Design: Case Series Jadad: NA Population: Adolescents, Females	1	Jejunal-ileal bypass	N entering: 4 N completing: 4	Excluded from meta-analysis because study sample size < 10.
Reddy 2002	Design: Case Series Jadad: NA Population: Adults, Females	1	Open RYGB, std	N entering: 103 N completing: 98	Excluded from meta-analysis because follow-up time was less than 12 months.
Reinhold 1994	Design: Case Series Jadad: NA Population: Adults, Females	1	Open loop gastric bypass	N entering: 66 N completing: ND	Excluded from meta-analysis because weight loss not reported by surgery type.
		2	Open RYGB, std	N entering: ND N completing: 3	
Rigg 1975	Design: Case Series Jadad: NA Population: Adolescents .	1	Jejunal-ileal bypass	N entering: 8 N completing: 8	Excluded from meta-analysis because study sample size < 10.

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
Schauer 2000	Design Case Series Jadad NA Population Adults, Adolescents, Females	1	LAP RYGB, std	N entering 275 N completing 5	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi Arm 1 = -16.8 (5.9) Average weight loss at 24 months in bmi Arm 1 = -20.9 (7.6)
Scopinaro 1996	Design Case Series Jadad NA Population Adults, Adolescents, Children	1	BPD/Duodenal switch	N entering 1217 N completing ND	Excluded from meta-analysis because study did not report mean weight loss.
Sjostrom 2000	Design Case Series Jadad NA Population Adults	1	Control	N entering 346 N completing 232	Excluded from meta-analysis because study reported data on another study already included in analysis (733).
		2	Open VBG	N entering 227 N completing 164	
		3	Open adjustable band	N entering 86 N completing 63	
		4	Open RYGB, std	N entering 33 N completing 24	
Sjostrom 1999	Design Case Series Jadad NA Population Adults	1	Control	N entering 845 N completing 712	Excluded from meta-analysis because study reported data on another study already included in analysis (733)
		2	Open adjustable band	N entering ND N completing 191	
		3	Open VBG	N entering ND N completing 534	
		4	Open RYGB, std	N entering ND N completing 42	

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
Sjostrom 2001	Design Case Series Jadad NA Population Adults	1	Control	N entering 1031 N completing ND	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -1.6 (6.6) Arm 2 = -30.7 (11.8) Arm 3 = -25.8 (12.9) Arm 4 = -44.0 (15.0) Average weight loss at 66 months in kg Arm 1 = 1.5 (10.2) Arm 2 = -20.8 (13.1) Arm 3 = -20.7 (16.6)
		2	Open VBG	N entering 834 N completing ND	
		3	Open adjustable band	N entering 255 N completing 988	
		4	Open RYGB, std	N entering 68 N completing ND	
Smith 2004	Design Case Series Jadad NA Population	1	LAP RYGB, std	N entering 328 N completing 328	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi Arm 1 = -17.2 (5.9) Arm 2 = -19.2 (5.9)
		2	Open RYGB, std	N entering 451 N completing 451	
Soper 1975	Design Case Series Jadad NA Population Adults, Adolescents	1	Open RYGB, std	N entering 834 N completing ND	Excluded from meta-analysis because study did not report mean weight loss.
		2	Open gastroplasty	N entering 3 N completing ND	
Stanford 2003	Design Case Series Jadad NA Population Adults, Adolescents, Females	1	LAP RYGB, std	N entering 4 N completing 4	Excluded from meta-analysis because study sample size < 10.
Stoner 1997	Design Case Series Jadad NA Population Adults	1	Open VBG	N entering 202 N completing 165	Included in meta-analysis of weight loss. Average weight loss at 12 months in lbs Arm 1 = -78.0 (34.1) Average weight loss at 42 months in lbs Arm 1 = -85.0 (44.7)

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
Strauss 2001	Design Case Series Jadad NA Population Adolescents	1	Open RYGB, std	N entering 10 N completing 9	Excluded from meta-analysis because study sample size < 10.
Sugerman 2003	Design Case Series Jadad NA Population Adolescents, Children	1	Open gastroplasty	N entering 1 N completing ND	Excluded from meta-analysis because study did not report mean weight loss.
		2	Open VBG	N entering 2 N completing ND	
		3	Open RYGB, std	N entering 15 N completing ND	
		4	LAP gastroplasty	N entering 2 N completing ND	
		5	Open RYGB, long	N entering 13 N completing ND	
Sugerman 1989	Design Case Series Jadad NA Population Adults	1	Open VBG	N entering 40 N completing 28	Included in meta-analysis of weight loss. Average weight loss at 12 months in lbs ^Arm 1 = -61.0 (34.1) ^Arm 2 = -96.0 (34.1) Average weight loss at 36 months in lbs Arm 1 = -54.0 (44.7) Arm 2 = -88.0 (44.7)
		2	Open RYGB, std	N entering 182 N completing 141	
Sugerman 1996	Design Case Series Jadad NA Population Adults	1	Open RYGB, std	N entering 54 N completing ND	Included in meta-analysis of weight loss. Average weight loss at 12 months in lbs Arm 3 = -99.0 (34.1) Average weight loss at 72 months in lbs Arm 3 = -92.0 (44.7) Arms 1 & 2 combined into single arm 3.
		2	Open RYGB, std	N entering 4 N completing ND	
Sugerman 1987	Design RCT Jadad 2 Population Adults, Females	1	Open RYGB, std	N entering 20 N completing 18	Included in meta-analysis of weight loss. Average weight loss at 12 months in lbs Arm 1 = -96.0 (25.0) Arm 2 = -71.0 (24.0) Average weight loss at 36 months in lbs Arm 1 = -91.0 (28.0) Arm 2 = -60.0 (32.0)
		2	Open VBG	N entering 20 N completing 16	

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
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Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
Suter 2000	Design Case Series Jadad NA Population Adults, Females	1	LAP adjustable band	N entering ND N completing 101	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi Arm 3 = -13.0 (5.9) Average weight loss at 24 months in bmi Arm 3 = -13.0 (7.6) Arms 1, 2 combined into single arm 3.
		2	LAP adjustable band	N entering ND N completing 47	
Suter 2003	Design Case Series Jadad NA Population Adults, Females	1	LAP RYGB, std	N entering 80 N completing ND	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi Arm 3 = -13.2 (5.9) Average weight loss at 24 months in bmi Arm 3 = -12.2 (7.6) Arms 1 & 2 combined into single arm 3.
		2	LAP RYGB, std	N entering 27 N completing ND	
Suter 1999	Design Case Series Jadad NA Population Adults, Females	1	Open VBG	N entering 73 N completing 73	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi Arm 4 = -12.5 (5.9) Arm 5 = -14.7 (5.9) Average weight loss at 24 months in bmi Arm 4 = -14.5 (7.6) Arm 5 = -14.7 (7.6) Arms 1, 2, 3 combined into single arm 5.
		2	Open VBG	N entering 40 N completing 76	
		3	Open VBG	N entering 84 N completing 76	
		4	LAP nonadjustable band	N entering 76 N completing 76	
Szold 2002	Design Case Series Jadad NA Population Adults, Adolescents, Females	1	LAP adjustable band	N entering 715 N completing 121	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi Arm 1 = -10.1 (5.9) Average weight loss at 36 months in bmi Arm 1 = -11.1 (7.6)
Tacchino 2003	Design Case Series Jadad NA	1	Control	N entering 53 N completing 53	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
	Population Adults, Females	2	BPD/Duodenal switch	N entering 101 N completing 101	Arm 2 = -43.3 (15.5) Average weight loss at 24 months in kg Arm 2 = -46.0 (20.3) Arm 1 excluded because mean weight loss not reported.
The Danish Obesity Project 1979	Design RCT Jadad 1 Population Adults	1	Control	N entering 69 N completing 52	Included in meta-analysis of weight loss. Average weight loss at 24 months in kg Arm 1 = -5.9 (13.1) Arm 2 = -42.9 (22.0)
		2	Jejunal-ileal bypass	N entering 133 N completing 130	
Toppino 1999	Design Case Series Jadad NA Population Adults	1	LAP nonadjustable band	N entering 10 N completing 1	Excluded from meta-analysis because study did not report mean weight loss.
		2	LAP adjustable band	N entering 361 N completing 56	
		3	LAP VBG	N entering 120 N completing 20	
Toppino 1999	Design Case Series Jadad NA Population Adults, Females	1	Open VBG	N entering 218 N completing ND	Excluded from meta-analysis because study did not report mean weight loss.
		2	LAP VBG	N entering 107 N completing ND	
Torgerson 2001	Design Case Series Jadad NA Population Adults	1	Control	N entering 712 N completing 232	Excluded from meta-analysis because study reported data on another study already included in analysis (733).
		2	Open adjustable band	N entering ND N completing ND	
		3	Open RYGB, std	N entering ND N completing ND	
		4	Open VBG	N entering ND N completing ND	
van de Weijgert 1999	Design Case Series Jadad NA Population Adults, Females	1	Open RYGB, std	N entering 100 N completing 75	Excluded from meta-analysis because study did not report mean weight loss.
		2	Open VBG	N entering 100 N completing 78	
van Gemert 1998	Design Case Series Jadad NA	1	Control	N entering 20 N completing 20	Included in meta-analysis of weight loss. Average weight loss at 86 months in kg Arm 2 = -41.4 (20.3)
		2	Open RYGB, std	N entering ND N completing 18	

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
	Population Adults, Females	3	Open VBG	N entering ND N completing 14	Arm 3 = -38.0 (20.3) Arm 4 = -48.3 (20.3)
		4	Open VBG	N entering ND N completing 30	

