

Identification and Treatment of Extreme Obesity— Considering Surgical Options: Frequently Asked Questions

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American Society for
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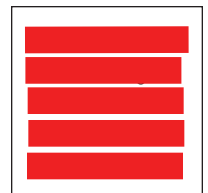


National Association of Bariatric Nurses

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Statement of Need

Obesity has become a worldwide epidemic, encompassing approximately 1.7 billion individuals. Worldwide, more than 2.5 million obesity-attributed deaths occur each year. In the United States alone, there are 300,000 to 400,000 annual deaths due to obesity, second only to those due to cigarette smoking. According to the Bariatric Surgery Consensus Panel, only 1 in 7 (14%) obese individuals will reach the US life expectancy of 76.9 years; in the severely obese, average life expectancy is reduced by 9 years in women and 12 years in men. In addition, obesity causes severe reductions in quality of life and is strongly associated with comorbidities such as diabetes and cardiovascular disease that further impact mortality and quality of life.

Behavior modification and nutritional and pharmacologic methods alone are usually not effective in achieving medically significant long-term weight loss in severely obese adults. In contrast, surgical intervention has been shown to achieve long-term weight control for severely obese individuals. However, to ensure success, surgical intervention must begin with realistic goals and proceed with diligent, long-term follow-up.

Important to the short-term and long-term success of managing this complex disease is the need to more fully explore the underlying behavioral and physiologic issues associated with severe obesity and the impact of various behavioral, pharmacologic, and surgical treatment modalities on patient outcomes. Long-term strategies that focus on evidence-based nutritional, behavioral, pharmacologic, and surgical interventions are necessary to ensure maximum therapeutic benefit and reduce the morbidity and mortality associated with this debilitating disease.

Educational Objectives

Upon completion of this educational activity, participants will be able to:

- Answer frequently asked questions about severe obesity and its management
- Understand the efficacy, safety, and therapeutic benefits of both pharmacologic and surgical intervention techniques in the management of severe obesity
- Recognize issues relevant to the optimum prevention and management of severe obesity
- Determine how to decide upon and implement therapeutic strategies, including bariatric surgery, for severely obese patients
- Optimize severe obesity treatment strategies that maximize short-term and long-term outcomes

Target Audience

This activity has been developed for weight management specialists, surgeons, coordinators, and nurses, other obesity management specialists, and other healthcare professionals.

Physician Accreditation Statement

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of NAASO, The Obesity Society, and SynerMed® Communications. NAASO, The Obesity Society, is accredited by the ACCME to provide continuing medical education for physicians.

Designation of Credit

This publication should take approximately 1 hour to complete. The participant should, in order, review the educational objectives, read the publication, and return the completed Registration/Posttest Answer Form/Evaluation to NAASO, The Obesity Society, to receive credit. The evaluation form provides each participant with the opportunity to comment on the extent to which the educational objectives were met, the quality of the instructional process, the perception of enhanced professional effectiveness, the perception of commercial bias, and participant views on future educational needs. The credit is valid through August 31, 2008. No credit will be given after this date.

NAASO, The Obesity Society, designates this educational activity for a maximum of *1 AMA PRA Category 1 Credit(s)*™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Method of Participation

Continuing medical education (CME) credit will be awarded to physicians who successfully complete this activity. Participation should take approximately 1 hour. To complete this activity and receive credit, the participant should:

- Read the educational objectives
- Read and review the newsletter
- Complete the posttest and evaluation form and mail or fax them to:
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NAASO, The Obesity Society
8630 Fenton Street, Suite 918
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Fax: 301-563-6595
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Please submit only one copy of your materials. If you fax your form, it is not necessary to mail it. For questions, please call the office of the Director, Education Programs, NAASO, The Obesity Society, at 301-563-6526 or email education@naaso.org.

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A portion of the content for this educational activity was developed during a scientific roundtable held in Atlanta, Georgia, in December 2006. Faculty at that scientific roundtable included Program Chairs: Marc Bessler, MD, FACS, and Patrick M. O'Neil, PhD; Faculty Members: Susan M. Cummings, MS, RD, LDN; Thomas H. Inge, MD, PhD, FACS, FAAP; Daniel B. Jones, MD, MS; Robert F. Kushner, MD, MS; Chris Nelson, MN, RN, FNP-C; David B. Sarwer, PhD; Philip R. Schauer, MD; and C. Daniel Smith, MD, FACS. Unless otherwise noted, this faculty assumes no responsibility for content.

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Dr. Bessler has received grant/research support from Tyco International, Ltd. He is a consultant/scientific advisor for Allergan Medical, CR Bard, Inc, Ethicon Inc, and USGI Medical.

