Meta-Analysis: Surgical Treatment of Obesity

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Background: Controversy exists regarding the effectiveness of surgery for weight loss and the resulting improvement in health-related outcomes.

Purpose: To perform a meta-analysis of effectiveness and adverse events associated with surgical treatment of obesity.

Data Sources: MEDLINE, EMBASE, Cochrane Controlled Trials Register, and systematic reviews.

Study Selection: Randomized, controlled trials; observational studies; and case series reporting on surgical treatment of obesity.

Data Extraction: Information about study design, procedure, population, comorbid conditions, and adverse events.

Data Synthesis: The authors assessed 147 studies. Of these, 89 contributed to the weight loss analysis, 134 contributed to the mortality analysis, and 128 contributed to the complications analysis. The authors identified 1 large, matched cohort analysis that reported greater weight loss with surgery than with medical treatment in individuals with an average body mass index (BMI) of 40 kg/m^2 or greater. Surgery resulted in a weight loss of 20 to 30 kg, which was maintained for up to 10 years and was accompanied by improvements in some comorbid conditions. For BMIs of 35 to 39 kg/m^2, data from case series strongly support superiority of surgery but cannot be considered conclusive. Gastric bypass procedures result in more weight loss than gastroplasty. Bariatric procedures in current use (gastric bypass, laparoscopic adjustable gastric band, vertical banded gastroplasty, and biliopancreatic diversion and switch) have been performed with an overall mortality rate of less than 1%. Adverse events occur in about 20% of cases. A laparoscopic approach results in fewer wound complications than an open approach.

Limitations: Only a few controlled trials were available for analysis. Heterogeneity was seen among studies, and publication bias is possible.

Conclusions: Surgery is more effective than nonsurgical treatment for weight loss and control of some comorbid conditions in patients with a BMI of 40 kg/m^2 or greater. More data are needed to determine the efficacy of surgery relative to nonsurgical therapy for less severely obese people. Procedures differ in efficacy and incidence of complications.

The prevalence of obesity in the United States is reaching epidemic proportions. An estimated 30% of individuals met the criteria for obesity in 1999–2002 (1, 2), and many industrialized countries have seen similar increases. The health consequences of obesity include heart disease, diabetes, hypertension, hyperlipidemia, osteoarthritis, and sleep apnea (3–7). Weight loss of 5% to 10% has been associated with marked reductions in the risk for these chronic diseases and with reducing the incidence of diabetes (8–14).

The increasing numbers of obese individuals have led to intensified interest in surgical treatments to achieve weight loss, and a variety of surgical procedures have been used (**Figure 1**). Bariatric surgery was first performed in 1954 with the introduction of the jejunoileal bypass, which bypasses a large segment of small intestine by connecting proximal small intestine to distal small intestine. With this procedure, weight loss occurs secondary to malabsorption from reduction of upstream pancreatic and biliary contents. However, diarrhea and nutritional deficiencies were common, and this procedure was discontinued because of the complication of irreversible hepatic cirrhosis. With the development of surgical staplers came the introduction of gastroplasty procedures by Gomez in 1981 (15) and Mason in 1982 (16). In these early procedures, the upper portion of the stomach was stapled into a small gastric pouch with an outlet (that is, a stoma) to the remaining distal stomach, which limited the size of the meal and induced early satiety. These procedures were prone to staple-line breakdown or stoma enlargement and were modified in turn by the placement of a band around the stoma (vertical banded gastroplasty).

The first gastric bypass was reported in 1967 by Mason and Ito (17). It combined the creation of a small gastric pouch with bypassing a portion of the upper small intestine. Additional modifications resulted in the Roux-en-Y gastric bypass (RYGB), a now common operation that involves stapling the upper stomach into a 30-mL pouch and creating an outlet to the downstream small intestine. The new food limb joins with the biliopancreatic intestine after a short distance. This procedure, performed laparoscopically or by using an open approach, generates weight loss by limiting gastric capacity, causing mild malabsorption, and inducing hormonal changes. A second

Context

The effectiveness of surgical therapy in the treatment of obesity is unclear.

Contribution

Many published studies of obesity surgery have significant limitations, and case series make up much of the evidence. Evidence is complicated by the heterogeneity of procedures studied. However, surgery can result in substantial amounts of weight loss (20 to 30 kg) for markedly obese individuals. One cohort study documented weight loss for 8 years with associated improvements in comorbid conditions, such as diabetes. Complications of surgery appear to occur in about 20% of patients.

Implications

Those considering surgical treatment for obesity should understand that, although patients who have surgery can lose substantial amounts of weight, the evidence base for these treatments is limited.

–The Editors

common technique, particularly outside of the United States, is the laparoscopic adjustable gastric band. This device is positioned around the uppermost portion of the stomach and can be adjusted to allow tailoring of the stoma outlet, which controls the rate of emptying of the pouch and meal capacity. Another procedure, preferred by a number of surgeons, is the biliopancreatic bypass, which combines a limited gastrectomy with a long Roux limb intestinal bypass that creates a small common channel (that is, an intestine where food and biliopancreatic contents mix). This procedure can be combined with a duodenal switch, which maintains continuity of the proximal duodenum with the stomach and uses a long limb Roux-en-Y bypass to create a short common distal channel. These latter 2 procedures generate weight loss primarily through malabsorption.

Recent worldwide survey data from 2002 and 2003 show that gastric bypass is the most commonly performed weight loss procedure (65.1%) (18). Slightly more than half of gastric bypasses are done laparoscopically. Overall, 24% of cases are laparoscopic adjustable band procedures; 5.4% are vertical banded gastroplasties; and 4.9% are biliopancreatic diversion, with or without the duodenal switch. In California, the number of bariatric cases increased 6-fold between 1996 and 2000 (19), from 1131 cases to 6304; an estimated 140 000 procedures were performed in the United States in 2004. With this escalation in the number of procedures, there have been reports of high postoperative complication rates (20–24).

Because of these reports and the increasing use of obesity surgery, we were asked to review the literature to estimate the effectiveness of bariatric surgery relative to nonsurgical therapy for weight loss and reduction in preoperative obesity-related comorbid conditions. We were also asked to compare outcomes of surgical techniques. This paper is part of a larger evidence report titled "Pharmacological and Surgical Treatment of Obesity," which was prepared for the Agency for Healthcare Research and Quality and is available at www.ncbi.nlm.nih.gov/books/bv .fcgi?rid=hstat1a.chapter.19289.

METHODS

Literature Search and Selection

We began with an electronic search of MEDLINE on 16 October 2002, followed by a search of EMBASE and subsequent periodic search updates (on 22 May, 2 June, 12 June, and 3 July 2003). We also assessed existing reviews of surgical therapy for obesity (10, 25, 26). Three reviewers independently reviewed the studies, abstracted data, and resolved disagreements by consensus (2 reviewers per study). The principal investigator settled any unresolved disagreements.

We focused on studies that assessed surgery and used a concurrent comparison group. This category includes randomized, controlled trials (RCTs); controlled clinical trials; and cohort studies. A brief scan of the literature showed that these types of studies were rare. Therefore, we also elected to include case series with 10 or more patients, since these studies can be used to assess adverse events and could potentially augment the efficacy data from comparative studies. Publication bias is one potential limitation of analyzing the available literature because poor or negative results are not as likely to be reported as are successes or positive results.

Extraction of Study-Level Variables

We abstracted data from the articles, including number of patients and comorbid conditions, adverse events, types of outcome measures, and time from intervention until outcome. Detailed data were also collected on characteristics of the study samples, including median age, percentage of women, median baseline weight (in kilograms or body mass index [BMI]), percentage of patients with comorbid conditions at baseline (diabetes, hypertension, dyslipidemia, and sleep apnea), percentage of improvement or resolution of preexisting comorbid conditions, and median follow-up time. We also recorded whether the case series studies reported on consecutive patients.

Choice of Outcomes

The main outcomes of interest were weight loss, mortality, complication rates, and control of obesity-related comorbid conditions. We used the most commonly reported measurement of weight loss, that is, kilograms, which allowed us to include the greatest number of studies. Among 111 surgical studies reporting weight loss, 43 reported weight loss in kilograms or pounds, 17 reported excess weight loss or some variant, 46 reported both of these outcomes, and 5 reported neither. A total of 89 stud-

ies had sufficient data to be included in the weight loss analysis. Because weight loss achieves health benefits primarily by reducing the incidence or severity of weight-related comorbid conditions, we also compared the effects on these outcomes. Quality of life, an important outcome in assessing tradeoffs between benefits and risks, was reported infrequently.

Statistical Analyses

Because we included both comparative studies and case series, we conducted several types of analyses. The vast number of types of surgical procedures and technical variations required that we aggregate those that were clinically similar and identify the comparisons that were of most interest to the clinical audience. On the basis of discussions with bariatric surgeons, we categorized obesity surgery procedures by procedure type (for example, gastric bypass, vertical banded gastroplasty), laparoscopic or open approach, and specific surgical details such as length of Roux limb (see the larger evidence report for details).

Analysis of the Efficacy of Surgical Weight Loss

We extracted the mean weight loss and standard deviation at 12 postoperative months and at the maximum follow-up time ($\geq$36 months). These times were chosen because they are clinically relevant and are most commonly reported. Of the 89 weight loss studies, 71 reported baseline BMI (average, 47.1 kg/m^2), 16 reported baseline weight in kilograms or pounds (average, 123.3 kg), and 2 did not report either. The average age of patients was 38 years, and more than three quarters were women.
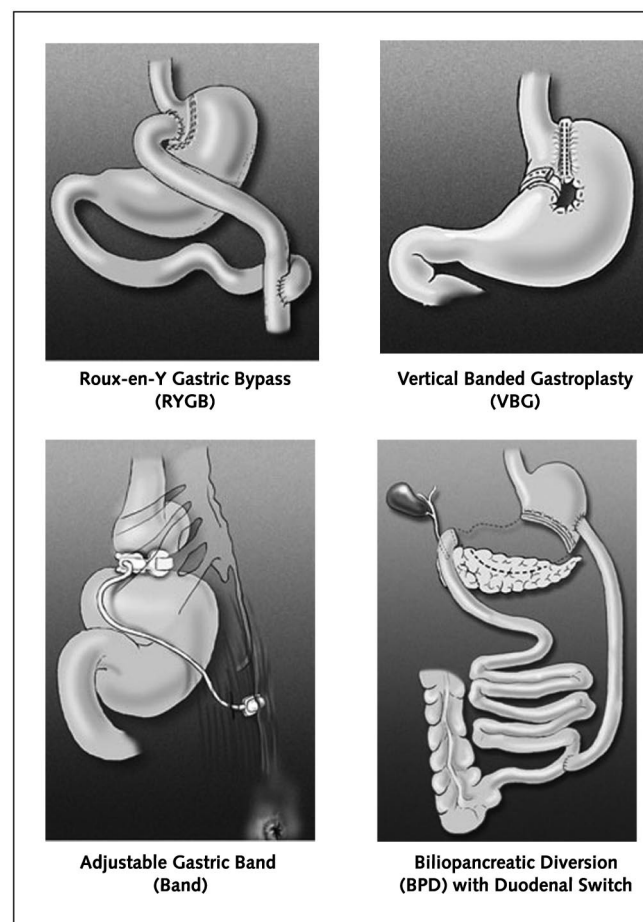
For comparative studies that reported a within-study comparison of 2 procedures, a mean difference was calculated. Mean differences were pooled by using a random-effects model, and 95% CIs were estimated; the same method was used to determine a pooled mean weight loss for each group considering all studies combined. However, mean difference in weight loss was not calculated.

Analysis of Surgery Mortality

We recorded the number of deaths observed and the total number of patients in each procedure group. If the study self-identified the deaths as "early" or "postoperative" or as occurring 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 occurring after 30 days, we termed them *late deaths*. If the study was unclear as to the timing of the recorded deaths, we termed them *unclear deaths* and combined them with early deaths for the analysis. If a study did not report data on death for a group, we recorded zero unclear deaths for that group. 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, we analyzed 4 separate combinations of death definition and type of study: late deaths for RCTs and controlled clinical trials, late deaths for case series, early or unclear deaths for RCTs and controlled clinical trials, and early or unclear deaths for

Figure 1. Surgical procedures.

Roux-en-Y Gastric Bypass (RYGB)

Vertical Banded Gastroplasty (VBG)

Adjustable Gastric Band (Band)

Biliopancreatic Diversion (BPD) with Duodenal Switch

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case series. We calculated the crude death rate by dividing the total number of deaths observed by the total number of patients in the relevant group. Two-sided 95% CIs were calculated for all mortality rates, except where the rate was found to be zero; in these cases, a 1-sided 97.5% CI was used.

