

Weight Loss Surgery for Severely Obese Patients

Information for Physicians from the Cleveland Clinic Bariatric and Metabolic Institute



excellent long-term track record

Bariatric surgery has an excellent long-term track record for helping morbidly obese individuals lose weight. Mean weight loss is between 40 percent and 70 percent of excess weight after one to four years. The average surgical candidate has multiple co-morbidities, making him or her at higher risk for further complications. Thus, careful evaluation, proper patient selection and stratification are vital to ensuring an excellent outcome.



Confidence in Our Program

The Cleveland Clinic Bariatric and Metabolic Institute has been named a Bariatric Surgery Center of Excellence by the American Society for Metabolic and Bariatric Surgery. We also have been accredited as a Level 1 facility by the Bariatric Surgery Center Network (BSCN) Accreditation Program of the American College of Surgeons (ACS). Additionally, several major insurance providers have designated the Bariatric and Metabolic Institute as a distinguished program, including Anthem Blue Cross Blue Shield, Aetna, Medical Mutual of Ohio, Cigna and many others.



Why Choose Cleveland Clinic?

- Skilled, experienced surgeons who have performed thousands of bariatric surgical procedures
- High success rates, and low complication and mortality rates
- More than 98 percent of surgeries performed are minimally invasive
- Bariatric surgeons meet or exceed standards set by the American Society for Metabolic and Bariatric Surgery and the American College of Surgeons
- Nurses accessible by phone during regular business hours, and physicians available 24/7 for urgent problems
- Ability to handle high-risk, complex cases
- Easy access to additional medical specialists
- Newly renovated, comfortable unit designed specifically for the care of bariatric patients
- Newly constructed endoscopy suite dedicated to bariatric patients
- Pre-surgical medical weight reduction program is available
- Medically supervised weight management program for those who don't qualify for surgery
- Commitment to interactive communication with referring physicians

Cleveland Clinic's Bariatric and Metabolic Institute is comprised of a team of experienced weight management professionals, including endocrinologists, bariatric surgeons, bariatricians, psychologists, social workers, nurses, nutritionists and dietitians. After conducting detailed physical examinations and mental health and nutritional evaluations, the surgical risks are carefully weighed against potential benefits for each individual.

For those who do not qualify, Cleveland Clinic's medical weight management program offers dietary and psychological guidance.



Reversing the Harmful Effects of Disease

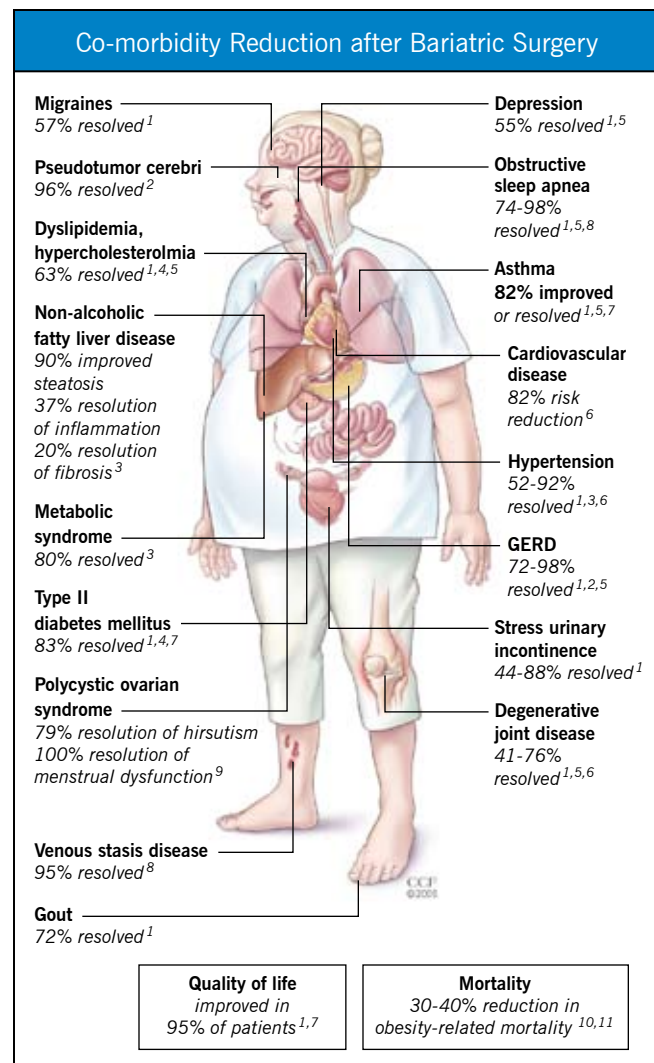
More than 30 co-morbid conditions are associated with severe obesity, the most serious of which are hypertension, diabetes, heart disease, stroke, obstructive sleep apnea and degenerative joint disease. Fatty deposits in the liver can progress to non-alcoholic steatohepatitis (NASH) and, if left untreated, ultimately liver failure. Studies show that the risk of death from these conditions reduces significantly after weight loss. Within the first six months of having surgery, patients usually no longer need to take medications for these conditions. In addition, women who were struggling with infertility before surgery find that conception is possible after surgery. Two recent landmark studies in the *New England Journal of Medicine* demonstrate significant evidence that bariatric surgery reduces long-term mortality associated with obesity.^{10,11}