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
Van Rij 1984	Design RCT Jadad 1 Population Adults .	1 2	Open RYGB, std Open gastroplasty	N entering 42 N completing 42 N entering 45 N completing 45	Excluded from meta-analysis because study did not report mean weight loss.
VanWoert 1992	Design RCT Jadad 1 Population Adults	1 2	Open RYGB, std Open VBG	N entering 15 N completing ND N entering 17 N completing ND	Excluded from meta-analysis because study did not report mean weight loss.
Viddal 1983	Design RCT Jadad 1 Population Adults, Females	1 2	Jejunal-ileal bypass Jejunal-ileal bypass	N entering 10 N completing ND N entering 11 N completing ND	Included in meta-analysis of weight loss. Average weight loss at 18 months in kg Arm 1 = -37.0 (20.3) Arm 2 = -40.0 (20.3)
Weiner 2001	Design RCT Jadad 1 Population Adults, Females	1 2	LAP adjustable band LAP adjustable band	N entering 51 N completing ND N entering 50 N completing ND	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -50.9 (15.5) Arm 2 = -55.8 (15.5) Average weight loss at 18 months in kg Arm 1 = -50.9 (20.3) Arm 2 = -56.8 (20.3)
Weiner 2003	Design Case Series Jadad NA Population Adults, Females	1	LAP adjustable band	N entering 984 N completing 955	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi Arm 1 = -12.8 (5.9) Average weight loss at 36 months in bmi Arm 1 = -14.8 (7.6)
Westling 2001	Design RCT Jadad 2 Population Adults, Females	1 2	LAP RYGB, std Open RYGB, std	N entering 30 N completing 30 N entering 21 N completing 21	Included in meta-analysis of weight loss. Average weight loss at 12 months in bmi Arm 1 = -14.0 (3.0) Arm 2 = -13.0 (3.0)
White 1974	Design Case Series	1	Jejunal-ileal bypass	N entering 1 N completing 1	Excluded from meta-analysis because study sample size < 10.

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

First author Year	Study design and Quality Population	Arm	Type of surgery	Sample size	Meta-analysis data
	Jadad NA Population Adults, Adolescents, Children, Males	2	Jejunal-ileal bypass	N entering 2 N completing 3	
Wiesner 2000	Design Case Series Jadad NA Population Adults, Females	1	LAP adjustable band	N entering 98 N completing ND	Excluded from meta-analysis because study did not report mean weight loss.
Wittgrove 2000	Design Case Series Jadad NA Population Adults	1	LAP RYGB, std	N entering 500 N completing 4	Excluded from meta-analysis because study did not report mean weight loss.
Yale 1989	Design Case Series Jadad NA Population Adults, Adolescents, Females	1	Open RYGB, std	N entering 251 N completing 225	Included in meta-analysis of weight loss. Average weight loss at 12 months in kg Arm 1 = -46.0 (13.0) Arm 2 = -30.0 (18.0) Arm 3 = -35.0 (11.0)
		2	Open gastroplasty	N entering 186 N completing 106	
		3	Open VBG	N entering 100 N completing 89	Average weight loss at 36 months in kg Arm 3 = -33.0 (15.0) Average weight loss at 60 months in kg Arm 1 = -41.0 (19.0)
Yale 1991	Design Case Series Jadad NA Population Adults, Females	1	Open VBG	N entering 100 N completing 98	Included in meta-analysis of weight loss. Average weight loss at 12 months in lbs Arm 1 = -75.0 (30.0) Arm 2 = -77.0 (24.0)
		2	Open VBG	N entering 100 N completing 97	
Yashko1997	Design Case Series Jadad NA Population Adults	1	Open VBG	N entering 24 N completing ND	Excluded from meta-analysis because study did not report follow-up time.

Meta-analysis data reported as an average with its standard deviation in parentheses.
NA = Not available or not applicable
NR, ND = Not reported or not described

Appendix C.

Evidence Table- Surgery

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Appendix D

Table 1. Technical Expert Panel members

Name	Institution
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Caroline Apovian, M.D.	Boston Medical Center
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Patricia Barry, M.D., MPH	Merck Institute of Aging and Health
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Nick Fitterman, M.D., FACP	North Shore Medical Group
Frank Greenway, M.D.	Pennington Biomedical Research Center
David Heber, M.D.	University of California Los Angeles, School of Medicine & Public Health
Marc Jacobson, M.D.	Schneider Children's Hospital
Sue Y.S. Kimm, M.D., MPH	University of Pittsburg
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Edward Livingston, M.D.	Southwestern Medical Center
Denis Prud'homme, M.D., M.Sc.	University of Ottawa
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Table 2. Peer Reviewers

Name	Institution
Richard L. Atkinson, M.D.	University of Wisconsin – Madison
Allison Avenell, M.D.	University of Aberdeen Medical School
Peter F. Crookes, M.D.	USC Healthcare Consultation Center
James O. Hill, Ph.D.	UCHSC Center for Human Nutrition
Francine Kaufman, M.D.	Keck School of Medicine
Carolyn Summerbell, Ph.D.	University of Teeside, UK
John Reilly, M.D.	University of Glasgow, Scotland

Appendix E

Obesity Peer and TEP Review		
Section	**Reviewer's Comments**	**Author's Response to Comments**
General comment	I have reviewed this document very carefully. I think you did a really good job with this review. It is very difficult to find anything to add or to critique. The only minor point is that you conclude that the medications produce a clinically significant weight loss yet you don't really talk about what clinically significant means. Those in the area know this means reductions in CVD and diabetes risk factors, but it might be useful to include this information, either in the individual reviews of the medications or at least in the conclusions.	We have noted this in the introduction.
General comment	This is a rigorous and helpful summary of the available evidence.	No response necessary.
General comment	It would be important to re-emphasize later in the report that questions 3 and 4 were not sufficiently addressed in the majority of studies.	Appropriate change made.
General comment	Since I am not an expert in this topic (obesity), I was most concerned with the methods used to identify evidence and the presentation and usefulness of the results. It appears that a rigorous search was used to find relevant articles, and a careful methodology was employed to establish and enforce criteria for inclusion.	No response necessary.
General comment	Conclusions appear to be warranted by the outcomes of the report, and will be especially useful for organizations seeking to clarify the evidence for quality clinical practice, such as the American College of Physicians. I did not perceive any significant bias in your presentation or discussion.	No response necessary.

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Obesity Peer and TEP Review		
Section	**Reviewer's Comments**	**Author's Response to Comments**
General comment	In the past year, I have reviewed a number of documents targeting obesity and overweight in adults. Several of the reports included similar methodologies to the ones used here but also included research that did not use medications. When comparing the conclusions of this project (medical studies section) with those of other projects, the results are very similar and they are presented in an unbiased manner. I also think your reference /literature search was exhaustive and very complete.	No response necessary.
General comment	p. 15-16 The text and tables should more consistently describe the types of patients enrolled e.g., avg. BMI where available.	Appropriate change made.
General comment	The average weight losses in pharmacological clinical trials are not representative of the weight loss effectiveness observed by clinicians in individual obese patients for several reasons.	We have now included total weight loss for each pooled analysis and have added text to the limitations and future research regarding this point.

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Obesity Peer and TEP Review		
Section	**Reviewer's Comments**	**Author's Response to Comments**
General comment	One potential biased statement is the recurrent mention that, "even modest weight loss may be clinically significant." You reference the introduction later in the document, but there it is referring to weight loss that is substantially greater than recognized by use of pharmacologic treatment.	We disagree, and now note in the report that the total weight loss in the treated groups is above 5 kg, or more than 10 lbs and more than 5% of pretreatment weight loss, which is consistent with a reduction in cardiovascular risk factors. As other reviewers have noted, a very recent study that we could not include in our review, the XENDOS trial, demonstrates a reduction in diabetes in orlistat-treated patients. So we believe the weight loss numbers reported here can have significant health effects.

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Obesity Peer and TEP Review		
Section	**Reviewer's Comments**	**Author's Response to Comments**
Introduction	It may be useful to state the inclusion criteria for drugs employed in this report.	This is done in the methods.
Introduction	Paragraph 2, line 2. This 19.8 figure comes from the BRFSS report and is "self-report" I would suggest you replace it with the NCHS data from Flegal, JAMA 2002 which is "measured" rather than "self-reported" data.	These comments all concern the introduction, which was extensively revised taking into account these comments.
Introduction	Paragraph 2, line 4, you say, "comparison is difficult because of changing definitions of obesity." Since the NHLBI evidence report in 1998, there have been uniform definitions that were used by Flegal and by Mokdad in many reports. Clearly this sentence needs to be modified.	
Introduction	Paragraph 4 line 5. Please insert "factors" after risk.	
	"Weight loss of only 20 pounds can be associated with marked reductions in the risk of these chronic diseases." I would suggest to present the weight loss in percentage because that is the universal way of expressing the amount of weight loss necessary to have some health benefits and/or reduce the incidence of chronic disease.	
Introduction	You quote data from 1999 regarding the prevalence of pediatric obesity. The latest data from 2000 indicates that 10.4% of 2-5 year olds, 15.3% of 6-11 year olds and 15.5% are overweight. Ogden, CI et al. Prevalence and trends in overweight among US children and adolescents, 1999-2000. JAMA 2002;288;1728-1732.	
Introduction	Discussion the health consequences of obesity, there is no mention of liver problems, i.e., non-alcoholic fatty liver disease (AFL). I think that this is a frequent and potentially serious complication and should also be mentioned. If you need references for this, the AGA has a technical and position paper regarding this. Likewise, I am not sure if you want to include psychological issues here, but that is felt to be the most common complication associated with pediatric obesity. (Dietz WH. Health consequences of obesity in youth: childhood predictors of adult disease. Pediatrics 101:S 518-525, 1998.	

