

# Bariatric Surgery for Weight Loss

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## Faculty

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## Faculty Disclosure

Contributing faculty, John J. Whyte, MD, MPH, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

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The division planners and director have disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

## Audience

This course is designed for healthcare professionals involved in the care of patients for whom surgical intervention is indicated for the treatment of obesity.

## Accreditations & Approvals



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### Course Objective

Severely obese patients who have lost substantial amounts of weight following bariatric surgeries have experienced significant remission of obesity-related conditions, but the procedures are not entirely without risk. The purpose of this course is to educate healthcare professionals about the role of bariatric surgery in the treatment of obesity, with particular attention to outcomes for obesity-related diseases.

### Learning Objectives

Upon completion of this course, you should be able to:

1. Outline the epidemiology of obesity and bariatric surgery in the United States.
2. Describe the different types of bariatric surgery and the criteria for patients who may be candidates for weight-loss surgeries.
3. Discuss possible perioperative complications of bariatric surgery.
4. Review the care of patients after bariatric surgery, including expected weight loss.
5. State the effects that bariatric surgery may have on obesity-related diseases, with particular attention to cardiovascular risk factors.
6. Describe potential long-term complications of bariatric surgery, including nutritional deficiencies and medication absorption issues.
7. Identify options for non-surgical treatments for obesity, including lifestyle change and weight-loss medication.



EVIDENCE-BASED  
PRACTICE  
RECOMMENDATION

Sections marked with this symbol include evidence-based practice recommendations. The level of evidence and/or strength of recommendation, as provided by the evidence-based source, are also included so you may determine the validity or relevance of the information. These sections may be used in conjunction with the course material for better application to your daily practice.

## INTRODUCTION

Obesity is a well-recognized problem in the United States, affecting 42.4% of adults and 18.5% of youth [1; 9]. Health problems related to obesity, including diabetes, heart disease, arthritis, and certain cancers, produce significant disability. In the United States, it is estimated that between 100,000 and 300,000 deaths each year are attributable to obesity [2].

Many of the health problems related to obesity can be ameliorated or eliminated with weight loss and exercise. The National Diabetes Prevention Program demonstrated that among obese adults at high risk of diabetes, losing 5% to 7% of total body weight and adding 150 minutes of exercise per week could delay or prevent the onset of type 2 diabetes by 58% and by up to 71% in individuals 60 years of age or older [3; 4; 18]. Another study noted that even moderate weight loss of 5% was marked with improvement in metabolic function in the liver, fat, and muscle tissues, and a decrease in plasma levels of glucose, insulin, triglycerides, and leptin [18]. In the Nurses' Health Study, weight loss was associated with a decreased risk for hypertension, while weight gain increased the risk [6].

Studies of bariatric surgery have shed additional light on the benefits of weight loss. Severely obese patients who have lost substantial amounts of weight following gastric bypass, gastric banding, or other bariatric surgeries have experienced significant remission of obesity-related conditions [7; 13; 14]. There is also ongoing investigation into the possibility that certain surgical procedures confer benefit beyond that attributable to weight loss alone.

Because weight loss through diet and exercise is difficult and studies suggest that obese patients tend to regain lost weight, interest in bariatric surgery has been increasing. In spite of its well-established benefits, however, bariatric surgery is not without risk. Healthcare professionals who hope to improve outcomes in severely obese patients need a clear understanding of how bariatric surgery fits into the care of these challenging patients. This includes the likely extent of weight loss, the expected benefits, the risks both during and after the surgery, and the long-term effects on nutrition and on quality of life.

This course will address the indications for bariatric surgery, the types of procedures currently in use, the specific benefits for the treatment of obesity-related diseases, and the short- and long-term risks. It will also briefly address other treatments for severe obesity, including medication and therapeutic lifestyle change.

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## EPIDEMIOLOGY

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### OBESITY IN THE UNITED STATES

National Health and Nutrition Examination Survey (NHANES) data illustrate how rapidly obesity has been increasing in the United States. NHANES II, covering 1976 through 1980, showed that 15% of adults 20 to 74 years of age were obese [15]. NHANES III, with data from 1988 through 1994, found that 23% of adults in this age group were obese. The 2003–2004 survey found obesity in 33% of adults, while the 2005–2006 survey found obesity in 34% of adults. Data from 2013–2014 indicated that 37.7% of U.S. adults were obese, further rising to 39.8% in 2015–2016 and 42.4% in 2017–2018 [1; 16; 9]. As shown, the prevalence of obesity is steadily increasing; the goal of 30.5% set by the U.S. Department of Health and Human Service's Healthy People 2020 was not accomplished, and a revised goal of 36.0% has been set in the Healthy People 2030 initiative [10; 17].

Obesity is not evenly distributed among the population. Statistics from the Centers for Disease Control and Prevention (CDC) show that adults 40 to 59 years of age (43.3% of women, 46.4% of men) are more likely to be obese than adults 20 to 39 years of age (39.7% of women, 40.3% of men) and adults 60 years of age or older (43.3% women, 42.2% men) [9].

Some racial and ethnic differences in obesity rates exist. In 2017–2018, among all adults, the prevalence of obesity according to race was 49.6% among non-Hispanic black, 44.8% among Hispanic, 42.2% among non-Hispanic white, and 17.4% among non-Hispanic Asian adults [9]. A difference in prevalence between men and women of each race was noted,

especially among non-Hispanic black adults (56.9% women vs. 49.6% men) and non-Hispanic white adults (39.8% women vs. 44.7% men) [9]. Hispanic adults were similar (43.7% women vs. 45.7% men), and non-Hispanic Asian adults were nearly identical (17.2% women vs. 17.5% men) [9].

Cases of type 2 diabetes, which is strongly associated with obesity, have increased along with obesity prevalence. According to an analysis of data collected during 2004–2016 by the Behavioral Risk Factor Surveillance System (BRFSS), the age-adjusted prevalence of diagnosed diabetes increased in every state, the District of Columbia, and Puerto Rico, with the median prevalence for all geographic areas increasing from 7.8% to 13.1%; in 1995 it was 4.5% [19; 20]. In 1995, the age-adjusted prevalence was  $\geq 6\%$  in only three states, DC, and Puerto Rico. In 2010, it was  $\geq 6\%$  in all areas [19]. During 1995–2010, the overall median increase in age-adjusted prevalence of diabetes was 82.2% [20]. According to data from the National Health Interview Survey, 5.6 million Americans had been diagnosed with diabetes in 1980 [21]. By 2005, the number had risen to 16.3 million. Estimates from the CDC show that there were approximately 34.2 million people with a diagnosis of diabetes in 2018. In addition, 2018 estimates indicate an additional 7.3 million individuals were unaware that they had the disease [19; 20; 22].

### BARIATRIC SURGERY IN THE UNITED STATES

With the substantial increase in the number of obese Americans over the past several decades, the use of bariatric surgery has increased as well. According to a statistical report from the Agency for Healthcare Research and Quality (AHRQ), the annual number of bariatric surgeries in the United States increased from 13,386 to 121,055 between 1998 and 2004, a change of more than 800% [23]. According to the American Society for Metabolic and Bariatric Surgery (ASMBS), the number of bariatric surgeries performed in the United States increased from 158,000 in 2011 to 256,000 in 2019, an increase of 62%, with the biggest jump occurring between 2017 and 2018 [24].



Weight loss and metabolic outcomes after bariatric surgery are of similar magnitude in men and women; however, women continue to undergo bariatric surgery more often than men, comprising more than 80% of procedures [25; 48]. Men also tend to wait longer and opt for the procedure only after their weight has led to serious health consequences. Most procedures are performed in adults 18 to 54 years of age, but the number of adults older than 55 years of age choosing bariatric surgery has increased greatly. The use of these procedures in adolescents is still limited, but new evidence shows effectiveness in this population. The procedure rate per 100,000 adolescents increased from 0.8 in 2000 to 2.3 in 2003 [27]. Another study showed that in academic centers alone, procedures increased to more than 100 cases from 2007–2009, double that seen from 2002–2006 [145].

Adolescent bariatric surgery (in patients younger than 18 years of age) has been proven effective but should be performed in a specialty center. Patient selection criteria should be the same as used for adult bariatric surgery.

The AHRQ report estimates that inpatient costs of bariatric surgery are greater than \$1.2 billion, with a mean per-procedure cost estimated to be approximately \$10,000 to \$15,000, depending on type of surgery and associated factors [11; 23; 56; 144]. Insurance coverage varies. Medicare covers common types of bariatric surgery for patients with body mass index (BMI) greater than 35 and at least one obesity-related comorbidity, if medical treatment for obesity has been unsuccessful. However, the surgery must be performed at a center approved by certification programs of the American College of Surgeons or the ASMBS [28]. A list of approved centers is available at the Medicare website. Device manufacturers are lobbying the U.S. government and the health insurance industry to more fully cover bariatric surgery in order to provide access to the millions of obese Americans who might benefit from treatment and help save billions of dollars in healthcare costs. Some states require some level of coverage, but the requirements vary and often are not mandated for employers [29].

## BARIATRIC SURGERY

Bariatric surgery is a general term for surgical procedures that alter the digestive tract to promote weight loss. The surgery may reduce the size of the stomach or portion off a small area, reconfigure the small intestine, or comprise a combination of such alterations. Procedures that change the size of the stomach are called “restrictive.” Those that reconfigure the intestine are “malabsorptive.”

By reducing the area of stomach available to hold ingested food, restrictive surgeries decrease the amount of solid food that a person can comfortably eat and promote a sense of satiety. When the stomach outlet is reduced in diameter, these surgeries also slow the flow of ingested nutrients, helping patients to feel full longer. Malabsorptive surgeries reduce the area of the small intestine available to absorb nutrients.

Weight-loss surgeries most commonly used in the United States are the laparoscopic sleeve gastrectomy (LSG), or “sleeve,” and Roux-en-Y gastric bypass (RYGB), surpassing the historically popular laparoscopic adjustable gastric band (LAGB), or “band.” RYGB is a mixed restrictive/malabsorptive procedure, while LSG and LAGB are purely restrictive. Based on data from the University HealthSystem Consortium Clinical Database, gastric bypass made up 66% of bariatric surgeries performed at academic medical centers in 2007, while LAGB accounted for 23% [30]. By 2016, LSG had become the leading procedure performed, accounting for 58.1% of bariatric surgeries, compared with 17.8% in 2011 [24]. In 2019, RYGB comprised 17.8% and LAGB made up only 0.9% [24]. Certain other surgeries, previously common, have fallen out of favor due to high complication rates. They are described briefly in this course because patients who had these surgeries will still be seen in primary and specialty care. Many publications regarding bariatric surgery incorporate multiple procedures or variations on RYGB; as much as possible, the original terminology will be used when discussing each study.

## CANDIDATES FOR BARIATRIC SURGERY

The National Institutes of Health (NIH) first offered guidelines for bariatric surgery in 1991 [31]. In their guidelines, the NIH stated that candidates for surgery were those patients with BMI greater than 40 or BMI greater than 35 if high-risk comorbid conditions, such as diabetes, were present. Surgery could also be considered in this group if obesity-related conditions interfered with daily life. In addition, patients must be well-informed, motivated, and able to participate in treatment and long-term follow-up. Patients also were expected to understand the risks of surgery and consider them acceptable [31].

In 2005, the American College of Physicians (ACP) published their own guidelines [32]. They recommend considering surgery as an option for patients with BMI of 40 or greater who have obesity-related conditions, such as diabetes, impaired glucose tolerance, hypertension, hyperlipidemia, or obstructive sleep apnea. Patients should have tried and failed “an adequate exercise and diet program,” with or without drug treatment [32]. The ACP cautions that physicians should discuss long-term side effects with patients, including the potential for cholelithiasis or malabsorption and the possibility that repeat surgery may be needed. These guidelines are considered inactive because they have not been updated in the last five years. However, the selection criteria closely align with recommendations made by other organizations and likely have current clinical relevance [32].