Analysis of Surgery Comorbidity

Data for diabetes, hypertension, dyslipidemia, and sleep apnea were extracted. We chose these subjects in consultation with bariatric experts because they are regarded as 4 of the most important health outcomes following obesity surgery. We collected data on the number of individuals who had these conditions at the start of the study and the number in whom the conditions resolved, improved, or remained unchanged (this being the level of detail most commonly found in case series of surgery). One hundred fourteen case series were reviewed for the 4 comorbid conditions. A crude proportion was calculated across studies (for example, the number of individuals in whom the condition resolved or improved divided by the number of people with the condition at baseline). A summary of the collective case series data found that 71% reported on

Figure 2. **Literature flow.**
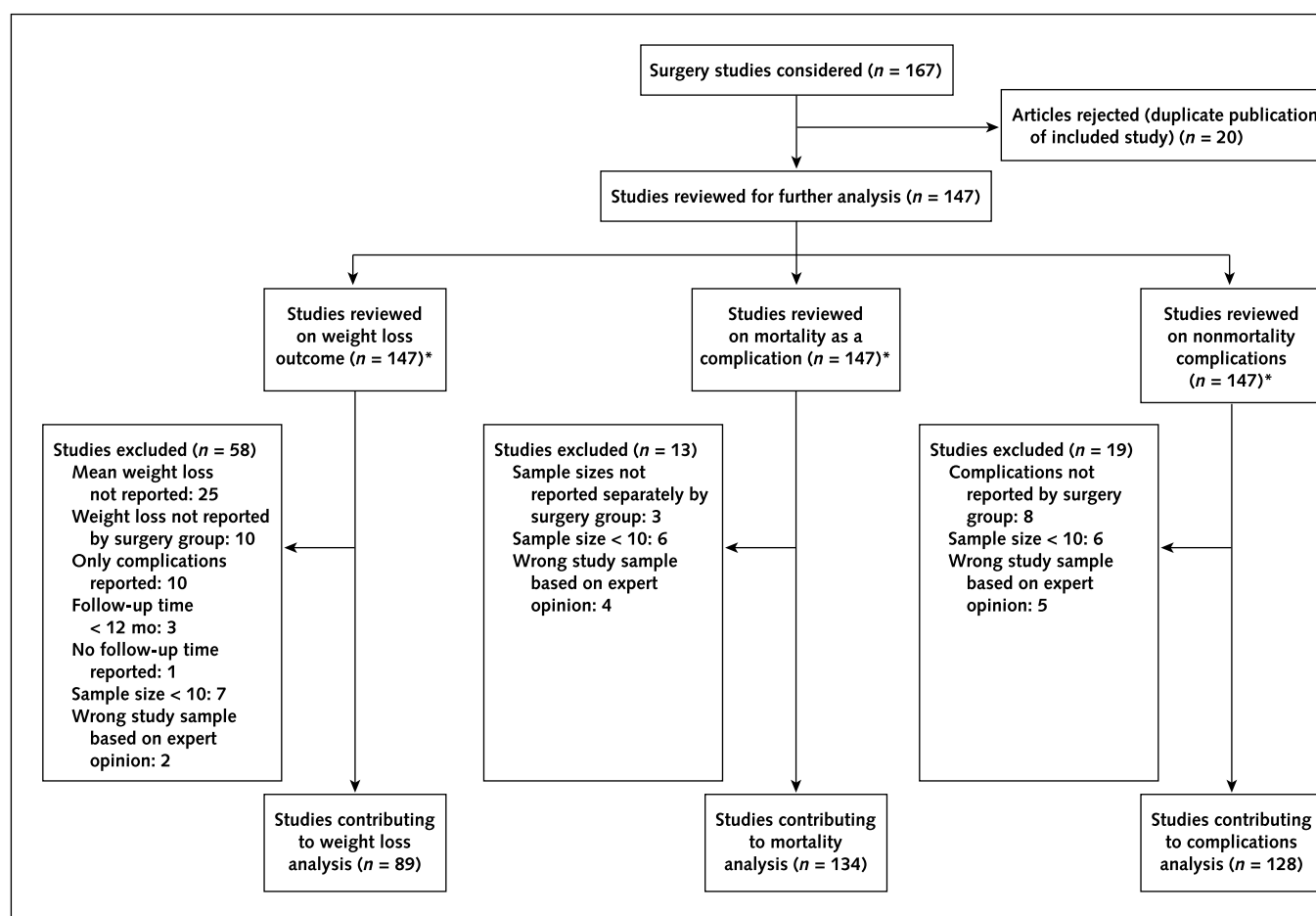
consecutive surgical patients. In addition, the baseline population of patients in the case series studies was similar to that in the controlled trials (82.7% women; mean age, 38.1 years; mean BMI, 46.8 kg/m^2; mean follow-up, 38.7 months).

Role of the Funding Source

The funding source had no role in the design or conduct of this study or in reporting the results.

Analysis of Adverse Events Associated with Surgery

Each study was examined to determine whether it reported data on adverse events other than death. We abstracted the number of events or the number of people. Most studies recorded the number of people who experienced the event, so each event was counted as if it represented a unique individual. Because an individual might have experienced more than 1 event, this assumption may have overestimated the number of people having an adverse event. We did not assume zero events occurred unless the trial report specifically stated so.

We identified mutually exclusive subgroups of similar events on the basis of clinical expertise. For example, one subgroup was "respiratory, all," consisting of all adverse events concerning the respiratory system. We again treated all observed events as having occurred in unique individuals.

For selected surgery comparisons where data from RCTs and controlled clinical trials were available, we estimated a pooled odds ratio and 95% CI using exact methods. We also report the crude adverse event rate for each RCT/controlled clinical trial group by procedure and for each group across all studies combined.

RESULTS

Our search (which also concerned pharmacotherapy and dietary therapy) identified 1103 articles (**Figure 2**). Of the 1064 articles screened, we reviewed 159 surgery studies reporting on weight loss and considered an additional 8 studies reporting only on complications, for a total of 167 studies. Of these, 20 were duplicate or additional publications of an already included study. Of the remaining 147 studies, 89 ultimately contributed to the weight loss analysis, 134 to the mortality analysis, and 128 to the complications analysis. Studies could contribute to 1 or more analyses. Sixty of the weight loss studies had follow-up of

Table 1. Pooled Results for Controlled Trials of Weight Loss following Bariatric Surgery*

Procedure	12-Month Follow-up				≥36-Month Follow-up			
	Weight Loss, kg	Mean Difference (95% CI), kg	Trials, n	Patients, n	Weight Loss, kg	Mean Difference (95% CI), kg	Trials, n	Patients, n
RYGB (all) vs. VBG (all)	42.43 vs. 34.45	7.97 (2.99 to 12.96)	2	114 vs. 117	39.73 vs. 30.65	9.29 (1.61 to 16.96)	2	103 vs. 96
RYGB (open) vs. RYGB (lap)	34.35 vs. 37.00	−2.64 (−11.28 to 6.00)	1	21 vs. 30	NR	NR	0	NR
VBG (all) vs. adjustable gastric banding (all)	38.58 vs. 24.20	14.41 (9.39 to 19.42)	2	71 vs. 76	35.51 vs. 32.97	2.79 (−16.63 to 22.21)	2	64 vs. 60

* Includes controlled trials comparing one procedure with another. lap = laparoscopic; NR = not reported; RYGB = Roux-en-Y gastric bypass; VBG = vertical banded gastroplasty.

greater than or equal to 24 months, with a median follow-up of 36 months. Detailed evidence from all studies included in the analysis is shown in **Appendix Tables 1** and **2** (available at www.annals.org).

Benefits of Surgery for Weight Loss

Weight Loss and Maintenance

We identified 2 RCTs that compared bariatric surgery with a nonsurgically treated control group. The first RCT compared horizontal gastroplasty and diet with diet alone (27–29). This RCT generated 3 articles that reported net weight loss at 6 months (27), 24 months (28), and 5 years (29). At 6 months, weight loss did not differ between the 2 groups, but at 24 months of follow-up, the net weight change from baseline greatly favored surgical therapy (30.5 kg vs. 8.0 kg for surgical and nonsurgical therapy, respectively). We also identified another RCT that compared jejunoileal bypass with "medical treatment" (otherwise unspecified) in 196 patients (30). At 24 months of follow-up, the mean difference in weight loss greatly favored surgical therapy (mean difference, 37 kg). These studies were conducted more than 20 years ago and assessed procedures that are not currently considered relevant.

In addition to the 2 RCTs, we identified numerous reports from the observational Swedish Obese Subjects (SOS) study (31–42). In the intervention portion of this study, obese adults (BMI, ≥34 kg/m^2 for men and ≥38 kg/m^2 for women) were assessed in 2 groups: those who voluntarily underwent bariatric surgery and a group of matched controls treated medically. Matching was done on 18 variables, including sex, age, height, and weight, and controls were selected to match the means of the variables between groups. The average age of enrolled patients was 47 years. Two thirds were women, and the average baseline BMI was 41 kg/m^2.

At 8 years of follow-up from the SOS study, average weight loss was 20 kg among 251 surgically treated patients, but average weight did not change among 232 medically treated patients. Patients treated with RYGB lost more weight than those treated with vertical banded gastroplasty or banding procedures (32). The SOS study recently reported 10-year follow-up data on 1703 patients and found that those treated with surgery had significantly better weight loss than controls (16.1% decrease vs. 1.6% increase; *P* < 0.001). Patients receiving gastric bypass lost

more weight than those treated with banding procedures or vertical banded gastroplasty (42). The SOS study also reported some results for persons with a BMI of 40 kg/m^2 or greater compared with those who had a BMI less than 40 kg/m^2; however, the results are presented in insufficient detail to draw firm conclusions (41).

Recently, a third RCT comparing surgery with medical treatment has been presented in abstract form (43). According to the abstract, 79 patients with mild to moderate obesity (BMI, 30 to 35 kg/m^2) were randomly assigned to laparoscopic adjustable band surgery or medical therapy (very-low-calorie diet, pharmacotherapy, and exercise). Weight loss outcomes at 2 years were reported as 71.5% excess body weight for the surgical group and 21.4% for the medical group (*P* < 0.001). The abstract did not provide enough additional details to evaluate the internal validity and generalizability; this assessment awaits publication of the full results.

Comorbid Conditions

A series of reports from the SOS study support the superiority of obesity surgery compared with medical therapy in ameliorating or preventing some obesity-related comorbid conditions. At 24 months after surgery, among 845 surgically treated patients and 845 matched controls, the incidence of hypertension, diabetes, and lipid abnormalities was markedly lower in the surgery group (adjusted odds ratios, 0.02 to 0.38) (33). At 8 years, 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) (32). However, significant decreases in both systolic (8.3 mm Hg) and diastolic (6.7 mm Hg) blood pressure persisted in the small (6%) subset of patients who underwent gastric bypass and lost significantly more weight compared with the 94% of patients who underwent vertical banded gastroplasty or gastric banding (31). The recent report of 10-year outcomes (42) in the SOS study found marked benefits favoring surgery for incidence and recovery from diabetes, hyperuricemia, and some lipid abnormalities. Additional reports from the SOS study support a substantial benefit of surgery in reducing sleep apnea (34) and improving symptoms of dyspnea and chest pain (34). Also of note, the SOS study found a significant improvement in quality of life

Figure 3. **Weight loss by procedure.**
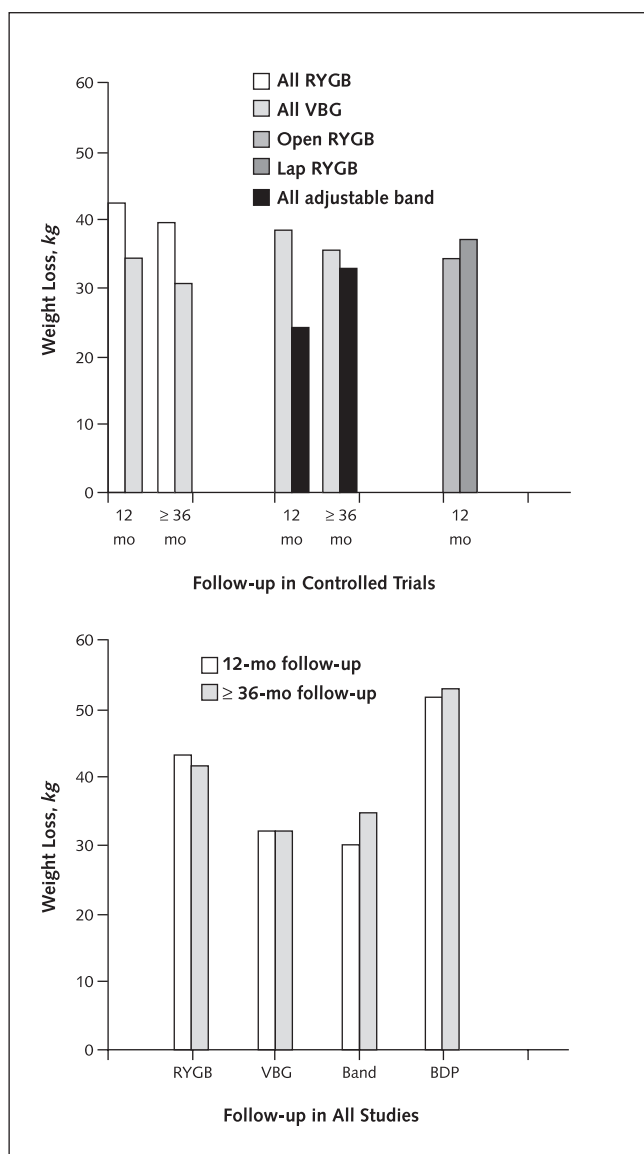
Lap = laparoscopic; RYGB = Roux-en-Y gastric bypass; VBG = vertical banded gastroplasty.

among patients who had had obesity surgery but not among those in the nonsurgical cohort (37). Differences were related to the degree of weight loss. The SOS study was the only one identified that compared comorbid conditions between surgically treated patients and a concurrent nonsurgical control group.