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Nonfaculty Disclosure

The medical writer, **Edward Baldwin, PhD**, disclosed that his spouse/partner is a stockholder in Eli Lilly, Johnson & Johnson, and Pfizer Inc.

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Disclaimer

The content and views presented in this educational program are those of the authors and do not necessarily reflect those of NAASO, The Obesity Society; Allergan, or SynerMed® Communications. This material is prepared based upon a review of multiple sources of information, but it is not exhaustive of the subject matter. Therefore, healthcare professionals and other individuals should review and consider other publications and materials on the subject matter before relying solely upon the information provided by the faculty.

Identification and Treatment of Extreme Obesity— Considering Surgical Options: Frequently Asked Questions

INTRODUCTION

The prevalence of obesity in the United States and worldwide is high and increasing. According to the Behavioral Risk Factor Surveillance System (BRFSS), rates of obesity, defined as a body mass index (BMI) >30 kg/m², have increased continually and dramatically since 1990.¹ By 2003-2004, the National Health and Nutrition Examination Study (NHANES) found that rates of obesity in the US adult population (≥ 20 years) were 31.1% for men and 33.2% for women.^{2,3} Because of this high prevalence and the serious health risks associated with obesity, the increase in this condition constitutes an epidemic that presents a serious and growing public health problem.

The prevalence of severe obesity is also increasing. Severe obesity is defined as BMI ≥ 40 kg/m². The related term “extreme obesity” is also defined as BMI ≥ 40 kg/m². Also referred to as “morbid obesity,” this term has fallen out of use among most nonsurgeon clinicians. Additionally, many patients consider the term “morbid obesity” to be insensitive and hurtful. According to *Obesity*, the official journal of NAASO, the Obesity Society, many journals discourage the use of the term, and practitioners should carefully select terminology when dealing with patients.⁴ However, it continues to appear in the literature, is used as a legacy term by some organizations, and is found in ICD-9 codes.⁵⁻⁷ In 2003-2004, 2.8% of US men and 6.9% of US women had BMI ≥ 40 kg/m² (Figure 1).² This represents a population of approximately 14 million severely obese individuals: 4 million men and 10 million women.^{2,8} As shown in Figure 1, there are significant racial and gender differences in the prevalence of extreme obesity. In 1999-2002, clinically severe obesity was approximately twice as common among women as among men and was particularly high among black women.²

Severe obesity has a substantially greater clinical impact than obesity in general, with higher rates of morbidity and mortality and decreased quality of life. Mortality rates increase with

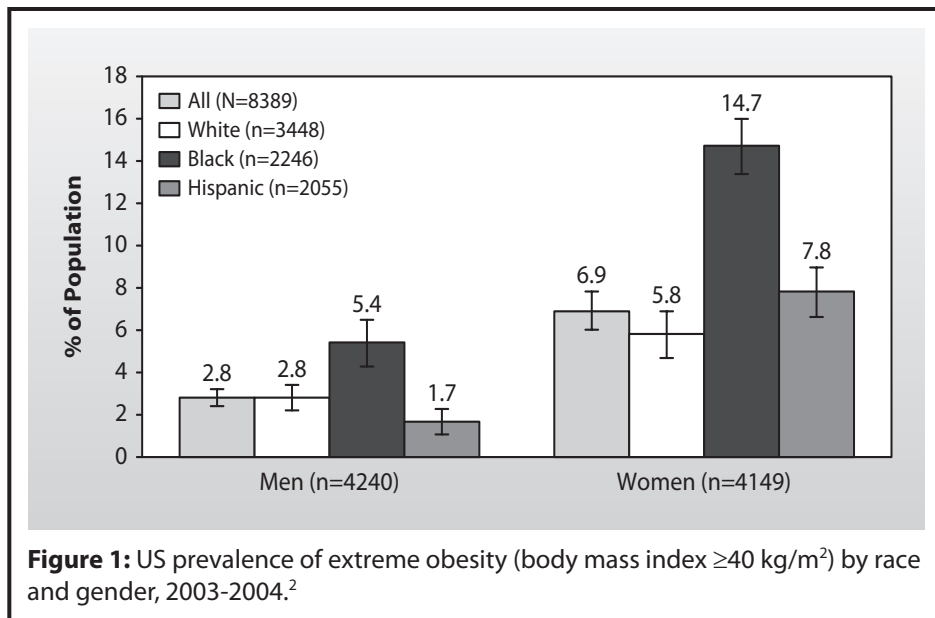


Figure 1: US prevalence of extreme obesity (body mass index ≥ 40 kg/m²) by race and gender, 2003-2004.²