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Obesity Peer and TEP Review		
Section	**Reviewer's Comments**	**Author's Response to Comments**
Introduction	The authors state, "although a precise comparison is difficult because of changing definitions of obesity." This is incorrect. The studies by Mokdad AH and Flegal KM that were published by the CDC after 1998 using BRFSS and NHANES data have used a uniform definition of obesity that was adopted in 1998 by the NIH and WHO. This classification scheme is still in use today.	
Introduction	The study by Flegal KM, Caroll, MD, et al. 2002. Prevalence and trends I obesity among US adults, 1999-2000. JAMA 288(14): 1723-7, used NHANES data (which used measured height and weight). The Mokdad studies used BRFSS data (which used self-reported height and weight), which is an underestimate of obesity prevalence. The Flegal paper reports a prevalence of overweight of 64.5% in 1999-20002.	
Introduction	Should have the diagram to help non-surgeons understand the anatomy of these surgeries.	
Introduction	In the *Introduction*, is appropriate for the report and sets the tone of the analyses that follow. The first paragraph suggests obesity is due to the modern high fat diet. The components of the diet that lead to obesity are known. This should be amended. The definitions used for children were not compatible with CDC definitions. This should be amended (i.e., seriously overweight, does this refer to >95th percentile of age and gender). Type II should be written as type 2. Isn't the WHO claim of > 300 million people with obesity inclusive of overweight and obese.	
Introduction	Somewhere in the report you should briefly summarize the basic types of surgical interventions.	

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Obesity Peer and TEP Review		
Section	**Reviewer's Comments**	**Author's Response to Comments**
Methods	It would be a good idea to define what you mean by baseline, do you mean from randomization point, as the orlistat studies often took their baseline as the beginning of the run-in phase, i.e. before randomization.	Often times in the original article this was not clear, although most articles did not have a run-in phase.
Methods	A height of 5 feet and 4 inches needs more justification.	We now state that it makes little difference whether any height between 5 feet and 6 feet is chosen, and as about two-thirds of all participants are women, this range of height encompasses nearly all women, so it doesn't matter what height you pick.
Methods	You need to discuss why adverse events analysis for orlistat and fluoxetine only was carried out.	We now present a pooled adverse event analysis for bupropion and topiramate in addition to orlistat and fluoxetine and the existing adverse event meta-analysis on sibutramine.

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Section	**Reviewer's Comments**	**Author's Response to Comments**
Methods	The search picked up only 1,010 hits, of which only 325 were identified from the electronic searching. This seems astonishingly low, and the reason for this is the very limited search strategy that was employed. A "usual" systematic (Cochrane type) review search for this topic would probably identify 15,000 – 25,000 hits. In Appendix A, it would be useful to state the number of hits identified through electronic searching after de-duplication – I assume that this is 325 (as in Fig 1)?	We report the numbers as we encountered them and our yield in this report was typical for EPC reports.
Methods	Why did the authors not use the same search strategies as those employed by the research team who carried out the Aberdeen? The update searches (and the Aberdeen report) specifically exclude children in the search strategies.	Children were a focus in this report and that is why we did not replicate this strategy.
Methods	I would be interested to see the list of 11 articles that were requested but not found.	These are included in the "Excluded Studies" section and characterized as "not found."
Methods	Second, was there a check against the studies included in the existing "recent" reviews and the articles identified in the update searches – there is no mention of this process in the text, and this would be helpful.	We have added this to the excluded list this was done. We term this "reference mining."
Methods	For studies included in existing "recent" reviews that were used in this report, did the authors go back to the original papers and abstract data on outcomes and adverse events, or simply use the abstracted data in the existing reports.	We abstracted original data.

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Obesity Peer and TEP Review		
Section	**Reviewer's Comments**	**Author's Response to Comments**
Methods	I suggest that it might be simpler to report the meta-analysis done by the authors of this report first, and then (if useful) compare these to those of existing "recent" reports.	Instead of this way to organize the drugs, we chose instead to present the results for FDA-approved drugs first, then non-FDA approved drugs.
Methods	Paragraph 3, Jadad quality score. I am unfamiliar with this, and it would help me to have a bit more description.	We have amplified a little bit on this.
Methods	Paragraph 3, line 3: Insert "said" after specifically.	Appropriate change was made.
Methods	Methods used were sound, and this section was well written. Assumptions made were explicit and the authors carefully considered whether any assumptions made might have altered their conclusions. The lack of pediatric and adolescent evidence could have been addressed in the Methods section, which tends to ignore this subgroup.	No response required.
Methods	I was a little unclear as to whether longer-term outcome evidence (beyond 12 months of treatment) was ineligible or simply very scarce. Outcome data to 12 months is a valuable end-point, but if there is a body of evidence with longer term outcome data (to 24 months for example) this would be informative.	It is scarce.
Methods	Within the 6 and 12-month periods of outcome reported, was treatment continuous for 6 and 12 months in all cases? Was there any attempt to analyze by studies sub-group in order to address the issue of weight loss vs. weight maintenance? I appreciate the complexity of this question, but feel that some statement as to whether the treatment effects summarized in this review are 'weight loss on treatment' as opposed to this plus 'weight maintenance post-treatment' would be helpful.	They are weight loss on treatment. Unfortunately, weight maintenance post-treatment data are exceedingly scarce.

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Section	**Reviewer's Comments**	**Author's Response to Comments**
Methods	The authors correctly point out the lack of evidence on differences in treatment by age/gender/race. There may also be differences by degree of initial obesity – was this variable considered for inclusion in the analysis?	No. In order to do this, we could only do it at the study level and the mean pretreatment BMI varied little in the drug studies. Therefore, there is not enough variance to have useful explanatory power. This would be possible if we had individual patient-level data, but we did not have the resources to request this from original authors.
Methods	I have reservations about how the authors handled heterogeneity among trials of orlistat and fluoxetine and how these results are presented. The authors state "there was significant heterogeneity among studies" of orlistat and fluoxetine at both 6 and 12 months. While the authors use the random effects model appropriately, explore potential reasons for heterogeneity, and present the results of these explorations in the text, the authors ultimately present the heterogeneous pooled effect estimates in the tables and figures. The authors do not go into enough detail about the implications of this heterogeneity for clinical practice – in other words, should we believe this estimate?	We now present sensitivity analyses exploring sources of heterogeneity.
Methods	"Extraction of Adverse Event Data." As you mention, the fact that each event was counted as if it represented a unique individual, this assumption overestimates the number of people having an adverse event. I would prefer that the adverse event be documented based on the number of events and not be attributed to a unique individual.	It's not possible to do a meaningful analysis without the patient as the unit of analysis.

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Section	**Reviewer's Comments**	**Author's Response to Comments**
Methods	The use of a pooled OR for diarrhea may be inappropriate here because the prevalence of diarrhea in exposed individuals is so high.	We agree and have noted this as a limitation.
Methods	Is it too cumbersome to go back and sort out which of these RCT or CT's of pharmacologic agents examined the "goodness of randomization" in terms of the mean BMI's or their equivalents in the different treatment groups? Baseline BMI could be a confounder in subject compliance not only with the underlying dietary recommendation but also with medications. What would have been a desirable design would have been if they had used stratified randomization based on initial BMI and also gender.	Sorry we could not go back and do this.
Methods	It was not clear to me what proportion of the trials of pharmacologic agents also provided dietary counseling for reduced caloric intake for their study subjects and also used caloric intake as a covariate in their analysis. Perhaps, the effect size could be enhanced if the pharmacologic agents are viewed more as adjuvant therapy to caloric restriction.	We now state for each analysis we conducted what proportion of studies had these cointerventions.
Methods	In discussing the decision to drop the review of diet studies, you can cite the fact that the U.S. Preventive Services Task Force is about to publish a review of dietary counseling studies which covers much of this ground. I will forward the correct citation for this report. The reference will be Ann Intern Med. 2003;139(11):933-949. but I will forward the author and title.	We did not drop it for this reason, more because the vast number of studies and heterogeneity would make synthesizing the diet studies a real big job.

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Section	**Reviewer's Comments**	**Author's Response to Comments**
Methods	Meta-analysis – I am not sure the "number needed to harm" is necessarily the best way to communicate the absolute rate difference. Most readers don't have an intuitive sense of the meaning (e.g. lower numbers are worse) and it is directly dependent on the event rate in the control group, which might be more variable than we assume. I think it would be more transparent to present the control rate you estimate from the available studies and the calculated rate of side effects in treated patients based on the odds ratio. E.g. for diarrhea, instead of saying the NNH is 1.48 for diarrhea from orlistat, it might be more informative to say Control rate = 30%, treated rate = 97%. (I am guessing at numbers). It gives the reader a clearer sense of what to expect on treatment, even if not all events are directly attributable to treatment.	We are not sure we agree with this comment. The NNH is certainly used by others in the literature.
Methods	As I mentioned, I do not think NNH is particularly useful. If you retain it, I would drop the decimal points – it conveys an exaggerated sense of precision.	
Methods	Given the significant heterogeneity, there should be greater discussion of the limitations of presenting a pooled estimate of effects. While recognizing the perils of post hoc analyses looking for sources of heterogeneity, given the consistency of the findings it might be useful to explore other possible sources of heterogeneity across the different medications – are there any common factors in the trials that produced the largest or smallest results with different medications.	We discussed this but did not have the time or resources to do this.
Methods	It would be useful to include start/end date of searches. It would be helpful to note (start of second paragraph on page vi) that the 'published review on phentermine…' was *systematic*. I would have preferred greater emphasis on research needs in the Abstract given the lack of evidence for many of the issues addressed.	These are noted now in the Methods section in the "Literature Search" section.