In 2019, the American Association of Clinical Endocrinologists (AACE), the Obesity Society (TOS), and the ASMBS released updated guidelines for the perioperative care of the bariatric surgery patient that increased the number of total recommendations from 74 to 85 [11; 33; 145]. Current selection criteria include BMI  $\geq 40$  if no comorbidities are present,  $\geq 35$  if there is one or more severe obesity-associated comorbidity, or greater than 30 with diabetes or metabolic syndrome [11; 145]. Guidelines indicate that the BMI criterion for bariatric procedures should be adjusted for ethnicity (e.g., among Asian patients, 18.5–22.9 is normal range, 23–24.9 is overweight, and  $\geq 25$  is obesity) [11]. In addition, patients must

have tried and failed non-surgical weight reduction and be willing and able to adhere to postoperative care. Any patient with current alcohol or drug abuse, psychiatric illness that is uncontrolled, or underlying disorder causing the obesity should undergo a formal mental health evaluation. Finally, patients must understand the risks, benefits, alternatives, necessary lifestyle changes, and expected outcomes. Since publication of these criteria, sufficient data were presented to the U.S. Food and Drug Administration (FDA) that led to the approval of more relaxed criteria (i.e., BMI less than 35 with an obesity-related comorbidity [mild obesity]) for LAGB. Researchers have demonstrated comparable safety and efficacy of LAGB between mildly obese and more severely obese patients [11; 34; 145].

Preoperative strategies vary among bariatric programs in the United States, including the controversial strategy of whether patients should lose weight prior to surgery. Studies have suggested that a preoperative weight loss of approximately 10% is associated with greater weight loss one year postoperatively, shorter length of hospital stay, and more rapid short-term postoperative weight loss [35; 36]. However, no improvement has been seen in the risk of postoperative complications and in long-term, sustained postoperative weight loss [37]. Another study found that insurance-mandated dietary counseling undertaken to produce preoperative weight loss led to no improvement in postoperative weight loss and was associated with increased patient dropout rates prior to gastric bypass surgery [38]. The mandate reportedly does not consider that individuals who seek bariatric surgery typically report an extensive dieting history [39]. In 2016, the ASMBS released a position statement that indicated that insurance-mandated weight loss “contributes to patient attrition, causes unnecessary delay of life-saving treatment, leads to the progression of life-threatening comorbid conditions, is unethical, and should be abandoned” [165]. The most important perceived benefit of preoperative weight loss may be the observed reductions in liver volume and visceral fat. Loss of visceral fat reduces intra-abdominal pressure, which may in turn lead to improvements in urinary incontinence, gastroesophageal reflux,

and systemic hypertension [33; 40; 41; 42]. The 2019 clinical practice guidelines continue to include preoperative weight loss in their recommendations for the reasons previously mentioned; however, the strength of recommendation was downgraded due to inconsistent results [145].



According to the American Association of Clinical Endocrinologists (AACE), The Obesity Society, American Society of Metabolic and Bariatric Surgery (ASMBS), Obesity Medicine Association, and American Society of Anesthesiologists

(ASA), all patients should undergo preoperative evaluation for obesity-related comorbidities and causes of obesity, with special attention directed to those factors that could affect a recommendation for bariatric surgery. The preoperative evaluation should include a comprehensive medical history, psychosocial history, physical examination, and appropriate laboratory testing to assess surgical risk.

([https://www.endocrinepractice.org/article/S1530-891X\(20\)42802-2/fulltext](https://www.endocrinepractice.org/article/S1530-891X(20)42802-2/fulltext). Last accessed May 26, 2021.)

**Strength of Recommendation/Level of Evidence:** A1  
(Recommended to be used with other conventional therapy or as first-line therapy based on strong evidence from large prospective, randomized, controlled trials)

### Non-English-Proficient Candidates

As a result of the evolving racial and immigration demographics in the United States, interaction with patients for whom English is not a native language is inevitable. Because patient understanding of the bariatric procedure, the associated risks, and the necessary lifestyle changes is such a vital aspect of identifying appropriate candidates for surgery, it is each practitioner's responsibility to ensure that information and instructions are explained in such a way that allows for patient understanding. When there is an obvious disconnect in the communication process between the practitioner and patient due to the patient's lack of proficiency in the English language, an interpreter is required. In this multicultural landscape, interpreters are a valuable resource to help bridge the communication and cultural gap between clients/patients and practitioners. Interpreters are more than passive agents who translate

and transmit information back and forth from party to party. When they are enlisted and treated as part of the interdisciplinary clinical team, they serve as cultural brokers, who ultimately enhance the clinical encounter. In any case in which information regarding diagnostic procedures, treatment options and medication/treatment measures are being provided, the use of an interpreter should be considered.

### LAPAROSCOPIC SLEEVE GASTRECTOMY

The LSG involves removing approximately 80% of the stomach, creating a tube-shaped passageway and reducing the size of the stomach significantly. The sleeve procedure has quickly increased in popularity since 2010, surpassing LAGB procedures in 2012, and becoming the most common form of bariatric surgery in 2013 [166]. The sleeve gastrectomy likely gained popularity as a stand-alone procedure due to its efficacy for weight loss in short-term follow-up and its low complication rates. However, long-term data published in 2019 and 2020 have indicated that patients have a tendency to regain weight within two to three years post-procedure, and some cases require a revisional surgery. Ongoing research is required to determine the long-term efficacy of LSG and influence clinical practice guidelines [50; 51; 52].

### Mechanism of Weight Loss

The change to the stomach resulting from sleeve gastrectomy not only reduces the amount of food the stomach can hold, but also decreases the production of ghrelin, a gut hormone that stimulates appetite and influences body weight [54]. In contrast, diet-induced weight loss causes increased concentrations of ghrelin, which drives appetite and promotes weight regain [55].

### Contraindications

According to the ASMBS, there is no consensus on absolute contraindications to bariatric surgery [11; 33; 145]. Individual risk should be evaluated and discussed with each patient. Surgery should not be offered to patients who cannot understand the risks and benefits or who are unable to commit to the lifestyle changes needed to maintain health after the procedure.

Relative contraindications to LSG include gastroesophageal reflux disease (GERD) and Barrett esophagus, a condition characterized by changes to the esophageal lining due to long-term GERD and increases the risk of esophageal cancer [168]. At an LSG consensus conference, 94.5% of experts indicated that Barrett esophagus is a major contraindication of the procedure due to the potential to impede future treatment in the case of development of esophageal cancer. However, it should also be noted that the incidence of the condition is only seen in about 1% of severely obese patients, making LSG safe in 99% of patients seeking bariatric surgery [168].

### Disadvantages of LSG

As with most bariatric surgery options, LSG has the potential for vitamin/mineral deficiencies due to a lessened amount of nutrition and/or decreased absorption. Early complication rates are less than RYGB, but higher than that of LAGB. In addition, LSG is non-reversible [166].

### Advantages of LSG

The increase in the number of LSG procedures reflects several advantages over other types of bariatric surgery. Initial excess weight loss is slightly less than RYGB (60% to 80% RYGB vs. >50% LSG); however, long-term weight maintenance rates are comparable at approximately 50% [166]. LSG requires no foreign objects in the body, as LAGB does, and does not re-route the food stream, as in RYGB. LSG hospitalization stays are shorter than other procedures, averaging two days [166].

### ROUX-EN-Y GASTRIC BYPASS (RYGB)

The second most common form of bariatric surgery involves the creation of a small proximal gastric pouch with a tight outlet and a Roux-en-Y configuration of the small bowel. The pouch is created by transecting the stomach a short distance below the esophagogastric junction. The gastric pouch holds approximately 30 mL, while a normal stomach holds approximately one liter. The small bowel is divided partway along the jejunum, and the distal portion is anastomosed to the gastric pouch. The proximal

portion of small bowel, which remains attached to the stomach remnant, is then reconnected to the distal portion further along its length, so gastric acid, intrinsic factor, and pepsin will continue to flow and will mix with ingested food.

RYGB may be performed laparoscopically or open. Factors that affect this decision include the patient's body habitus, prior abdominal surgeries, and the skill of the surgeon [43]. Patients with extremely high BMI may be better candidates for open rather than laparoscopic surgery. For the surgeon, laparoscopic gastric bypass is technically demanding and has a steep learning curve.

### Mechanism of Weight Loss

Gastric bypass works primarily by restricting food intake and promoting a sense of satiety with relatively small amounts of food. The usual form of the procedure bypasses a small enough portion of intestine that malabsorption of caloric nutrients is thought not to be a significant mechanism of weight loss, although the configuration does decrease absorption of certain vitamins and minerals [43; 44; 166]. Because the surgeon may, at times, choose to alter the surgery to promote more significant malabsorption, healthcare professionals who care for patients who have had bariatric surgery should obtain the details of the procedure whenever possible. A distal gastric bypass is a more malabsorptive procedure.

### Contraindications

As mentioned, there is no consensus on absolute contraindications to bariatric surgery [33; 145]. Individual risk should be evaluated and discussed with each patient. Surgery should not be offered to patients who cannot understand the risks and benefits or who are unable to commit to the lifestyle changes needed to maintain health after the procedure.

### Advantages of RYGB

RYGB appears to produce more substantial weight loss than LSG and LAGB, with an initial weight loss of 60% to 80% excess weight loss; however, long-term maintenance rates remain controversial, with some studies indicating that RYGB is comparable



with LSG, with >50% of excess weight loss, and other studies indicating that RYGB is superior to LSG for percent of excess weight loss and remission of obesity-related comorbidities [45; 166; 50]. There is some evidence that alterations in gut hormones, including peptide YY and glucagon-like peptide 1 (GLP-1), may lead to suppression of appetite and thus decreased food intake, supporting increased weight loss over purely restrictive procedures. In addition, RYGB may lead to conditions that increase energy expenditure, furthering initial weight loss and maintenance [166].

### Disadvantages of RYGB

Because RYGB alters the configuration of the digestive tract, it changes the body's response to certain foods. A "dumping syndrome" may occur, particularly with the ingestion of foods with high sugar content. Within a short time after eating, patients with dumping syndrome experience lightheadedness, palpitations, flushing, and diarrhea. Dumping syndrome occurs in 70% or more of gastric bypass patients initially [33; 145]. In some, it resolves over time, but others have ongoing intolerance to certain foods. Some experts and patients feel that dumping syndrome is actually an advantage, because it discourages consumption of high-calorie, low-nutrient foods [166]. Reversal of RYGB has been proven as a safe and effective way to treat dumping syndrome [46; 167].



EVIDENCE-BASED  
PRACTICE  
RECOMMENDATION

The AACE, the ASMBS, the Obesity Society, Obesity Medicine Association, and the ASA assert that concentrated sweets should be avoided after Roux-en-Y gastric bypass (RYGB) to minimize symptoms of the dumping syndrome or after any bariatric procedure to reduce caloric intake.

([https://www.endocrinepractice.org/article/S1530-891X\(20\)42802-2/fulltext](https://www.endocrinepractice.org/article/S1530-891X(20)42802-2/fulltext). Last accessed May 26, 2021.)

**Strength of Recommendation:** D (Consensus statement based on no clinical evidence)

Another disadvantage of RYGB is that it is typically more complex than LSG and LAGB, often requires longer length of hospital stay, and could result in greater complications. Long-term maintenance is also more intensive, with life-long commitment to dietary restrictions and vitamin/mineral supplementation, especially vitamins B12, iron, calcium, and folate [166].

### LAPAROSCOPIC ADJUSTABLE GASTRIC BAND

The first LAGB was approved in the United States in 2001. Earlier types of gastric bands included non-adjustable versions and bands placed using open surgery. The current version is designed to be placed laparoscopically.

The LAGB is a device that is placed around the upper portion of the stomach just below the esophagogastric junction, creating a pouch that holds only a few ounces. A piece of tubing connects the band to a subcutaneous infusion port, placed below the skin of the abdomen. Saline is used to inflate the band and adjust the diameter of the gastric pouch outlet [47].