BMI, with all-cause mortality among severely obese women equal to 116.85 deaths per 10,000 person-years, approximately 1.4 times higher than among obese women and almost twice as high as mortality among women of healthy weight.⁹ Table 1 gives examples of common comorbidities.¹⁰⁻¹⁶ Risk factors for cardiovascular disease are accentuated, including diabetes, hypertension, and hyperlipidemia. Diabetes, in particular, is strongly associated with obesity: the prevalence (\pm standard deviation) of diabetes was $3.1 \pm 0.14\%$ among individuals of healthy weight, $6.0 \pm 0.22\%$ among over-

weight individuals, $11.4 \pm 0.37\%$ among obese individuals, and $19.5 \pm 1.20\%$ among the extremely obese.¹⁷ Overall cardiorespiratory fitness is severely reduced among the extremely obese, with an impact similar to that of systolic dysfunction heart failure.¹⁸ Severely obese individuals who are critically ill tend to have higher rates of morbidity, complications, and mortality.^{7,19-21} A variety of other physical and psychiatric disorders are also highly prevalent among the severely obese. Medical disorders include sleep apnea, obesity hypoventilation, asthma, gastroesophageal reflux disease (GERD), hypertension, coronary artery disease and congestive heart failure, stroke, non-alcoholic liver disease and nonalcoholic steatohepatitis with cirrhosis, low back pain, degenerative joint disease (hips, knees), pseudotumor cerebri, urinary stress incontinence, polycystic ovary syndrome, increased risk of cancers (esophagus, uterus, breast, prostate, liver, kidney), and ventral and incisional hernias.^{6,10-13,15,16,22} Severely obese individuals are also at an elevated risk for depression, anxiety, and eating disorders.^{11,23-25} Severe obesity is generally associated with low scores in all health-related quality-of-life domains in children, adolescents, and adults.^{26,27} In addition, severe obesity is associated with

Table 1: Prevalence of Disorders Associated With Severe Obesity

Disorder	Prevalence (Severe Obesity)
Sleep apnea ¹⁰	32.2%
Asthma ¹⁰	30.4%
Depression ¹¹	30.0%-45.0% (adolescents)
Diabetes ¹²⁻¹⁴	15.0%-30.0%
Hypertension ^{12,13}	38.0%-51.0%
Dyslipidemia ¹³	35.0%
Lower back pain ¹⁵	58.0%
GERD ¹⁶	38.0%

GERD, gastroesophageal reflux disease.

increased healthcare costs: the estimated annual cost of care for severely obese patients was more than double the cost of healthcare for patients of healthy weight, accounting for approximately \$11 billion in healthcare expenditures in 2000.^{28,29}

Fortunately, effective weight loss therapy can reverse many of the adverse effects of severe obesity. Available therapies include lifestyle changes (diet and exercise), very-low-calorie diets, pharmacologic therapy, and surgery. Of these, bariatric surgery is documented as the most consistently effective therapeutic intervention for the severely obese.³⁰ There are several observational studies that have reported a considerable decrease in mortality for severely obese patients treated with bariatric surgery.³¹⁻³⁴ There are now 4 additional preliminary unpublished studies, including the Swedish Obese Subjects (SOS) study, which indicates a 32% aggregate reduction in mortality for patients who underwent bariatric surgery versus those who received nonsurgical therapy.⁵ This decrease in mortality was a result of a decrease in myocardial infarction and cancer deaths. The study by Adams and colleagues³⁵ also found a decrease in cardiovascular disease and cancer mortality. These, in addition to the decrease in cancer incidence noted in the study by Christou and colleagues,³¹ are the first studies providing strong evidence that weight loss decreases the risk of cancer associated with severe obesity.³⁵⁻³⁷ In addition, patients who undergo bariatric surgery have substantially improved rates of recovery from a variety of cardiovascular risk factors, including diabetes, hypertension, and hypertriglyceridemia.³⁸ As a result of these dramatic benefits, bariatric surgery is being used more and more frequently, with the number of procedures increasing from 16,000 per year in the early 1990s to more than 140,000 in 2004.^{39,40} The American Society of Metabolic and Bariatric Surgery (ASMBS) estimated the total number of weight loss surgical procedures in the United States to be approximately 172,200 in 2005 and 177,600 in 2006.⁴¹ However, bariatric operations constitute major surgeries that require lifelong follow-up and involve possible complications and some risk of mortality. This paper discusses frequently asked questions (FAQs) related to bariatric surgery.

FAQ: Which patients are appropriate candidates for bariatric surgery?