Effective Treatment of Type 2 Diabetes

Bariatric surgery is not only successful for weight loss, but also for preventing, improving or resolving type 2 diabetes. Recent studies demonstrate that bariatric operations, particularly gastric bypass, can achieve a resolution rate as high as 83 percent, rendering these patients normoglycemic. Other studies have shown that patients with a BMI as low as 30 may have successful resolution of diabetes with gastric bypass surgery or gastric banding. We work in close collaboration with our Department of Endocrinology, Diabetes and Metabolism to prepare and manage these patients pre- and postoperatively. Cleveland Clinic bariatric surgeons have lectured on the surgical treatment of diabetes internationally and are conducting the first randomized controlled trial comparing bariatric surgery and medical treatment of type 2 diabetes. Physicians who have patients with even mild obesity and inadequately controlled diabetes should consider bariatric surgery as an option for better diabetes control.

Indications for Bariatric Surgery

- BMI > 40 kg/m² or BMI > 35 kg/m² with significant obesity-related co-morbidities
- Acceptable operative risk
- Failure of non-surgical weight loss programs
- Psychologically stable with realistic expectations
- Well-informed and motivated patient
- Supportive family/social environment
- Absence of active alcohol or substance abuse
- Absence of uncontrolled psychotic or depressive disorder



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BMI Categories

Underweight	< 18.5
Normal	18.5–24.9
Overweight	25–29.9
Obesity (Class 1)	30–34.9
Severe obesity (Class 2)	35–39.9
Severe obesity (Class 3)	40–49.9
Super-obesity	> 50



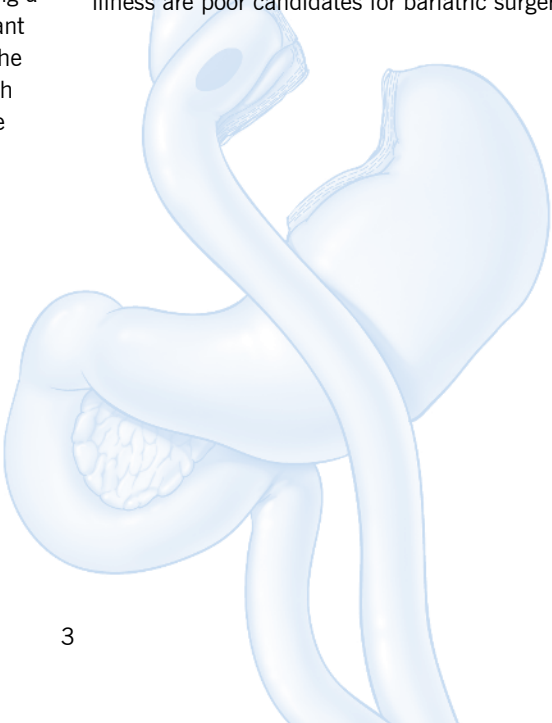
Candidates for Surgery

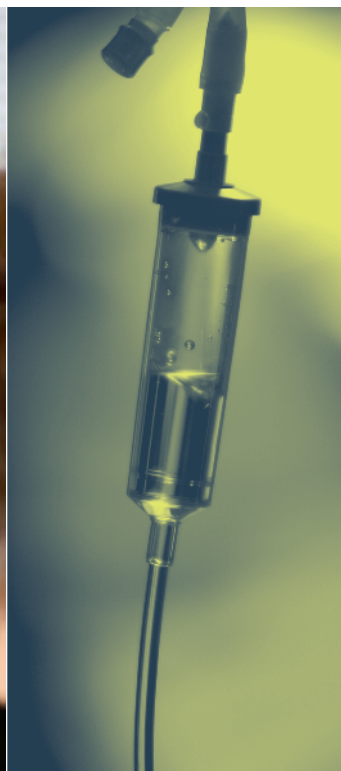
To be eligible for bariatric surgery, individuals must be between 16 and 70 years of age (with some exceptions) and have a body mass index (BMI) > 35 kg/m² with obesity-related co-morbidities or a BMI > 40 kg/m² with or without co-morbidities. Patients also must have attempted medical weight-loss programs and should be highly motivated to change their lifestyle after surgery.

If the individual is a woman of childbearing age and planning a pregnancy, it is vital to know that she should not get pregnant within the first 18 months to two years following surgery. The rapid weight loss and nutritional deficiencies associated with bariatric surgery make pregnancy potentially harmful for the mother and for a developing fetus.

Contraindications

Patients who cannot tolerate general anesthesia due to cardiac, pulmonary or hepatic insufficiency are not candidates for surgery. Additionally, patients must be able to understand the consequences of the surgery and comply with the extensive preoperative evaluation and the postoperative lifestyle changes, diet, vitamin supplementation and follow-up program. Patients who have ongoing substance abuse or unstable psychiatric illness are poor candidates for bariatric surgery.





Medical Weight-Loss Management Program

For patients who do not meet the surgical guidelines — those with metabolic syndrome and BMI < 35 kg/m², for example — Cleveland Clinic offers an intensive medically supervised weight management program, with a success rate higher than the national average. The program includes a team of physicians, dietitians and psychologists who address diet, exercise, behavior modification and medications with patients.