Approximately six weeks after the initial surgery, the first saline injection is given, usually about 3–4 cc. The "tightness" of the band may be tested using a barium swallow and fluoroscopy or more simply by making sure that sips of water are tolerated comfortably [49]. Band tightness is titrated to achieve a safe rate of weight loss, about 1 to 2 pounds per week. The amount of saline needed varies from person to person.

After each adjustment, patients are generally advised to consume a liquid diet for a day or two, then soft foods for a day or two, before returning to their usual diet. Patients may notice that they are more aware of the restriction for the first few days after an adjustment.

The surgery involves no permanent alterations to the anatomy of the digestive tract. The band is removable, although it is generally intended to remain in place long-term.

### Mechanism of Weight Loss

Placement of a gastric band is not thought to interfere with the normal process of digestion. It simply slows the movement of food through the digestive system and, by causing discomfort when large amounts of food are eaten at once, helps to reduce intake.

### Contraindications

Individual evaluation is essential to determining if a patient is a good candidate for LAGB. Contraindications to the use of an LAGB device include [49]:

- Crohn disease or other inflammatory diseases of the digestive tract
- A high risk of upper gastrointestinal (GI) bleeding
- Abnormal anatomy of the digestive tract
- Severe heart disease
- Severe lung disease
- Cirrhosis of the liver
- Portal hypertension
- Chronic pancreatitis
- Chronic steroid use or, in some cases, steroid use within 15 days of initial surgery
- Pregnancy
- Current infection
- Addiction to alcohol and/or drugs

As with any bariatric surgery, patients who are not able or willing to alter their diet and lifestyle should not undergo gastric band placement [49].

### Advantages of Gastric Banding

Gastric banding appears to have a lower complication rate and a lower mortality rate than other forms of bariatric surgery. Because it does not alter normal digestive function, it does not directly precipitate anemia or vitamin deficiencies and does not cause a dumping syndrome. It also has the advantage of being removable. Time in the hospital is generally brief, and many patients return home the same day.

### Disadvantages of Gastric Banding

As with any bariatric surgery, follow-up is essential. The LAGB, in particular, requires consistent follow-up because band tightness must be adjusted to achieve optimal weight loss. The LAGB also has the lowest rate of initial weight loss (40% to 50%) and the lowest weight maintenance rate (<50%) [166]. This method also has the potential for mechanical failure and complications with the band and requires a foreign device to remain in the body. LAGB has the highest rate of re-operation of the bariatric surgeries [166].

### NOVEL PROCEDURES

Several novel procedures are being investigated and/or have recently received FDA approval. Among the newly approved devices are intragastric balloon systems and a gastric electrical stimulation technique. It should be noted that these techniques do not yet have reliable long-term outcome data, and further studies and research are required to prove safety and efficacy.

#### Intragastric Balloon Systems

Intragastric balloon systems, brand names Orbera and the ReShape Integrated Balloon System, were approved by the FDA in 2015, and accounted for 1.8% of all bariatric surgeries in 2019 [24]. These systems are intended as a minimally invasive, short-term treatment. They involve placement of an inflatable, free-floating balloon in the stomach and are intended to be used in conjunction with diet and exercise. Both Orbera and ReShape are placed into the stomach through the mouth with the patient under mild sedation, using a minimally invasive endoscopic procedure. These balloons are then filled with 400–700 cc of saline to restrict the amount of space in the stomach. (ReShape also adds methylene blue dye.) These balloons may be placed for up to six months. A third balloon system, brand name Obalon, was approved by the FDA in 2016 and consists of up to three balloons in a capsule that is attached to a thin inflation catheter. The balloons are swallowed and then inflated with air to reduce the amount of free space in the stomach [170].

Intragastric balloon systems may have indications for individuals with BMIs between 30 and 40 and for morbidly obese patients who need to lose weight before bariatric surgery. A 2007 Cochrane Review suggests that intragastric balloon treatment may not provide benefits over conventional therapy. However, evidence was limited and different trials used different techniques and clinical considerations [171].

Little information is available regarding the effectiveness and long-term indications of balloon systems. In clinical trials for Orbera, patients lost an average of 21.8 lbs (10.2% total body weight) after six months, compared with 7 lbs in the same period in a group that received behavior modification. In addition, three months after placement, patients maintained an average weight loss of 19.4 lbs [172].

In 2017, the FDA issued a letter to healthcare providers warning that there have been incidences of spontaneous overinflation of the two brands of liquid-filled balloons (Orbera and ReShape), causing abdominal pain, difficulty breathing, and vomiting [171]. A risk of acute pancreatitis caused by compression of gastrointestinal structures was also noted. Later that same year, the FDA issued a letter to healthcare providers warning of adverse events associated with the saline-inflated versions. It was noted that five unanticipated deaths had occurred—one patient with ReShape and four with Orbera. At the time of publication of the letter, there was no known root cause, although all five patients died within hours to one month of placement [173]. In 2020, the FDA followed up and indicated that since the approvals of Orbera and ReShape, they have received reports of eight deaths in the United States (five with Orbera and three with ReShape). It should be noted that since the completion of the required post-approval studies by the device manufacturers, there have been no reports of hyperinflation reported with ReShape, and Orbera has reported hyperinflation in 2.3% of patients, prompting the FDA to require changes to the labeling of the device [4]. Further investigation of the safety and effectiveness of these balloon devices is required.

## Gastric Electrical Stimulation Technique

Gastric electrical stimulation is a technique involving an implanted device similar to a cardiac pacemaker. In 2015, the FDA approved the Maestro Rechargeable System for the treatment of obesity in patients 18 years or older with a BMI of 40 to 45, or 35 to 39.9 with one or more obesity-related health conditions. In addition, the patient must have tried to lose weight with diet and exercise in a supervised program within the past five years.

Controllable from outside the body, the gastric stimulator is intended to reduce caloric intake [57]. The Maestro device is implanted into the abdomen and entails an electronic pulse generator that sends impulses to the vagus nerve. The wire leads and electrodes then directly stimulate the vagus nerve to control appetite. A study of those using the Maestro device showed that the active group lost 8.5% more weight than the placebo group. In addition, 52.5% of the active electronic device group lost at least 20% of excess weight and 38.3% lost at least 25% of their starting weight [174]. As of 2018, the Maestro Rechargeable System is no longer marketed.

## Gastric Emptying System

In 2016, the FDA approved the AspireAssist device, a gastric emptying system in which a tube is surgically inserted into the stomach through a small incision in the abdomen and is connected to a port valve that lies flush against the outside of the body on the abdomen. The port valve remains in place, and the patient is instructed to connect an external connector with tubing approximately 20 to 30 minutes after eating to empty contents from the stomach into a toilet. The process of gastric emptying takes approximately 5 to 10 minutes to complete, and it is estimated that approximately 30% of calories are removed through the process. Candidates for the gastric emptying system include obese patients 22 years of age and older with a BMI of 35 to 55 with a proven record of failure to lose weight through non-surgical interventions. In addition, it is cautioned that the device is not appropriate for patients with eating disorders [175].

In a clinical trial of 171 patients, 111 used AspireAssist combined with lifestyle therapy and 60 control patients received only lifestyle therapy. In the group with the gastric emptying system in place, patients lost 12.1% of total body weight in one year, compared with 3.6% in the control group [175]. However, this device is controversial, with the Academy for Eating Disorders issuing expressing concern of the FDA-approval of a “mechanized purging device” [176]. The organization maintains that the device could be inappropriately prescribed due to the common under- and misdiagnosis of eating disorders, and could lead to unhealthy eating disorder-related behaviors [176]. Further studies are required to determine safety and efficacy of the device.

### **TransPyloric Shuttle**

In 2019, the FDA approved the minimally invasive TransPyloric Shuttle (TPS) system for the treatment of obesity in adult patients with a BMI of 35–40 or a BMI of 30–34.9 with an obesity-related comorbid condition [5]. The TPS system consists of large and small bulbs connected by a flexible silicone tether and an endoscopic delivery device. During delivery, the large bulb is distended with an internal coil and locked into the correct shape. Once the TPS is deployed endoscopically into the stomach, it causes faster filling times and delayed gastric emptying as peristalsis guides the small bulb into the small intestine and the large bulb to the pylorus. This device can remain in the stomach for 12 months, at which time it is retrieved endoscopically after removing the internal coil and collapsing the large bulb. The mean total body weight loss at 12 months was 9.5%, compared with 2.8% in the control group. Further studies are required to determine the long-term efficacy of this device [5].

### **Hydrogel Capsule**

In 2019, the FDA approved a first-in-class hydrogel therapeutic for the treatment of overweight and obesity in adults with a BMI between 25 and 40 [8]. This is the first prescription weight-loss aid to be approved for those considered overweight with no requirement for a comorbid condition. The

hydrogel, brand name Plenity, is a capsule taken with water before lunch and dinner. It cross-links two naturally-derived building blocks (cellulose and citric acid) to create a three-dimensional hydrogel matrix. The capsules release thousands of non-aggregating particles that rapidly absorb water in the stomach, creating small individual gel pieces with the elasticity of plant-based foods, without caloric value. The gel pieces increase the volume and elasticity of the stomach and small intestine contents, contributing to a feeling of fullness and inducing weight loss. This novel, non-stimulant, and non-systemic treatment has been shown in clinical studies to be effective, safe and well-tolerated. Patients lost approximately 10% of their total body weight within six months. There is no limit to the amount of time a patient can continue use [8].

## **STAGED PROCEDURES**

For most patients, surgically-induced weight loss involves a single surgical procedure. In some patients, however, extreme obesity or serious comorbidities preclude the use of the procedure that, in the surgeon’s judgment, would provide the most effective weight loss. A surgeon may feel that a patient with a very high BMI and heart disease will have the best long-term result from LSG or RYGB. However, the risk-benefit ratio in such a patient may be better for a less invasive procedure, such as LAGB, intragastric balloon, or gastric electrical stimulation. In this case, the surgeon may opt to begin with one of these techniques. After significant weight loss has been achieved, the patient’s risk profile may become more favorable, allowing removal of the band and completion of the more definitive procedure.

## **OTHER SURGERIES**

Many other procedures have been used in bariatric surgery, but for the most part they have fallen out of favor. These include jejunioileal bypass, vertical banded gastroplasty (VBG), and biliopancreatic diversion (BPD). However, research on new techniques and devices is being conducted, with the goal of reducing complications while maximizing weight loss.



Jejunioileal bypass, used in the 1960s and 1970s, was a purely malabsorptive procedure, bypassing most of the small intestine without altering the size of the stomach [57]. Weight loss was substantial, but complications included liver disease and liver failure, severe vitamin deficiency, electrolyte imbalances, malnutrition, osteomalacia, cholelithiasis due to reduced bile salts, and excess oxalate absorption leading to kidney stones [33; 58]. This procedure has essentially been abandoned.

Vertical banded gastroplasty involves the partitioning of the stomach, with the creation of a small pouch with a tight stoma. It was a common procedure during the 1980s, but long-term weight loss was unsatisfactory [57]. In addition, the use of mesh or silicone tubing to reinforce the small opening led to problems with localized infection and erosion of foreign material into the stomach. Some patients developed vomiting due to intolerance of the gastric constriction.

Biliopancreatic diversion is another malabsorptive procedure, now used less often than any other form of bariatric surgery, accounting for just 0.6% in 2016 [24]. In this surgery, the intestine is configured similarly to the RYGB, but a larger segment of intestine is bypassed and pancreatic enzymes are diverted so they enter directly into the ileum rather than the duodenum. Absorption of fats is particularly affected. Removal of the lower half of the stomach reduces the production of gastrin, thus decreasing the amount of stomach acid released. In a variant of BPD called duodenal switch, the proximal portion of the duodenum, which is more resistant to stomach acid than the small intestine, remains connected to the stomach. Duodenal switch maintains the malabsorptive component of BPD but adds a more significant restrictive component as well. Adverse effects of BPD and duodenal switch include nutritional deficiencies and foul-smelling flatus and diarrhea related to malabsorption of fat [59].