As our paper was being revised, a new matched cohort study by Christou and colleagues (44) was published that compared 1035 patients undergoing bariatric surgery (mean age, 45 years; 66% women; initial BMI, 50 kg/m²) with 5746 controls matched on 3 variables: first diagnosis of morbid obesity, age, and sex. The study reported that at 2 years of follow-up, 6.17% of controls but only 0.68% of surgery patients had died (including a 0.4% perioperative death rate). The 10-year follow-up of patients in the SOS

study did not report a statistically significant mortality benefit favoring surgery or medical therapy, but the investigators stated that "the study is ongoing with respect to mortality" (42).

We assessed reports of case series for data on the control of 4 comorbid conditions: diabetes, hypertension, dyslipidemia, and sleep apnea. Of the 114 case series, 21 reported quantitative information on the control of diabetes. The proportion of patients who had preoperative diabetes (median, 11% [range, 3% to 100%]) and showed improvement or resolution of diabetes after surgery ranged from 64% to 100% (median, 100%). For hypertension, among the 19 papers that reported results, 38% (range, 16% to 83%) of patients had hypertension preoperatively. Of these patients, 25% to 100% (median, 89%) showed improvement or resolution of hypertension. The range of improvement was 95% to 100% (median, 100%). In 11 studies that reported on dyslipidemia, 32% (range, 3% to 65%) had this disorder at baseline and 60% to 100% (median, 88%) reported improvement or resolution of dyslipidemia following surgery. In the 14 studies that reported results for sleep apnea, 15% (range, 2% to 50%) of patients had this condition preoperatively. These reported improvements are substantial and suggest that surgery helps relieve the burden of comorbid conditions. 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 not assessed in this report, improvements in cardiac dysfunction (38, 45–47), gastroesophageal reflux (48–53), pseudotumor cerebri (54, 55), the polycystic ovary syndrome (56), complications of pregnancy (57–59), stress urinary incontinence (60), degenerative joint disease (61, 62), severe venous stasis disease (63), nonalcoholic hepatitic steatosis (64–66), and overall quality of life (67–77) have been reported in some case series of obesity surgery. As mentioned, a cause-and-effect relationship cannot be conclusively proven from case series data alone.

Comparing Weight Loss among Surgical Procedures

We also identified several RCTs and case series that compared weight loss between or among surgical procedures. Results from controlled trials at 12 months and 36 months (or longer) are summarized in **Table 1** and **Figure 3**. Results from all studies, which are mostly case series studies, are summarized in **Table 2** and **Figure 3**. The case series are limited by incomplete reporting of data that are crucial to an understanding of their validity. One quarter of studies did not state whether consecutive patients were studied, and fewer than half reported the proportion of original patients contributing data to the outcome at follow-up. For these reasons, we do not draw conclusions

Table 2. **Pooled Results for All Studies on Weight Loss following Bariatric Surgery***

Procedure	12-Month Follow-up		≥36-Month Follow-up	
	Weight Loss (95% CI), *kg*	Studies/Patients, *n/n*	Weight Loss (95% CI), *kg*	Studies/Patients, *n/n*
RYGB (all)	43.46 (41.24–43.46)	32/2937	41.46 (37.36–45.56)	21/1281
RYGB (open)	43.89 (41.09–46.69)	25/2074	41.58 (37.38–45.78)	20/1266
RYGB (lap)	42.17 (38.95–45.38)	10/863	38.32 (28.04–48.60)	1/15
VBG (all)	32.16 (29.92–34.41)	21/2080	32.03 (27.67–36.38)	18/1877
Adjustable gastric banding (all)	30.19 (27.95–32.42)	27/5562	34.77 (29.47–40.07)	17/3076
BPD (all)	51.93 (45.10–58.75)	3/735	53.10 (47.36–58.84)	1/50

* Includes all controlled trials and case series. BPD = biliopancreatic diversion; lap = laparoscopic; RYGB = Roux-en-Y gastric bypass; VBG = vertical banded gastroplasty.

from "all studies" data but rather compare these findings with those available from clinical trials.

Five RCTs compared surgical procedures and reported data sufficient for pooling. In 2 studies comparing RYGB procedures with vertical banded gastroplasty (78, 79) and involving 231 patients, pooled weight loss outcomes for both procedures were substantial (≥30 kg at 36 months for both) and favored RYGB at both 12 and 36 months (8 and 9 kg of additional weight lost). These results are supported by the pooled results from all studies combined (both RCTs and case series), which report data on more than 2000 patients for each procedure. These combined data indicate that at both 12 and 36 months, patients who had RYGB reported about 10 kg more weight loss than patients treated with vertical banded gastroplasty. Several additional RCTs compared RYGB and other gastric bypass procedures with vertical banded gastroplasty or other gastric partitioning procedures (80–84), but the results could not be included in our pooled analysis because they were not reported in terms of kilograms of weight lost or were not reported in sufficient statistical detail. Nevertheless, the results of all of these studies support the conclusion that gastric bypass produces weight loss superior to that produced by gastroplasty procedures. In 2 other RCTs, the weight lost using vertical banded gastroplasty compared with laparoscopic adjustable gastric banding was 14 kg more at 12 months of follow-up but only about 3 kg more at 36 months of follow-up. In contrast to these results, the

net weight loss observed in the pooled results from all studies combined was about the same at both 12 months and longer follow-up for vertical banded gastroplasty and adjustable band procedures.

Finally, 1 RCT compared open and laparoscopic RYGB (85) and found no significant differences (≥30 kg for both at 12 months). Of note, although we identified 2 other RCTs comparing open and laparoscopic RYGB, their data could not be included in the formal weight loss analysis, either because of how weight loss was reported or because duration of follow-up was inadequate. However, neither study found statistical difference in weight loss between the 2 surgical approaches. This result was supported by the "all studies" pooled analysis at both 12 months and up to 36 months.

Risks of Surgery for Weight Loss

Our findings for operative mortality are presented in **Table 3.** The early mortality rate for RYGB was 1.0% (95% CI, 0.5% to 1.9%) in controlled trials and 0.3% (CI, 0.2% to 0.4%) for case series data. Adjustable gastric banding had an associated early mortality rate of 0.4% (CI, 0.01% to 2.1%) for controlled trials and 0.02% (97.5% CI, 0% to 0.78%) for case series data. No statistically significant differences in mortality were seen among procedures, and no differences were seen in terms of higher or lower early mortality rates in RCTs compared with case series. Early mortality rates following bariatric surgery were

Table 3. **Mortality Analysis for Surgical Procedures***

Procedure	Early or Time-Unspecified Deaths†				Late Deaths‡			
	Controlled Trials		Case Series		Controlled Trials		Case Series	
	Mortality Rate, %	Studies/Patients, *n/n*	Mortality Rate, %	Studies/Patients, *n/n*	Mortality Rate, %	Studies/Patients, *n/n*	Mortality Rate, %	Studies/Patients, *n/n*
RYGB	1.0 (0.5–1.9)	15/907	0.3 (0.2–0.4)	50/11 290	1.1 (0.4–2.5)	9/524	0.6 (0.4–0.8)	24/5411
VBG	0.2 (0–1.4)§	11/401	0.3 (0.1–0.5)	33/4091	0.0 (0–16.8)§	1/20	0.6 (0.4–1.0)	20/2638
Adjustable gastric banding	0.4 (0.01–2.1)	6/268	0.02 (0–0.78)§	35/9222	NR	0/0	0.1 (0.02–0.2)	11/3975
BPD	NR	0/0	0.9 (0.5–1.3)	7/2808	NR	0/0	0.3 (0.01–0.6)	4/2362

* Values in parentheses are 95% CIs unless otherwise indicated. BPD = biliopancreatic diversion; NR = not reported; RYGB = Roux-en-Y gastric bypass; VBG = vertical banded gastroplasty.
† Early = ≤30 days from procedure, or designated "early" in the original report.
‡ Late = >30 days from procedure, or designated "late" in the original report.
§ One-sided 97.5% CI.

Table 4. **Pooled Results from All Studies for Postoperative Adverse Events by Bariatric Procedure***

Procedure	GI Symptoms, All†		Reflux		Vomiting		Nutritional and Electrolyte Abnormalities‡		Surgical, Preventable and Not Preventable§	
	Adverse Events, %	Studies/ Patients, n/n	Adverse Events, %	Studies/ Patients, n/n	Adverse Events, %	Studies/ Patients, n/n	Adverse Events, %	Studies/ Patients, n/n	Adverse Events, %	Studies/ Patients, n/n
RYBG	16.9	34/7374	10.9	3/727	15.7	8/1324	16.9	10/2088	18.7	49/10 088
VBG	17.5	21/1692	2.2	7/823	18.4	10/1177	2.5	4/397	23.7	34/3247
Adjustable gastric banding	7.0	17/3400	4.7	4/485	2.5	4/562	NR	0/0	13.2	34/8846
BPD	37.7	1/305	NR	0/0	5.9	1/305	NR	0/0	5.9	5/2663

* Seventy trials of RYGB, 48 trials of VBG, 41 trials of adjustable gastric banding, and 7 trials of BPD were considered for analysis by procedure. BPD = biliopancreatic diversion; GI = gastrointestinal; NR = not reported; RYGB = Roux-en-Y gastric bypass; VBG = vertical banded gastroplasty.
† Including reflux, vomiting, dysphagia, dumping syndrome, and others.
‡ Including mineral, vitamin, and protein deficiencies.
§ Including anastomotic, stoma-related, bleeding, reoperation, wound, and others.
‖ Including those related to anastomosis, band, bleeding, revision, and others.
¶ Including cardiac, stroke, or severe hypertension.

1% or less in these published controlled trials and case series data (which came from a specific clinic or surgeon performing procedures on patients enrolled in a research study).

Recently, there have been several assessments of 30-day or inpatient mortality rates in unselected patients. In 2004, Flum and Dellinger (86) reported on one of the largest of such studies. In more than 3328 procedures performed in the state of Washington between 1987 and 2001, the 30-day mortality rate was 1.9%, as assessed by using administrative data (86). In addition, in 2003, Liu reported on data from the California inpatient database and found that among 16 232 gastric bypass cases, the in-hospital mortality rate was 0.3% (19). Courcoulas and associates (20) examined administrative data from Pennsylvania and found that the in-hospital mortality rate was 0.6% in 4685 patients who had had gastric bypass.

Reports of adverse events other than mortality varied among studies. We aggregated these reports by using clinical judgment. The pooled results from 5 controlled trials comparing RYGB with vertical banded gastroplasty, which involved a few hundred patients, did not yield any statistically significant differences between rates of adverse events (**Appendix Table 3**, available at www.annals.org). However, the 95% CIs were wide, meaning we can neither conclude that clinically important differences exist nor exclude that possibility. **Table 4** presents the results from all studies, which are mostly case series. These data do not support strong conclusions. The absolute rates of some complications are substantial, although many may be minor in severity. Some differences among procedures in the proportions of patients with different adverse events are compatible with the anatomic changes caused by the procedure. For example, nutritional and electrolyte abnormalities are reported by almost 17% of patients treated with RYGB but by fewer than 3% of patients treated with vertical banded gastroplasty. At a minimum, these data indi-

cate that the proportion of patients with adverse events may be approximately 10% to 20% (although most of the events may be mild) and that the occurrence may differ among procedures in clinically important ways.

Table 5 presents our comparisons of adverse events for all bariatric procedures performed with an open or laparoscopic approach. In contrast to previous data presented in this report, **Table 5** includes several comparisons that have a statistically significant or prima facie difference between procedures favoring laparoscopic approaches: all wounds, major wound infection, minor wound infection, and incisional hernia. However, reoperations were more common in patients who had laparoscopic procedures. Data are insufficient to reach conclusions about differences in other complications. **Appendix Table 4** (available at www.annals.org) shows all studies that reported outcomes according to open or laparoscopic approaches.

