

Comparative Effectiveness of Bariatric Surgery and Nonsurgical Therapy in Adults With Metabolic Conditions and a Body Mass Index of 30 to 34.9 kg/m²

Research Focus for Clinicians

In response to a request from the public, the Agency for Healthcare Research and Quality (AHRQ) provided support to the Southern California Evidence-based Practice Center to perform a systematic review of the comparative effectiveness and safety of bariatric surgery as a way to treat diabetes and other metabolic conditions in patients with a body mass index (BMI) of at least 30 kg/m² but less than 35 kg/m². This review included studies in which participants had a BMI of 30.0 to 34.9 kg/m² or in which a major subgroup of the study participants were in this BMI range. The systematic review included 54 studies published through September 2012. An online version of this summary provides links directly to the sections of the full report with references for individual findings, inclusion criteria for the studies, and an explanation of the methods for rating the studies and determining the strength of evidence for individual findings. The online version of this summary and the full report are available at www.effectivehealthcare.ahrq.gov/weight-loss-surgery.cfm. This summary is provided to assist in decisionmaking along with a patient's values and preferences. Reviews of evidence should not be construed to represent clinical recommendations or guidelines.

Background

Bariatric surgery is an accepted practice for patients with a BMI of 40 kg/m² or greater and for patients with a BMI between 35 and 40 kg/m² who have significant obesity-related comorbidities such as diabetes, hypertension, cardiovascular disease, dyslipidemia, obstructive sleep apnea, and degenerative arthritis. Currently, the most common types of bariatric surgery include laparoscopic adjustable gastric banding (LAGB), Roux-en-Y gastric bypass (RYGB), biliopancreatic diversion with duodenal switch (BPD/DS), and sleeve gastrectomy. Studies show that these bariatric surgical procedures cause significant weight loss and are more effective at improving diabetes in the short term (up to 2 years) than conventional nonsurgical interventions (diet, exercise, and other behavioral interventions). Diabetes improvement has been shown to start rapidly after surgery, before significant weight loss has occurred. The mechanism for postoperative metabolic improvements has not been fully elucidated and may be, in part, independent of weight loss. This suggests that bariatric surgery may improve metabolic comorbidities even in patients who are not morbidly obese. Thus, bariatric surgery has been suggested as an option for treating diabetes and other metabolic conditions such as impaired glucose tolerance (IGT) in patients with a lower BMI (at least 30 but less than 35 kg/m²).

Conclusion

According to the surrogate measures of blood glucose outcomes, bariatric surgery is an effective treatment for diabetes and IGT in patients with a BMI of at least 30 but less than 35 kg/m² followed up to 2 years. Weight-loss and glucose-control outcomes achieve greater improvement than typically seen with behavioral interventions (e.g., diet, exercise). Head-to-head comparisons are needed to determine comparative effectiveness among surgical interventions. The rates of short-term adverse effects (cardiovascular, respiratory, gastrointestinal, and metabolic) were low. Reported complications of LAGB include band slippage, leakage, and pouch dilation, and those reported for RYGB include stricture, ulcers, and rarely hemorrhage. While not discussed in the review, it has been suggested that weight regain and recurrence of diabetes might be observed after bariatric surgery. Despite promising short-term outcomes, very few studies of this target population have followup durations greater than 2 years, and the long-term effects of bariatric surgical procedures on major clinical endpoints (all-cause mortality, cardiovascular mortality and morbidity, and peripheral arterial disease) in patients with metabolic conditions and a BMI of 30.0 to 34.9 kg/m² are not known. Studies comparing surgical intervention to comprehensive care and behavioral interventions to each other are also needed to determine the relative effectiveness of these strategies in the long term.



Clinical Bottom Line

Evidence of Benefits in Adults With Metabolic Conditions and a BMI of 30.0 to 34.9 kg/m²

- Bariatric surgery is an effective treatment for weight-control and glucose-control outcomes (diabetes and IGT) in the short term (up to 2 years).
 - RYGB, LAGB, and sleeve gastrectomy ●●○
 - BPD ●○○
- In patients with diabetes or IGT who have undergone bariatric surgery, improvements in glucose-control outcomes can be measured as early as 1 month postsurgery; however, this effect is not seen in all patients. ●●○
- At 1 year after bariatric surgery, decreases in both weight and hemoglobin A1c (HbA1c) are greater than typically achieved in studies of diet, exercise, or other behavioral interventions (see the Outcomes Table for details). ●●○
- Several studies report improvement in hypertension and cholesterol at 1 year postsurgery. ●○○
- The evidence is insufficient to permit conclusions about effectiveness of bariatric surgery, when compared with other interventions, regarding these outcomes:
 - Continued weight loss or weight maintenance in the long term (more than 2 years) ○○○
 - HbA1c levels in the long term (more than 2 years) ○○○
 - Prevention of diabetes ○○○
 - Microvascular outcomes (renal disease, neuropathy, retinopathy, etc.) ○○○
 - Macrovascular outcomes (cardiovascular disease, stroke, and heart attack) ○○○
- The evidence is insufficient to permit conclusions about how the effectiveness and safety of bariatric surgical procedures compare with each other as treatment for diabetes or IGT. ○○○