Other procedures and devices are in development and/or undergoing evaluation for use in the weight-loss setting. One relatively new restrictive procedure that has demonstrated encouraging results is transoral gastric volume reduction (TGVR) [63; 65]. TGVR encompasses several techniques to reduce gastric volume and absorption without the need for open surgery, including the use of sutures, staples, implanted devices, or endoluminal barriers [66]. An endoluminal barrier is a gastrointestinal liner designed to mimic the effects of gastric bypass surgery without the risks. It is undergoing clinical trials and investigational studies [52; 66].

Transoral gastroplasty (TOGA) surgery is an incision-free, restrictive procedure using a set of flexible staplers that are introduced through the mouth and esophagus to create a sleeve in the stomach [43; 61; 62]. The TOGA device was used as an investigational device; however, research and development of the TOGA device has been halted indefinitely due to set targets not being reached during clinical trials [169].

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## COMPLICATIONS OF BARIATRIC SURGERY

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### PERIOPERATIVE MORTALITY

The mortality rate of bariatric surgery is often related as “less than 1%.” In fact, mortality rates differ according to procedure, patient characteristics, and the surgeon’s skill.

According to data from the Healthcare Cost and Utilization Project, reported by the AHRQ, between 1998 and 2004 the national inpatient death rate associated with bariatric surgery declined from 0.89% to 0.19% [23]. Death rates differed by gender, with the rate for men being 2.8 times higher than the rate for women. This gap has narrowed, down from a six-fold increased risk in men in 1998.

In 2007, Buchwald and colleagues conducted a meta-analysis of mortality data using studies published between 1990 and 2006 [67]. Based on a total of 361 studies including 478 treatment arms and 85,048 patients, they found an overall mortality rate of 0.28% within the first 30 days and 0.35% between 31 days and two years. For gastric bypass, 30-day mortality was 0.44% for open procedures and 0.16% for laparoscopic procedures. Mortality from 31 days to two years was 0.69% and 0.09%, respectively. For gastric banding, open procedures had a short-term mortality rate of 0.18%, while the short-term mortality for laparoscopic procedures was 0.06%. The longer-term mortality rates were statistically 0.00% for both groups. For the most part, this analysis found that mortality trended downward with more recent studies, and smaller studies had higher mortality rates than larger ones. Mortality was highest in observational studies (0.7%) compared with other study designs (0.07% to 0.30%) [67]. In addition, mortality among patients who have undergone LSG have shown to be similar to those of the more well-studied procedures, with a mortality rate ranging from 0% to 1.2% depending on study type [178]. Nguyen and colleagues conducted an audit of bariatric surgery cases at 29 institutions participating in the University HealthSystem Consortium Bariatric Surgery Benchmarking Project [30]. For each institution, 40 consecutive cases were examined; a total of 1,144 cases met inclusion criteria, which was age older than 17 years and younger than 65 years, BMI of 35–70, and no previous bariatric surgery. Procedures were primarily gastric bypass (91.7%), with smaller numbers of gastroplasty or gastric banding (8.2%) and BPD (0.1%). For gastric bypass, with about three-fourths of the procedures done laparoscopically, 30-day mortality was 0.4%. Restrictive procedures had a 30-day mortality of 0%, with 92% of procedures done laparoscopically. Data support the low incidence of severe adverse events and mortality.

Other studies have shown that increased physician experience and higher case volumes are associated with lower mortality. For example, lower mortality rates have been reported at hospitals doing more than 100 bariatric surgeries annually compared with hospitals with lower numbers. Length of stay, morbidity, and costs were also lower at the high-volume institutions [68]. Concerns regarding the safety and uneven quality of bariatric surgeries performed across hospitals prompted the American College of Surgeons (ACS) and the ASMBS to implement an accreditation program for bariatric surgery centers—the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program [69]. The general guidelines to receive accreditation vary between programs but typically include a minimum volume of procedures, availability of resources for morbidly obese patients, and submission of outcomes data to a central registry [69; 70]. The ASMBS and ACS also partnered with the Society for American Gastrointestinal and Endoscopic Surgeons to establish credentialing guidelines for bariatric surgeons to ensure that surgeons maintain a certain skill level and are prepared for potential complications during bariatric surgery [71].

## PERIOPERATIVE COMPLICATIONS

Bariatric surgery is widely considered a safe procedure, but complications do occur. Possible early complications of RYGB include leaks at the anastomosis sites, GI hemorrhage, and the usual surgical risks of pulmonary embolism and infection [72]. Early complications with LSG include bleeding, staple line leak, and possibility of abscess [177]. LAGB complications may include gastric or bowel perforation, slippage of the band, and obstruction due to edema [72]. During recovery after surgery, patients may experience reflux or regurgitation, nausea, diarrhea, and constipation.

Following LSG, RYGB, and LAGB, patients may experience vomiting related to the small size of the stomach pouch. This is expected to resolve as healing occurs and as patients learn how much food they are able to tolerate. Persistent vomiting may signal stomal stenosis, a too-restrictive band, or other problems requiring intervention.

The precise incidence of serious complications with RYGB and LAGB is unclear. A review of 128 studies (primarily case series) conducted for the AHRQ revealed that surgical complications, including anastomotic leaks, bleeding, and reoperations, occurred in 18.7% of RYGB cases and 13.2% of LAGB cases [72]. Medical complications, including cardiac events, stroke, and severe hypertension, were seen in 4.8% and 0.7%, respectively. Gastrointestinal symptoms following surgery, including reflux, dysphagia, and dumping syndrome, occurred in 16.9% of RYGB patients and 7% of LAGB patients. Less data are available regarding LSG, although bleeding is estimated to occur in 1% to 6% of patients, with approximately 3% of patients not requiring intervention [177]. However, no firm conclusions are able to be drawn from any of these numbers because the severity of included complications is unknown.

## LATE COMPLICATIONS

Late and chronic complications of LSG include stricture (0.49%), GERD (6%), and nutrient deficiency [177]. Later complications of RYGB include incisional or internal hernia, stenosis at the anastomosis sites, bowel obstruction, ulcers near the stomach pouch outlet, and vitamin or mineral deficiencies [73]. With LAGB, patients may experience problems related to migration of a portion of the stomach above the band, erosion of the band into the stomach, infection at the port site, or disconnection of the tubing leading to the port [73]. Incisional hernia may also occur [60].

Some adverse effects are not technically surgical complications, but occur as a result of rapid weight loss. Cholelithiasis is a common result of rapid weight loss and is frequently seen in bariatric surgery patients [60]. Estimates of symptomatic cholelithiasis after RYGB, for example, range from 3% to 28% in various studies [74].

During the first several months after surgery, if weight loss is successful, patients may experience discomfort due to hypometabolism. They may experience fatigue, cold intolerance, and hair loss, all of which are expected to resolve as weight loss stabilizes [33].

## CARING FOR PATIENTS AFTER BARIATRIC SURGERY

### DIET AND EATING

After any bariatric surgery procedure, patients must change their eating habits significantly. Shortly after surgery, patients will usually be able to begin a liquid diet. Depending on the specific instructions from the surgeon, patients will slowly advance, over a matter of weeks, from clear to full liquids, then to pureed foods, and eventually to solids.

Small portions, chewed thoroughly, are essential for safety, comfort, and weight loss. Taking in too much food at once can lead to vomiting as the capacity of the gastric pouch is exceeded [75]. Food that has not been thoroughly chewed can become lodged in the stomach pouch outlet. Adequate protein intake is important both to reduce hunger between meals and to ward off malnutrition. Foods high in sugar can cause dumping syndrome following RYGB and should therefore be eaten in moderation or avoided altogether.

Patients should also pay special attention to liquid intake. Liquids should be sipped slowly. With LSG and LAGB, combining solids and liquids can speed transit of food from the upper pouch through the digestive system, so intake should be separated by approximately 30 minutes. After RYGB, consuming liquids and solids together may trigger dumping syndrome [33].

Patients should generally be advised to take a daily multivitamin-mineral supplement containing iron, in addition to supplemental calcium and a B-complex preparation [33]. Other supplements may also be required. Nutritional concerns following bariatric surgery will be discussed in greater detail later in this course.

## EXERCISE

Patients will generally be instructed to begin exercising shortly after surgery. With LSG and LAGB placement, patients can generally resume light exercise soon after returning home and progress to more vigorous exercise after a few weeks. After laparoscopic procedures, patients can begin taking short walks early after surgery, with the surgeon's approval, and usually begin or resume heavier exercise after about six weeks. Open surgery requires a longer healing time before exercise can be started or resumed.

## PREGNANCY

In a review of the literature, researchers examined published studies and case series of pregnancy following bariatric surgery [76]. They concluded that, overall, pregnancy after RYGB or LAGB appeared to be safe and bariatric surgery patients seem to have lower risk of several obesity-related gestational complications [76; 77]. However, they noted that patients in published studies often received careful prenatal care, including nutritional monitoring and LAGB adjustment, and that community practitioners should take care to provide a similar level of monitoring and intervention as needed. They also observed that surgery-related complications, such as internal hernia, do occasionally occur, although rates appear to be low.

The current recommendation from the American College of Obstetricians and Gynecologists (ACOG) is that women should delay pregnancy for 12 to 24 months after bariatric surgery to ensure that gestation does not occur during the rapid weight-loss phase [78; 79]. However, the opportune timing of pregnancy after surgery is unknown. The ACOG also strongly recommends preconception assessment and counseling and education regarding possible complications. Prior to attempting pregnancy, obese patients should be encouraged to undertake a weight-reduction program that includes diet, exercise, and behavior modification. Evaluation for nutritional deficiencies and the need for vitamin supplementation are also recommended [80].

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## WEIGHT LOSS AFTER BARIATRIC SURGERY

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Weight loss after bariatric surgery is usually most rapid in the first year. It may be fastest in the first few months, when caloric restriction is greatest. Weight loss is expected to slow at about six to nine months, and maximal total loss generally occurs at around 12 to 18 months [33].

With gastric bypass, about 80% of patients can be expected to achieve 60% to 80% excess weight loss during the first year, with later stabilization at about 50% to 60% [57]. In a meta-analysis of reports on various bariatric procedures, Buchwald and colleagues concluded that excess weight loss averaged 61.2% two years after surgery [7]. Weight loss with specific surgeries was 47.5% for gastric banding, including both adjustable and non-adjustable versions; 61.6% for gastric bypass, primarily variants of RYGB; and 70.1% for BPD or duodenal switch.

In a meta-analysis based on controlled trials comparing procedures, researchers reported actual weight lost instead of percentages and found that patients achieved weight loss of 30 kg (about 66 pounds) or more at 36 months with RYGB, LAGB, and VBG [72]. Of the three procedures, RYGB appeared to provide the most substantial weight loss.

In 2007, Angrisani and colleagues published a randomized controlled trial comparing laparoscopic RYGB to LAGB. In terms of weight loss, RYGB had better outcomes at five years, with significantly greater weight loss and fewer patients failing to achieve BMI less than 35. However, more serious surgical complications occurred in the RYGB patients [81]. Several case series and retrospective studies support this pattern, although the data on complications are not entirely consistent [33].



A 2008 review of studies comparing RYGB and LAGB, conducted by Tice and colleagues, concluded that weight loss, at least in the short term, was better with RYGB [82]. Perioperative morbidity appeared to be higher with RYGB, with long-term complications more frequent after LAGB. However, the review authors note that problems with data reporting, including missing details about complications, make it difficult to truly weigh the tradeoffs.

A 2011 review of studies comparing three laparoscopic procedures in bariatric surgery—sleeve gastrectomy, RYGB, and LAGB—found RYGB and sleeve gastrectomy to be more effective at achieving weight loss than LAGB. However, LAGB was found to be safer with frequent (but less severe) long-term complications. All three procedures achieved similar resolution of obesity-related comorbidities [83].