Several studies have reported that a significant learning curve is associated with these surgical techniques. Flum and Dellinger (86), using administrative data from the state of Washington (1987–2001), reported that surgeons who had performed fewer than 20 procedures had a patient mortality rate of 6% compared with rates near 0% for those who had performed more than 250 procedures. Schauer (87) reported an anastomotic leak rate of 10% following laparoscopic RYGB in the first 50 procedures and 0% in the subsequent 100 to 150 procedures. Wittgrove and Clark (88) reported a 3% leak rate in the first 300 procedures and a 1% rate thereafter. Higa and colleagues (89) reported in 2000 that operative time for laparoscopic gastric bypass stabilized after 150 procedures, and Suter and colleagues (23) reported major complication rates of 12.5% for the first two thirds of procedures and 2.7% for the last third. Although 4 of these 5 studies are case series, they support the existence of a technical learning curve. Of note, some of these studies reported on surgeons who were instrumental in developing these tech-

Table 4—**Continued**

Anastomotic, Gastric Pouch or Duodenal Leak		Anastomotic or Stomal Stenosis		Bleeding		Reoperation‖		Medical¶	
Adverse Events, %	Trials/ Patients, n/n	Adverse Events, %	Trials/ Patients, n/n	Adverse Events, %	Trials/ Patients, n/n	Adverse Events, %	Trials/ Patients, n/n	Adverse Events, %	Trials/ Patients, n/n
2.2	30/5645	4.6	27/6078	2.0	19/5026	1.6	9/4356	4.8	5/2161
1.0	14/1456	6.0	16/1696	0.7	6/1027	11.3	7/520	4.7	2/473
NR	0/0	NR	0/0	0.3	6/2844	7.7	11/2140	0.7	1/150
1.8	4/2358	NR	0/0	0.2	2/1617	4.2	2/1101	NR	0/0

niques. It is possible that the potential learning curve for surgeons currently being trained will be lower because the details of the procedures have become optimized. In addition, the potentially higher complication rates of low-volume surgeons may not be represented in the literature because poor results are less likely to be reported or published.

Use of Bariatric Surgery in Adolescents and Children

We attempted to identify studies that reported data specific to adolescents (those 13 to 17 years of age) and children (those ≤12 years of age). Too few studies were identified to permit quantitative analysis. Our literature search identified 12 papers that reported weight loss after bariatric surgery in adolescents. In total, these case series report on 172 patients and document benefits in terms of weight loss and resolution of complications and harms in terms of surgical complications. No studies have compared these benefits and harms with those seen among similar patients who received nonsurgical therapies such as diet or medication. It is unclear whether extrapolation of adult

Table 5. **Pooled Results from Controlled Trials of Postoperative Adverse Events following Bariatric Procedures***

Adverse Event and Type of Procedure	Adverse Event Rate, %	Odds Ratio (95% CI)	Trials, n	Patients, n
Respiratory (including pneumonia, atelectasis, and respiratory insufficiency) Open vs. laparoscopic	3.0 vs. 1.9	1.54 (0.17–19.42)	2	101 vs. 104
Surgical, preventable and not preventable (including wound, hernia, splenic injury, repeated operation, anastomotic events, and others) Open vs. laparoscopic	31.1 vs. 26.1	1.32 (0.72–2.43)	3	122 vs. 134
Wound, all Open vs. laparoscopic	13.1 vs. 0.0	Not estimable	3	122 vs. 134
Wound infection, major Open vs. laparoscopic	3.0 vs. 0.0	Not estimable	2	101 vs. 104
Wound infection, minor Open vs. laparoscopic	14.3 vs. 0.0	Not estimable	1	21 vs. 30
Incisional hernia Open vs. laparoscopic	8.2 vs. 0.0	Not estimable	3	122 vs. 134
Internal hernia Open vs. laparoscopic	0.0 vs. 1.3	0.00 (0.00–40.40)	1	76 vs. 79
Reoperation Open vs. laparoscopic	0.0 vs. 4.0	0.00 (0.00–38.94)	1	25 vs. 25
DVT, PE, or both Open vs. laparoscopic	1.0 vs. 0.9	1.22 (0.02–96.69)	2	97 vs. 109

* DVT = deep venous thrombosis; PE = pulmonary embolism.

data for bariatric surgery to the pediatric population is appropriate.

DISCUSSION

When considering the evidence on surgical treatment of obesity, we required statistically and clinically significant within-study comparisons of outcomes to judge whether a treatment showed conclusive evidence of effect. To confidently draw cause-and-effect conclusions between treatment and outcome when assessing a difference between 2 groups receiving different treatments, we need to be sure 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 with the possibility that pretreatment differences between groups might explain the outcome differences. If a large number of patients are randomly assigned to groups, the 2 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 could account for the differences in outcome.

Considering this, the data we identified show that surgical treatment for obesity in severely obese individuals (BMI $\geq$ 40 kg/m^2) results in greater weight loss than does medical treatment. Surgical treatment results in 20 to 30 kg of weight loss that is maintained up to 10 years and longer and is accompanied by significant improvements in several comorbid conditions. For patients with BMIs between 35 and 39 kg/m^2, data strongly support the superiority of surgical therapy. However, these data cannot be considered conclusive in the absence of a study with a concurrent comparison group. No evidence from controlled trials points to a benefit or proof of lack of benefit for mortality rates in surgical versus medical therapy for obesity.

Further supporting the superiority of surgical therapy in patients with a BMI of at least 40 kg/m^2 is the observation that weight loss reported with surgical therapy is an order of magnitude greater than that reported in pharmaceutical or diet studies of obesity (20 to 40 kg vs. 2 to 5 kg at 1 or 2 years). However, direct comparisons cannot be made because the patient samples are clearly different. Surgical studies enrolled patients who are severely obese, whereas the average BMI in the medical weight loss studies was about 33 kg/m^2. In addition, many studies of surgical therapy report sustained weight loss (that is, at $\geq$24 months), whereas studies of medical weight loss therapies

that report data beyond 12 months are rare and tend to report regain of most initial weight lost. However, patients and clinicians should not erroneously assume that patients can resume their previous eating habits after undergoing a surgical procedure. Substantial changes in diet are reinforced by the nature of the surgery (with the exception of some strictly malabsorptive procedures) and are necessary to maintain long-term weight loss. Recently, another group independently reported a meta-analysis of mostly case series data on obesity surgery (90). The findings were similar to ours with respect to weight loss, control of comorbid conditions, and perioperative mortality, but the group did not assess adverse events other than death (90).

The existing literature is almost bereft of data (outside of case series reports) on 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. Given the increasing rate of obesity in adolescent and pediatric populations, more data about the relative efficacy of treatments are urgently needed. Conducting an RCT of surgery in the adolescent population is feasible. Such a study would go a long way toward establishing the role of surgery in this patient population.

The primary limitation of this review, similar to most other systematic reviews, is the quality of the original studies. To date, no complete report of an RCT comparing modern medical to modern surgical treatment for obesity has been published. We based many of our conclusions on the SOS study, which was observational. As we discussed previously, where the SOS study reported very large differences in outcomes between groups, we judged it more likely that these differences were due to differences in treatment than to differences in unmeasured variables between groups at baseline. Where the differences in outcomes between groups were smaller, we are less confident that these observations are due to the differences in treatment. We believe that much can be concluded from well-conducted observational studies, but we also acknowledge their limitations. One outcome likely to be influenced by the selection bias unavoidable in observational studies is quality of life. Persons who feel that being overweight has a greater impact on their quality of life may be more likely than other persons to consider surgical treatment and consequently report greater improvements in quality of life after successful surgery. Therefore, observational study data do not support definitive conclusions about the effect of obesity surgery on quality of life. Another limitation of the available data is insufficient statistical power to detect differences, should they really exist. Lack of evidence indicating a difference is not the same as evidence indicating that there is no difference. Last, publication bias may be skewing the results toward showing a greater benefit for both surgical and medical treatment because studies with negative results may not have been published.

In conclusion, surgical treatment is more effective than

nonsurgical treatment for weight loss and the control of some comorbid conditions in patients with BMIs of 40 kg/m^2 or greater. For patients with BMIs of 35 to 39 kg/m^2, we do not regard the existing published data as conclusive because they are derived from case series without a concurrent comparison group. More data are needed to confirm or refute the relative efficacy of surgery for less severely obese persons. One of the common issues facing the internist or surgeon with regard to the surgical treatment of obesity lies with the selection of the procedure (for example, RYGB vs. laparoscopic adjustable band) that will offer the greatest benefit for a particular patient type (age, sex, BMI, or comorbidity profile). Controlled trials or well-matched observational studies are needed to address these procedures' effectiveness, comparable ability to generate sustainable weight loss, complication rates, reduction in comorbid conditions, and improvement in quality of life for a particular patient profile. Last, researchers must seek to characterize, understand, and reduce the variation in operative adverse events so that appropriately selected patients can achieve the full benefit from bariatric surgery.

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Appendix Table 1. **Evidence Table for Controlled Trials of Surgical Treatment of Obesity***

Study, Year (Reference)	Study Type	Quality Score†	Women, %	Average Age, y	Average Weight, BMI, or Ideal Body Weight‡	Comorbid Conditions at Baseline	Arm	Surgery	Patients In/ Patients Out, n/n	Follow-up, mo	Mean Weight Change ± SD	Postoperative Comorbidity Outcomes (Improved or Resolved)
Agren and Naslund, 1989 (81)	RCT	1	NR	36	43 kg/m²	NR	1	VBG	27/NR	12	Excluded from meta-analysis because study did not report mean weight loss	NR
							2	Gastric by-pass, loop	25/NR			
							3	Nonadjustable gastric band	25/NR			
Andersen et al., 1987 (91)	RCT	1	81	34	125 kg	NR	1	Gastroplasty (horizontal)	22/20	12	At 12 mo: arm 1, +1.0 ± 12.8 kg; arm 2, −9.7 ± 14.2	NR
							2	VBG	23/21			
Andersen et al., 1984 (28)	RCT	2	88	34	117 kg	NR	1	Gastroplasty (horizontal)	30/26	24	At 12 mo: arm 1, −22.0 ± 15.5 kg; arm 2, −18.0 ± 15.5 kg; At 24 mo: arm 1, −30.5 ± 20.3 kg; arm 2, −8.0 ± 20.3 kg	NR
							2	Very-low-calorie diet	30/29			
Andersen et al., 1988 (29)§	RCT	2	88	34	Arm 1, 120 kg; arm 2, 115 kg	NR	1	Gastroplasty (horizontal)	30/26	72	Excluded from analysis because study reported data on another study already included in analysis (28)	NR
							2	Very-low-calorie diet	30/30			
Andersen et al., 1982 (27)	RCT	1	88	NR	117 kg	NR	1	Gastroplasty (horizontal)	30/28	6	Not in analysis because follow-up time was too short. Study reported data on another study already included in analysis (28)	NR
							2	Very-low-calorie diet	30/30			
Brolin et al., 1992 (92)	RCT	1	73	38	63 kg/m²	Diabetes, 13%; hypertension, 73%; dyslipidemia, 13%; sleep apnea, 7%	1	Gastric by-pass, stan-dard limb	22/22	43	At 12 mo: arm 1, −118.0 ± 35.0 lb; arm 2, −140.0 ± 41.0 lb; At 48 mo: arm 1, −140.0 ± 63.0 lb; arm 2, −159.0 ± 70.0 lb	Diabetes, 100%; hy-pertension, 91%; dys-lipidemia, 83%; sleep apnea, 100%
							2	Gastric by-pass, long limb	23/23			
Buck-walter, 1977 (93)	RCT	2	97	36	142 kg	NR	1	Jejunoileal bypass	19/19	12	At 12 mo: arm 1, −31.5 ± 15.5 kg; arm 2, −43.0 ± 15.5 kg	NR
							2	Gastric by-pass (loop or standard)	19/19			
Choban and Flanc-baum, 2002 (94)	RCT	2	82	40	Arms 1–2, 44 kg/m²; arms 3–4, 61 kg/m²	NR	1	Gastric bypass (75-cm limb)	35/33	18	At 12 mo: arm 1, −44.0 ± 15.5 kg; arm 2, −39.0 ± 15.5 kg; arm 3, −60.0 ± 15.5 kg; arm 4, −64.0 ± 15.5 kg; At 36 mo: arm 1, −41.0 ± 20.3 kg; arm 2, −31.0 ± 20.3 kg; arm 3, −59.0 ± 20.3 kg	NR
							2	Gastric bypass (150-cm limb)	34/34			
							3	Gastric bypass (150-cm limb) in patients with BMI > 50 kg/m²	33/33			
							4	Gastric bypass (250-cm limb) in pa-tients with BMI > 55 kg/m²	31/28			