Bariatric surgery is the standard of care for severely obese patients who have failed medical management. The standard guidelines for selection of candidates for bariatric surgery were developed by a National Institutes of Health (NIH) consensus panel in 1991.⁴² According to the guidelines, bariatric surgery should be considered for patients who have clinically severe obesity (BMI ≥ 40 kg/m²) or with BMI ≥ 35 kg/m² with major obesity-related complications and who have failed to achieve substantial and sustained weight loss with nonsurgical therapies. In addition, patients should be well informed, highly motivated, and accepting of the surgical risks.^{40,42} There are currently no generally accepted criteria that go beyond the NIH recommendations and the 2004 ASMBS Consensus Conference.⁶

Several relative contraindications to bariatric surgery have been noted. They include unstable coronary artery disease, severe pulmonary disease, portal hypertension, substance abuse, and the inability to understand or carry out the lifestyle changes necessary to achieve and maintain weight loss after surgery.^{40,43} Concerns about adolescent and elderly patients have been noted by some authors. Adolescents may have difficulties understanding the significance of weight loss surgery and the commitment required to maintain weight loss. In addition, the long-term effects of bariatric surgery on growth and nutritional deficiencies in adolescents are not known.⁴⁰ In elderly patients (≥ 65 years), the risks of bariatric surgery are accentuated, and its efficacy decreases.⁴³⁻⁵⁰ However, bariatric surgery has been successfully performed in both adolescent and elderly (>70 years) patients.^{6,51-56}

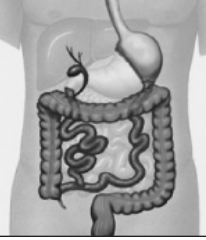
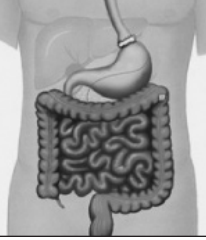
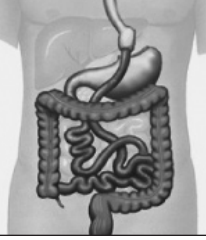
Preliminary data on adolescents suggest that bariatric surgery leads to substantial resolution of comorbidities. However, the long-term effects of dietary restriction and malabsorption are not well known.⁵⁷ Some experts believe that early bariatric surgery is likely to be beneficial based on the hypothesis that bariatric surgery is likely to resolve comorbidities when performed during adolescence but may only improve them when surgery is

delayed until adulthood.⁵⁸ The American Pediatric Surgical Association considers adolescent bariatric surgery if there is a BMI ≥ 40 kg/m² for those with severe comorbidities or a BMI ≥ 50 kg/m² for those with less severe comorbid conditions.^{57,59,60} According to the ASMBS, more recent recommendations have expressed concern that these requirements are too high and that earlier surgery in adolescents with a BMI ≥ 35 kg/m² may be considered, given appropriate patient selection (ie, consideration of age-related metabolic, developmental and psychological factors).^{57,59,61,62} In addition, there are ongoing efforts to study the effect of bariatric surgery on adolescents, including a multicenter research initiative that will follow adolescents undergoing bariatric surgery to assess health outcomes.^{59,63}

FAQ: What surgical therapies are appropriate for severely obese patients?

Bariatric surgical procedures can be categorized as malabsorptive, restrictive, or combined, based on their effects on the digestive system. These categories correspond to the 3 bariatric procedures currently in common use. Biliopancreatic diversion (BPD) and BPD with duodenal switch (BPD/DS) are malabsorptive, laparoscopic adjustable gastric banding (LAGB) is restrictive, and Roux-en-Y gastric bypass (RYGB) combines both malabsorptive and restrictive features. All of these procedures provide considerable and sustained weight loss for many patients, with improvement or reversal of obesity-related comorbidities.^{6,30,64} Several long-term studies and a meta-analysis have reported that weight loss from bariatric surgery is maintained for at least 8 to 10 years.^{38,65-69} These long-term results should be viewed with discretion because of several possible confounding factors, including high and frequently unreported dropout rates, small numbers of patients and studies, and possible reporting bias on the part of both physicians and patients. Because these procedures have different effects on the digestive system, they differ considerably in terms of the typical course of weight loss and typical complication profiles.^{30,64} **Table 2** summarizes the 3 procedures.^{38,68-72}

Table 2: Summary of Bariatric Surgical Procedures in Common Use

	Biliopancreatic Diversion (BPD) or BPD With Duodenal Switch (BPD/DS)	Laparoscopic Adjustable Gastric Banding (LAGB)	Roux-en-Y Gastric Bypass (RYGB)
Schematic			
Type	Malabsorptive	Restrictive	Combined (restrictive and malabsorptive)
Description	Bypasses most of the small intestine	An adjustable gastric band creates a small pouch and stoma	Creates a small pouch and bypasses a portion of the small intestine
Method	Open or laparoscopic	Usually laparoscopic	Usually laparoscopic
Weight loss, %EWL			
3 years	76.3 ⁶⁹	41.2, ⁷⁰ 47.3, ⁷¹ 54.8 ⁶⁹	62.5, ⁶⁹ 67.3 ⁷¹
5 years	73.3 ⁶⁹	37.3, ⁷⁰ 47.5, ⁷¹ 55.2 ⁶⁹	58.2, ⁶⁹ 66.6 ⁷¹
8 years	75.8 ⁶⁹	37.7, ⁷⁰ 54.0 ⁶⁸	55.0 (7 y) ⁶⁹
10 years	77.0 ⁶⁹	35.4 ⁷⁰	52.5, ⁶⁹ 67.6 ⁷²
SOS study ^{38*} % of weight lost from start (standard deviation) at 10 years	N/A	-13.2 (13) [†]	-25 (11)
Notes	Most invasive Used less frequently in the United States	Least invasive Most commonly used procedure outside the United States	Most commonly used procedure in the United States