Evidence of Adverse Effects in Adults With Metabolic Conditions and a BMI of 30.0 to 34.9 kg/m²

- Although the reported rates of mortality are low in this population (the rate of mortality was 0.48 percent for LAGB and 0.0 percent for gastric sleeve, RYGB, and BPD), studies are too limited to accurately predict risks. ●○○
- The surgical complication rates for sleeve gastrectomy and RYGB were similar. However, the types of complications observed with these two procedures vary. ●○○
- Complications reported in more than one study included:
 - LAGB: band slippage (2.3%), port or tube problems and band erosion (2%), postsurgery pouch dilation (5.4%), and reflux/hiatal hernia (2.7%) ●○○
 - RYGB: stricture (5%), ulcers (9%), incisional hernias (4.5%), and wound infections (4.3%) ●○○
- The evidence is insufficient to evaluate the risks of adverse effects of bariatric surgery in the long term (beyond 2 years) for patients with diabetes or IGT. ○○○

Strength of Evidence Scale

- High: ●●● High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
- Moderate: ●●○ Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- Low: ●○○ Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of effect and is likely to change the estimate.
- Insufficient: ○○○ Evidence is either unavailable or does not permit a conclusion.

Outcomes of Surgical and Nonsurgical Treatments in Adults With Metabolic Conditions and a BMI of 30.0 to 34.9 kg/m²

Outcomes (at 1 year unless otherwise specified)	Bariatric Surgery*	Behavioral Changes**	Medications**
Weight	<ul style="list-style-type: none"> ■ A BMI decrease of 5 to 7 kg/m² (about 15 to 20 kg for someone whose height is 5 ft 6 in). 	<ul style="list-style-type: none"> ■ Weight loss of 2.8 kg with diet, exercise, and behavioral interventions versus usual care. 	<ul style="list-style-type: none"> ■ Weight gain from 1 to 5 kg with some drugs.[†] ■ Weight loss of 2.8 kg with GLP-1R agonists. ■ No weight change with metformin.
HbA1c, percentage of total hemoglobin	<ul style="list-style-type: none"> ■ Decrease of 2.6 to 3.7 percentage points. 	<ul style="list-style-type: none"> ■ Decrease of 0.3 to 2.2 percentage points. 	<ul style="list-style-type: none"> ■ Decrease of 0.5 to 1.0 percentage points.
Other metabolic outcomes	<ul style="list-style-type: none"> ■ Significant improvements in diastolic blood pressure, lipids, and metabolic syndrome at 2 years were reported in one RCT. The prevalence of metabolic syndrome decreased by 34.8 percent in that study. ■ Significant decreases in hypertension and cholesterol medications at 1 year were reported in another RCT. ■ Fasting blood glucose was reported to have improved significantly in two RCTs. ■ Improvements in blood pressure and lipids at 1 or 2 years were also reported in observational studies. However, outcomes reporting was inconsistent in these studies. 	<ul style="list-style-type: none"> ■ Diet improved fasting glucose (a reduction of 1.3–36.6%) and triglycerides (a reduction of 11.3–58.9%). ■ The PREDIMED study conducted in Spain found that a Mediterranean diet reduced metabolic syndrome prevalence by 13.7 percent at 1 year. ■ The Finnish Diabetes Prevention Study found that behavioral change reduced metabolic syndrome prevalence at 3.9 years (OR = 0.62). 	<ul style="list-style-type: none"> ■ Most medications had minimal effects on systolic and diastolic blood pressures with changes less than 5 mmHg. ■ Metformin and second-generation sulfonylureas generally decreased LDL-cholesterol levels.
Prevention of diabetes	<ul style="list-style-type: none"> ■ Data unavailable. 	<ul style="list-style-type: none"> ■ The U.S. Diabetes Prevention Program (DPP) found diabetes incidence at 10 years reduced by 34 percent by behavioral change versus placebo. 	<ul style="list-style-type: none"> ■ The DPP found diabetes incidence at 10 years reduced by 18 percent in the metformin group versus placebo.