Study, Year (Reference)	Study Type	Quality Score†	Women, %	Average Age, y	Average Weight, BMI, or Ideal Body Weight‡	Comorbid Conditions at Baseline	Arm	Surgery	Patients In/Patients Out, n/n	Follow-up, mo	Mean Weight Change ± SD	Postoperative Comorbidity Outcomes (Improved or Resolved)
de Wit et al., 1999 (95)	RCT	2	68	NR	Arm 1, 51 kg/m²; arm 2, 50 kg/m²	Diabetes, 6%, hypertension, 12%; dyslipidemia, NR; sleep apnea, NR	1	Adjustable gastric band, lap	25/25	12	At 12 mo: arm 1, −35.0 ± 15.5 kg; arm 2, −34.4 ± 15.5 kg	NR
							2	Adjustable gastric band	25/24			
Fobi et al., 2001 (96)	CCT	0	92	45	47 kg/m²	NR	1	Gastric bypass (vertical ring, stapled)	25/22	72	At 12 mo: arm 1, −110 ± 34.1lb; arm 2, −109 ± 34.1 lb. At 72 mo: arm 1, −108 ± 44.7 lb; arm 2, −107 ± 44.7 lb	NR
							2	Gastric bypass (vertical ring, transected)	25/20			
Griffen et al.,1977 (97)	CCT	0	61	33	Arm 1, 148 kg; arm 2, 158 kg	Diabetes, 29%; hypertension, 24%; dyslipidemia, 9%; sleep apnea, NR	1	Gastric bypass	32/18	12	At 12 mo: arm 1, −51.0 ± 21.8 kg; arm 2, −57.9 ± 25.3 kg	NR
							2	Jejunoileal bypass	27/22			
Hall et al., 1990 (78)	RCT	3	71	34	194%–198%	Diabetes, 3%; hypertension, 13%; dyslipidemia, NR; sleep apnea, NR	1	Gastroplasty (vertical)	106/80	36	At 12 mo: arm 1, −36.0 ± 16.3 kg; arm 2, −29.0 ± 29.0 kg; arm 3, −42.0 ± 18.8 kg. At 36 mo: arm 1, −33.0 ± 20.3 kg; arm 2, −17.0 ± 24.0 kg; arm 3, −39.0 ± 21.3 kg	Diabetes, 75%; hypertension, 56%; dyslipidemia, NR; sleep apnea, NR
							2	Gastric partitioning	105/67			
							3	Gastric bypass	99/85			
Howard et al., 1995 (82)	RCT	1	79	37	Arm 1, 154 kg; arm 2, 142 kg	NR	1	Gastric bypass	20/6	60	Excluded from meta-analysis because study did not report mean weight loss	NR
							2	VBG	22/16			
Laws and Piantadosi, 1980 (84)	RCT	2	NR	NR	Women, 136 kg; men, 174 kg	Diabetes, 58%; hypertension, 34%; dyslipidemia, 30%; sleep apnea, NR	1	Gastric bypass	27/10	12	Excluded from meta-analysis because study did not report mean weight loss	NR
							2	Gastric partitioning	26/16			
Lechner and Elliott, 1983 (98)	CCT	0	93	35	Arm 1, 119 kg; arm 2, 120 kg	NR	1	Gastric partitioning	147/16	24	At 12 mo: arm 1, −28.6 ± 17.1 kg; arm 2, −43.6 ± 12.1 kg. At 24 mo: arm 1, −28.8 ± 18.0 kg; arm 2, −45.5 ± 13.3 kg	NR
							2	Gastric bypass	95/8			
Lechner and Callender, 1981 (99)‖	RCT	1	91	36	Arm 1, 266 lb; arm 2, 267 lb	NR	1	Gastric partitioning	50/50	12	Study reported data on another study already included in analysis (98)	NR
							2	Gastric bypass	50/50			

Study, Year (Reference)	Study Type	Quality Score†	Women, %	Average Age, y	Average Weight, BMI, or Ideal Body Weight‡	Comorbid Conditions at Baseline	Arm	Surgery	Patients In/ Patients Out, n/n	Follow-up, mo	Mean Weight Change ± SD	Postoperative Comorbidity Outcomes (Improved or Resolved)
Lundell et al., 1987 (100)	RCT	2	78	NR	115 kg	NR	1 2	VBG Gastroplasty	12/12 15/15	6	Excluded from meta-analysis because weight loss was not reported by surgery type	NR
Lundell et al., 1997 (101)	RCT	1	54	48	43 kg/m²	NR	1 2	VBG Nonadjustable gastric band	24/NR 26/NR	6	Excluded from meta-analysis because weight loss was not reported by surgery type	NR
MacLean et al., 1993 (102)	RCT	1	NR	39	Arm 1, 48 kg/m²; arm 2, 50 kg/m²	NR	1 2	VBG Gastric bypass	54/54 52/52	36	Excluded from meta-analysis because weight loss was not reported by surgery type	NR
Morino et al., 2003 (103)	RCT	1	81	38	44 kg/m²	NR	1 2	Adjustable gastric band, lap VBG, lap	49/44 51/49	33	At 12 mo: arm 1, −9.2 ± 5.9 kg/m²; arm 2, −9.0 ± 5.9 kg/m² At 36 mo: arm 1, −14.1 ± 7.7; arm 2, −13.5 ± 7.7 kg/m²	NR
Naslund, 1987 (104)	RCT	1	89	37	118 kg	NR	1 2	Gastric bypass, loop Gastroplasty (horizontal)	29/29 28/28	18	At 12 mo: arm 1, −42.3 ± 10.9 kg; arm 2, −29.9 ± 10.0 kg At 36 mo: arm 1, −38.4 ± 13.2 kg; arm 2, −24.7 ± 13.1 kg	NR
Naslund et al., 1988 (105)	RCT	1	100	37	Arm 1, 116 kg; arm 2, 114 kg	NR	1 2	Gastric bypass, loop Gastroplasty (horizontal)	26/26 25/25	18	Study reported data on another study already included in analysis (104)	NR
Naslund et al., 1988 (106)¶	RCT	1	100	36	116 kg	NR	1 2	Gastric bypass Gastroplasty (horizontal)	26/26 25/25	18	Study reported data on another study already included in analysis (104)	NR
Naslund and Beckman, 1987 (107)¶	RCT	1	89	NR	NR	NR	1 2	Gastric bypass, loop Gastroplasty (horizontal)	29/29 28/28	18	Study reported data on another study already included in analysis (104)	NR
Naslund et al., 1986 (108)¶	RCT	1	89	36	118 kg	Diabetes, 5%; hypertension, 16%; dyslipidemia, NR; sleep apnea, NR	1 2	Gastric bypass, loop Gastroplasty (horizontal)	29/29 28/28	24	Study reported data on another study already included in analysis (104)	NR
Naslund, 1986 (109)¶	RCT	1	89	37	118 kg	NR	1 2	Gastric bypass, loop Gastroplasty (horizontal)	29/29 28/28	12	Study reported data on another study already included in analysis (104)	NR

Study, Year (Reference)	Study Type	Quality Score†	Women, %	Average Age, y	Average Weight, BMI, or Ideal Body Weight‡	Comorbid Conditions at Baseline	Arm	Surgery	Patients In/ Patients Out, n/n	Follow-up, mo	Mean Weight Change ± SD	Postoperative Comorbidity Outcomes (Improved or Resolved)
Nguyen et al., 2001 (110)	RCT	1	90	41	48 kg/m²	Diabetes, 14%; hypertension, 37%; dyslipidemia, 17%; sleep apnea, 28%	1 / 2	Gastric bypass / Gastric bypass, lap	79/29 / 76/25	12	Excluded from meta-analysis because study did not report mean weight loss	NR
Nilsell et al., 2001 (111)	RCT	2	76	39	Arm 1, 44 kg/m²; arm 2, 42 kg/m²	Diabetes, 7%; hypertension, 10%; dyslipidemia, NR; sleep apnea, NR	1 / 2	VBG / Adjustable gastric band	30/27 / 29/26	54	At 12 mo: arm 1, −41.0 ± 15.5 kg; arm 2, −24.0 ± 15.5 kg At 60 mo: arm 1, −35.0 ± 19.2 kg; arm 2, −43.0 ± 12.0 kg	NR
Pories et al., 1982 (112)	RCT	1	79	36	Arm 1, 288 lb; arm 2, 308 lb	Diabetes, 14%; hypertension, 40%; dyslipidemia, NR; sleep apnea, NR	1 / 2	Gastric bypass / Gastric partitioning	42/42 / 45/45	18	At 12 mo: arm 1, −108.5 ± 34.1 lb; arm 2, −68.3 ± 34.1 lb At 18 mo: arm 1, −113.3 ± 44.7 lb; arm 2, −66.2 ± 44.7 lb	Diabetes, 100%; hypertension, 88%; dyslipidemia, NR; sleep apnea, NR
Sjostrom et al., 2001 (31)	Matched cohort	NA	68	48	Arm 1, 40 kg/m²; arms 2–4, 42 kg/m²	NR	1 2 3 4	Control, obese (matched to surgery group) Adjustable gastric band VBG Gastric bypass	1031/NR 255/NR 834/NR 68/NR	66	At 12 mo: arm 1, −1.6 ± 6.6 kg; arm 2, −30.7 ± 11.8 kg; arm 3, −25.8 ± 12.9 kg; arm 4, −44.0 ± 15.0 kg At 66 mo: arm 1, +1.5 ± 10.2 kg; arm 2, −20.8 ± 13.1 kg; arm 3, −20.7 ± 16.6 kg; arm 4: −33.98 ± 18.1 kg	Blood and pulse pressure improved in those who had gastric bypass surgery
Sjostrom et al., 2000 (32)**	Matched cohort	NA	66	47	41 kg/m²	Diabetes, 13% (arm 1) and 10% (arms 2–4); hypertension, 41% (arm 1) and 50% (arms 2–4); dyslipidemia, NR; sleep apnea, NR	1 2 3 4	Control, obese (matched to surgery group) VBG Adjustable gastric band Gastric bypass	346/232 227/164 86/63 33/24	96	Study reported data on another study already included in analysis (31)	Diabetes and hypertension increased in controls but was stable in surgery group
Sjostrom et al., 1999 (33)**	Matched cohort	NA	69	47–49	41 kg/m²	Diabetes, 13%; hypertension, 41%; dyslipidemia, NR; sleep apnea, NR	1 2 3 4	Control, obese (matched to surgery group) Adjustable gastric band VBG Gastric bypass	845/712 NR/191 NR/534 NR/42	24	Study reported data on another study already included in analysis (31)	Diabetes, hypertension, and lipid levels decreased markedly in the surgery arms Diabetes decreased by 30-fold at 2 y Sleep apnea was not reported

Study, Year (Reference)	Study Type	Quality Score†	Women, %	Average Age, y	Average Weight, BMI, or Ideal Body Weight‡	Comorbid Conditions at Baseline	Arm	Surgery	Patients In/ Patients Out, n/n	Follow-up, mo	Mean Weight Change ± SD	Postoperative Comorbidity Outcomes (Improved or Resolved)
Karason et al., 2000 (34)**	Matched cohort	NA	67	48	Arm 1, 40 kg/m²; arm 2, 42 kg/m²	Diabetes, 18% (arm 1) and 19% (arm 2); hypertension, 38% (arm 1) and 53% (arm 2); dyslipidemia, NR; sleep apnea, 22% (arm 1) and 23% (arm 2)	1	Control, obese (matched to surgery group)	1310/1099	24	Study reported data on another study already included in analysis (31)	Diabetes, −7% (arm 1) and −48% (arm 2); hypertension, +3% (arm 1) and −42% (arm 2); dyslipidemia, NR; sleep apnea, −9% (arm 1) and −65% (arm 2)
							2	Gastric sur gery, NOS	1310/1220			
Karason et al., 1999 (35)**	Matched cohort	NA	43	49	38 kg/m²	Diabetes, NR; hypertension, 25%; dyslipi- demia, NR; sleep apnea, NR	1	Control, obese (matched to surgery group)	28/24	12	Study reported data on another study already included in analysis (31)	Hypertension improved in surgery group
							2	Gastric sur- gery, NOS	28/28			
Karason et al., 1999 (36)**	Matched cohort	NA	21	49	37 kg/m²	Diabetes, NR; hyperten- sion, 21%; dyslipidemia, NR; sleep apnea, NR	1	Control, obese (matched to surgery group)	19/17	48	Study reported data on another study already included in analysis (31)	Overall im- provement was seen in blood pres- sure and levels of triglycer- ides, insu- lin, and HDL cho- lesterol Sleep apnea was not reported
							2	Gastric sur- gery, NOS	20/19			
Karlsson et al., 1998 (37)**	Matched cohort	NA	67	Arm 1, 47; arms 2–4, 48	Arm 1, 39 kg/ m²; arms 2–4, 41 kg/m²	NR	1	Control, obese (matched to surgery group)	487/487	24	Study reported data on another study already included in analysis (31)	NR
							2	VBG	315/315			
							3	Adjustable gastric band	136/136			
							4	Gastric by- pass	36/36			
Karason et al., 1997 (38)**	Matched cohort	NA	49	37–61	Arm 1, 18–27 kg/m²; arms 2–3, 30–47 kg/m²	NR	1	Control, nonobese	43/43	12	Study reported data on another study already included in analysis (31)	NR
							2	Control, obese (matched to surgery group)	35/31			
							3	Gastric sur- gery, NOS	41/41			
Narbro et al., 1999 (39)**	Matched cohort	NA	66	48	Arm 1, 41 kg/ m²; arm 2, 42 kg/m²	NR	1	Control	371/339	48	Study reported data on another study already included in analysis (31)	NR
							2	Gastric sur- gery, NOS	369/339			