The sustainability of weight loss after bariatric surgery is thought to be good, although lifelong data are not yet available. Evidence is available from two large studies: the Swedish Obese Subjects (SOS) study, which has reached 20 years of follow-up, and a Canadian study reporting on outcomes after up to 16 years. In the SOS study, obese patients who underwent bariatric surgery were compared with matched controls who received conventional treatment for obesity [84]. A total of 4,047 subjects were enrolled, and by the time of the first analysis, 1,703 had been followed for at least 10 years. Surgical treatments were gastric banding (fixed or adjustable), VBG, or gastric bypass. Weight loss was maximal after one year in the surgical groups. Gastric bypass produced the most weight loss, followed by VBG, and then banding. At two years, some weight regain was apparent, with weight loss among surgery patients averaging 23%. At 10 years, weight regain had continued and surgery patients were only 16% below their starting weight, with gastric bypass patients still having the largest weight

loss. At 20 years, surgery patients were 18% below their starting weight [84]. Meanwhile, however, the comparison group had a 10-year weight gain of 1% and a 20-year weight loss of 1% [84]. There were 129 deaths in the control group compared with 101 in the surgery group. The unadjusted overall mortality was reduced by 23.7% in the surgery group; gender-, age-, and risk factor-adjusted mortality was reduced by 30.7% [85].

The assessment of weight loss reported in the Canadian study was part of a study that also compared morbidity and mortality among surgery patients and controls [86]. This study included 1,035 bariatric surgery patients treated for morbid obesity at the McGill University Health Centre between 1986 and 2002. Approximately 81% of the procedures were RYGB and 19% were VBG. With a mean overall follow-up of 5.3 years, excess weight loss was 43.4% to 90.8%. Weight loss was significantly higher after RYGB than VBG. Many patients were followed to 10 years and some to 16 years, with weight loss sustained at close to maximal levels. Data on weight loss among the control population was not available. A systematic review examined medium- and long-term weight loss after RYGB, RYGB variants (e.g., long-limb bypass), BPD and duodenal switch, and LAGB [87]. Overall, weight loss appeared to be durable to at least 10 years. However, weight regain was most apparent with RYGB, with excess weight loss declining from nearly 70% at two years to about 50% at 10 years. LAGB showed gradual progression of weight loss for three years, followed by stabilization. At years 1 and 2, pooled data showed that mean excess weight loss was superior with RYGB over LAGB, with a statistically significant difference. At years 3 through 8, the difference was no longer significant. The authors note that there was limited data on the number of patients lost to follow-up and on the number of patients measured at each data point.

A study published in 2010 followed 442 case-matched patients with a BMI of less than 50 who underwent either RYGB or gastric banding [88]. Outcomes measured were operative morbidity, weight loss, residual BMI, quality of life, food tolerance, lipid profile, and long-term morbidity. Early morbidity was higher after RYGB than after gastric banding; overall morbidity was similar. In patients who underwent RYGB, a more rapid weight loss was reported, and maximal weight loss was greater and more sustained. A greater number of long-term complications and need for repeat procedures were reported in the gastric banding group. Comorbidities improved more significantly in the RYGB group [88].

There is some evidence that weight loss due to bariatric surgery may vary not just by procedure but also by setting and patient population. A retrospective review of 59 patients who underwent RYGB between 1997 and 2002 at the Veterans Administration-Greater Los Angeles Health Care System found peak excess weight loss to be 52%, substantially lower than that reported in other studies [89]. However, maintenance of weight loss was good. The percentage of patients who achieved more than 50% excess weight loss was 54% at 12 months, 58% at two years, 47% at three years, and 44% at four years. Another retrospective review analyzed postoperative comorbidities and percent of excess weight loss in a group of 70 U.S. veterans who underwent laparoscopic RGYB between 2003 and 2006 [90]. Average preoperative weight and BMI were 310 pounds and 46, respectively. The incidence of major complications was 1.4%; no mortalities were reported. Excess weight loss was 61% at one year, 53% at three years, and 59% at five years (56% at mean follow-up of 39 months).

There are less long-term data available for the most commonly used bariatric surgery, LSG. Some studies have indicated that initial and maintenance weight loss is similar to that of RYGB, while others show that RYGB has better outcomes [50]. A five-year outcome study published in 2017 of 156 patients who had undergone LSG showed a mean percent of excess of weight loss was 82.0% at one year, 76.7% at three years, and 60.3% at five years [166; 179].

A small number of patients will not have large amounts of weight loss after surgery. Precise numbers of “failures” are not known, in part because there is no set cut-off for “acceptable” or “successful” weight loss. Because suboptimal weight loss and/or weight regain are not uncommon, considerable attention is being given to identifying reliable outcome predictors. Researchers have just begun to identify the complex contributing factors that influence postoperative outcomes, including preoperative psychologic status (e.g., mood disorders, anxiety disorders), patient expectations regarding anticipated weight reductions, and concurrent unhealthy behaviors (e.g., binge eating, emotional eating, night eating). Understanding these factors is expected to contribute to improved weight-loss management and prevention of weight regain. The long-term success of bariatric surgery relies on patients’ ability to make sustained lifestyle changes [91; 92; 93; 94; 95; 96].

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## EFFECTS ON OBESITY-RELATED CONDITIONS

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### DIABETES

A paradigm shift has expanded the role of bariatric surgery from a focus on the effects on obesity to include the effects on metabolic disorders, specifically type 2 diabetes. Because of the improvements seen in metabolic disorders, bariatric surgery is sometimes referred to as “metabolic surgery.” This shift is reflected in a position statement issued by the International Diabetes Federation (IDF) in 2011 [34]. In this statement, the IDF supports bariatric surgery as a treatment option for select patients with type 2 diabetes. This position is endorsed by the American Association of Clinical Endocrinologists in their 2015 guidelines for comprehensive diabetes care, and the use of bariatric surgery for treatment of type 2 diabetes has been endorsed by more than 50 organizations [97; 98; 99]. In addition, the American Diabetes Association has included bariatric surgery in the treatment algorithm for type 2 diabetes [11].

The connection between type 2 diabetes and obesity has become increasingly clear as the prevalence of both conditions has risen. Exercise and weight loss are now established as ways to reduce the risk of developing type 2 diabetes. The Look AHEAD trial, designed to evaluate the effects of weight loss on cardiovascular risk in patients with diabetes, has published early data demonstrating improved diabetes control with a lifestyle intervention designed to promote weight loss [100]. Using portion control, a home-based exercise program, and optional weight-loss medication, patients in this study lost an average of 8.6% of initial weight. At present, however, some of the strongest data linking weight loss to improvement in diabetes come from studies of bariatric surgery. Reviews and meta-analyses of publications concerning bariatric surgery have consistently found improvement or resolution of diabetes in the majority of patients.

The AHRQ evidence report related that, in published bariatric surgery case series, diabetes improved or resolved in 69% to 100% of cases [23]. In the meta-analysis by Buchwald and colleagues, among studies that reported resolution of diabetes, 76.8% of patients had complete resolution [7]. In studies that also reported improvement, 86.0% had either resolution or improvement. A 2007 review found that diabetes resolved in more than 75% of bariatric surgery patients [9].

In the SOS study, at two years of follow-up, diabetes had resolved in 21% of conventionally treated patients and 72% of surgery patients. Among those who had been followed for 10 years, the recovery rate was 13% for conventional treatment compared with 36% for surgery [8].

In 2008, researchers published data from a randomized controlled trial comparing lifestyle change, including the option of medication to treat obesity, to LAGB in patients with type 2 diabetes [101]. Out of 60 patients enrolled, 55 were followed to two years. Starting BMI was between 30 and 40, and diabetes diagnosis was recent, having been made within the past two years. The surgery group lost

62.5% of excess body weight, and 73% experienced remission of type 2 diabetes. In the non-surgical group, excess weight loss was 4.3% and diabetes remission was 13%. Remission of diabetes correlated with weight loss and also with lower hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) levels at baseline. A study published in 2012 showed remission of type 2 diabetes in 62% of RYGB patients at a six-year follow-up [180].

The American Diabetes Association (ADA) previously defined remission of type 2 diabetes as when a patient has a normal fasting blood glucose level or HbA<sub>1c</sub> less than 6% without the aid of hypoglycemic medications [97]. The ADA has revised this definition to include HbA<sub>1c</sub> less than 6% and fasting glucose levels of less than 5–6 mmol/L without medication at least one year following bariatric surgery. In a report published in 2012, researchers used the revised ADA definition and data from 1,006 patients, 209 of whom had type 2 diabetes at the time of gastric surgery. Median follow-up was 23 months. Based on the new ADA standard, remission rates were 40.6% after gastric bypass, 26% after sleeve gastrectomy, and 7% after gastric banding. On average, patients remained obese after surgery, and oral hypoglycemic medications were still used by 29.4% of gastric bypass patients, 63% of sleeve gastrectomy patients, and 83% of gastric banding patients [97; 102].

Some studies have attempted to compare the effects of different bariatric procedures on diabetes. While weight loss consistently appears to be greater with RYGB than with LAGB, at least in the initial years following surgery, the long-term impact on diabetes is less clear. Parikh and colleagues have reported a case series of 282 patients with diabetes who underwent bariatric surgery at an academic hospital in New York [103]. Two hundred and eighteen patients had LAGB, 53 had RYGB, and 11 had BPD/duodenal switch. Percent excess weight loss was significantly higher with BPD/duodenal switch and RYGB than with LAGB. However, the differences between groups with regard to postoperative use of hypoglycemic medications or insulin were not statistically significant.

In a series reported by Kim and colleagues, 232 patients undergoing gastric bypass were compared with 160 patients undergoing LAGB [104]. In each group, about 20% of patients had diabetes. While excess weight loss was greater with gastric bypass, improvement or resolution of diabetes was similar: 72.1% in the gastric bypass group and 77.1% with LAGB, a non-significant difference.

In other studies, diabetes resolution has proven to be better with gastric bypass than with LAGB. The meta-analysis by Buchwald and colleagues found a gradation of effects on the resolution of diabetes: 98.9% for BPD or duodenal switch, 83.7% for gastric bypass, 71.6% for gastropasty, and 47.9% for gastric banding [7]. Later, Cottam and colleagues reported a matched-pair study comparing RYGB and LAGB and found that, in addition to more substantial weight loss in the gastric bypass group, resolution of diabetes was greater (78%) compared with the gastric banding group (50%) [105]. A 2016 study found that rates of diabetes remission were 68.7% in RYGB patients and 30.2% in LAGB patients at three years post-surgery [53]. In a prospective study of surgery in 106 super-obese patients (BMI >50), all patients with diabetes who underwent gastric bypass had normalization of blood glucose, while normalization occurred in only 40% of those treated with LAGB [106].

### **Possible Additional Mechanisms for Diabetes Resolution**

Although weight loss is clearly an important element in the improvement or resolution of type 2 diabetes, there has been much attention to the possibility that hormonal mechanisms unrelated to weight loss may have an impact as well. Investigations into this possibility have been spurred by the fact that many patients are able to discontinue their diabetes medications after undergoing RYGB, before any significant weight loss occurs.

Early normalization of blood glucose is occasionally seen in LAGB patients as well as in RYGB patients, suggesting that simple caloric restriction may play a significant role. However, there is some evidence that malabsorptive surgery increases both beta-cell sensitivity to glucose and peripheral insulin sensitivity [107]. The diversion of nutrients away from the normal digestive pathway and the release of partially digested food into the distal small intestine appear to cause alterations in incretin signals to the pancreatic islets [108]. In addition, changes in gut hormones may influence appetite and other responses to food [109]. However, the interplay of these hormones and their influence on glucose metabolism is still being investigated. For example, GLP-1 has often been implicated in the improvements in glucose metabolism, but study measures of GLP-1 do not indicate that the hormone is critical in the improvement of glucose homeostasis after gastric bypass [110].

While malabsorptive procedures may have additional mechanisms of action against diabetes, similar changes in gut hormones do not occur with purely restrictive procedures [111]. The reduction in diabetes associated with LAGB appears to be due to weight loss alone.