* Data are primarily from observational studies and a few RCTs.

** Data are almost entirely from systematic reviews and RCTs.

[†] Oral medications include second-generation sulfonylureas, biguanides, thiazolidinediones, meglitinides, and alpha-glucosidase inhibitors.

Abbreviations: GLP-1R = glucagon-like peptide 1 receptor; LDL = low-density lipoprotein; OR = odds ratio; RCT = randomized controlled trial

Note: There are additional considerations that clinicians should recognize that were not the subject of the review summarized here. Depending on the type of surgery, these might include regular postsurgical monitoring for:

- Weight regain
- Recurrence of diabetes
- Nutritional deficiencies
- Other postsurgical complications

Other Findings of This Systematic Review

- Evidence is insufficient to know if racial or demographic disparities affect the potential benefits and adverse effects associated with bariatric surgery for patients with a BMI of 30.0 to 34.9 kg/m² and diabetes or IGT. ○○○
- Evidence is insufficient to know if other patient factors (social support, counseling, preoperative weight loss, or treatment compliance) are related to successful postsurgical outcomes. ○○○

Gaps in Knowledge

- There is a scarcity of high-quality studies for this population (a BMI of 30.0–34.9 kg/m² with metabolic comorbidities). There is a need for more randomized controlled trials with larger sample sizes. The U.S. clinical trials database indicates that such trials are in progress.
- Very few studies had long-term followup (more than 2 years).
- The effectiveness of bariatric surgery in preventing the clinical consequences of diabetes (diabetic retinopathy, kidney failure, and myocardial infarction) has not been studied. No evidence was found on major clinical endpoints such as all-cause mortality, cardiovascular mortality or morbidity, or peripheral arterial disease. Nutritional endpoints should also be measured.
- Of the 54 studies included in this review, a very limited number were conducted in the United States. Applicability of findings from studies conducted outside the United States to American patients is unclear because diet, behavior, and culture may differ dramatically from country to country. There may also be biological or genetic differences between the populations.
- Quality-of-life and psychological outcomes after surgery were rarely reported.
- Most studies evaluating surgical procedures were not designed to assess adverse events and reflected events reported by the surgeon or the surgical team. As such, the reported rates of adverse events may be biased and lower than actual rates experienced in the wider community.
- For all surgical procedures, there is concern that published studies usually come from academic medical centers with high-performing surgical teams and careful patient selection. Outcomes for such patients may not reflect the outcomes achieved in the wider community.

What To Discuss With Your Patients and/or Their Caregivers

- The possible benefits of bariatric surgery for patients with a BMI between 30.0 and 34.9 kg/m² and with diabetes or IGT
- The possibility that the patient could be referred to a surgeon who would discuss the different types of bariatric surgery approaches recommended for the patient
- Whether or not the specific bariatric surgery recommended for the patient would be covered by the patient's insurance and how that would impact the patient's decisionmaking
- The possible adverse effects of bariatric surgery

Resource for Patients

Weight-Loss Surgery for Adults With Diabetes or Prediabetes Who Are at the Lower Levels of Obesity, A Review of the Research for Adults With a BMI Between 30 and 35 is a free companion to this clinician research summary. It covers:

- A description of BMI and obesity
- A discussion of diabetes and prediabetes
- A description of the different types of bariatric surgery
- A discussion of the amount of weight loss and improvement in blood glucose-control measurements that have been found in studies of bariatric surgery and how these results compare with nonsurgical treatments such as diets and medications
- A discussion of the side effects and possible harms from the different types of bariatric surgery



Ordering Information

For electronic copies of *Weight-Loss Surgery for Adults With Diabetes or Prediabetes Who Are at the Lower Levels of Obesity, A Review of the Research for Adults With a BMI Between 30 and 35*, this clinician research summary, and the full systematic review, visit www.effectivehealthcare.ahrq.gov/weight-loss-surgery.cfm. To order free print copies, call the AHRQ Publications Clearinghouse at 800-358-9295.

Source

The information in this summary is based on *Bariatric Surgery and Nonsurgical Therapy in Adults With Metabolic Conditions and a Body Mass Index of 30.0 to 34.9 kg/m², Comparative Effectiveness Review No. 82*, prepared by the Southern California Evidence-based Practice Center under Contract No. HHSA 290-2007-10062-I for the Agency for Healthcare Research and Quality, June 2013. Available at www.effectivehealthcare.ahrq.gov/weight-loss-surgery.cfm. This summary was prepared by the John M. Eisenberg Center for Clinical Decisions and Communications Science at Baylor College of Medicine, Houston, TX.