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Section	**Reviewer's Comments**	**Author's Response to Comments**
sibutramine	Perhaps you should state that you used this unpublished sibutramine review in preference to the published review by O'Meara for the HTA programme/NICE as it post-dated O'Meara: O'Meara S, Riemsma R, Shirran L, Mather L, ter Riet G. The clinical effectiveness and cost-effectiveness of sibutramine in the management of obesity: a technology assessment. Health Technol Assess 2002;6(6).	The sibutramine meta-analysis we used was more up to date, being published in 2004.
sibutramine	First, I am puzzled why the O'Meara review (HTA report) was not included. If it had then the authors could have avoided conducting any meta-analysis (except perhaps for fluoxetine).	
sibutramine	Why was the HTA review on sibutramine by O'Meara (2002 vol 6 No 6) not included in this report? The authors clearly identified the other two HTA reports in this series; orlistat 2001 vol 5 No 18, surgery 2002 vol 6 No 12.	
sibutramine	Last line-I thought that there was "weight" related decrease in lipids in the sibutramine studies	This meta-analysis did report a decrease in lipids with sibutramine treatment, but did not attribute it to weight loss or the drug.
sibutramine	Paragraph 2- There seems to be a discrepancy between numbers of studies. You indicate there are 28, and the in the next two paragraphs you site 11 and 21 studies. Can you please reconcile the differences?	Some studies reported both 6 and 12 month outcomes.
sibutramine	Is the 20-30% increase in achieving 5% weight loss *absolute* or *relative*?	We abstracted this from the original article, we think this it is relative.

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sibutramine	Why aren't sibutramine and the other agents included in Table 1?	Table 1 only lists the adverse event descriptors we identified for the drugs for which we conducted meta-analysis. For sibutramine we relied on an existing meta-analysis.
sibutramine	More clearly state that the average weight loss with sibutramine was 4.5 kg OVER the weight loss achieved via placebo.	We have now added both the weight loss over placebo and the total weight loss for each of the pooled analysis we did.
sibutramine	In the case of sibutramine, the patients with hypertension appear early and can be ascertained by following blood pressure. There is also data suggesting that 8 weeks of treatment may be adequate to differentiate responders from non-responders. To prevent hypertension, there are clear methods for using a lower initial dose of 10 mg vs. 15 mg. in patients with pre-existing hypertension. For those patients who do not have this idiosyncratic reaction, the effects of sibutramine on blood pressure are mild with only an attenuation of the normally observed decrease in blood pressure that occurs with weight loss.	This comment is noted, but not incorporated into our report because our report summarizes an existing meta-analysis which does not make this point, and we did not systematically search for evidence regarding the temporal relationship of blood pressure response.

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orlistat	This report does a good job of summarizing the current state of the evidence for screening and treatment of obesity. Its methodological rigor and detail surpass the earlier, now outdated reviews of this topic.	No response necessary.
orlistat	The literature search did identify, but the text does not discuss the preliminary results of an important RCT of orlistat (Scheen, AJ 2002. [Info-congress. Prevention of type 2 diabetes in obese patients: first results with orlistat in the XENDOS study]. Rev Med Liege 57(9): 617-21.). This study describes the potential long-term (4 years follow-up) outcomes of treatment with orlistat – it is the first study to show that weight loss with a drug reduces incident type 2 diabetes. I realize this study is not yet a published manuscript, but it may deserve mention because of the importance of the findings.	We could not include this because it was published too late to be incorporated into our meta-analysis.
orlistat	The literature review includes most of the important papers except for Orlistat. The "Xendos" trial is a 4 year study which unfortunately is available only in abstract form. This is the longest recent trial of pharmacotherapy – it can be found in: International Journal of Obesity – presented at IASO, San Paolo Brazil, September 2002. Sjostrom, L	
orlistat	In the Orlistat trials a higher fat diet was used to enable the effect of the drug to be seen. A specific 30 percent fat target was used and fat was added if the target was not reached.	This comment is noted but we made no change to the manuscript.
orlistat	The pooled random effects estimate of the mean weight loss for orlistat-treated patients, compared to placebo-treated patients, was 2.51 kg . . ." Was the mean weight loss for placebo-treated groups calculated? In general, it is clearer if you report the mean weight loss for treated and the mean weight loss for placebo groups.	We calculated all of these numbers and how present the total and placebo-corrected weight loss.

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phentermine	Phentermine and diethylproprion, although the reviews reported no side effect or adverse event data, were these mentioned in the actual trials?	We did not go back to the original trials for phentermine, diethylpropion, or sibutramine. Adverse event data were not reported in the meta-analysis of phentermine or diethylpropion.
phentermine	The authors say "We note that while phentermine is an FDA-approved weight loss medication it is no longer available in Europe because of concerns about a possible link between phentermine use and heart and lung problems ." What data is this based on?, or is it simply a bureaucratic pronouncement?	We attempted to find the justification for the European decision, could not find any, and have therefore removed this sentence from the report.
phentermine	The section of phentermine is concise, however, it was a little hard to reconcile the banning of the drug in Europe with the report of no side effects. The same holds for diethypropion.	
phentermine	It is irrelevant information to include any comment about the fact that a drug is not available in Europe due to possible concerns about heart and lung problems.	

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fluoxetine	For drugs used for other indications such as fluoxetine, it was not clear that the side effects were different from other approved uses.	We now comment regarding fluoxetine and bupropion that the side effects in the weight loss trials were similar to those reported in other approved uses.
fluoxetine	S Paragraph 2-Same problem of reconciling the number of studies. You indicate there were 9 studies and then you discuss 7 and 6.	Some studies reported both 6 and 12 month outcomes.

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bupropion	Bupropion studies in general do not emphasize behavior mod and diet and exercise as much as the sibutramine and orlistat studies do. This should be emphasized and likely do contribute to the lesser weight losses seen in the bupropion studies.	This comment is noted, but we made no change to our report because we did not systematically assess the intensity of the cointerventions, merely their presence or absence.
bupropion	Bupropion – Is there a specific reason why these 4 studies were not pooled?	These are now pooled.
bupropion	Bupropion you switch from using kg for effect size to % weight loss. Wouldn't it be better to use a kg effect size throughout?	We now present a pooled kg meta-analysis.
bupropion	Can you describe the meaning of a Beck Depression score of 15 – were these patients depressed or normal?	
bupropion	In the bupropion section, it was confusing in that weight loss was for the first time reported in %. There was a much greater in depth report of these limited studies for bupropion. Was this done because there is less familiarity with this agent? Is this the same for zonisamide and topiramate?	

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topiramate	Why couldn't studies reporting % weight loss be included (couldn't one convert using average baseline weight?)	Average baseline weight wasn't available for topiramate studies.

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Miscellaneous drugs	The coverage of these trials seems disproportionately lengthy in relation to the rest of the review, could some of this information be tabulated?	We have attempted to redress this apparent imbalance.
Miscellaneous drugs	Three drugs, bupropion, zonisamide, topiramate and sertraline were discussed based on the 1-4 available trials that varied in their quality. For the reader there is some disconnect in quality and quantity of discussion.	
Miscellaneous drugs	For other drugs reviewed for completeness, the level of detail was excessive.	
Miscellaneous drugs	Zonisamide, topiramate and sertraline. Same issue of presenting data as % versus kg as you did for the other studies.	Only % weight loss was reported as an outcome in these studies.
Miscellaneous drugs	It is unclear again why the last 2 agents are reported in percent weight loss.	
Miscellaneous drugs	It would be helpful to mention that these investigative drugs are currently licensed only for treatment of seizures.	We mention in the methods that these drugs are not FDA approved for weight loss.

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Surgery	RCTs between discredited therapeutic procedures or medications are worthless! All forms of unbanded gastroplasty procedures have been found to be inadequate and should not even be mentioned, except for historical interest, in any comparison.	All of these comments concern the synthesis and reporting of the evidence regarding surgery. In response, we have completely rewritten the surgical section, including new articles, new analyses, and new conclusions.
Surgery	The data are clear that unbanded gastroplasty procedures are inadequate and should only be mentioned for historical interest, but they figure prominently in both reports. I believe the data are also clear that a gastric bypass (GBP) is associated with significantly more weight loss than a vertical banded gastroplasty (VBG). Two additional CSs supporting this statement were not referenced	
Surgery	One of our studies that followed our RCT comparing VBG to GBP in which we selectively assigned patients to VBG and GBP, having found from retrospective analysis of the data that "sweets eaters" do poorly after VBG, was not listed. In that study, despite selective assignment, we continued to find a significantly better weight loss at 1,2 and 3 years with GBP.	
Surgery	We and others have found that patients with a VBG and an inadequate weight loss or with severe gastroesophageal reflux problems that develop after VBG respond well to conversion to GBP.	
Surgery	There was no mention of the partial biliopancreatic diversion procedure or its modification, the duodenal switch.	
Surgery	I believe a RCT comparing surgery to non-surgery for any age group would be impractical.	
Surgery	You make the point that there is no evidence that surgery gives better weight loss than medical treatment. There may be a paucity of data to support a difference from randomized clinical trials, but the difference is so dramatic from case control studies like the SOS, making this point seems more confusing than helpful.	