Patients benefit from a hypocaloric diet along with either a fat blocker or appetite suppressant, or the more aggressive protein-sparing modified fast, which allows them to shed fat without sacrificing lean body mass.

Preoperative Testing

A thorough history, physical exam and focused preoperative testing will uncover previously undiagnosed co-morbidities, including cardiovascular disease, in up to two-thirds of obese patients.

All bariatric patients undergo thorough nutritional evaluation and counseling preoperatively. Patients must understand how their diet will change after surgery and what supplements are necessary to prevent specific nutritional deficiencies. The dietitian plays a key role in determining whether a patient understands the significant changes in diet that will occur after bariatric surgery.

Psychologic testing is performed preoperatively to assess a patient's expectations and to ensure that there are no active psychiatric issues that would put the patient at risk for failure or poor compliance postoperatively.

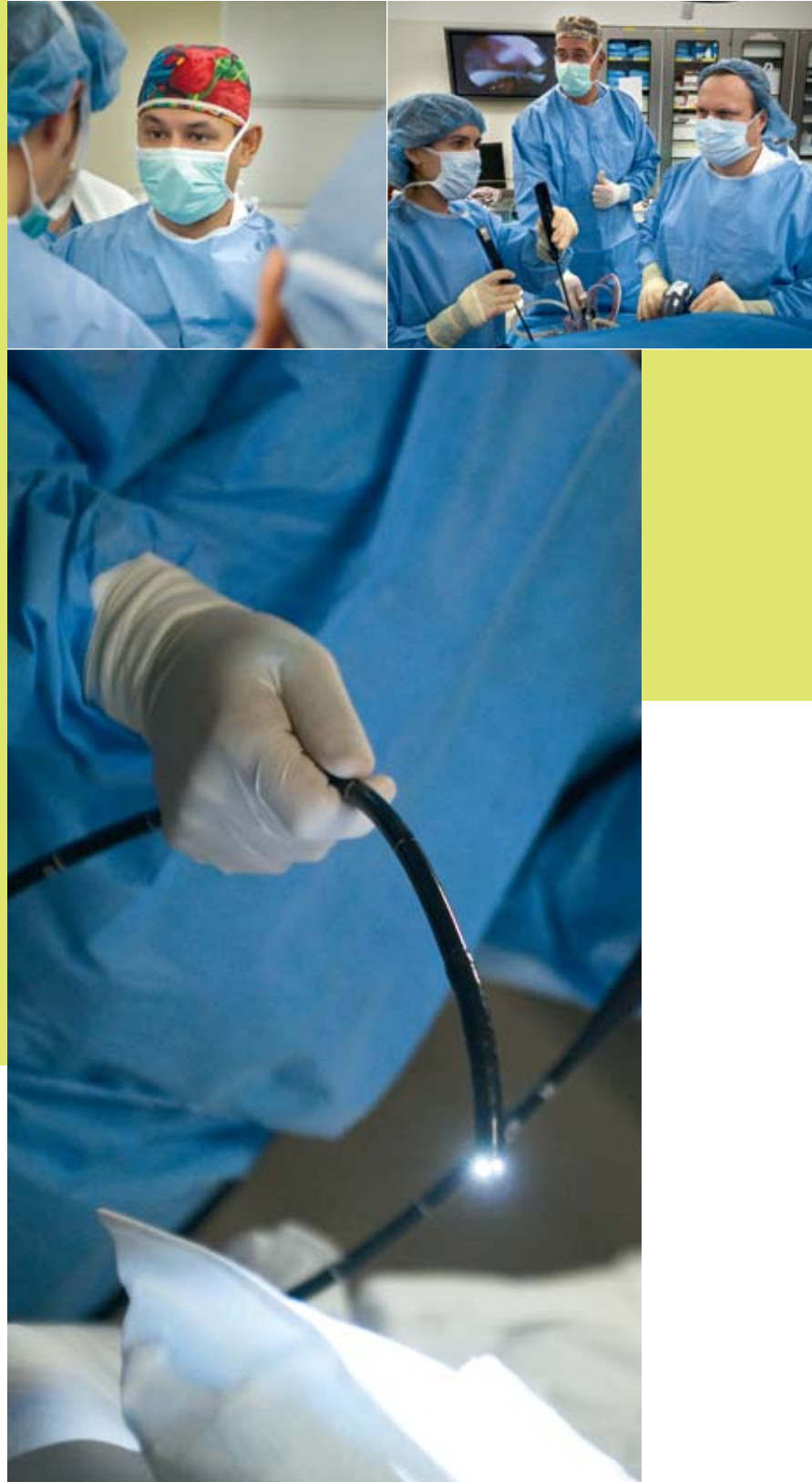
Metabolic Syndrome

According to the American Heart Association, metabolic syndrome is characterized by a group of metabolic risk factors. Metabolic syndrome can be identified in patients if they present with three or more of the following:

- Abdominal obesity (> 40 inches (102 cm) in men; > 35 inches (88 cm) in women)
- Atherogenic dyslipidemia (> 150 mg/dL triglycerides; < 40 mg/dL HDL in men; < 50 mg/dL in women)
- Elevated blood pressure (> 130/85 mm Hg)
- Insulin resistance or glucose intolerance (> 100 mg/dL fasting glucose)
- Prothrombotic state
- Proinflammatory state

Metabolic syndrome increases the risk of coronary artery disease, stroke, peripheral vascular disease and type 2 diabetes.