Study, Year (Reference)	Study Type	Quality Score†	Women, %	Average Age, y	Average Weight, BMI, or Ideal Body Weight‡	Comorbid Conditions at Baseline	Arm	Surgery	Patients In/ Patients Out, n/n	Follow-up, mo	Mean Weight Change ± SD	Postoperative Comorbidity Outcomes (Improved or Resolved)
Torgerson and Sjostrom, 2001**	Matched cohort	NA	NR	NR	NR	NR	1	Control, obese (matched to surgery group)	712/232	96	Study reported data on another study already included in analysis (31)	Diabetes was 5-fold lower in the surgery group; hypertension did not change Dyslipidemia and sleep apnea were not reported
							2	Adjustable gastric band	767/251			
							3	Gastric bypass				
							4	VBG				
Sugerman et al., 1987 (79)	RCT	2	90	38	Arm 1, 213%; arm 2, 225%	NR	1	Gastric bypass	20/18	36	At 12 mo: arm 1, −96.0 ± 25.0 lb; arm 2, −71.0 ± 24.0 lb At 36 mo: arm 1, −91.0 ± 28.0 lb; arm 2, −60.0 ± 32.0 lb	NR
							2	Vertical banded gastroplasty	20/16			
The Danish Obesity Project, 1979 (30)	RCT	1	82	32	125 kg	NR	1	Control	69/52	45	At 24 mo: arm 1, −5.9 ± 13.1 kg; arm 2, −42.9 ± 22.0 kg	NR
							2	Jejunoileal bypass	133/130			
Quaade, 1979 (202)‖	RCT	1	84	32	125 kg	NR	1	Controls (low-calorie diet)	66/NR	15	Study reported data on another study already included in analysis (30)	NR
							2	Jejunoileal bypass	130/NR			
Van Rij, 1984 (80)	RCT	1	NR	NR	NR	Diabetes, 54%; hypertension, 92%; dyslipidemia, NR; sleep apnea, NR	1	Gastric bypass	42/42	12	Excluded from meta-analysis because study did not report mean weight loss	Diabetes, 83%; hypertension, NR; dyslipidemia, NR; sleep apnea, NR
							2	Gastric partitioning	45/45			
VanWoert et al., 1992 (83)	RCT	1	88	38	53 kg/m²	NR	1	Gastric bypass	15/NR	36	Excluded from meta-analysis because study did not report mean weight loss	NR
							2	VBG	17/NR			
Viddal, 1983 (113)	RCT	1	95	34	110 kg	NR	1	Jejunoileal bypass (end-to-side)	10/10	36	At 18 mo: arm 1, −37.0 ± 20.3 kg; arm 2, −40.0 ± 20.3 kg	NR
							2	Jejunoileal bypass (side to side)	11/10			
Weiner et al., 2001 (114)	RCT	1	85	35	49 kg/m²	NR	1	Adjustable gastric band, lap (retrogastric)	51/NR	18	At 12 mo: arm 1, −50.9 ± 15.5 kg; arm 2, −55.8 ± 15.5 kg	NR
							2	Adjustable gastric band, lap (esophagogastric)	50/NR		At 18 mo: arm 1, −50.9 ± 20.3 kg; arm 2, −56.8 ± 20.3 kg	

* Procedures were performed with an open approach unless otherwise stated. BMI = body mass index; CCT = controlled clinical trial; HDL = high-density lipoprotein; NA = not applicable; NOS = not otherwise specified; NR = not reported; RCT = randomized, controlled trial; VBG = vertical banded gastroplasty.
† Jadad score ranging from 0 (lowest quality) to 5 (highest quality).
‡ Ideal body weight is reported in percentages.
§ Contains data from Andersen et al., 1984 (28).
‖ Contains data from Lechner and Elliott, 1983 (98).
¶ Contains data from Naslund, 1987 (104).
** Contains data from Sjostrom et al., 2001 (31).

Appendix Table 2. **Evidence Table for Case Series of Surgical Treatment of Obesity***

Study, Year (Reference)	Women, %	Average Age, y	Average Weight, BMI, or Ideal Body Weight†	Comorbid Conditions at Baseline	Arm	Surgery	Patients In, n	Consecutive Cases?	Average Follow-up, mo	Mean Weight Change ± SD	Comorbidity Outcomes (Improved or Resolved)
Abu-Abeid et al., 2003 (115)	76	38	43 kg/m²	NR	1	Adjustable gastric band, lap	391	Yes	18	In BMI at 12 mo: arm 1, −11.2 ± 5.9 kg/m² In BMI at 18 mo: arm 1, −13.3 ± 7.6 kg/m²	NR
Aghahosseini et al., 2001 (116)	86	36	40 kg/m²	Diabetes, 9%; hypertension, 21%; dyslipidemia, 5%; sleep apnea, 2%	1	Adjustable gastric band, lap	84	No	24	In BMI at 12 mo: arm 1, −11.2 ± 5.9 kg/m² In BMI at 18 mo: arm 1, −13.3 ± 7.6 kg/m²	NR
Alden, 1977 (117)	94	32	127 kg	NR	1 2	Jejunoileal bypass Gastric bypass loop	100 100	Yes	12	At 12 mo: arm 1, −40.6 ± 14.8 kg; arm 2, −40.2 ± 11.8 kg	NR
Alper et al., 2000 (118)	73	40	46 kg/m²	NR	1	VBG	450	NR	38	At 62 mo: arm 1, −37.0 ± 23.2 kg	NR
Anthone et al., 2003 (119)	78	42	52 kg/m²	NR	1	BPD/duodenal switch	701	Yes	12	At 12 mo: arm 1, −127.0 ± 41.0 lb At 60 mo: arm 1, −118.0 ± 46.0 lb	NR
Balsiger et al., 2000 (120)	76	40	49 kg/m²	NR	1	VBG	73	Yes	120	At 120 mo: arm 1, −28.0 ± 33.4 kg	NR
Baltasar et al., 1998 (121)	75	36	48 kg/m²	NR	1	VBG	100	Yes	72	At 12 mo: arm 1, −32.0 ± 15.5 kg At 114 mo: arm 1, −32.0 ± 20.3 kg	NR
Belachew et al., 1998 (122)	79	36	43 kg/m²	NR	1	Adjustable gastric band, lap	350	Yes	36	In BMI at 12 mo: arm 1, −11.0 ± 5.9 kg/m² In BMI at 41 mo: arm 1, −15.0 ± 7.6 kg/m²	NR
Belachew et al., 2002 (123)	78	34	42 kg/m²	NR	1	Adjustable gastric band, lap	763	NR	48	In BMI at 12 mo: arm 1, −10.0 ± 5.9 kg/m² In BMI at 48 mo: arm 1, −12.0 ± 7.6 kg/m²	NR

Study, Year (Reference)	Women, %	Average Age, y	Average Weight, BMI, or Ideal Body Weight†	Comorbid Conditions at Baseline	Arm	Surgery	Patients In, n	Consecutive Cases?	Average Follow-up, mo	Mean Weight Change ± SD	Comorbidity Outcomes (Improved or Resolved)
Bloomston et al., 1997 (124)	85	40	NR	Diabetes, 20%; hypertension, 38%; dyslipidemia, 54%; sleep apnea 8%	1 2	VBG Gastric by-pass	157	NR	72	Excluded from meta-analysis because weight loss was not reported by surgery type	NR
Brolin et al., 2000 (125)	NR	NR	NR	Dyslipidemia, 35%;	1 2 3	Gastroplasty (horizontal) VBG Gastric by-pass	56 30 565	Yes	41	Excluded from meta-analysis because weight loss was not reported by surgery type	NR
Brolin et al., 1994 (126)	85	38	43 kg/m²	Diabetes , 7%; hypertension, 34%; dyslipidemia, 37%; sleep apnea, 2%	1 2	VBG Gastric by-pass	30 108	Yes	38	At 12 mo: arm 1, −74.0 ± 23.0 lb; arm 2, −91.0 ± 34.1 lb At 48 mo: arm 1, −57.0 ± 44.7 lb; arm 2, −90.0 ± 44.7 kg	Diabetes, 90%; hypertension, 94%; dyslipidemia, 90%; sleep apnea, 100%
Mertens et al., 1999 (127)	83	37	52 kg/m²	NR	1 2	VBG Gastric by-pass	329 623	Yes	36	At 60 mo: arm 1, −66.0 ± 44.7 lb; arm 2, −100.0 ± 44.7 lb	NR
Choban et al., 1999 (67)	85	40	51 kg/m²	NR	1	Gastric by-pass	107	NR	23	At 23 mo: arm 1, −42.0 ± 20.3 kg	NR
Choi et al., 1999 (128)	93	41	48 kg/m²	NR	1 2	VBG Gastric by-pass	17 12	NR	12	At 12 mo: arm 1, −39.3 ± 15.5 kg; arm 2, −46.7 ± 15.5 kg At 19 mo: arm 1, −38.4 ± 15.5 kg; arm 2, −54.6 ± 15.5 kg	NR

Study, Year (Reference)	Women, %	Average Age, y	Average Weight, BMI, or Ideal Body Weight†	Comorbid Conditions at Baseline	Arm	Surgery	Patients In, n	Consecutive Cases?	Average Follow-up, mo	Mean Weight Change ± SD	Comorbidity Outcomes (Improved or Resolved)
Cook and Edwards, 1999 (129)	95	NR	NR	NR	1	Gastric bypass	100	No	84	Excluded from meta-analysis because weight loss was not reported by surgery type	NR
Courcoulas et al., 2003 (130)	94	43	46 kg/m²	NR	1	Gastric bypass, lap	80	No	6	In BMI at 12 mo: arm 1, −15.2 ± 5.9 kg/m²; arm 2, −15.1 ± 5.9 kg/m²	NR
					2	Gastric bypass, open	80				
Crampton et al., 1997 (131)	81	39	44 kg/m²	NR	1	Gastric bypass	64	Yes	43	At 24 mo: arm 1, −48.0 ± 20.5 kg	NR
Dargent, 1999 (132)	84	39	43 kg/m²	NR	1	Adjustable gastric band, lap	500	Yes	36	Excluded from meta-analysis because study did not report mean weight loss	NR
Das et al., 2003 (133)	100	39	49 kg/m²	NR	1	Gastric bypass	20	No	14	At 12 mo: arm 1, −44.7 ± 14.6 kg	NR
Davila-Cervantes et al., 2000 (134)	88	35	45 kg/m²	NR	1	VBG, open	20	Yes	12	At 12 mo: arm 1, −31.0 ± 15.5 kg; arm 2, −28.0 ± 15.5 kg	NR
					2	VBG, lap	20				
De Luca et al., 2000 (135)	78	36	50 kg/m²	NR	1	Adjustable gastric band, lap	22	Yes	36	At 12 mo: arm 1, −35.1 ± 15.5 kg; arm 2, −25.1 ± 15.5 kg At 36 mo: arm 1, −54.9 ± 20.3 kg; arm 2, −43.0 ± 20.3 kg	NR
					2	Adjustable gastric band, open	47				

Study, Year (Reference)	Women, %	Average Age, y	Average Weight, BMI, or Ideal Body Weight†	Comorbid Conditions at Baseline	Arm	Surgery	Patients In, n	Consecutive Cases?	Average Follow-up, mo	Mean Weight Change ± SD	Comorbidity Outcomes (Improved or Resolved)
de Zwaan et al., 2002 (136)	86	40	44 kg/m²	NR	1 2	Control Gastric by-pass	164 100	Yes	168	In BMI at 168 mo: arm 2, −11.0 ± 6.7 kg/m² Arm 1 excluded because mean weight loss was not reported	NR
DeMaria and Sugerman, 2000 (137)	NR	NR	NR	NR	1	Adjustable gastric band, lap	300	NR	NR	Excluded from meta-analysis because study did not report mean weight loss	Diabetes, 40%; hypertension, NR; dyslipidemia, NR; sleep apnea, NR
DeMaria et al., 2001 (138)	NR	39	45 kg/m²	NR	1	Adjustable gastric band, lap	37	Yes	24	At 12 mo: arm 1, −44.0 ± 34.1 lb At 36 mo: arm 1, −61.0 ± 44.7 lb	NR
Doherty et al., 2002 (139)	73	34	Arm 1, 50 kg/m²; arm 2, 47 kg/m²	NR	1 2	Adjustable gastric band, open Adjustable gastric band, lap	40 22	Yes	45	At 12 mo: arm 1, −34.0 ± 15.5 kg; arm 2, −19.0 ± 15.5 kg At 72 mo: arm 1, −21.0 ± 20.3 kg; arm 2, −10.0 ± 20.3 kg	NR
Doherty et al., 1998 (140)	65	34	50 kg/m²	NR	1	Adjustable gastric band, open	40	Yes	38	At 12 mo: arm 1, −35.0 ± 15.5 kg At 48 mo: arm 1, −29.0 ± 20.3 kg	NR
Doldi et al., 2000 (141)	NR	38	46 kg/m²	NR	1 2	Adjustable gastric band, open Adjustable gastric band, lap	64 109	Yes	36	Excluded from meta-analysis because study did not report mean weight loss by surgery type	NR