### **HYPERTENSION**

Multiple studies of bariatric surgery have reported significant declines in blood pressure at follow-up, although the role of bariatric surgery in preventing hypertension is less clear [112]. There may be a relationship between the length of pre-existing hypertension preoperatively and the likelihood for resolution following bariatric surgery [113].

In the SOS study, the incidence of hypertension was the same in both the treatment and the control groups at two and 10 years of follow-up [8]. Recovery from hypertension, however, was significantly higher in the surgery group. At two years, 21% of controls no longer had hypertension, compared with 34% of surgery patients. Among patients followed to 10 years, 11% of previously hypertensive controls were normotensive, while recovery was 19% in the surgery group.



Studies with this length of follow-up are uncommon, but some additional evidence is available on blood pressure several years after surgery. White and colleagues used data from a single surgeon's gastric bypass cases (variations on RYGB), collected over 14 years, to examine outcomes including the resolution of hypertension [112]. With a median follow-up of just over four years, 62% of previously hypertensive patients had normal blood pressure and 25% showed improvement.

Shorter-term studies have also found resolution of hypertension to be common after bariatric surgery. Ahmed and colleagues conducted follow-up with 100 patients for one year after RYGB to evaluate changes in blood pressure [114]. By the end of one year, both the percentage of patients who were hypertensive and the number of patients taking medication for hypertension had decreased substantially. At baseline, 53 patients were on medication, with a decline to 15 at one year. Decreases in blood pressure occurred rapidly, beginning in the first week for some patients.

## DYSLIPIDEMIA

Changes in lipids are also widely seen in follow-up studies of bariatric surgery patients, although long-term data are somewhat mixed [10]. In the SOS cohort, rates of recovery from hypertriglyceridemia and from low high-density lipoprotein (HDL) were better in surgery patients than in the control group at both 2 and 10 years of follow-up. Recovery from hypercholesterolemia, on the other hand, was not statistically different in surgical patients compared with controls at either time point. The incidence of hypercholesterolemia was similar as well.

Shorter-term evaluations of LAGB and gastric bypass have found significant improvements in low-density lipoprotein (LDL), HDL, and total cholesterol, generally at 12 months after surgery but with some studies having follow-up to four or five years [115; 116; 117; 118; 119; 120; 121]. The meta-analysis by Buchwald and colleagues, which included studies having at least 30 days of follow-up, concluded that hyperlipidemia typically improved in at least 70% of patients [7]. Improvements were greatest with BPD, duodenal switch, and gastric bypass.

A 2017 analysis found that improvements in dyslipidemia varied according to the type of bariatric surgery performed. Normal total cholesterol levels (<200 mg/dL) were noted in 76% of RYGB, 43.5% of LSG, and 25.6% of LAGB patients [26]. The study also noted that LDL was improved in an equivalent pattern, but HDL was most improved with LSG (58.1%) and RYGB (39.5%). Triglyceride levels showed a decrease in approximately 75% of both LSG and RYGB patients [26]. While more research is needed, the type of surgery has been shown to be a predictive factor in improvements of dyslipidemia.

## METABOLIC SYNDROME

In addition to individual cardiovascular risk factors, metabolic syndrome has been shown to improve or resolve in many patients following weight loss surgery [7]. Metabolic syndrome is a constellation of cardiovascular risk factors, including obesity, hypertension, dyslipidemia, and insulin resistance. A retrospective study examined data from patients with metabolic syndrome who were evaluated for bariatric surgery at the Mayo Clinic's Rochester site between 1990 and 2003. One hundred eighty patients underwent RYGB, and 157 were assessed in a weight-loss program but did not have surgery [11]. Patients were followed for a mean of 3.4 years. Before the procedure, 87% of the patients in the surgery group had metabolic syndrome. This number decreased to 29% after surgery. In the non-surgical group, metabolic syndrome was present in 85% at baseline and 75% at follow-up. The authors concluded that weight loss was largely responsible for metabolic syndrome resolution, and that the number-needed-to-treat to resolve one case was 2.1.

Other case series and observational studies have shown similar results. Gasteyger and colleagues followed 36 obese women, 24 to 52 years of age, with a mean BMI of 43.8 for 24 months after LAGB [122]. The proportion of patients with metabolic syndrome declined from 58% at baseline to 25% at one year and 3% at 24 months. Another series with 31 female patients found a reduction from 89% with metabolic syndrome before LAGB to 15% at one year after surgery [123].

## CHANGES IN OVERALL CARDIAC RISK

Several studies have attempted to assess changes in cardiac risk following bariatric surgery. Most have simply calculated risk using the Framingham score or a similar model. However, at least one study has compared predicted risk with actual cardiovascular events.

Studies of predicted risk have consistently found that bariatric surgery is beneficial in lowering scores. In 2008, Batsis and colleagues published a review of studies that provided numeric data about cardiovascular risk factors with follow-up of at least one year [13]. The studies, conducted in the United States, Italy, Mexico, New Zealand, and Sweden between 1996 and 2004, included LAGB, non-adjustable gastric banding, RYGB, and VBG in a total of more than 3,000 patients. The researchers used Framingham risk and a score based on the German Prospective Cardiovascular Munster Heart Study (PROCAM), both of which incorporate multiple individual risk factors. When studies did not report certain factors, values were imputed using the risk models' original data. Consistently, and with multiple ways of examining the data, cardiovascular risk was found to decline after surgery. Standardizing patients' ages produced an even stronger apparent benefit. When control groups were used, risk was consistently lower in the surgical groups.

The two studies with the longest follow-up included in the review were the SOS study and a study by Batsis and colleagues comparing a cohort of surgical patients with non-operative patients from the same database. The Batsis study used data from the Mayo Clinic Nutrition Center in Rochester, Minnesota, from 1990 to 2003. It involved 197 consecutive patients treated with bariatric surgery and 163 patients evaluated in a weight-reduction program who did not have surgery [10]. Patients had class II or III obesity, defined as a BMI of 35 or more. Patients were treated with RYGB, with mean follow-up of 3.3 years. Based on risk data from NHANES I and the NHANES I Epidemiological Follow-up Study, the authors found that, in the

operative group, the 10-year risk for cardiovascular events was 37% at baseline and 18% at follow-up. In the control group, risk remained unchanged at 30%. The number needed to treat to avoid one cardiovascular event was calculated to be 16. Using Framingham risk scores, risk fell from 7.0% to 3.5% in the surgery group and from 7.1% to 6.5% in the control group [13].

The SOS study did not directly report changes in overall cardiovascular risk. However, calculations by Batsis and colleagues based on the reported data showed that risk scores declined after two years of follow-up. After 10 years, cardiovascular risk had risen, but risk in the surgical group remained numerically lower than in the non-surgical controls. Statistical significance was not reported [13].

A post hoc analysis of the SOS study, conducted after nearly 15 years of follow-up, has shown that bariatric surgery led to a 30% reduction in the incidence of cardiovascular events in obese patients compared with non-operative patients and an almost 50% reduction in cardiovascular deaths [85]. Baseline insulin concentration, rather than BMI at baseline or post-surgery weight loss, was the strongest predictor of future cardiovascular benefit.

Other publications, including several case series with RYGB patients, further support a decrease in estimated risk [124; 125; 126]. To determine the relationship between risk scores and actual cardiovascular outcomes, one group of researchers followed patients for five years after surgery. They calculated Framingham risk and then compared it to actual coronary heart disease events in 500 patients without prior cardiovascular disease who had undergone gastric bypass [127]. These patients lost 46.7% to 90.7% of excess body weight at one year after surgery and showed improvement in risk factors, including diabetes. The 10-year Framingham risk of cardiac events declined from 5.4% to 2.7%, with similar changes in subgroups based on diabetes status and gender. At five years after surgery, the actual occurrence of coronary heart disease events was 1%.

In a 2008 report, Kligman and colleagues used Framingham risk score to demonstrate reduced 10-year cardiovascular risk at one year after surgery in 101 consecutive patients who underwent RYGB [126]. Systolic blood pressure fell by 14%, with a reduction in diastolic pressure of 12%. Total cholesterol was 202 at baseline and 165 at follow-up, a reduction of 18%. LDL decreased 18%, from 118 to 97; HDL increased 14%, from 45 to 51. All of these changes were statistically significant. Ten-year risk fell by more than half.

In 2010, researchers conducted a systemic review of published literature to determine the impact of bariatric surgery on cardiovascular risk factors and mortality [128]. The review included reported outcomes following bariatric surgery from 1950 to 2010 and included 52 studies involving 16,867 patients. The baseline prevalence of hypertension, diabetes, and dyslipidemia was 49%, 28%, and 46%, respectively. Mean follow-up was 34 months. Most studies reported significant decreases in the post-operative prevalence of cardiovascular risk factors. A 40% relative risk reduction for one-year coronary heart disease risk was observed, as determined by the Framingham risk score [128].

In a 2017 study, 1,724 patients that received RYGB metabolic surgery were assessed for up to 12 years and compared against a nonsurgical matched control group. The researchers found that, compared with the control group, there was a 56% reduction in deaths caused by coronary artery disease (mean follow-up 7.1 years), and a 45% reduction in major cardiovascular events, including myocardial infarction, stroke, and congestive heart failure [12]. Further research is needed to determine if the type of surgical procedure results in different cardiovascular outcomes and mortality.

## OTHER OBESITY-RELATED CONDITIONS

Follow-up studies have noted improvements in many other obesity-related conditions. In various cohorts and case series, patients have been observed to have improvements in or resolution of conditions including nonalcoholic fatty liver disease, polycystic

ovarian syndrome, venous stasis disease, obstructive sleep apnea, gastroesophageal reflux disease, and degenerative joint disease [14]. There is also some evidence for weight loss leading to improvement in depression, resolution of migraine, and resolution of or improvement in asthma. Patients may also experience improvement in urinary incontinence, pseudotumor cerebri, and hypoventilation [33]. In a retrospective cohort study of 30,318 overweight or obese patients, those who underwent bariatric surgery had a significantly lower risk of obesity-associated cancer and related mortality than non-surgical controls [181].

## LONG-TERM MORTALITY

As discussed, in the short term there is a small but definite mortality risk associated with bariatric surgery. However, long-term mortality data suggest that, compared with obese controls, patients who choose surgery experience a reduced risk of premature death. Data from the SOS study show that, with an average of 10.9 years of follow-up, there were 129 deaths in the control group and 101 deaths in the surgery group. The unadjusted overall hazard ratio was 0.76 in the surgery group [129]. A review of data from the SOS study at 20 years follow-up found a long-term reduction in overall mortality as well as decreased incidences of diabetes, myocardial infarction, stroke, and cancer with bariatric surgery compared with usual care [84].

Similar benefit was noted in a retrospective cohort study that compared mortality among 9,949 gastric bypass patients and 9,628 severely obese controls [130]. Matching for age, sex, and BMI was achieved in 7,925 of each group, and the mean follow-up was 7.1 years. Adjusted long-term mortality from any cause decreased by 40% in the surgery group compared with the controls, with 37.6 and 57.1 deaths, respectively, per 10,000 person-years. Cause-specific mortality in the surgery group decreased by 56% for coronary artery disease, by 92% for diabetes, and by 60% for cancer. Rates of death not caused by disease, such as accidents and suicide, were 58% higher in the surgery group than in the control group.

## LONG-TERM COMPLICATIONS

In addition to the long-term benefits of bariatric surgery, long-term complications should also be considered. LSG makes permanent changes to the anatomy of the stomach and is nonreversible, and RYGB changes the anatomy of the stomach and small intestine. LAGB, while designed to be removable, is intended to be used as a long-term treatment. In each case, the changes in dietary habits that should be made following surgery can put patients at risk for nutritional deficiencies, and the Roux-en-Y configuration raises particular concerns about adequate absorption of certain vitamins and minerals. Intolerance to certain foods, particularly meats, occurs in many patients after bariatric surgery and can lead to restricted dietary choices. Management of long-term needs can be a challenge, as patients do not always keep to recommended follow-up plans. The Endocrine Society recommends that an accredited, integrated medical support team provide patients with dietary instruction and behavior modification postoperatively and during long-term follow-up [131].