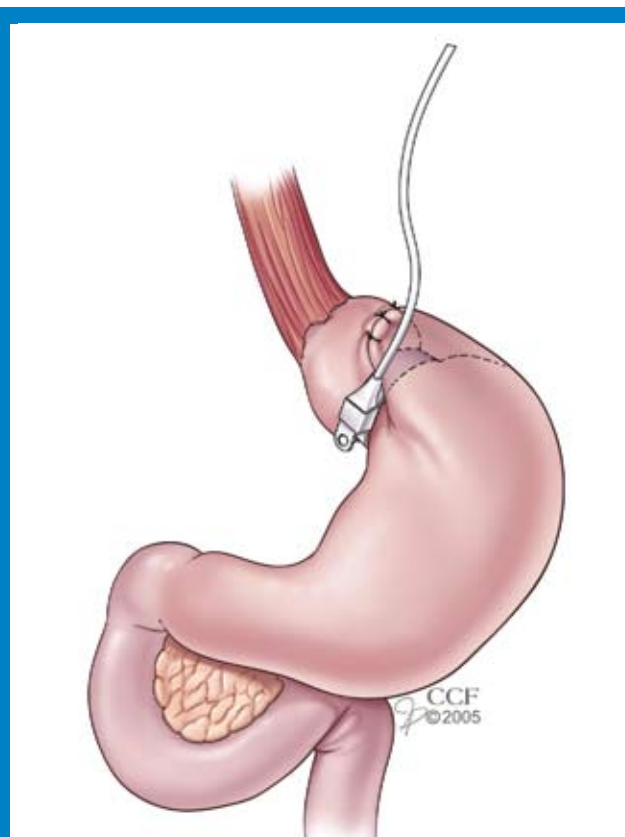
The primary clinical management goal is to reduce the risk for cardiovascular disease and type 2 diabetes. Risk-reduction steps include smoking cessation; reduction of LDL cholesterol, blood pressure and glucose levels to the recommended levels; increased physical activity; and developing healthy dietary habits. Weight loss resulting from medical or surgical treatment has been shown to be an extremely effective therapy for metabolic syndrome.





Procedures

Bariatric operations currently performed in the United States include gastric restriction (vertical banded gastroplasty, laparoscopic adjustable gastric banding and laparoscopic sleeve gastrectomy), malabsorption (biliopancreatic diversion and biliopancreatic diversion with duodenal switch), or both (Roux-en-Y gastric bypass). At Cleveland Clinic, our bariatric surgeons most commonly perform the laparoscopic adjustable gastric banding procedure or laparoscopic Roux-en-Y gastric bypass.

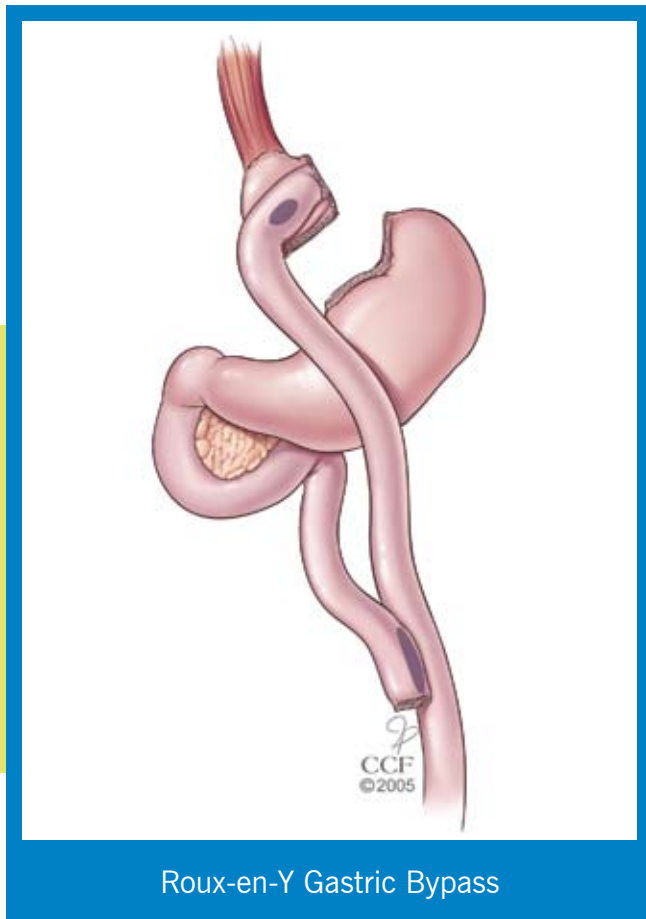


Laparoscopic Adjustable Gastric Banding

Laparoscopic Adjustable Gastric Banding

A restrictive procedure, laparoscopic adjustable gastric banding (LAGB) involves placing a silicone band with an inflatable inner collar around the upper stomach. The band is connected to a port that is placed in the subcutaneous tissue of the abdominal wall. The inner diameter of the band can be adjusted according to weight loss by injecting saline through the port.