%EWL, percentage of excess weight loss; SOS, Swedish Obese Subjects; N/A, not available.

* BPD was not included in this study; however, mean (SD) of % of weight lost from start was assessed for vertical banded gastroplasty (VBG) at -16.5% (11%).

[†] Assessed with nonadjustable bands or adjustable bands.

There is uncertainty in comparing trials that are not head to head and do not have similar trial design. When reviewing these data, one should note that this is a review of trial data.

Malabsorptive procedures such as BPD reroute the digestive system so that food bypasses a substantial portion of the small intestine. This causes weight loss by drastically decreasing nutrient absorption. Although purely malabsorptive procedures also typically involve resection of some part of the stomach, the residual stomach volume is substantially larger than in restrictive procedures and may be less important than the malabsorptive effects in causing weight loss.⁶ In addition, the procedure affects the absorption of proteins as well as micronutrients such as vitamins (A, D, E, K) and minerals

(calcium, zinc, iron), so patients who undergo malabsorptive procedures require lifelong nutritional supplementation to avoid nutritional deficiencies.⁶

Restrictive procedures such as LAGB limit food intake, decrease appetite, and increase satiety by restricting the volume of the stomach available to hold ingested food. LAGB creates a small pouch (typically 15 mL) at the entry to the stomach with a small stoma, allowing food to pass to the rest of the gastrointestinal (GI) tract.^{6,73,74} It is the least invasive of the bariatric procedures because the stomach and intestines are not cut or stapled.⁶

Another restrictive procedure is vertical banded gastroplasty (VBG). Use of VBG has decreased substantially in recent years, but it is still used by some centers for selected patients.⁶

Several long-term studies and a meta-analysis have reported that weight loss from bariatric surgery is maintained for at least 8 to 10 years.

Patients who undergo restrictive procedures such as LAGB may experience postoperative vomiting due to overeating until they become accustomed to the small gastric volumes and develop appropriate eating habits.⁶ Unlike malabsorptive procedures, restrictive procedures have little or no impact on nutrient absorption in the small intestine and have not been associated with long-term nutritional problems.

Combined procedures involve both malabsorptive and restrictive aspects, creating a small gastric pouch and rerouting the small intestine. Thus, outcomes and complications of combined procedures discussed later in this paper usually have characteristics of both types of operations. RYGB is currently the standard combined procedure.⁶ Variations of RYGB include banded RYGB, in which the gastric pouch is restricted with an implanted band, and long-limb RYGB, which bypasses a larger segment of the small intestine than does typical RYGB, thereby increasing its malabsorptive character.⁶

The 2 most commonly used procedures, RYGB and LAGB, are the focus of this white paper.⁶ The following sections discuss and compare RYGB and LAGB in more detail.

FAQ: What factors are prognostic of success or failure in bariatric surgery?

Weight loss is generally accepted as a key outcome measure for bariatric surgery.⁶⁴ Several measures of weight loss are used, including absolute weight loss, percentage of weight lost, change in BMI, and percentage of excess weight loss (%EWL, the amount of weight lost expressed as a percentage of the

patient's weight in excess of his or her ideal weight). Of these terms, the first 3 are used throughout the weight management community, whereas %EWL is used almost exclusively in the field of bariatric surgery. It is not clear which of these measures is the most clinically appropriate measure of success, and the question is under discussion within the bariatric care community.⁵ Although bariatric surgery usually causes significant weight loss, not all patients benefit from the procedure: some patients experience complications, some do not experience significant weight loss (up to 5% with RYGB and up to 20% with LAGB), and others regain the lost weight within a few years.⁷⁵ Numerous studies have attempted to identify factors that predict the benefits and risks of bariatric surgery. These factors may be both treatment-related and patient-related.