## NUTRITIONAL DEFICIENCIES

Vitamin and mineral deficiencies may occur after any bariatric procedure if the patient's diet does not supply adequate nutrition. Due to the altered configuration of the small intestine, patients who undergo RYGB and other surgeries with a malabsorptive element, such as LSG, are particularly at risk of specific deficiencies. Folate, thiamine, riboflavin, niacin, pyridoxine, vitamin C, zinc, and copper are primarily absorbed in the duodenum and jejunum, and iron is primarily absorbed in the duodenum [132]. After RYGB, ingested food does not pass through the duodenum and bypasses a portion of jejunum as well.

Anemia is a common problem following any type of bariatric surgery. In patients 3 months to 10 years post-surgery, iron deficiency occurs in approximately 14% with LAGB, <18% with LSG, 20% to 55% with RYGB, and 13% to 62% with BPD [64; 135]. In the case of RYGB, direct malabsorption due to lack of contact with the duodenum may be a contributing factor, and other malabsorption surgeries may produce low or absent secretion of gastric acid required to convert iron to its absorbable form. Overall decrease in food intake, combined with a common intolerance of red meat, may also contribute to deficiency [133]. Giving iron with vitamin C can help to provide the acidic environment needed for absorption [134].



The AACE, the ASMBS, the Obesity Society, Obesity Medicine Association, and the ASA recommend that iron status should be monitored in postbariatric patients at regular intervals using an iron panel, complete blood count, total iron-binding capacity, ferritin, and soluble transferrin receptor (if available), along with clinical signs and symptoms. Treatment regimens 150–200 mg of elemental iron daily to amounts as high as 300 mg two to three times daily. Oral supplementation should be taken in divided doses separately from calcium supplements, acid-reducing medications, and foods high in phytates or polyphenols. Vitamin C supplementation may be added to increase iron absorption and decrease risk of iron overload.

([https://www.endocrinepractice.org/article/S1530-891X\(20\)42802-2/fulltext](https://www.endocrinepractice.org/article/S1530-891X(20)42802-2/fulltext). Last accessed May 26, 2021.)

**Strength of Recommendation:** D (Consensus statement based on no clinical evidence)

Anemia may also be due to deficiencies in vitamin B12, seen in approximately 20% of RYGB patients and 4% to 20% of LSG patients (two to five years post-surgery) [64; 135]. Although vitamin B12 is absorbed primarily in the ileum, which is not bypassed by the RYGB and LSG procedures, decreased gastric acid, decreased exposure to intrinsic factor, and other changes in the digestive process may all contribute to malabsorption [132].



The ASMBS notes that vitamin B12 deficiency may be present in the general population and pre-operative levels in severely obese patients are not well-established, making it prudent to screen for low levels before surgery [135]. This deficiency appears to be less common after LAGB and other procedures that either leave the stomach intact or cause less restriction than RYGB and LSG [135]. Additional contributors to anemia may include deficiencies in copper, folate, and other vitamins absorbed in the upper portion of the small intestine [135; 136].

Folate deficiency appears to be particularly common. Prevalence after weight-loss surgery occurs in up to 65% of patients [135]. In addition to reduced absorption, low levels of vitamin B12 may contribute to low folate levels. However, the actual role of surgery in causing folate deficiency is not clear, given that inadequate intake is not rare in the general population. One study found deficiency in 54% of pre-operative bariatric surgery patients [135]. However, another study showed a 46% folate deficiency pre-LSG with an improvement to 12.5% after four years [64]. The ASMBS estimates that B12 deficiency two to five years post-surgery is less than 20% for RYGB and 4% to 20% for sleeve gastrectomy [135]. Folate deficiency has also been seen following LAGB.

Symptomatic thiamine deficiency after bariatric surgery is not usual, but cases of Wernicke-Korsakoff syndrome, a degenerative brain disorder, after both malabsorptive and restrictive procedures have appeared in the literature [135]. Patients who have unresolved nausea and vomiting may be particularly at risk. Case reports of beriberi have also been published, and the ASMBS guideline notes that occurrence may, in fact, not be rare [137; 138]. Beriberi can cause irreversible neuromuscular disorders as well as defects in memory. Preoperative deficiency of thiamine has been estimated at <1% to 49% depending on time frame and type of weight-loss surgery [135].

Vitamin D is absorbed in the ileum and jejunum, suggesting that deficiency of this nutrient would not be severe following RYGB. However, studies of vitamin D deficiency before and after bariatric surgery suggest that suboptimal levels of vitamin D are quite common preoperatively, making supplementation an issue. In a 2007 series of 95 patients, 54% were vitamin D deficient (<50 nmol/L) and another 34% had suboptimal levels (50–79 nmol/L) [139]. In another study, 80% of preoperative patients had 25-OH vitamin D (the storage form of the vitamin) levels less than 32 ng/mL [140]. The ASMBS estimates that as many as 90% of obese patients may have low levels of vitamin D preoperatively [135]. Although supplementation has been shown to increase levels following surgery, a pilot study involving 45 post-RYGB patients suggests that, for many patients, current levels of supplementation may not be high enough to normalize levels [141]. A 2017 study indicated that 96.2% of pre-procedure patients were deficient in vitamin D and, after four years, 86% still had a deficiency [64]. In addition, the ASMBS estimates that up to 100% of post-bariatric surgery patients have a vitamin D deficiency [135].

Calcium is primarily absorbed in the duodenum and proximal jejunum. Low calcium intake and low levels of vitamin D can both contribute to deficiency in whole-body calcium, leading to increased bone resorption and potentially osteoporosis [135]. One study, a prospective design with one year of follow-up in a small group of patients, found a strong association between declining bone mineral density at the hip and degree of weight loss after RYGB [142]. Intake of both calcium and vitamin D increased after surgery, but most patients continued to have levels of vitamin D less than 30 ng/mL. Deficits in calcium and vitamin D, with associated increases in bone resorption, may also occur after LAGB [135]. The long-term significance of bone density changes is unknown, however. For calcium supplementation, calcium citrate, which does not require high acidity for absorption, may be a better choice than calcium carbonate, particularly in RYGB and LSG patients and others with reduced gastric acid.

Zinc and copper are both absorbed in the duodenum and proximal jejunum. In surgeries in which these structures are bypassed, primarily BPD and RYGB, deficiency is common. Zinc deficiency occurs in up to 70% of post-BPD surgeries, 40% of RYGB, 34% of LAGB, and 19% of LSG [135]. Screening for zinc deficiency is recommended for bariatric surgery patients who have symptoms of anemia with negative results for iron deficiency. Copper deficiency is noted in up to 90% of post-BPD patients and 10% to 20% of post-RYGB patients, compared with only one case reported for LSG patients [135].

Recommendations for specific supplements, including dosage, can be found in an updated guideline published by the ASMBS [135]. Essentially, it is recommended that postsurgery patients take a high-potency multivitamin/mineral supplement, B12, vitamin D, calcium, iron, and an optional B complex [135]. Supplements for fat-soluble vitamins (A, E, and K), zinc, and copper should also be taken, with the dose dependent on the type of bariatric procedure [135]. The ASMBS notes that supplementation should be individualized to patient need. Laboratory tests to assess nutrition levels are also recommended.

Anatomical changes are likely not the only cause of nutritional deficiencies after bariatric surgery. The ASMBS guideline notes that purely restrictive surgeries, while once thought not to be associated with nutritional deficiencies, may in fact lead to deficiencies due to poor diet and food intolerance. Research on dietary habits after a restrictive procedure reinforces this concern, as demonstrated in a case study of consecutive patients in one surgical ward who had undergone VBG, a restrictive surgery, between 1986 and 1992 [143]. Sixty-two percent of eligible patients participated, and the average time of follow-up after surgery was 5.4 years. Patients' overall food intake had declined since before surgery, except for fluids, dairy products, and sweet foods. Fruit and vegetable consumption had declined the most, and then meat, fish, and complex carbohydrates. The authors of the study questioned whether the patients' relatively unhealthy diets might eventually counterbalance the benefits of weight loss.

## Protein Deficiency

Protein deficiency has been suggested as a concern following bariatric surgery due to malabsorption and/or reduced caloric intake and possible food intolerances. In fact, hypoalbuminemia does not appear to be common following bariatric surgery, except perhaps in patients whose diets are very low in protein. It may be more of a problem in patients who undergo more significantly malabsorptive procedures, such as BPD.

The ASMBS recommends somewhat higher than normal levels of protein intake following bariatric surgery, noting that 60–80 g per day is a common amount, although ideal levels are dependent on response to specific type of surgery and individual needs [135]. Patients with a history of BPD or duodenal switch do need higher levels of protein than the usual recommended amounts; the ASMBS suggests an increase of approximately 30%, for a daily total of about 90 g. These amounts may be modified by individual patient need.

## MEDICATION ABSORPTION

After RYGB, changes in the physical structure of the GI tract can influence the absorption of certain medications. Extended-release formulations that are designed to remain in the intestine for long periods may not be absorbed as well or according to the expected time course [134]. Immediate-release formulations are generally recommended in these patients; however, healthcare providers are not always aware of recommended vitamin regimens, dosages, and appropriate formulations. A retrospective study conducted from 2006 through 2007 in patients with a history of bariatric surgery examined vitamin/nutrient supplements and medication dosage formulations given upon admission. Daily multivitamin, calcium, iron, vitamin B12, and folic acid supplementation were evaluated. Of 133 patient admissions, 88% had a history of a malabsorptive procedure. Approximately 33% of patients were given a multivitamin; 5.1% were given supplemental vitamin B12; 7.7% received supplemental calcium; 11.1% received additional folic acid; and

12% received iron. Inappropriate formulations (e.g., non-immediate-release, enteric-coated) were ordered in 61.5% of patients. Fifty percent of patients were discharged with inappropriate formulations [146].

Although medication absorption in bariatric surgery patients is not well studied, the reduction in acid due to structural changes in the stomach may alter absorption of medications that require an acidic environment. More pharmacokinetic clinical studies are needed to address the specific effects of various bariatric procedures on drug absorption [147].

## BOWEL HABITS

Beyond information about nutrition, day-to-day life after bariatric surgery is rarely addressed in the literature. To help illuminate patients' experiences following these procedures, Potoczna and colleagues reported on bowel habits after gastric banding, RYGB, and BPD [148]. Compared with before surgery, patients who had adjustable gastric banding were more likely to report increased constipation at three or more months after surgery. RYGB patients were more likely to report loose stools or diarrhea (46% after surgery, compared with 8% before). RYGB patients were also more likely to report malodorous flatus, to be bothered by it, and to feel that their social life was affected. A similar pattern was seen with BPD. For both RYGB and BPD, severity of flatus was inversely correlated with quality of life subscores on the bariatric analysis reporting outcome system scale.

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## NON-SURGICAL WEIGHT-LOSS METHODS

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As noted, candidates for bariatric surgery are often required to attempt non-surgical methods of weight loss. Even after surgery, these patients benefit from healthy lifestyle changes to maintain weight reduction and associated benefits.

## DIET AND EXERCISE

Studies consistently show that weight loss purely through lifestyle change is a challenge. Some studies have found reductions of only about 3–10 kg over one to two years with either pharmacologic or behavioral treatments [57].

However, some patients will be able to lose weight and keep it off through increased physical activity and healthier eating. The U.S. Preventive Services Task Force (USPSTF) recommends intensive counseling and behavioral interventions to promote sustained weight loss for obese adults [149]. Counseling may address diet, exercise, or both, and behavioral interventions may be aimed at skill development, motivation, and support. The USPSTF concluded that these strategies could result in a typical weight loss of about 3–5 kg (6.6–11 lbs), lasting one year or more. Some patients will struggle to lose this amount of weight, while others will be able to lose substantially more.