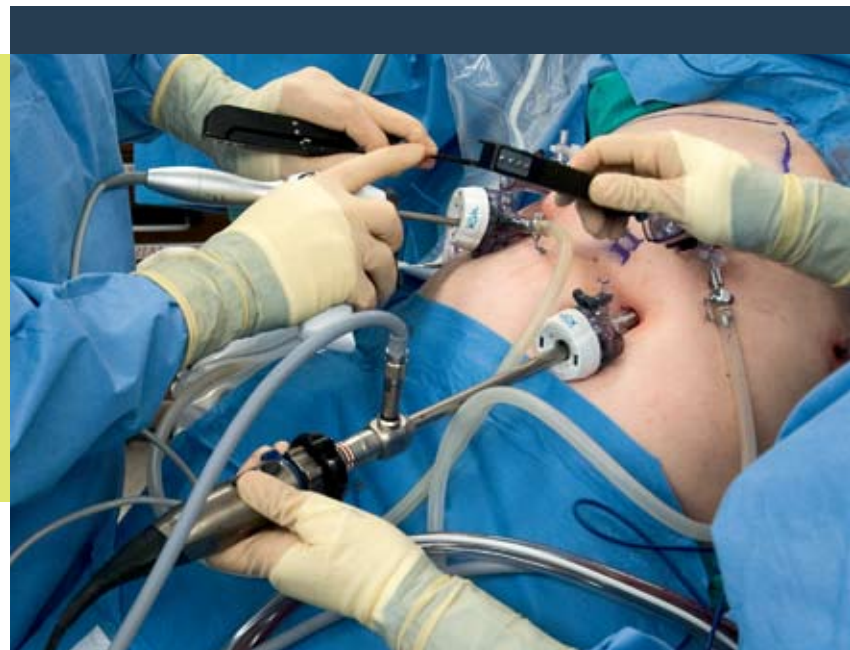
LAGB surgery is performed laparoscopically, offering less surgical trauma in the wound and to the viscera, improved postoperative pulmonary function and decreased incidence of wound-related complications such as hematomas, seromas, infections, hernias and dehiscence. LAGB is technically the simplest bariatric surgery to perform and requires less operating time than other procedures. No anastomoses are created, and the morbidity and mortality are low. The procedure is reversible and, if patients fail to lose adequate weight after LAGB, it can be converted to a Roux-en-Y gastric bypass.



The disadvantages of LAGB include the need for frequent postoperative visits for band adjustments and band slippage or gastric prolapse through the band (5 percent to 10 percent), which requires re-operation. Band erosion into the stomach, gastroesophageal reflux, esophageal dilation and dysmotility also can occur.

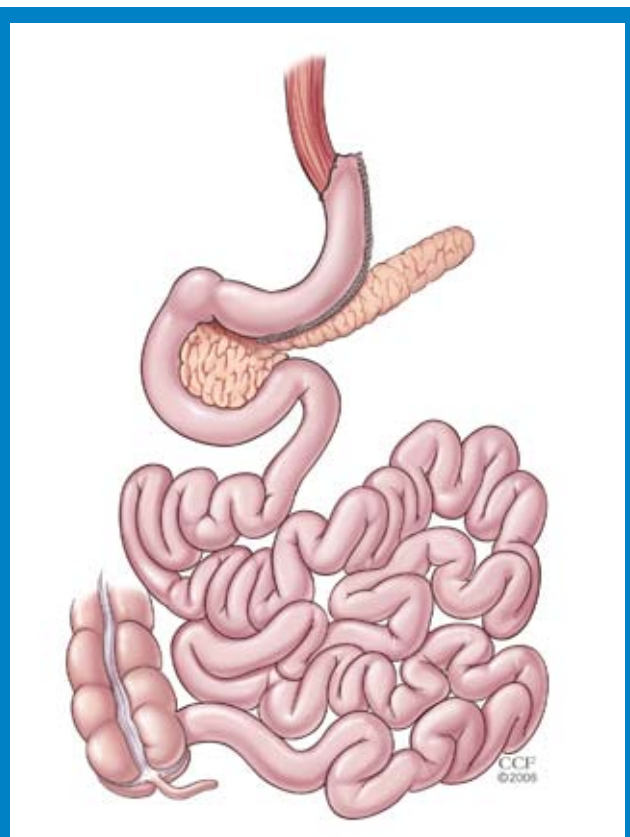
Laparoscopic Roux-en-Y Gastric Bypass

The most common bariatric procedure performed in the United States, Roux-en-Y gastric bypass (RYGB) combines a restrictive and a malabsorptive procedure. A small (15-30 cc) gastric pouch is created to restrict food intake and a Roux-en-Y gastrojejunostomy provides the mild malabsorptive component. In most patients (> 95 percent), Cleveland Clinic bariatric surgeons perform the Roux-en-Y gastric bypass laparoscopically.



The advantages of RYGB include superior weight loss when compared to vertical banded gastroplasty, with excellent long-term weight reduction and resolution or elimination of comorbidities (> 80 percent resolution of type 2 diabetes after surgery). Early and late complication rates are reasonably low, and operative mortality ranges from 0.2 percent to 1 percent.