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Surgery	In view of the length and the size of the SOS study, I find it difficult to believe that the superior weight loss efficacy of surgical treatment over medical treatment of obesity is not obvious to any reasonable person, despite the lack of a randomized trial design.	
Surgery	In terms of surgery, I think it would be appropriate to include more detail about the SOS study, even though this is not a RCT.	
Surgery	From my perspective the report does not adequately address the status of bariatric surgery. The report concludes that heterogeneity in the surgical trials selected for review precluded statistical pooling. This may be a fair assessment of the quality of existing publications regarding bariatric surgery, however, the same approach should have been applied to the summary of adverse events. Most of the report concentrated on summarizing adverse events, a discussion that aggregated studies of widely different procedures with variable short and long-term risks. It was not clear to me why the reviewers took the position that heterogeneity precluded analysis of outcomes but not adverse events.	
Surgery	The literature summarizing bariatric surgery experience is lacking in many ways. However, the vast majority of studies describing operations currently accepted by the surgical community demonstrate obesity-related comorbidity control, duration and extent of weight loss that far exceed any trial of medical therapy. Granted that there may not be a statistical methodology for comparing the literature summarizing these therapeutic approaches but for those of us engaged in the practice of treating the obese the results are obvious.	
Surgery	The report dismissed bariatric surgery outcomes because the available literature could not be assessed by the methodology selected by the reviewers. Given this, I was surprised that they did not recommend the performance of controlled trials, as did the 1991 NIH panel. Rather, the current report states that these trials cannot be done and recommends conducting observational studies. I cannot agree with that recommendation.	

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Surgery	In summary, the report as currently written does not adequately summarize the available evidence in support of bariatric surgery. Should the reviewers not be able to revise this the section on adult bariatric surgery it should be eliminated. I would retain the part on the pediatric literature, being that assessment of outcomes for children was the original question posed and the summary provided for pediatrics is adequate.	
Surgery	The conclusions concerning surgery were more difficult to determine since there are limited number of RCTs that have compared surgery to diet and the variety of surgical procedures to each other with regards to efficacy and safety.	
Surgery	The surgical results again were confusing. In the second report, for example, is the weight gain in the 5 patients related to one procedure versus another?	
Surgery	The surgical results again were confusing. In the second report, for example, is the weight gain in the 5 patients related to one procedure versus another?	
Surgery	I wonder if you could specify the mean duration (with the range) of the follow up post surgery and the ranges in your report. I am concerned about the current lack of follow up and potential problem of osteopenia in these youngsters from calcium malabsorption, as the mean age of the surgery is at the time of peak bone formation.	
Surgery	My first comment is that data for efficacy surgery (magnitude of weight loss) abound in the literature. They tend to be reported as case series.	
Surgery	Readers will gain the impression that there is no evidence that surgery provides greater weight loss than diet alone. Yet this conclusion was based on a single RCT performed 20 years ago, and reported an outmoded procedure, which has been abandoned for years.	
Surgery	Comparing surgery with conventional treatment in a contemporaneous RCT is idealogically problematic because one of the entry criteria for surgical treatment is the prior attempts, and failure of medical treatments.	
Surgery	The implications of a review claiming that there is no evidence that surgery is more efficacious than conservative methods is potentially very profound.	

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Surgery	The other major omission in the discussion about surgery is any concept of the magnitude of weight loss, which may be expected.	
Surgery	Reference #203 is missing and this is a key reference regarding bariatric surgery in adolescents.	
Surgery	I would also suggest that you include comments under Surgery in Chapter 4, the importance of long-term follow up of post surgery for adolescents. I also would like to see a plea made for a centralized registry where core clinical information is gathered prospectively in a standardized manner for future pooling of the data as bariatric surgery is on the increase for adolescents.	
Surgery	I don't find sufficient justification (other than lack of time) to exclude analysis of the weight loss outcomes from the case-series of surgical treatment.	
Surgery	The fact that there is significant heterogeneity in the results of the studies that were reviewed doesn't seem like an argument for not reviewing them – in fact, one could argue that pointing out and exploring reasons for the heterogeneity could be an important contribution of the report.	
Surgery	Perhaps, given the number of studies, one could set inclusion criteria based on duration of follow-up that might result in a more manageable number of studies. I think the most important unanswered question is probably the long term effects on weight loss so setting more stringent follow-up requirements (e.g. 2 years or greater) would be reasonable.	
Surgery	The description of how individual and aggregate adverse event rates were calculated is not explained in enough detail to understand exactly what was done or the possible effects of your assumptions on your estimates of adverse event rates (especially for surgery). It is unclear what studies contribute to the comparisons of adverse events for different surgical procedures – does a study have to have compared outcomes of both procedures to be included, as opposed to reporting rates for one procedure?	

Appendix E

Obesity Peer and TEP Review		
Section	**Reviewer's Comments**	**Author's Response to Comments**
Surgery	There are at least three critical assumptions that could affect the validity of the estimates you present for individual and aggregated outcomes: 1) the assumption that reported events are an approximation of individuals; 2) the assumption that events in related categories (e.g. nausea and vomiting) occur in different individuals; the 3) the assumption you can aggregate reports of events in broad categories (such as "GI symptoms") even though studies do not uniformly report all the outcomes under each category.	
Surgery	• Reorganize the adverse event categories on 49-67 to mimic the "tree" structure used, by indenting subcategories. For example: **1) Respiratory major** a) PE DVT/PE PE Major pulmonary embolus… b) Respiratory insufficiency ARDS Respiratory failure c) Chest infections Respiratory chest infections	
Surgery	More emphasis should be placed on the raw estimates for single endpoints (e.g. vomiting) than on the aggregated endpoints (e.g. GI symptoms).	
Surgery	Estimates of combined rates such as "GI, all" should only come from studies that report a minimum number of outcomes, such as at least one outcome in each of the subcategories. Alternatively, estimates calculated by different means could be compared to give a range.	
Surgery	Summary tables that highlight the most important and reliable endpoints should be included – the undifferentiated list of comparisons in Table 13 is difficult to wade through.	

Appendix E

Obesity Peer and TEP Review		
Section	**Reviewer's Comments**	**Author's Response to Comments**
Surgery	Methods need to clarify which studies contribute to which estimates. I am still unclear why the number of studies contributing to specific outcomes varies depending on what the comparison is (e.g. for "GI, all" 16 studies are cited for the estimate for VBG in the RYBG vs. VBG, but 18 studies for VBG two lines below in the VBG vs. band. I suspect these are errors.	
Surgery	It would be preferable if the groupings of symptoms for the surgery studies matched that for the medication studies as closely as possible. Fore example, why is gastritis/reflux not included with other related symptoms like abdominal pain under "GI symptoms" as in the medication studies?	
Surgery	As noted above, this section needs to be expanded perhaps with some examples and numbers to illustrate how different numerators and denominators were constructed for individual outcomes and aggregated outcomes. The effect of assuming that each reported adverse event occurred in different patients should be explicitly discussed.	
Surgery	What do the non-surgery patients represent here – diet treated? Please define "early" and "late." Please clarify what the definition of outlier means – the definition does not seem consistent for an individual study.	
Surgery	I'm surprised at the finding of no data showing greater weight loss with surgery than diet. That alone will make this newsworthy.	
Surgery	When reviewing results of the different bariatric surgeries it is important to recognize what the male:female ratio is as female pattern (gynecoid) obesity patients are easier to operate on and generally suffer from less comorbidities and recover from surgery with less risk for morbidity and mortality.	
Surgery	Most of the laparoscopic series are selective of who has a laparoscopic procedure reserving this approach for the less risky less heavy patients, therefore, skewing the data in their favor.	

Appendix E

Obesity Peer and TEP Review		
Section	**Reviewer's Comments**	**Author's Response to Comments**
Surgery	Today three procedures are performed with frequency, the RYGBP, the DS and the laparoscopic gastric band (LAP BAND). The LAP BAND best serves the less heavy, most compliant, motivated patient. The long term consequences of this procedure are yet to be determined but most experienced bariatric surgeons worry about the development of esophageal motility disorders and band erosions. The RYGBP has stood the test of time as far as efficacy and safety are concerned. However, side effects such as the inability to tolerate certain solid foods and d the development of dumping symptoms are the major drawbacks of this procedure. The laparoscopic RYGBP can be performed with safety in certain centers with similar results to that of an open approach. However, what is not known are the results of the laparoscopic RYGBP in certain centers and surgeons who are not experienced with bariatric surgery and the leak rate may be significantly higher in these centers/surgeons hands.	
Surgery	The DS has certain advantages and disadvantages. The safety and efficacy are comparable if not better than that see n with the RYGBP (Anthone et al, Ann Surg 2003;238:618-628). The advantages include better tolerance of solid food and the absence of dumping symptoms. In addition, the leak rate is low because of the lack of tension at the anastomotic suture line. The disadvantages are the higher risk of malodorous stools and the development of protein calorie malnutrition if the diversion of bile/pancreatic secretions is performed to a degree significant enough to provide an element of fat malabsorption.	
Surgery	The malnutrition and other problems with Roux-en-Y need to be documented but so should the benefits of the Roux-en-Y for Type II diabetes (see studies of Porrier).	
Surgery	The whole issue of which surgical procedure (page 13) was performed was difficult to understand. It might be better understood if there were diagrams showing the different procedures and locations and how they were lumped together.	