Study, Year (Reference)	Women, %	Average Age, y	Average Weight, BMI, or Ideal Body Weight†	Comorbid Conditions at Baseline	Arm	Surgery	Patients In, n	Consecutive Cases?	Average Follow-up, mo	Mean Weight Change ± SD	Comorbidity Outcomes (Improved or Resolved)
Dymek et al., 2002 (75)	81	41	55 kg/m²	NR	1 2	Control Gastric by-pass	80 236	No	12	In BMI at 12 mo: arm 2, −18.3 ± 5.9 kg/m² Arm 1 excluded because weight loss was not reported	NR
Feng and Gagner, 2002 (142)	NR	NR	60 kg/m²	NR	1	BPD/duodenal switch	40	Yes	12	Excluded from meta-analysis because study did not report mean weight loss	NR
Field et al., 1992 (143)	94	37	41 kg/m²	Diabetes, 28%; hypertension, 47%; dyslipidemia, 3%; sleep apnea, NR	1	VBG	36	No	72	In BMI at 120 mo: arm 1, −7.5 ± 7.6 kg/m²	Diabetes, 40%; hypertension, 42%; dyslipidemia, 0%; Sleep apnea, NR
Fielding et al., 1999 (144)	85	41	47 kg/m²	NR	1	Adjustable gastric band, lap	335	No	12	At 12 mo: arm 1, −37.0 ± 10.0 kg At 18 mo: arm 1, −41.0 ± 18.0 kg	NR
Fobi, 1993 (145)	95	NR	Arm 1, 220%; arm 2, 223%	NR	1 2	VBG Gatric by-pass	100 100		120	Excluded from meta-analysis because study did not report mean weight loss	NR
Forestieri et al., 1998 (146)	79	36	50 kg/m²	NR	1	Adjustable gastric band, lap and open	62	Yes	24	At 12 mo: arm 1, −35.6 ± 17.0 kg At 24 mo: arm 1, −61.6 ± 13.7 kg	NR
Forsell et al., 1999 (147)	76	40	125 kg	NR	1	Adjustable gastric band, open	326	Yes	28	At 28 mo: arm 1, −37.0 ± 20.3 kg	NR
Forsell and Hellers, 1997 (148)	70	41	46 kg/m²	NR	1	Adjustable gastric band, open	50	Yes	48	At 12 mo: arm 1, −42.0 ± 9.0 At 48 mo: arm 1, −54.5 ± 8.0 kg	NR

Study, Year (Reference)	Women, %	Average Age, y	Average Weight, BMI, or Ideal Body Weight†	Comorbid Conditions at Baseline	Arm	Surgery	Patients In, n	Consecutive Cases?	Average Follow-up, mo	Mean Weight Change ± SD	Comorbidity Outcomes (Improved or Resolved)
Freeman et al., 1997 (149)	86	36	46 kg/m²	NR	1	Gastric by-pass (standard limb)	40	No	24	In BMI at 12 mo: arm 1, −13.0 ± 5.9 kg/m²; arm 2, −14.0 ± 5.9 kg/m² In BMI at 36 mo: arm 1, −18.0 ± 7.7 kg/m²; arm 2, −16.0 ± 7.7 kg/m²	NR
					2	Gastric by-pass (long limb)	81				
Goulding and Hovell, 1995 (150)	86	38	46 kg/m²	NR	1	VBG	200	Yes	12	In BMI at 12 mo: arm 1, −13.2 ± 5.9 kg/m²	NR
Gustavsson and Westling, 2002 (151)	NR	NR	NR	NR	1	Adjustable gastric band, lap	90	Yes	84	In BMI at 60 mo: arm 1, −9.3 ± 7.6, kg/m²	NR
Hedenbro and Frederiksen, 2002 (152)	NR	37	48 kg/m²	NR	1	Gastric by-pass	146	Yes	12	At 12 mo: arm 1, −47.0 ± 15.5 kg At 36 mo: arm 1, −53.0 ± 20.3 kg	NR
Hess and Hess, 1998 (153)	78	40	50 kg/m²	NR	1	BPD/duo-denal switch	440	Yes	96	At 12 mo: arm 1, −55.0 ± 15.5 kg	NR
Hesse et al., 2001 (154)	75	37	44 kg/m²	NR	1	Adjustable gastric band, lap (silicone)	29	Yes	24	At 12 mo: arm 1, −24.8 ± 15.5 kg	NR
					2	Adjustable gastric band, lap (Swed-ish)	41			Arm 2 ex-cluded be-cause it reported only 6-mo follow-up	
Higa et al., 2000 (155)	83	13–72	48 kg/m²	NR	1	Gastric by-pass, lap	1040	Yes	12	Excluded from meta-analysis because study did not report mean weight loss	NR
Higa et al., 2000 (89)	83	43	46	NR	1	Gastric by-pass, lap	400	Yes		Excluded from meta-analysis because study re-ported data on another study al-ready in-cluded in analysis (155)	NR

Study, Year (Reference)	Women, %	Average Age, y	Average Weight, BMI, or Ideal Body Weight†	Comorbid Conditions at Baseline	Arm	Surgery	Patients In, n	Consecutive Cases?	Average Follow-up, mo	Mean Weight Change ± SD	Comorbidity Outcomes (Improved or Resolved)
Horchner and Tuinebreijer, 1999 (156)	100	18–59	41 kg/m²	NR	1	Adjustable gastric band, lap	42	No	12	At 12 mo: arm 1, −22.4 ± 15.5 kg	NR
Kalfarentzos et al., 1999 (157)	80	34	Arm 1, 44 kg/m²; arm 2, 49 kg/m²; arm 3, 60 kg/m²	NR	1 2 3	VBG Gastric bypass (standard limb) Gastric bypass (long limb)	35 38 17	Yes	36	In BMI at 12 mo: arm 1, −13.3 ± 5.9 kg/m²; arm 2, −16.5 ± 5.9 kg/m² In BMI at 36 mo: arm 1, −10.2 ± 7.6 kg/m²; arm 2, −14.0 ± 7.6 kg/m² Arm 3 excluded because follow-up time reported was 24 mo	NR
Kothari et al., 2002 (158)	NR	NR	NR	Diabetes, 11%; hypertension, NR; dyslipidemia, NR; sleep apnea, NR	1	Adjustable gastric band, lap	36	Yes	38	Excluded from meta-analysis because study did not report mean weight loss	Diabetes, 75%; hypertension, NR; dyslipidemia, NR; sleep apnea, NR
Lujan et al., 2002 (159)	80	34	47 kg/m²	NR	1	Gastric bypass, lap	50	No	18	In BMI at 12 mo: arm 1, −14.0 ± 5.9 kg/m² In BMI at 18 mo: arm 1, −17.0 ± 7.6 kg/m²	NR
MacLean et al., 2000 (160)	NR	NR	49 kg/m²	NR	1	Gastric bypass	277	Yes	60	In BMI at 60 mo: arm 1, −17.3 ± 7.6 kg/m²	NR
MacLean et al., 1990 (161)	NR	NR	NR	NR	1	VBG	201	Yes	48	Excluded from meta-analysis because study did not report mean weight loss	NR

Study, Year (Reference)	Women, %	Average Age, *y*	Average Weight, BMI, or Ideal Body Weight†	Comorbid Conditions at Baseline	Arm	Surgery	Patients In, *n*	Consecutive Cases?	Average Follow-up, *mo*	Mean Weight Change ± SD	Comorbidity Outcomes (Improved or Resolved)
MacLean and Rhode, 1996 (162)	NR	NR	NR	NR	1	VBG or gastric bypass	77	No	52	Excluded from meta-analysis because weight loss was not reported by surgery type (reported by family characteristics)	NR
Marceau et al., 1993 (163)	78	38	47 kg/m²	NR	1 2	BPD BPD/duodenal switch	149 156	Yes	18	Excluded from meta-analysis because study did not report mean weight loss	NR
Mason et al., 1998 (164)	NR	41	NR	NR	1 2	VBG (5-cm outlet) VBG (4.5-cm outlet)	70 40	NR	120	Excluded from meta-analysis because study did not report mean weight loss	NR
Mason, 1982 (165)	NR	NR	138–144 kg	NR	1	VBG	42	Yes	6	Excluded from meta-analysis because follow-up time was <12 mo	NR
Matthews et al., 2000 (166)	83	41	52 kg/m²	NR	1	Gastric bypass, lap	48	Yes	12	At 12 mo: arm 1, −115.0 ± 34.1 lb	NR
Melissas et al., 1998 (167)	84	37	48 kg/m²	NR	1	VBG	63	Yes	48	At 12 mo: arm 1, −44.0 ± 13.0 kg At 48 mo: arm 1, −47.0 ± 18.0 kg	NR
Miller and Hell, 1999 (168)	85	36	Arm 1, 45 kg/m²; arm 2, 43 kg/m²	NR	1 2	Adjustable gastric band, lap (silicone) Adjustable gastric band, lap (Swedish)	102 54	Yes	28	At 12 mo: arm 1, −12.0 ± 15.5 kg; arm 2, −17.0 ± 15.5 kg At 36 mo: arm 1, −44.0 ± 20.3 kg; arm 2, −48.0 ± 20.3 kg	NR

Study, Year (Reference)	Women, %	Average Age, y	Average Weight, BMI, or Ideal Body Weight†	Comorbid Conditions at Baseline	Arm	Surgery	Patients In, *n*	Consecutive Cases?	Average Follow-up, *mo*	Mean Weight Change ± SD	Comorbidity Outcomes (Improved or Resolved)
Mitchell et al., 2001 (169)	83	NR	44 kg/m^2	NR	1	Gastric by-pass	100	No	180	At 180 mo: arm 1, −30.1 ± 20.3 kg	NR
Mittermair et al., 2003 (170)	84	38	47 kg/m^2	Diabetes, 18%; hypertension, 73%; dyslipidemia, 83%; sleep apnea, NR	1	Adjustable gastric band, lap	454	Yes	30	At 12 mo: arm 1, −35.5 ± 15.5 kg. At 36 mo: arm 1, −54.0 ± 20.3 kg	Diabetes, 86%; hypertension, 75%; dyslipidemia, 95%; sleep apnea, NR
Nguyen et al., 2000 (171)	88	41	40–60 kg/m^2	Diabetes, 30%; hypertension, 50%; dyslipidemia, 26%; sleep apnea, 41%	1 / 2	Gastric by-pass, lap / Gastric by-pass, open	35 / 35	NR	12	Excluded from meta-analysis because weight loss was not reported by surgery type	NR
Nowara, 2001 (172)	84	32	49 kg/m^2	NR	1	Adjustable gastric band, lap	108	NR	24	In BMI at 12 mo: arm 1, −11.7 ± 5.9 kg/m^2. In BMI at 24 mo: arm 1, −14.6 ± 7.6 kg/m^2	NR
O'Brien et al.,1999 (173)	89	39	43 kg/m^2	NR	1	Adjustable gastric band, lap	302	Yes	12	Excluded from meta-analysis because study did not report mean weight loss	NR
O'Brien et al., 2002 (174)	85	41	45 kg/m^2	Diabetes, NR; hypertension, NR; dyslipidemia, 34%; sleep apnea, 33%	1	Adjustable gastric band, lap	659	Yes	24	In BMI at 12 mo: arm 1, −10.0 ± 5.9 kg/m^2. In BMI at 72 mo: arm 1, −13.0 ± 7.6 kg/m^2	Diabetes, 96%; hypertension, 86%; dyslipidemia, 74%; sleep apnea, 94%
Oh et al., 1997 (175)	87	33	45 kg/m^2	NR	1	Gastric by-pass	194	Yes	48	At 12 mo: arm 1, −47.5 ± 15.5 kg. At 48 mo: arm 1, −48.5 ± 20.3 kg	NR
Olbers et al., 2003 (176)	77	39	43 kg/m^2	NR	1	Gastric by-pass, lap	150	Yes	36	In BMI at 12 mo: arm 1, −15.0 ± 5.9 kg/m^2. In BMI at 60 mo: arm 1, −14.5 ± 7.6 kg/m^2	NR

Study, Year (Reference)	Women, %	Average Age, y	Average Weight, BMI, or Ideal Body Weight†	Comorbid Conditions at Baseline	Arm	Surgery	Patients In, n	Consecutive Cases?	Average Follow-up, mo	Mean Weight Change ± SD	Comorbidity Outcomes (Improved or Resolved)
Papasavas et al., 2002 (177)	87	42	49 kg/m²	Diabetes, 33%; hypertension, 49%; dyslipidemia, 9%; sleep apnea, 4%	1	Gastric bypass, lap	114	Yes	12	In BMI at 12 mo: arm 1, −16.3 ± 5.9 kg/m² In BMI at 18 mo: arm 3, −17.3 ± 7.6 kg/m²	Diabetes, 66%; hypertension, 37%; dyslipidemia, 55%; sleep apnea 100%
Peace et al., 1989 (178)	92	NR	123 kg	NR	1	Gastroplasty	36	Yes	17	At 17 mo: arm 1, −42.3 ± 15.8 kg	NR
Perugini et al., 2003 (179)	84	44	53 kg/m²	Diabetes, 26%; hypertension, 44%; dyslipidemia; NR; sleep apnea, 22%	1	Gastric bypass, lap	188	Yes	12	At 12 mo: arm 1, −48.0 ± 15.5 kg	NR
Pontiroli et al., 2002 (180)	81	43	Arm 1, 44 kg/m²; arm 2, 45 kg/m²	Diabetes, 46%; hypertension, NR; dyslipidemia, NR; sleep apnea, NR	1 2	Control Adjustable gastric band, lap	120 143	Yes	24	In BMI at 12 mo: arm 2, −8.0 ± 5.9 kg/m² In BMI at 36 mo: arm 2, −7.9 ± 7.6 kg/m² Arm 1 excluded because no final sample size was reported	Diabetes, 78%; hypertension NR; dyslipidemia, NR; sleep apnea, NR
Pories et al., 1987 (181)	86	38	131 kg	Diabetes, 36%; hypertension, 57%; dyslipidemia, NR; sleep apnea, NR	1	Gastric bypass	397	Yes	24	At 12 mo: arm 1, −106.0 ± 34.1 lb At 72 mo: arm 1, −85.0 ± 44.7 lb	Diabetes, 99%; hypertension, 63%; dyslipidemia, NR; sleep apnea, NR
Reddy et al., 2002 (182)	83	39	56 kg/m²	Diabetes, 24%; hypertension, 43%; dyslipidemia, NR; sleep apnea, NR	1	Gastric bypass	103	Yes	5	Excluded from meta-analysis because follow-up time was <12 mo	Diabetes, 50%; hypertension, 50%; dyslipidemia, NR; sleep apnea, NR
Reinhold, 1994 (183)	NR	NR	47 kg/m²	Diabetes, 12%; hypertension, 17%; dyslipidemia, NR; sleep apnea, NR	1 2	Gastric bypass, loop Gastric bypass, standard	66 3	Yes 87	30	Excluded from meta-analysis because weight loss was not reported by surgery type	Diabetes, 50%; hypertension, 26%; dyslipidemia, NR; sleep apnea, NR