Disadvantages of RYGB include the potential for anastomotic leaks and strictures, severe dumping syndrome symptoms and procedure-specific complications, including internal hernias. RYGB is technically more challenging to perform than the restrictive procedures, particularly when using the laparoscopic approach. In experienced hands, the conversion rate of laparoscopic RYGB to open is < 5 percent.

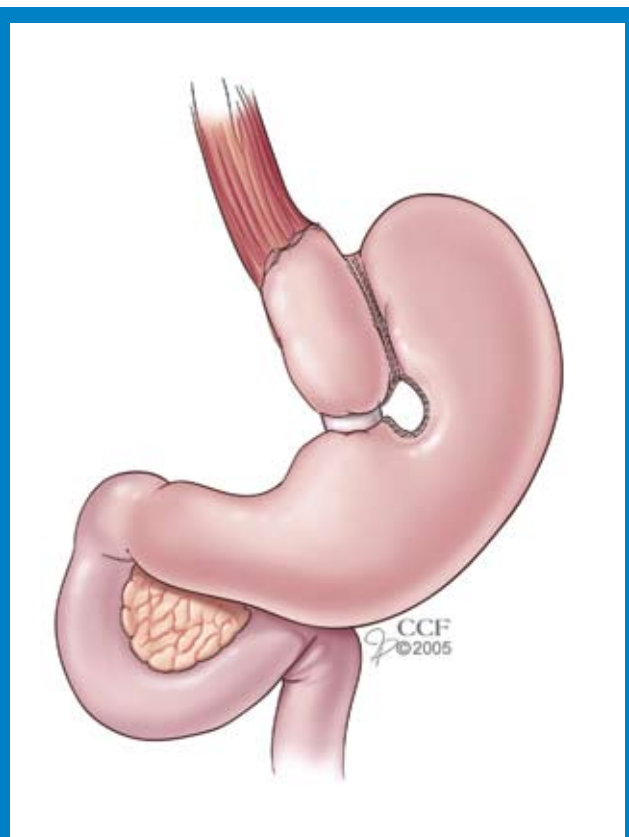


Laparoscopic Sleeve Gastrectomy

Laparoscopic Sleeve Gastrectomy

A restrictive procedure, the laparoscopic sleeve gastrectomy (LSG) involves removing approximately 75 percent of the stomach, leaving a narrow gastric sleeve. This procedure primarily is used as part of a staged approach to surgical weight loss for high-risk patients. In patients who undergo LSG as a first-stage procedure, the second stage (gastric bypass) is performed 12 to 18 months later after significant weight loss has occurred and the risk of surgery is lower. LSG also can be used as a primary procedure, although this is done very infrequently.

Risks of the procedure include a leak from the staple line used to divide the stomach; this is rare and major complications occur less than 1 percent of the time. Overall, the risks are similar to those seen with the laparoscopic adjustable band, but lower than the risks associated with gastric bypass.

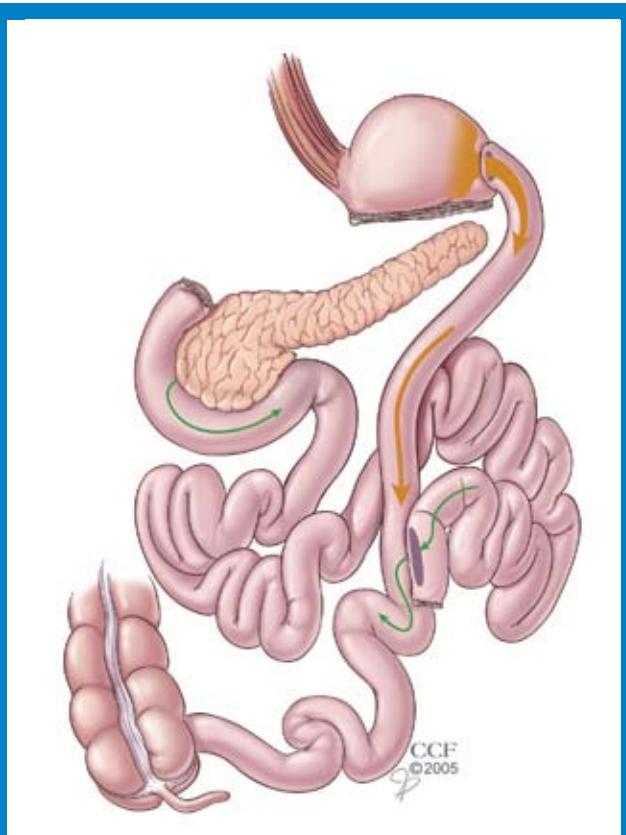


Vertical Banded Gastroplasty

Vertical Banded Gastroplasty

This purely restrictive procedure limits the amount of solid food that can be consumed at one time. A proximal gastric pouch empties through a fixed, calibrated stoma that is reinforced with an external silastic band or mesh ring. The advantages of vertical banded gastroplasty (VBG) include improvement of co-morbidities after weight loss, minimal nutritional deficiencies, the absence of any gastrointestinal anastomosis, and a lower morbidity and mortality rate than RYGB. It can be performed laparoscopically and is technically easier than RYGB.