Appendix E

Obesity Peer and TEP Review		
Section	**Reviewer's Comments**	**Author's Response to Comments**
Surgery	The surgical discussion seems out of place against the clinical trial data that are presented in the first parts of the paper	
Surgery	It might be important to include the number of centers and surgeons in the multicenter reports.	

Appendix E

Obesity Peer and TEP Review		
Section	**Reviewer's Comments**	**Author's Response to Comments**
Children	The statement is a bold one specially since I know of one Polish study **Ref**: Przegl Lek. 1981;38(3):355-8 "Clinical evaluation of Teronac (Mazindol) in the treatment of obesity in children. Part II. Anorectic properties and side effects." Therefore I suggest modifying the statement to ' Current studies in pharmacological management of obesity in children (<12y/o) is limited to 'obesity due to secondary causes' e.g. "Metformin for weight loss in Pediatric patients taking psychotropic drugs." **Ref**: American Journal of Psychiatry Morrison et al. 159 (4):655 or in certain syndromes like 'Prader-Willi syndrome' and familial hyperlipidemia.	This medication (mazindol) was not a subject of our study. We have noted the presence of this paper in our report.
Children	For pharmacological management of obesity in adolescents, one study should be particularly included, **Ref**. Int J Obes Relat metab disord. 2000 Dec; 24(12): 1573-8 "Safety and efficacy of treatment with an ephedrine/caffeine mixture. The first double-blind placebo-controlled pilot study in adolescents."	This medication was not a subject of our study. We have noted the presence of this paper in our report.
Children	For surgical management of obesity in adolescents with LAGB (laparoscopic adjustable gastric banding), there are two excellent recent studies and need inclusion for their direct relevance to the topic in hand and specially since there is a dearth of data in the field, **Ref A**.: J Pediatr Surg. 2003 Sep; 38(9): 1379-82 "Bariatric surgery in adolescence," Abu-Abeid S et al and **Ref. B**: Obes Surg. 2003 Feb; 13(1): 101-4 "Laparoscopic gastric banding in morbidly obese adolescents," Dolan K et al.	We have added these references to our synthesis.
Children	The authors have made great efforts to obtain evidence, and their methodology for doing so has been appropriate. My particular expertise is in reviews of obesity treatment in children and adolescents and so I cannot comment specifically on the evidence in adults, other than to note the methodological rigour, which has been applied here. I am unaware of any evidence on children and adolescents, which has been missed.	No response necessary.

Appendix E

Obesity Peer and TEP Review		
Section	**Reviewer's Comments**	**Author's Response to Comments**
Children	From a pediatric perspective, the review emphasizes well the need for data. A minor point: adolescents are pediatric patients. I tried to reword things to reflect that.	We did not mean to imply that adolescents are not pediatric patients, we used the terms adolescents and children to denote different ages.

Appendix E

Obesity Peer and TEP Review		
Section	**Reviewer's Comments**	**Author's Response to Comments**
Discussion	This was largely a well-written summary of what had gone before. Much of the 'Discussion' material had been addressed in earlier sections of the review. I would have welcomed a brief treatment of similarities/differences in conclusions between the present review and other recent systematic reviews in this area - to what extent does this review add to what was known? To what extent are recent reviews in agreement?	For sibutramine, phentermine, and diethylpropion, we relied on existing systematic reviews. For orlistat, we produced a new review but did not compare our results to previous reviews in a systematic way. For the other drugs ours is the first systematic review and meta-analysis that we are aware of.
Discussion	While it is likely that there are few data on the health economic outcomes of treatment (e.g. financial costs and benefits of pharmacotherapy) was such evidence eligible in the review? Was there simply very little evidence?	This was not one of our key questions. We note, however, that very few of the treatment studies we reviewed have any cost data.
Discussion	The *Summary* is daunting. Essentially there is little difference between agents from an effectiveness standpoint and only modest weight loss is apparent atone year. However, there is the suggestion that it is better to have lost and gained, then never to have lost at all with regards to risk factors. There is nothing beyond sibutramine for disease state, such as diabetes.	No response necessary.

Appendix E

<table>
<tr><th colspan="3">Obesity Peer and TEP Review</th></tr>
<tr><th>Section</th><th>Reviewer's Comments</th><th>Author's Response to Comments</th></tr>
<tr><td>Discussion</td><td>The comparison of Surgery and Pharmacological agents might be facilitated by a table such as the following:

<table>
<tr><td>Treatment</td><td><24.9</td><td>25-26.9</td><td>27-29.9</td><td>30-35</td><td>35-39.9</td><td>>40</td></tr>
<tr><td>Lifestyle</td><td>0</td><td>+ comorbids</td><td>+ comorbids</td><td>+</td><td>+</td><td>+</td></tr>
<tr><td>Meds</td><td>0</td><td>+ comorbids</td><td>+ comorbids</td><td>+</td><td>+</td><td>+</td></tr>
<tr><td>Surgery</td><td>0</td><td></td><td></td><td></td><td>+ comorbids</td><td>+</td></tr>
</table>
</td><td>This is a good idea, but the data are way too sparse to be able to meaningfully fill in the cells.</td></tr>
<tr><td>Discussion</td><td>On page vi, under Conclusions; I completely disagree with the statement "All of these drugs have significant side effects or safety concerns." This statement is repeatedly made in the document.</td><td>We have eliminated this statement.</td></tr>
<tr><td>Discussion</td><td>A review of the literature of this magnitude should specify which are minor side effects, which can be handled with medical supervision, and which are real safety concerns.</td><td>We think the classification of "minor" and "real safety concerns" are judgments for the reader to make. We have tried to present the data as accurately as possible for readers to make their own judgments.</td></tr>
</table>

Appendix E

Obesity Peer and TEP Review		
Section	**Reviewer's Comments**	**Author's Response to Comments**
Discussion	The only effective therapies for severe obesity are VLCD and surgery.	This is an expert opinion based on this evidence, statements such as this are not allowed in Evidence Reports but are perfectly appropriate for guidelines or other products that use opinion to supplement the evidence in our report.
Discussion	Not enough attention is given to issues of generalizability/external validity. I assume that the studies might have varied considerably in the recruitment/inclusion criteria in ways that might affect their applicability to primary care outpatients. For example, were there run-in periods?	Most studies did not have run-in periods. We have added text to the limitations regarding generalizability.

Appendix E

Obesity Peer and TEP Review		
Section	**Reviewer's Comments**	**Author's Response to Comments**
Future Research	This was a useful summary of the main 'gaps' in the evidence. In view of the scale of the obesity epidemic, the lack of evidence for many aspects of treatment is alarming, and this might have merited greater emphasis on research needs in the Abstract and in this section. The paucity of high quality data on bariatric surgery is a particular concern.	No response necessary.
Future Research	The trials summarized were quite heterogeneous with respect to treatment regimen – is it possible to comment on whether pharmacotherapy effects over 12 months are enhanced by lifestyle change? E.g. can the separate effects of dietary and/or assessed physical activity treatments going on simultaneously with the pharmacotherapy be assessed even in general terms?	We included this as a topic for future research, because the existing literature are insufficient to answer this question.
Future Research	Another area of future research would be attempting to determine if the age of onset of obesity has an effect on magnitude of weight loss or if early and rapid responders to medications have a more or less favorable long-term outcome.	This is a good suggestion, but we judge it as a second-level topic for future research, below the topics we list in our report.
Future Research	The Surgical results beg to establish Centers of Excellence for Bariatric Surgery and robust databases to characterize which surgical procedures are being employed.	We agree and note NIH has recently established Bariatric Surgical Centers. We hope our suggestion for future research will be acted on by these Centers.
Future Research	Surgical Therapy – It should be discussed in the discussion section that beyond the RCT that should be done, there should also be a registry developed for adult and adolescent and pediatric surgical therapy. This has already been established for diet and exercise therapy (Wing RR, Hill JO). Furthermore, NIH guidelines for adolescent and pediatric surgery for obesity have not yet been established.	We have suggested observational studies, which would require such registers.

Appendix E

Obesity Peer and TEP Review		
Section	**Reviewer's Comments**	**Author's Response to Comments**
References	Reference 20 should be: Avenell A, Broom J, Brown TJ, Poobalan A, Aucott L, Stearns SC, Smith WCS, Jung RT, Campbell MK, Grant AM. Systematic review of the long-term outcomes of the treatments for obesity and implications for health improvement and the economic consequences for the National Health Service. Health Technol Assess 2003 (in press).	Appropriate changes made.
References	Reference 23 should be: Clegg AJ, Colquitt J, Sidhu MK, Royle P, Loveman E, Walker A. The clinical effectiveness and cost-effectiveness of surgery for people with morbid obesity: a systematic review and economic evaluation. Health Technol Assess 2002;6(12).	Appropriate changes made.
References	Reference 44 should be: Broom I, Hughes E, Dodson P, Reckless J, on behalf of the Orlistat UK Study Group. The role of orlistat in the treatment of obese patients with mild to moderate hypercholesterolaemia: consequences for coronary risk. *Br J Cardiol* 2002;9(8):460-8.	Appropriate changes made.
References	Reference #203 is not listed in the Reference section	Appropriate changes made.
References	Typographical error--Reference 203 appears omitted but actually has been included under ref. 202.	Appropriate changes made.