Study, Year (Reference)	Women, %	Average Age, y	Average Weight, BMI, or Ideal Body Weight†	Comorbid Conditions at Baseline	Arm	Surgery	Patients In, n	Consecutive Cases?	Average Follow-up, mo	Mean Weight Change ± SD	Comorbidity Outcomes (Improved or Resolved)
Schauer et al., 2000 (184)	81	42	48 kg/m²	NR	1	Gastric by-pass, lap	275	Yes	17	In BMI at 12 mo: arm 1, −16.8 ± 5.9 kg/m² In BMI at 24 mo: arm 1, −20.9 ± 7.6 kg/m²	NR
Scopinaro et al., 1996 (185)	69	37	128 kg	Diabetes, 9%; hyper-tension, 37%; dys-lipidemia, 35%; sleep apnea, NR	1	BPD	1217	Yes	115	Excluded from meta-analysis because study did not report mean weight loss	Diabetes, 100%; hyperten-sion, 94%; dyslipide-mia, 100%; sleep ap-nea, NR
Smith et al., 2004 (186)	NR	39	49 kg/m²	NR	1 2	Gastric by-pass, lap Gastric by-pass, open	328 451	Yes	12	In BMI at 12 mo: arm 1, −17.2 ± 5.9 kg/m²; arm 2, −19.2 ± 5.9 kg/m²	NR
Stoner et al., 1997 (187)	NR	NR	NR	NR	1	VBG	202	Yes	42	At 12 mo: arm 1, −78.0 ± 34.1 lb At 42 mo: arm 1, −85.0 ± 44.7 lb	NR
Sugerman et al., 1989 (188)	63	NR	49 kg/m²	Diabetes, 11%; hy-pertension, 45%; dys-lipidemia, NR; sleep apnea, 15%	1 2	VBG Gastric by-pass	40 182	Yes	48	At 12 mo: arm 1, −61.0 ± 34.1 lb; arm 2, −96.0 ± 34.1 lb At 36 mo: arm 1, −54.0 ± 44.7 lb; arm 2, −88.0 ± 44.7 lb	Diabetes, 96%; hy-perten-sion, 78%; dyslipide-mia, NR; sleep ap-nea, 97%
Sugerman et al., 1996 (53)	NR	NR	38 kg/m²	NR	1	Gastric by-pass, open (con-verted from VBG)	58	No	36	At 12 mo: arm 1, −99.0 ± 34.1 lb At 72 mo: arm 1, −92.0 ± 44.7 lb	NR
Suter et al., 2000 (189)	87	38	45 kg/m²	NR	1	Adjustable gastric band, lap	148	Yes	24	In BMI at 12 mo: arm 1, −13.0 ± 5.9 kg/m² In BMI at 24 mo: arm 1, −13.0 ± 7.6 kg/m²	NR
Suter et al., 2003 (23)	77	40	45 kg/m²	Diabetes, 39%; hy-pertension, 34%; dys-lipidemia, 42%; sleep apnea, 20%	1	Gastric by-pass, lap	107	Yes	24	In BMI at 12 mo: arm 1, −13.2 ± 5.9 kg/m² In BMI at 24 mo: arm 1, −12.2 ± 7.6 kg/m²	Diabetes, NR; hy-perten-sion, 100%; dyslipide-mia, NR; sleep ap-nea, 90%

Study, Year (Reference)	Women, %	Average Age, y	Average Weight, BMI, or Ideal Body Weight†	Comorbid Conditions at Baseline	Arm	Surgery	Patients, In n	Consecutive Cases?	Average Follow-up, mo	Mean Weight Change ± SD	Comorbidity Outcomes (Improved or Resolved)
Suter et al., 1999 (190)	88	36	Arm 1, 43 kg/m²; arm 2, 46 kg/m²	NR	1 2	VBG Adjustable band, lap	197 76	Yes	24	In BMI at 12 mo: arm 1, −14.7 ± 5.9 kg/m²; arm 2, −12.5 ± 5.9 kg/m² In BMI at 24 mo: arm 1, −14.7 ± 7.6 kg/m²; arm 2, −14.5 ± 7.6 kg/m²	NR
Szold and Abu-Abeid, 2002 (191)	NR	35	43 kg/m²	NR	1	Adjustable gastric band, lap	715	Yes	24	In BMI at 12 mo: arm 1, −10.1 ± 5.9 kg/m² In BMI at 36 mo: arm 1, −11.1 ± 7.6 kg/m²	NR
Tacchino et al., 2003 (192)	100	41	46 kg/m²	NR	1 2	Control BPD	53 101	NR	24	At 12 mo: arm 2, −43.3 ± 15.5 kg At 24 mo: arm 2, −46.0 ± 20.3 kg Arm 1 excluded because mean weight loss was not reported	NR
Toppino et al., 1999 (193)	NR	NR	44 kg/m²	NR	1 2 3	Nonadjustable gastric band, lap Adjustable gastric band, lap VBG, lap	10 361 120	NR	12	Excluded from meta-analysis because study did not report mean weight loss	NR
Toppino et al., 1999 (194)	89	38	46 kg/m²	NR	1 2	VBG, open VBG, lap	218 107	Yes	24	Excluded from meta-analysis because study did not report mean weight loss	NR
van de Weijgert et al., 1999 (195)	87	34	Arm 1, 41 kg/m²; arm 2, 44 kg/m²	Diabetes, 15%; hypertension, 60%; dyslipidemia, NR; sleep apnea, NR	1 2	Gastric bypass VBG	100 100	Yes	84	Excluded from meta-analysis because study did not report mean weight loss	Diabetes, 100%; hypertension, 93%; dyslipidemia, NR; sleep apnea, NR

Study, Year (Reference)	Women, %	Average Age, y	Average Weight, BMI, or Ideal Body Weight†	Comorbid Conditions at Baseline	Arm	Surgery	Patients In, n	Consecutive Cases?	Average Follow-up, mo	Mean Weight Change ± SD	Comorbidity Outcomes (Improved or Resolved)
van Gemert et al., 1998 (196)	71	33	Arm 1, 47 kg/m²; arms 2–4, 47–49 kg/m²	NR	1 2 3 4	Control Gastric by-pass VBG (Mar-tex) VBG (Da-cron)	20 18 14 30	Yes	12	At 86 mo: arm 2, −41.4 ± 20.3 kg; arm 3, −38.0 ± 20.3 kg; arm 4, −48.3 ± 20.3 kg	NR
Weiner et al., 2003 (197)	78	38	47 kg/m²	Diabetes, 16%; hy-pertension, 42%; dys-lipidemia, NR; sleep apnea, 8%	1	Adjustable gastric band, lap	984	Yes	96	In BMI at 12 mo: arm 1, −12.8 ± 5.9 kg/m² In BMI at 36 mo: arm 1, −14.8 ± 7.6 kg/m²	Diabetes, 93%; hy-perten-sion, 50%; dyslipide-mia NR; sleep ap-nea, 85%
Wiesner et al., 2000 (198)	82	39	47 kg/m²	NR	1	Adjustable gastric band, lap	98	Yes	12	Excluded from meta-analysis because study did not report mean weight loss	NR
Wittgrove and Clark, 2000 (88)	NR	NR	NR	Diabetes, 17%; hy-pertension, 24%; dys-lipidemia, 55%; sleep apnea, 45%	1	Gastric by-pass, lap	500	Yes	60	Excluded from meta-analysis because study did not report mean weight loss	Diabetes, 98%; hy-perten-sion, 92%; dyslipide-mia, 97%; sleep ap-nea, 98%
Yale, 1989 (199)	84	34	132 kg	NR	1 2 3	Gastric by-pass Gastro-plasty VBG	251 186 100	Yes	36	At 12 mo: arm 1, −46.0 ± 13.0 kg; arm 2, −30.0 ± 18.0 kg; arm 3, −35.0 ± 11.0 kg At 36 mo: arm 3, −33.0 ± 15.0 kg At 60 mo: arm 1, −41.0 ± 19.0 kg	NR
Yale and Weiler, 1991 (200)	77	37	285 lb	NR	1 2	VBG (4.5 band) VBG (5.0 band)	100 100	Yes	12	At 12 mo: arm 1, −75.0 ± 30.0 lb; arm 2, −77.0 ± 24.0 lb	NR
Yashkov et al., 1997 (201)	67	33–59	52 kg/m²	NR	1	VBG	24	Yes	NR	Excluded from meta-analysis because study did not report fol-low-up time	NR

*Procedures were performed with an open approach unless otherwise stated. BMI = body mass index; BPD = biliopancreatic diversion; lap = laparoscopic; NR = not reported; VBG = vertical banded gastroplasty.
† Ideal body weight is reported in percentages.

Appendix Table 3. **Postoperative Adverse Events by Bariatric Procedure in Controlled Trials***

Category of Adverse Event	Patients (Adverse Event Rate), *n (%)*		OR (95% CI)	Trials, *n*
	RYGB	VBG		
Gastrointestinal symptoms (including reflux, vomiting, dysphagia, dumping syndrome; and others)	169 (18.3)	178 (15.2)	1.29 (0.70–2.42)	3
Surgical, preventable and not preventable (including anastomotic, stoma-related, bleeding, reoperation, wound, and others)	241 (20.3)	252 (15.1)	1.48 (0.88–2.49)	5
Anastomotic or gastric pouch leak	70 (1.4)	72 (2.8)	0.49 (0.01–9.74)	2
Anastomotic or stomal stenosis	72 (6.9)	74 (14.9)	0.51 (0.13–1.72)	2
Bleeding	99 (1.0)	106 (0.0)	Not estimable	1
Reoperation (including those related to anastomosis, band, bleeding, revision, and others)	52 (0)	54 (3.7)	0 (0–5.73)	1

* Controlled trials include those comparing one procedure with another. OR = odds ratio; RYGB = Roux-en-Y gastric bypass; VBG = vertical banded gastroplasty.

Appendix Table 4. **Pooled Results for All Studies of Postoperative Adverse Events following Bariatric Procedures according to Operative Approach***

Procedure	Respiratory†		Pneumonia		Medical‡		Surgical, Preventable and Not Preventable§		Wound, All		Wound Infection, Major	
	Adverse Events, %	Studies/ Patients, n/n	Adverse Events, %	Studies/ Patients, n/n	Adverse Events, %	Studies/ Patients, n/n	Adverse Events, %	Studies/ Patients, n/n	Adverse Events, %	Studies/ Patients, n/n	Adverse Events, %	Studies/ Patients, n/n
Open	2.4	26/5317	0.9	11/3555	6.0	5/1360	22.1	68/11 094	11.4	47/8333	4.0	8/907
Lap	1.5	18/5437	0.8	7/2064	3.1	5/1463	12.4	47/13 752	2.3	27/8320	1.6	17/4694

* Ninety-eight studies of the open procedure and 53 studies of the lap procedure were considered for analysis by operative approach. DVT = deep venous thrombosis; Lap = laparoscopic; PE = pulmonary embolism.
† Including pneumonia, atelectasis, respiratory insufficiency, and others.
‡ Cardiac, stroke, and severe hypertension.
§ Including wound, hernia, splenic injury, reoperation, anastomotic, and others.
‖ Including splenectomy or repair.

Wound Infection, Minor		Incisional Hernia		Internal Hernia		Splenic Injury‖		Reoperation		DVT, PE, or Both	
Adverse Events, %	Studies/ Patients, *n/n*	Adverse Events, %	Studies/ Patients, *n/n*	Adverse Events, %	Studies/ Patients, *n/n*	Adverse Events, %	Studies/ Patients, *n/n*	Adverse Events, %	Studies/ Patients, *n/n*	Adverse Events, %	Studies/ Patients, *n/n*
10.8	9/739	11.9	29/3686	1.4	4/287	1.2	18/5065	8.1	18/3465	1.3	23/4704
3.3	5/1555	0.4	7/1075	2.9	6/3422	0.2	4/1541	2.7	9/5018	0.6	16/3995