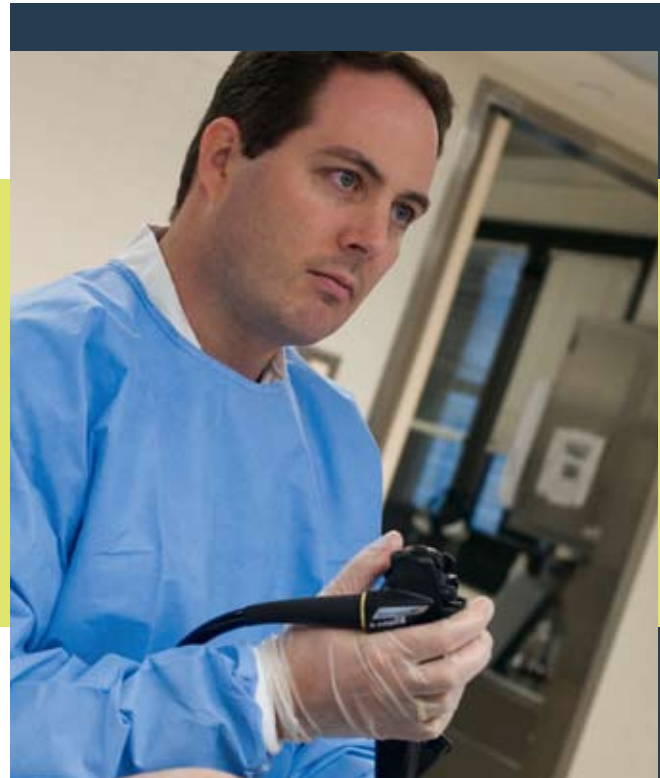
The disadvantages of this procedure include long-term weight loss that is inferior to RYGB, particularly in sweet-eaters, and multiple long-term complications that frequently require re-operation. VBG currently is not a preferred procedure at Cleveland Clinic. Patients referred to us for severe heartburn or weight regain after VBG are often converted to RYGB.



Biliopancreatic Diversion

Biliopancreatic Diversion

This malabsorptive procedure is less commonly performed and involves a distal gastrectomy, the creation of a long Roux-en-Y limb and an enteroenterostomy 50 to 100 cm from the ileocecal valve to form the common channel. A modification of biliopancreatic diversion (BPD) with a duodenal switch (BPD-DS) consists of a sleeve gastrectomy and duodenoileostomy with a long alimentary limb and a common channel measuring 50-100 cm. The advantages of BPD include substantial, durable weight loss (> 70 percent beyond 10 years) and resolution of many obesity-related co-morbidities. This procedure may be more effective than RYGB or restrictive procedures for super-obese patients and can be used as a secondary procedure in patients who have failed to lose weight with gastric bypass or restrictive procedures. BPD-DS also can be performed laparoscopically. BPD and BPD-DS, particularly if done laparoscopically, are technically challenging operations, and they have higher postoperative complication and operative mortality rates than other bariatric procedures. Metabolic complications occasionally require re-operation to lengthen the common channel.



Surgical Reversal

LAGB surgery is reversible in a minimally invasive manner. Gastric bypass surgery is potentially reversible. Reversal requires another operation of the same, or greater, magnitude with the same, or greater, risks.

Experience with Revisional Surgery

Occasionally bariatric operations require revisions due to surgical complications such as fistula, obstructions, ulcers, severe reflux or band slippage. Revisional surgery also may be indicated for weight regain because of a dilated gastric pouch or opening, or an ineffective gastric band. The majority of revisional surgeries are performed laparoscopically at Cleveland Clinic. A careful evaluation that includes endoscopy and imaging helps determine the cause of suspected surgical complications or inadequate weight loss. Although revisional bariatric surgery is higher risk, our surgeons have achieved successful outcomes in the vast majority of patients as a result of their experience performing hundreds of revisional procedures.

Endoscopy: The Future of Bariatric Surgery

Patients may require gastrointestinal endoscopy for preoperative evaluation as well as management of complications such as strictures or ulcers. Bariatric surgeons at Cleveland Clinic are at the forefront of using new endoscopic procedures to improve weight loss. This includes postoperative endoscopic suturing to reduce gastric pouch volume or gastrojejunostomy stoma diameter. A newly constructed bariatric endoscopy suite within the Institute provides operating-room-like capabilities, along with advanced radiologic tools, and is equipped for general anesthesia.

High-Risk, High-BMI Patients

The surgical treatment of obesity in the high-risk, high-BMI (> 60) patient remains a challenge. The results of an initial two-year study led by Philip R. Schauer, M.D., Director of Advanced Laparoscopic and Bariatric Surgery at Cleveland Clinic, showed that high-risk patients who underwent a two-stage gastric bypass experienced lower morbidity and mortality as compared with high-risk patients who underwent a one-stage gastric bypass. Study patients underwent laparoscopic sleeve gastrectomy (LSG) as a first stage. After achieving a predetermined weight loss, patients then completed the second stage, the laparoscopic Roux-en-Y gastric bypass (LRYGBP). Findings showed the staging concept of LSG followed by LRYGBP is a safe and effective surgical approach for high-risk patients.