Appendix E

Obesity Peer and TEP Review		
Section	**Reviewer's Comments**	**Author's Response to Comments**
Figures and Tables	Is overwhelming and it is hard to determine its importance.	This table has been reviewed.
Figures and Tables	Acceptable and add to the report	No response necessary. This table has been revised.
Figures and Tables	Table 11 is confusing in that it appears to be looking at overall surgical effectiveness and then compares different procedures. It is not as concise as the other tables.	
Figures and Tables	Table 12 conveys information in an understandable format.	No response necessary.
Figures and Tables	Tables 13 and 14 are difficult to follow.	These tables have been revised.
Figures and Tables	Figure 1 is excellent	No response necessary.
Figures and Tables	All other figures are good	No response necessary.
Figures and Tables	Evidence tables should include more details on the nature of enrolled patients.	Appropriate change made.
Figures and Tables	The Tables need to be much more clearly titled and labeled, with explanations of the sources of data and meaning of different columns and abbreviations.	Appropriate change made.
Figures and Tables	This figure is unclear – which studies correspond to which subgroups? Are A, B, and C mutually exclusive?	This has been revised in this report.
Figures and Tables	What do these tables represent – needs title to indicate these are weight loss outcomes expressed as difference vs. controls in kgs.	Appropriate change made.
Figures and Tables	I would include some information on the patient populations in these summary tables – e.g., these were patients with fairly severe obesity – BMI 35+.	Appropriate change made.

Appendix F

Included Studies

Abu-Abeid S, Gavert N, Klausner JM, et al. Bariatric surgery in adolescence. J Pediatr Surg 2003;38(9):1379-82.
Notes: Quality Reviewed for Surgery Analyses.

Abu-Abeid S, Szold A. Laparoscopic management of Lap-Band erosion. Obes Surg 2001;11(1):87-9.
Notes: Reports complications, considered for surgery analysis.

Abu-Abeid S, Szold A. Results and complications of laparoscopic adjustable gastric banding: an early and intermediate experience. Obes Surg 1999;9(2):188-90.
Notes: Quality Reviewed for Surgery Analyses.

Aghahosseini H, Roulet D, Cavin R. [Treatment of morbid obesity with adjustable gastric prosthesis: experience and results at the Riviera Hospital in Montreux]. Rev Med Suisse Romande 2001 ;121(10):709-12.
Notes: Quality Reviewed for Surgery Analyses.

Agren G, Naslund I. A prospective randomized comparison of vertical banded gastroplasty (VBG), loop gastric bypass (GBY), and gastric banding (GB). Int J Obes 1989;13:595.
Notes: Quality Reviewed for Surgery Analyses.

Al-Jiffry BO, Shaffer EA, Saccone GT, et al. Changes in gallbladder motility and gallstone formation following laparoscopic gastric banding for morbid obesity. Can J Gastroenterol 2003;17(3):169-74.
Notes: Quality Reviewed for Surgery Analyses.

Alden JF. Gastric and jejunoileal bypass. A comparison in the treatment of morbid obesity. Arch Surg 1977;112(7):799-806.
Notes: Quality Reviewed for Surgery Analyses.

Alper D, Ramadan E, Vishne T, et al. Silastic ring vertical gastroplasty- long-term results and complications. Obes Surg 2000;10(3):250-4.
Notes: Quality Reviewed for Surgery Analyses.

Andersen T, Backer OG, Astrup A, et al. Horizontal or vertical banded gastroplasty after pretreatment with very-low-calorie formula diet: a randomized trial. Int J Obes 1987;11(3):295-304.
Notes: Quality Reviewed for Surgery Analyses.

Andersen T, Backer OG, Stokholm K H, et al. [Gastroplasty versus very low calorie diet in morbid obesity. Short-term results of a randomized clinical trial]: <Original> Gastroplastik versus ekstrem lavkalorie-diaet (very-low-calorie diet) ved svaer adipositas. Korttidsresultater af en randomiseret klinisk undersogelse. Ugeskrift for laeger 1982;144(6):390-4.
Notes: Quality Reviewed for Surgery Analyses.

Andersen T, Backer OG, Stokholm K H, et al. Randomized trial of diet and gastroplasty compared with diet alone in morbid obesity. *New England journal of medicine* 1984;310(6):352-6.
Notes: Quality Reviewed for Surgery Analyses. Reports on Diethylproprion; no analysis performed, summary of recent meta-analysis provided.

Andersen T, Stokholm KH, Backer OG, et al. Long-term (5-year) results after either horizontal gastroplasty or very-low-calorie diet for morbid obesity. Int J Obes 1988;12(4):277-84.
Notes: Quality Reviewed for Surgery Analyses. Reports on Diethylproprion; no analysis performed, summary of recent meta-analysis provided.

Anderson AE, Soper RT, Scott DH. Gastric bypass for morbid obesity in children and adolescents. J Pediatr Surg 1980;15(6):876-81.
Notes: Quality Reviewed for Surgery Analyses.

Anderson JW, Greenway FL, Fujioka K, et al. Bupropion SR enhances weight loss: a 48-week double-blind, placebo-controlled trial. Obes Res 2002;10(7):633-41.
Notes: Quality Reviewed for Medication Analyses.

Anderson James W, Greenway Frank, Fujioka Ken, et al. Buproprion SR significantly enhances weight loss when used with a moderate-intensity lifestyle intervention. *Diabetes* 2001;50(Supplement 2):A21.
Notes: Quality Reviewed for Medication Analyses.

Anderson JW on behalf of the orlistat weight maintenance study group. Prevention of weight regain after conventional dieting: a 1-year study with orlistat (xenical), a new gastrointestinal lipase inhibitor. *Obesity Research* 1997;5(Suppl 1):S2.
Notes: Quality Reviewed for Medication Analyses. Excluded at meta-analysis.

Anthone GJ, Lord RVN, DeMeester TR, et al. The duodenal switch operation for the treatment of morbid obesity. *Ann Surg* 2003;238(4):618-628.
Notes: Quality Reviewed for Surgery Analyses.

Bakris G, Calhoun D, Egan B, et al. Orlistat improves blood pressure control in obese subjects with treated but inadequately controlled hypertension. *J Hypertens* 2002;20(11):2257-67.
Notes: Quality Reviewed for Medication Analyses.

Balsiger BM, Poggio JL, Mai J, et al. Ten and more years after vertical banded gastroplasty as primary operation for morbid obesity. *J Gastrointest Surg* 2000;4(6):598-605.
Notes: Quality Reviewed for Surgery Analyses.

Baltasar A, Bou R, Arlandis F, et al. Vertical banded gastroplasty at more than 5 years. *Obes Surg* 1998;8(1):29-34.
Notes: Quality Reviewed for Surgery Analyses.

Belachew M, Belva PH, Desaive C. Long-term results of laparoscopic adjustable gastric banding for the treatment of morbid obesity. *Obes Surg* 2002;12(4):564-8.
Notes: Quality Reviewed for Surgery Analyses.

Belachew M, Legrand M, Vincent V, et al. Laparoscopic adjustable gastric banding. *World J Surg* 1998;22(9):955-63.
Notes: Quality Reviewed for Surgery Analyses.

Berkowitz RI, Wadden TA, Tershakovec AM, et al. Behavior therapy and sibutramine for the treatment of adolescent obesity: a randomized controlled trial. *JAMA* 2003;289(14):1805-12.
Notes: Reports on Sibutramine; no analysis performed, summary of recent meta-analysis provided.

Bloomston M, Zervos EE, Camps MA, et al. Outcome following bariatric surgery in super versus morbidly obese patients: does weight matter? *Obes Surg* 1997;7(5):414-9.
Notes: Quality Reviewed for Surgery Analyses.

Bray G, Klein S, Levy B, Fitchet M, Perry B. Topiramate produces dose-related weight loss in obese patients. Presented at the 62nd American Diabetes Association Scientific Sessions. 2002 (Abstract)
Notes: Quality Reviewed for Medication Analyses.

Bray GA, Hollander P, Klein S, et al. A 6-Month Randomized, Placebo-Controlled, Dose-Ranging Trial of Topiramate for Weight Loss in Obesity. *Obes Res* 2003;11(6):722-733.
Notes: Quality Reviewed for Medication Analyses.

Breaux CW. Obesity Surgery in Children. *Obes Surg* 1995;5(3):279-284.
Notes: Quality Reviewed for Surgery Analyses.

Breum L, Bjerre U, Bak JF, et al. Long-term effects of fluoxetine on glycemic control in obese patients with non-insulin-dependent diabetes mellitus or glucose intolerance: influence on muscle glycogen synthase and insulin receptor kinase activity. *Metabolism* 1995;44(12):1570-6.
Notes: Quality Reviewed for Medication Analyses.

Brolin RL, Robertson LB, Kenler HA, et al. Weight loss and dietary intake after vertical banded gastroplasty and Roux-en-Y gastric bypass. *Ann Surg* 1994;220(6):782-90.
Notes: Quality Reviewed for Surgery Analyses.

Brolin RE, Bradley LJ, Wilson AC, et al. Lipid risk profile and weight stability after gastric restrictive operations for morbid obesity. *J Gastrointest Surg* 2000;4(5):464-9.
Notes: Quality Reviewed for Surgery Analyses.

Brolin RE, Kenler H A, Gorman J H, et al. Long-limb gastric bypass in the superobese. A prospective randomized study. *Annals of surgery* 1992;215(4):387-95.
Notes: Quality Reviewed for Surgery Analyses.

Broom I. Randomised trial of the effect of orlistat on body weight and CVD risk profile in overweight and obese patients with co-morbidities. *Int J Obes Relat Metab Disord* 2001;25(Suppl):S106.
Notes: Quality Reviewed for Medication Analyses. Excluded at meta-analysis.