Treatment-related factors: The experience of the surgeon and surgical team performing the surgery and providing preoperative and postoperative support is critical to the success of bariatric surgery.⁴⁶ The learning curve involved in becoming proficient with these techniques is substantial, with mortality and complications much more common early in a bariatric surgeon's career.⁶⁴ For instance, Flum and Dellinger³³ found the hazard ratio for death within 30 days of RYGB was 4.7 times higher for the surgeon's first 19 procedures than for later ones. In one study, adverse outcomes and mortality were 28% (144/515 patients) and 1.6% (8/515 patients), respectively, when performed by surgeons who did fewer than 10 procedures a year compared with 14% (269/1853 patients) ($P<.05$) and 0.3% (6/1853 patients) ($P=.06$) for high-volume surgeons.⁷⁶ The hospital's volume of bariatric procedures is also a strong predictor of complications, with complications much more likely in low-volume (<100 procedures a year) than in high-volume hospitals (>200 procedures a year) (odds ratio, 2.7).^{77,78} Many reports on long series of patients describe reductions in complication rates due to improvements in technique that occurred as the surgeon and the surgical center became more proficient.⁷⁹⁻⁸¹

Patient-related factors and predictors of weight loss: Several studies have identified patient characteristics associated with treatment success and with

complications. Proposed characteristics include preoperative weight and related variables such as BMI or fat, weight, age, gender, diabetes and other characteristics related to insulin resistance, eating behaviors, and psychological or personality profiles. Note that not all studies find all of these variables to be significant, and there is considerable disagreement about some.^{43-48,50,82-87}

High initial weight is an important negative predictor of %EWL^{44,82} and a positive predictor of the absolute weight loss (the actual amount of weight lost, usually measured in kg).^{45,83,85} The different trends in %EWL and absolute weight loss are a mathematical phenomenon: as patients become heavier, more of their weight is excess weight. Thus, a given absolute weight loss corresponds to a smaller %EWL as patients become heavier.

Results on other possible prognostic factors such as age, diabetes, and insulin resistance have been inconsistent. Advanced age, diabetes, and insulin resistance have been associated with less weight loss (%EWL) in multiple studies,^{43-46,73} but other data contradict these results.⁸² Most authors recommend bariatric surgery for severely obese patients with these conditions despite the potential risks involved because of the considerable benefits that result from sustained weight loss.^{43,44,46}

Several other prognostic factors have been proposed in individual trials but not reproduced in multiple studies. They include moderate alcohol consumption and high physical component scores on the Short Form 36 (SF-36) quality-of-life questionnaire (associated with increased weight loss after LAGB), asthma and hypertension (associated with less weight loss after RYGB), and gender. The effects reported for gender are somewhat contradictory. They include reduced %EWL for women, increased weight loss for younger women, poor weight loss for older men, and increased risk of complications for men.^{44,82,85,87} Because these results have not been reproduced, they cannot be considered reliable.

Predictors of complications: The main predictors of complications following bariatric surgery include older age, male gender, and high BMI.⁸⁷⁻⁹¹ Additionally, several controversies surround

the use of adjustable gastric banding in patients with esophageal disorders such as GERD and hiatal hernia. First, the impact of LAGB on GERD is not clear. Several studies have reported that LAGB placement reduces or resolves GERD symptoms, whereas others find that band placement worsens symptoms.⁹²⁻⁹⁴ Historically, GERD and hiatal hernia have been associated with an increased risk of band slippage and other complications and were considered to be contraindications for gastric banding by some authors.⁹⁵ However, several studies suggest that repair of hiatal hernias simultaneously with band placement is effective in reducing GERD without increasing the risk of complications.^{92,96} Inaccurate positioning and pouch formation have been suggested as factors that influence the effects of LAGB on GERD.⁹³

Some upper GI conditions, such as gastric ulceration, should be treated before bariatric surgery, and others, such as hiatal herniation, affect the surgical procedure. Upper GI studies, including endoscopy or radiography, are often used to preoperatively assess patients' upper GI status, but there is some debate as to which studies are appropriate. Several studies suggest that upper GI radiographic studies are unlikely to produce findings that affect treatment.^{97,98} Studies of upper GI endoscopy suggest that it has a high diagnostic yield in terms of identifying patients with upper GI conditions that affect treatment, and that it is relatively inexpensive.⁹⁹⁻¹⁰¹ However, some authors suggest reserving it for patients with symptoms suggestive of upper GI pathology.¹⁰²

Other proposed but unvalidated risk factors include hypertension,^{46,50} high fasting plasma glucose levels,⁴⁸ asthma (forced expiratory volume in 1 second [FEV₁] <80% predicted), abnormal electrocardiogram, previous abdominal surgery,⁸⁶ sleep apnea,⁴⁶ and long-limb procedures.⁵⁰