Recovery and Support Following Surgery

Patients considering bariatric surgery are most afraid of failure; afraid they won't be able to stay committed to the dramatic lifestyle changes required for success. This is why bariatric surgery patients require lifetime follow-up and a solid support network.

Early postoperative visits with the surgeon focus on potential complications and dietary changes. Diet is progressively advanced from liquid to solid food over the first month in consultation with a dietitian. Later follow-up visits focus on psychological support, nutritional assessment, vitamin supplementation and exercise programs. Patient support groups are held every month and cover a variety of topics such as nutrition, fitness, plastic surgery and psychosocial issues.

After surgery, patients are referred back to their primary care physicians for their routine healthcare. In addition, Cleveland Clinic specialists require patients to follow the comprehensive post-surgery schedule as described below:

	1 wk	1 mo	3 mos	6 mos	9 mos	1 yr	Annually
Surgical follow-up	✓	✓	✓	✓	✓	✓	✓
Lab work				✓		✓	✓
Dietary counseling		✓	✓	as needed			
Psychological counseling		✓	as needed				
Exercise prescription		✓	as needed				

Life-altering Therapy Requires Close Communication

Careful patient selection for bariatric surgery is vital to the success of this life-altering therapy. Watchful monitoring for nutritional deficiencies and short- and long-term complications after surgery is essential and requires close communication between the patient's surgeon and primary care physician.

We promise to communicate with you regularly and at key decision points. After treatment and annual follow-up, we encourage your patients to return to you for their primary care needs.

Online Access to Your Patient's Treatment Progress

Whether you are referring from near or far, our new eCleveland Clinic service, DrConnect, can streamline communication from Cleveland Clinic physicians to your office. This new online tool offers you secure access to your patient's treatment progress at Cleveland Clinic. With one-click convenience, you can track your patient's care using the secure DrConnect Web site. To establish a DrConnect account, visit eclevelandclinic.org or e-mail drconnect@ccf.org.

Outcomes

Few, if any, therapies in medicine result in the simultaneous treatment of multiple diseases the way bariatric surgery does. Two randomized, controlled trials comparing surgical weight loss and non-surgical weight loss demonstrated the superiority of surgery over medical therapy in achieving long-term success. Since then, the procedures used in these two trials have been replaced with the more effective and less morbid procedures used today. The risks of bariatric surgery have decreased with increasing experience and technical refinements. The operative mortality for restrictive procedures, gastric bypass and BPD are 0.1 percent, 0.5 percent and 1.1 percent, respectively. Mortality after bariatric surgery is primarily due to pulmonary embolism and anastomotic leak.

Hospital volume and surgeon experience are crucial factors in bariatric surgery. Morbidity and mortality rates are higher in low-volume hospitals and centers. For example, in low volume centers (< 50 cases/year), mortality rates average 1.2 percent. In high-volume centers (> 100 cases/year), such as Cleveland Clinic, mortality rates average 0.3 percent.

Insurance

Many insurance companies now recognize obesity as a substantial health risk and are paying for bariatric surgery. Patients should contact their insurance providers to find out if bariatric surgery is a covered benefit under their insurance contract (gastric bypass CPT code 43644; laparoscopic adjustable gastric banding CPT code 43770).

Bariatric Surgery at Cleveland Clinic

Cleveland Clinic board-certified bariatric surgeons meet or exceed the standards of qualifications and credentialing for bariatric surgery and have performed thousands of bariatric procedures. Active members of the American Society for Metabolic and Bariatric Surgery, our surgeons emphasize laparoscopic procedures for more than 95 percent of bariatric surgeries performed at Cleveland Clinic, thus minimizing complications and speeding recovery.



Credentials

For the last nine years, *U.S. News & World Report* has ranked Cleveland Clinic among the nation's top five hospitals. The world-class surgeons at the Bariatric and Metabolic Institute are backed by a world-class team of multidisciplinary specialists — including Ohio's best digestive, endocrinology, neurology and orthopaedic programs, and cardiologists from the nation's No. 1 heart center. Cleveland Clinic nurses have achieved the highest national award for nursing excellence — magnet status — something less than 5 percent of all U.S. hospitals have earned. Cleveland Clinic is accredited by the Joint Commission.

Subspecialty medical care

Morbidly obese patients often require the skills of a cardiology and orthopaedics team. Cleveland Clinic's Heart Center has been ranked No. 1 in the country for 13 years in a row, and our Department of Orthopaedic Surgery consistently has been ranked among the nation's top five orthopaedic programs by *U.S. News & World Report* for the past several years. Following bariatric surgery, patients may desire abdominoplasty and other skin-removal techniques. Cleveland Clinic plastic surgeons routinely perform circumferential abdominoplasty and other body contouring procedures for people who have lost massive amounts of weight.



Information/Referrals

Please call 216.445.2224 or 800.CCF.CARE (223.2273), ext. 52224.

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Physicians and patients are invited to visit our Web site at clevelandclinic.org/bariatricsurgery.

For the latest information on upcoming CME activities, visit clevelandclinicmeded.com.



9500 Euclid Avenue, Cleveland, OH 44195

Cleveland Clinic is a nonprofit multispecialty academic medical center. Founded in 1921, it is dedicated to providing quality specialized care and includes an outpatient clinic, a hospital with more than 1,000 staffed beds, an education institute and a research institute.

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