Broom I , Hughes E , Dodgson P , et al. The role of orlistat in the treatment of obese patients with mild to moderate hypercholesterolaemia: consequences for coronary risk. 2001.
Notes: Quality Reviewed for Medication Analyses.

Broom I, Wilding J, Stott P, et al. Randomised trial of the effect of orlistat on body weight and cardiovascular disease risk profile in obese patients: UK Multimorbidity Study. *Int J Clin Pract* 2002;56(7):494-9.
Notes: Quality Reviewed for Medication Analyses.

Buckwalter JA. A prospective comparison of the jejunoileal and gastric bypass operations for morbid obesity. *World J Surg* 1977;1(6):757-68.
Notes: Quality Reviewed for Surgery Analyses.

Capella JF, Capella RF. The weight reduction operation of choice: vertical banded gastroplasty or gastric bypass*? Am J Surg* 1996;171(1):74-9.
Notes: Quality Reviewed for Surgery Analyses.

Caterson I, Astrup A, Zelissen P, Guy-Grand B, Carruba M, Levy B, et al. The long-term effect of Topiramate on body weight maintenance after low-calorie diet-induced wieght loss in obese subjects. Presented at the 18th International Diabetes Federation Congress. 2003 (Abstract)
Notes: Quality Reviewed for Medication Analyses.

Chiasson JL, Lau W, Leiter LA. Fluoxetine has potential in obese NIDDM--multi-center Canadian Trial. *Diabetes* 1989;38((suppl 2)):603.
Notes: Quality Reviewed for Medication Analyses. Excluded at meta-analysis.

Choban PS, Flancbaum L. The effect of Roux limb lengths on outcome after Roux-en-Y gastric bypass: a prospective, randomized clinical trial. *Obes Surg* 2002;12(4):540-5.
Notes: Quality Reviewed for Surgery Analyses.

Choban PS, Onyejekwe J, Burge JC, et al. A health status assessment of the impact of weight loss following Roux-en-Y gastric bypass for clinically severe obesity. *J Am Coll Surg* 1999;188(5):491-7.
Notes: Quality Reviewed for Surgery Analyses.

Choi Y, Frizzi J, Foley A, et al. Patient satisfaction and results of vertical banded gastroplasty and gastric bypass. *Obes Surg* 1999;9(1):33-5.
Notes: Quality Reviewed for Surgery Analyses.

Connolly VM, Gallagher A, Kesson CM. A study of fluoxetine in obese elderly patients with type 2 diabetes. *Diabet Med* 1995;12(5):416-8.
Notes: Quality Reviewed for Medication Analyses.

Cook CM, Edwards C. Success habits of long-term gastric bypass patients. *Obes Surg* 1999;9(1):80-2.
Notes: Quality Reviewed for Surgery Analyses.

Courcoulas A, Perry Y, Buenaventura P, et al . Comparing the outcomes after laparoscopic versus open gastric bypass: a matched paired analysis. *Obes Surg* 2003;13(3):341-6.
Notes: Quality Reviewed for Surgery Analyses.

Crampton NA, Izvornikov V, Stubbs RS. Silastic ring gastric bypass: results in 64 patients. *Obes Surg* 1997;7(6):489-94.
Notes: Quality Reviewed for Surgery Analyses.

Croft H, Houser TL, Jamerson BD, et al. Effect on body weight of bupropion sustained-release in patients with major depression treated for 52 weeks. *Clin Ther* 2002;24(4):662-72.
Notes: Quality Reviewed for Medication Analyses.

Darga LL, Carroll-Michals L, Botsford SJ, et al. Fluoxetine's effect on weight loss in obese subjects. *Am J Clin Nutr* 1991;54(2):321-5.
Notes: Quality Reviewed for Medication Analyses.

Dargent J. Laparoscopic adjustable gastric banding: lessons from the first 500 patients in a single institution. *Obes Surg* 1999;9(5):446-52.
Notes: Quality Reviewed for Surgery Analyses.

Das SK, Roberts SB, Kehayias JJ, et al. Body composition assessment in extreme obesity and after massive weight loss induced by gastric bypass surgery. *Am J Physiol Endocrinol Metab* 2003;284(6):E1080-8.
Notes: Quality Reviewed for Surgery Analyses.

Davidson MH, Hauptman J, DiGirolamo M, et al . Weight control and risk factor reduction in obese subjects treated for 2 years with orlistat: a randomized controlled trial. *JAMA* 1999;281(3):235-42.
Notes: Quality Reviewed for Medication Analyses.

Davila-Cervantes A, Ganci-Cerrud G, Gamino R, et al. Open vs. laparoscopic vertical banded gastroplasty: a case control study with a 1-year follow-up. *Obes Surg* 2000;10(5):409-12.
Notes: Quality Reviewed for Surgery Analyses.

de Csepel J, Nahouraii R, Gagner M. Laparoscopic gastric bypass as a reoperative bariatric surgery for failed open restrictive procedures. *Surg Endosc* 2001;15(4):393-7.
Notes: Quality Reviewed for Surgery Analyses.

De Luca M, de Werra C, Formato A, et al. Laparotomic vs laparoscopic lap-band: 4-year results with early and intermediate complications. *Obes Surg* 2000; 10(3):266-8.
Notes: Quality Reviewed for Surgery Analyses.

de Wit LT, Mathus-Vliegen L, Hey C, et al. Open versus laparoscopic adjustable silicone gastric banding: a prospective randomized trial for treatment of morbid obesity. *Annals of surgery* 1999;230(6):800-5.
Notes: Quality Reviewed for Surgery Analyses.

de Zwaan M, Lancaster KL, Mitchell JE, et al . Health-related quality of life in morbidly obese patients: effect of gastric bypass surgery. *Obes Surg* 2002;12(6):773-80.
Notes: Quality Reviewed for Surgery Analyses.

Deerochanawong Chaicharn. Effect of treatment with orlistat in overweight or obese Thai patients with type 2 diabetes. *Diabetes* 2001;50(Supplement 2):A433.
Notes: Quality Reviewed for Medication Analyses.

DeMaria EJ, Sugerman HJ. A critical look at laparoscopic adjustable silicone gastric banding for surgical treatment of morbid obesity: does it measure up? *Surg Endosc* 2000;14(8):697-9.
Notes: Quality Reviewed for Surgery Analyses.

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Notes: Quality Reviewed for Medication Analyses. Excluded at meta-analysis.

Appendix G

Excluded Studies

Executive summary of the clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults. Arch Intern Med 1998;158(17):1855-67. [Rec#: 545]
Excluded. Topic unrelated.

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Excluded. Topic unrelated.

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Excluded. Subject unrelated.

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Excluded. Not RCT/CCT (medication and surgery), not case report or case series (surgery only).

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Excluded. Duration of treatment < 6 months.

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Excluded. Diet, not reviewed further.

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Excluded. Topic unrelated.

Appendix G

Andersen T, Backer OG, Stokholm K H, et al. Randomized trial of diet and gastroplasty compared with diet alone in morbid obesity. *New England journal of medicine* 1984;310(6):352-6.
Notes: Quality Reviewed for Surgery Analyses. Reports on Diethylproprion; no analysis performed, summary of recent meta-analysis provided.

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Notes: Quality Reviewed for Surgery Analyses. Reports on Diethylproprion; no analysis performed, summary of recent meta-analysis provided.

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Excluded. Diet, not reviewed further.

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Excluded. Topic unrelated.

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Excluded. Sibutramine, not analyzed. Previous meta-analysis reviewed.

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Excluded. Topic unrelated.

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Excluded. Topic unrelated.

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Excluded. Topic unrelated.

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Excluded. Topic unrelated.

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Excluded. Not RCT/CCT (medication and surgery), not case report or case series (surgery only).

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Excluded. Subject unrelated.

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Excluded. Study design, review or meta-analysis.

Appendix G

Ash S, Reeves MM, Yeo S, Morrison G, Carey D, Capra S. Effect of intensive dietetic interventions on weight and glycaemic control in overweight men with Type II diabetes: a randomised trial. *Int J Obes Relat Metab Disord* 2003;27(7):797-802. [Rec#: 974]
Excluded. Subject unrelated.

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Excluded. Subject unrelated.

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Excluded. Subject unrelated.

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Astrup A, <Editors> Herpetz S, Saller B. The role of dietary fat in the prevention and treatment of obesity.Efficacy and safety of low-fat diets. *Int J Obes Relat Metab Disord* 2001;25(Supplement 1):S46-S50. [Rec#: 509]
Excluded. Diet, not reviewed further.

Astrup A, Grunwald GK, Melanson EL, Saris WH, Hill JO. The role of low-fat diets in body weight control: a meta-analysis of ad libitum dietary intervention studies. *Int J Obes Relat Metab Disord* 2000;24(12):1545-52. [Rec#: 830]
Excluded. Diet, not reviewed further.

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Excluded. Diet, not reviewed further.

Astrup A, Toubro S. When, for whom and how to use sibutramine? *Int J Obes Relat Metab Disord* 2001;25 Suppl 4:S2-7. [Rec#: 819]
Excluded. Study design, review or meta-analysis.

Atkinson RL, Greenway F L, Bray G A, Dahms W T, Molitch M E, HamiltonK, et al. Treatment of obesity: comparison of physician and nonphysician therapists using placebo and anorectic drugs in a double-blind trial. *Int J Obes* 1977;1(2):113-20. [Rec#: 261]
Excluded. Mazindol, not reviewed.

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Excluded. Diet, not reviewed further.

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Excluded. Topic unrelated.

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