Psychosocial factors: Physical and medical factors cannot explain all of the variation in weight loss following bariatric surgery.⁷⁵ Psychosocial conditions are common among bariatric surgery candidates. Common conditions include major depressive disorder, dysthymia, generalized anxiety disorder, social phobia, and substance abuse disorders.⁷⁵ These conditions could potentially account for some of

the remaining variability. Estimates of the preoperative prevalence of psychosocial disorders among bariatric surgery candidates vary widely, ranging from 20% to 60% for Axis I disorders, as high as 48% for anxiety disorders, and up to 72% for personality disorders.⁷⁵ One recent study found at least one psychosocial diagnosis in 62.2% of candidates, with mood disorders in 47.8%, anxiety in 4.4%, substance abuse disorders in 16.7%, and binge eating in 26.7%.¹⁰³

Eating behaviors represent another potential predictor of poor weight loss. The presence of binge eating disorder or a tendency toward binge eating predicted poor weight loss in several retrospective studies, but not in prospective studies.⁸⁴ A large intake of calories in liquid or soft form may make bariatric surgery less effective, particularly in restrictive procedures where these foods readily pass through the small stoma. A systematic review concluded that this hypercaloric eating behavior was correlated with less weight loss.⁸⁴ The impact of one form of hypercaloric eating behavior, sweet eating, is more controversial.^{104,105} Several small studies found that patients who obtain a large percentage of their calories from sweets (eg, soda, cookies, cakes, or ice cream) have less long-term weight loss after restrictive bariatric surgery than non-sweet eaters.^{106,107} However, later studies have found no relationship between sweet eating and weight loss, and the sweet-eating concept has been challenged in the literature.^{43,104,108}

A variety of different methods for assessing the effects of psychosocial factors have been investigated, including clinical interviews, symptom inventories, and objective personality or psychopathology tests. These investigations have proposed many psychosocial characteristics as prognostic factors for weight loss.^{85,109-112} However, several systematic reviews have found that no psychosocial factors consistently predict successful weight loss, with the possible exception of patients with serious psychiatric disorders who may experience poor weight loss.^{75,84,112}

In routine clinical practice, at least 80% of bariatric surgery programs require a preoperative mental health evaluation.^{113,114} The evaluation assesses the patient's psychiatric history, current

function, and eating behaviors to identify factors that might contribute to a poor outcome.¹¹⁵ Virtually all (99%) of these evaluations include a clinical interview, and most include symptom inventories (69%), objective tests (63%), and a nutritional evaluation (78%).^{114,116} Historically, these evaluations assess approximately 70% (64.4%-81.5%) of patients as appropriate candidates for bariatric surgery, approximately 25% (15.8%-32.0%) as needing preoperative psychosocial treatment, and <5% (2.7%-3.9%) as inappropriate candidates.^{103,116,117}

FAQ: Is bariatric surgery appropriate for patients with BMI >50 kg/m²?

Individuals with BMI >50 kg/m² form a subset of the severely obese population, sometimes referred to in the literature as superobese patients. Because of the health risks and quality-of-life issues associated with this extremely high weight, these individuals would receive substantial benefit from successful bariatric surgery. However, many of the factors associated with lesser weight loss and high complication rates in bariatric surgery are themselves related to obesity. Thus, patients with BMI >50 kg/m² are likely to have worse ratios of efficacy to risks than less obese patients. Several studies have shown that both RYGB and LAGB performed by an experienced treatment team are safe and effective in treating these patients.¹¹⁸⁻¹²² Because bariatric surgery is the only proven effective method of weight reduction in the severely obese, withholding surgery from patients with BMI >50 kg/m² leaves them vulnerable to the significant risks and adverse effects of their obesity. Thus, bariatric surgery should be considered even for these high-risk patients.

FAQ: How do RYGB and LAGB compare in terms of efficacy?

Although bariatric surgery confers a variety of important benefits to severely obese patients, weight loss is regarded as the primary measure of efficacy. A variety of studies have reported on weight loss

subsequent to RYGB and LAGB. Most of the trials and all of the direct comparisons have been short to medium term.

Data from the comparative trials are discussed later in this paper. Meta-analyses of data from short-term (0-2 years) follow-up found that weight loss after RYGB was higher and less variable than weight loss after LAGB. Based on these results, RYGB is generally considered to provide more weight loss than LAGB.^{30,64,69}

Few studies have reported long-term results of either RYGB or LAGB procedures.

It is not clear whether these results apply over longer follow-up periods (≥ 3 years). Few studies have reported long-term results of RYGB and LAGB procedures. This is particularly true for LAGB in the United States because the LAGB device only received US Food and Drug Administration approval in 2001. As previously noted, those studies that do report medium-term to long-term data have several limitations: they are generally not randomized, usually include few patients, and tend to have poor follow-up. In addition, there is considerable potential for reporting bias.