Weight loss of 1 to 2 pounds per week is considered a safe amount for patients making lifestyle changes. To achieve this level of weight loss, patients with a BMI between 27 and 35 should generally reduce their total food intake by 300–500 calories daily. Patients with a BMI greater than 35 should reduce their total intake by 500–1,000 calories daily. Patients can check their own caloric needs using a simple calculator at <https://www.myplate.gov>.

Obese patients may be reluctant to attempt an exercise program or concerned that they will not have the stamina for vigorous exercise. In fact, a simple walking program can serve as the important first step to a healthier lifestyle. If there are no contraindications to exercise, patients can begin with a 10- or 15-minute walk, a few times a week, and build up gradually to recommended levels. Some patients may find it helpful to have exercise advice written out as a “prescription,” just as advice to take a certain medication would be.

The specifics of exercise recommendation vary, but most authorities recommend at least 30 minutes of moderate exercise on most days. The 2018 Physical Activity Guidelines for Americans and the American Heart Association (AHA) both recommend the following minimum levels for adults [150; 151]:

- 150 minutes (2 hours and 30 minutes) to 300 minutes (5 hours) each week of moderate-intensity aerobic activity, such as brisk walking, OR
- 75 minutes (1 hour and 15 minutes) to 150 minutes (2 hours and 30 minutes) each week of vigorous-intensity aerobic activity, such as jogging or running, OR
- An equivalent mix of moderate- and vigorous-intensity aerobic activity

Also recommended are muscle-strengthening activities, working all major muscle groups, on two or more days a week.

Both the AHA and the 2018 Physical Activity Guidelines for Americans specify that exercise can be accumulated in shorter bursts [150; 151]. Bouts of moderate or vigorous exercise lasting at least 10 minutes can be added together toward the goal.

## WEIGHT-LOSS MEDICATIONS

Some patients will benefit from pharmacotherapy to aid in weight loss. Approval criteria for anti-obesity drugs include a 5% or more mean placebo-subtracted weight loss after one year of therapy or a minimum of 35% of participants achieving more than 5% weight loss. The European Medicines Agency guideline requirements are similar. Both agencies also call for evidence of improvements in metabolic comorbidities [152]. At present, five weight-loss drugs are FDA-approved for long-term use: orlistat, phentermine/topiramate, bupropion/naltrexone, semaglutide, and liraglutide [152; 153; 154]. Weight loss achieved through the use of medication tends to be modest, and weight is often regained when the drugs are stopped [155; 156; 157].

Orlistat inhibits nutrient absorption. Orlistat has been shown to increase weight loss and improve cardiovascular risk factors. Primary side effects are gastrointestinal discomfort and a decrease in absorption of fat-soluble vitamins [152]. Independent reports of liver injuries (including six cases of liver failure between 1999 and 2008) prompted the FDA to approve a label revision for orlistat that includes a warning of possible severe liver injury [152]. However, the risk of severe liver injury is low, and this risk should be weighed against potential benefits [153]. Orlistat is indicated for the treatment of obesity in conjunction with a reduced-calorie diet [152].

In 2012, the FDA approved both lorcaserin and phentermine/topiramate, the first new weight-loss medications in more than a decade [153; 158]. Lorcaserin is a selective 5-HT<sub>2C</sub> receptor agonist and acts to promote weight loss by giving the patient a feeling of satiety [159]. Trials indicate that lorcaserin is safe and effective treatment, in conjunction with diet modification and exercise, for adults with a BMI  $\geq 30$  or adults with a BMI  $\geq 27$  with at least one weight-related comorbidity (e.g., hypertension, dyslipidemia, sleep apnea). The recommended dose is 10 mg twice daily [153]. Originally rejected, the manufacturer was required to submit additional safety data, specifically related to the risk for valvular heart disease, prior to approval [159]. However, lorcaserin was voluntarily withdrawn from the market by the manufacturer in 2020 due to results from safety clinical trials showing an increased occurrence of cancer [153].

Phentermine/topiramate (extended-release) combines an anorexiant and an anticonvulsant to improve short-term weight-loss outcomes in patients who have already attempted lifestyle changes (i.e., calorie-restricted diet and increased physical activity) [153]. Eligible patients will have a BMI  $\geq 30$  or a BMI  $\geq 27$  with a weight-related comorbidity [158].



The recommended initial dose of phentermine/topiramate is 7.5 mg phentermine/46 mg topiramate extended-release once per day [158]. The dose may be titrated to a maximum of 15 mg/92 mg. The medication is contraindicated in persons with glaucoma and hyperthyroidism and is not recommended for patients with a recent history of stroke or heart disease [158]. It is also teratogenic, with proven fetal defects with first trimester exposure. Therefore, all women of childbearing age should use effective contraception consistently while taking the drug and have documented proof of a negative pregnancy test prior to the initiation of treatment and every month thereafter [158].

In 2014, combination bupropion/naltrexone was approved as a treatment option for chronic weight management [163]. Studies show that these drugs are effective in improving the percentage of total body weight lost compared with placebo [163; 164]. The dosage is gradually titrated up, starting with one tablet (naltrexone 8 mg/bupropion 90 mg) once daily in the morning for one week and increasing one daily tablet each week for four weeks. The maintenance dose is two tablets twice daily [153]. If 5% of initial body weight has not been lost after 12 weeks, the medication should be discontinued.

Any patient taking bupropion should be carefully monitored for suicidal ideation and behaviors [163]. This medication may also increase blood pressure and heart rate and is contraindicated in patients with hypertension. It is also contraindicated in patients with a history of seizures, who are taking another bupropion-containing medication, or who are pregnant.

Also in 2014, the FDA approved liraglutide for use in obese adults (BMI  $\geq 30$ ) and adults who are overweight (BMI  $\geq 27$ ) who have at least one weight-related condition (e.g., hypertension, type 2 diabetes, dyslipidemia) [154]. Liraglutide is a glucagon-like peptide-1 (an incretin hormone) that increases glucose-dependent insulin secretion, decreases inappropriate glucagon secretion, increases B-cell

growth/replication, slows gastric emptying, and decreases food intake [153]. The recommended initial dose of liraglutide is 0.6 mg subcutaneously once per day for one week. The dose should be increased by 0.6 mg daily at weekly intervals until a target dose of 3 mg once daily is achieved [153]. Liraglutide is contraindicated in individuals with hypersensitivity to the drug or to any component of the formulation. The drug is also contraindicated in pregnant patients, patients with a history/family history of medullary thyroid carcinoma, and patients with multiple endocrine neoplasia syndrome. Liraglutide carries a boxed warning of thyroid C-cell tumor risk. Increased heart rate, headache, and gastrointestinal complaints (i.e., nausea/vomiting, diarrhea, constipation) are the most common side effects [153].

In 2021, the FDA approved semaglutide injection for chronic weight management in adults with obesity (BMI  $\geq 30$ ) or overweight (BMI  $\geq 27$ ) with at least one weight-related condition (e.g., hypertension, type 2 diabetes, hyperlipidemia) [160]. This agent is a glucagon-like peptide-1 (GLP-1) receptor agonist and is intended to be used in conjunction with lifestyle changes. When used for weight management, semaglutide is administered subdermally at a dose of 2.4 mg once weekly [161]. Medication, if it is used, should be part of an overall plan for lifestyle change. There is some research to suggest that the combination of medication and lifestyle counseling may be more effective than medication alone. Wadden and colleagues conducted a randomized trial with 224 patients assigned at random to one of four tracks: sibutramine, 30 group sessions of lifestyle counseling, a combination of counseling and sibutramine, or sibutramine with brief counseling by primary care provider. After one year, the combined therapy patients lost 12.1 kg. The patients using sibutramine alone lost 5.0 kg, lifestyle counseling alone 6.7 kg, and sibutramine plus brief counseling 7.5 kg. Sibutramine combined with brief therapy and lifestyle counseling also produced more weight loss than sibutramine alone [162].

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## CONCLUSION

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Weight loss has been demonstrated to be a highly effective means of reducing or eliminating obesity-related comorbidities, including diabetes, hypertension, and hyperlipidemia, and of reducing overall cardiometabolic risk. Bariatric surgery provides substantial weight loss, with surgical mortality rates of less than 1%, and current guidelines recommend considering this option for severely obese patients, those with BMI of 35 or greater if comorbidities are present, and those with BMI of 30 or greater if diabetes or metabolic syndrome is present [11; 145]. The BMI criterion for bariatric procedures should be adjusted for ethnicity [11]. All of the options for weight loss should be thoroughly discussed with patients, including the benefits, risks, and challenges.

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## RESOURCES

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### **American College of Surgeons**

633 N Saint Clair Street  
Chicago, IL 60611-3295  
312-202-5000  
<https://www.facs.org>

### **American Society for Metabolic and Bariatric Surgery**

14407 SW 2nd Place, Suite F-3  
Newberry, FL 32669  
352-331-4900  
<https://asmbs.org>

### **Centers for Medicare and Medicaid Services**

7500 Security Boulevard  
Baltimore, MD 21244  
<https://www.cms.hhs.gov>

### **The Obesity Society**

110 Bonifant Street, Suite 500  
Silver Spring, MD 20910  
301-563-6526  
<http://www.obesity.org>

### Implicit Bias in Health Care

The role of implicit biases on healthcare outcomes has become a concern, as there is some evidence that implicit biases contribute to health disparities, professionals' attitudes toward and interactions with patients, quality of care, diagnoses, and treatment decisions. This may produce differences in help-seeking, diagnoses, and ultimately treatments and interventions. Implicit biases may also unwittingly produce professional behaviors, attitudes, and interactions that reduce patients' trust and comfort with their provider, leading to earlier termination of visits and/or reduced adherence and follow-up. Disadvantaged groups are marginalized in the healthcare system and vulnerable on multiple levels; health professionals' implicit biases can further exacerbate these existing disadvantages.

Interventions or strategies designed to reduce implicit bias may be categorized as change-based or control-based. Change-based interventions focus on reducing or changing cognitive associations underlying implicit biases. These interventions might include challenging stereotypes. Conversely, control-based interventions involve reducing the effects of the implicit bias on the individual's behaviors. These strategies include increasing awareness of biased thoughts and responses. The two types of interventions are not mutually exclusive and may be used synergistically.

### FACULTY BIOGRAPHY

**John J. Whyte, MD, MPH**, is currently the Chief Medical Officer at WebMD. In this role, he leads efforts to develop and expand strategic partnerships that create meaningful change around important and timely public health issues. Previously, Dr. Whyte was the Director of Professional Affairs and Stakeholder Engagement at the FDA's Center for Drug Evaluation and Research and the Chief Medical Expert and Vice President, Health and Medical Education at Discovery Channel, part of the media conglomerate Discovery Communications.

Prior to this, Dr. Whyte was in the Immediate Office of the Director at the Agency for Healthcare Research Quality. He served as Medical Advisor/Director of the Council on Private Sector Initiatives to Improve the Safety, Security, and Quality of Healthcare. Prior to this assignment, Dr. Whyte was the Acting Director, Division of Medical Items and Devices in the Coverage and Analysis Group in the Centers for Medicare & Medicaid Services (CMS). CMS is the federal agency responsible for administering the Medicare and Medicaid programs. In his role at CMS, Dr. Whyte made recommendations as to whether or not the Medicare program should pay for certain procedures, equipment, or services. His division was responsible for durable medical equipment, orthotics/prosthetics, drugs/biologics/therapeutics, medical items, laboratory tests, and non-implantable devices. As Division Director as well as Medical Officer/Senior Advisor, Dr. Whyte was responsible for more national coverage decisions than any other CMS staff.

Dr. Whyte is a board-certified internist. He completed an internal medicine residency at Duke University Medical Center as well as earned a Master's of Public Health (MPH) in Health Policy and Management at Harvard University School of Public Health. Prior to arriving in Washington, Dr. Whyte was a health services research fellow at Stanford and attending physician in the Department of Medicine. He has written extensively in the medical and lay press on health policy issues.

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