The first long-term results were reported by Pories and colleagues⁶⁵ in 1995, which reported a %EWL of 55 among 158 patients 10 years after RYGB, and a %EWL of 49 among 10 patients 14 years after RYGB. In a later study of RYGB, Jones⁶⁶ reported a %EWL of 62 among 36 patients 10 years postoperatively. Similarly, White and colleagues⁶⁷ reported a %EWL of 74.6 (± 55.2) and 58.5 (± 3.5) at 10 and 14 years, respectively. The number of patients and percentage of follow-up at these time points were not reported. Weiner and colleagues⁶⁸ reported on their experience with LAGB among 984 patients. At a mean follow-up of 8.2 years for the first 100 patients treated, %EWL was 59.3 for patients whose band was still in place and 54% for all patients.

In the SOS study, patients underwent either VBG (n=451), gastric banding, with a nonadjustable band or an adjustable band (n=156), or RYGB (n=34). At 10 years of follow-up, the mean percent-

age and standard deviation of weight loss from start in obese patients was -25% (11%) for RYGB, -13.2% (13%) for banding, and -16.5% (11%) for VBG.³⁸ In contrast, weight increased by 1.6% (12%) among control subjects who did not undergo bariatric surgery.

A systematic review of the medium-term results of bariatric surgery, published by O'Brien and colleagues in 2006,⁶⁹ included multiple trials of each procedure (7 for RYGB, 11 for LAGB) with durations ranging up to 10 years. The review concluded that levels of weight loss from RYGB and LAGB tend to converge at approximately 50% EWL to 60% EWL in the medium term, with differences between the procedures becoming insignificant approximately 3 years postprocedure.⁶⁹

This conclusion from O'Brien and colleagues does not include newer data such as those from a smaller randomized comparison (N=51) of RYGB and LAGB.⁷¹ This study found that RYGB provided significantly better weight loss than did LAGB at 5 years postoperatively (%EWL of 66.6 and 47.5, respectively; $P<.001$). The researchers concluded that RYGB provides greater weight loss than does LAGB but has a higher risk of complications and longer operation time. To be able to make conclusive recommendations, larger prospective comparative trials are warranted.⁷¹

Also, a 2007 publication reported up to 12-year follow-up results for 1791 consecutive LAGB patients.⁷⁰ It showed less weight loss with LAGB than that found in O'Brien et al's meta-analysis, including %EWL of 35.4 at 10 years (n=74), %EWL of 38.4 at 11 years (n=22), and %EWL of 49.2 at 12 years (n=4).

Initial weight loss appears to be rapid after RYGB and gradual after LAGB. Weight loss in RYGB tends to plateau after 1 to 2 years, after which patients frequently regain some of the lost weight. LAGB patients often experience slower, continued weight loss for several years.⁶⁹ The gradual course of weight loss in LAGB is attributed to the band's adjustability: if the patient's weight loss plateaus, it may be feasible to adjust the stoma diameter to further restrict intake and promote continued weight loss.¹²³ A recent and somewhat controversial systematic review suggests that this slow weight loss

may be beneficial in that it may help preserve fat-free mass.¹²⁴ Based on the relatively few studies that have reported on fat-free mass loss (as a proportion of total weight lost), the review concluded that RYGB was associated with a higher percentage of fat-free mass loss than LAGB, with median (interquartile ratio) percentage of fat-free mass loss values of 31.3% (12.2%) for RYGB and 17.5% (3.7%) for LAGB.¹²⁴ However, several factors may have influenced these results: the mean initial BMI of patients in the RYGB studies was higher than that of patients in the LAGB studies (ranges, 48.7-50.0 kg/m² vs 40.5-47.2 kg/m², respectively), most of the LAGB studies were conducted outside the United States, and many open RYGB procedures were included.

FAQ: What are the operational characteristics and potential surgical complications of RYGB and LAGB?

Although both RYGB and LAGB are major operations, there are substantial differences between them in terms of the difficulty of the procedure, the recovery time needed, and their complication profiles (Table 3).^{6,64,125-134} RYGB is generally regarded as more invasive and more technically challenging than LAGB.⁶ The time required for an operation can be viewed as a measure of its difficulty, although this is substantially dependent on the skill of the surgeon and

the characteristics of the patient. Typical mean laparoscopic operating times given in literature reports of case series are 162 to 209 minutes for RYGB^{129,130} and 42 to 66 minutes for LAGB.¹²⁷⁻¹²⁹ Patient recovery time as measured by hospital stay is typically 2 to 4 days for RYGB and 0 to 2 days for LAGB.^{128-131,133,134}

Both RYGB and LAGB have acceptable mortality rates as well. A recent guideline stated that perioperative mortality is approximately 0.5% for RYGB and 0.1% for LAGB.⁶ A recent systematic review calculated mortality rates of 1% for RYGB and 0.4% for LAGB controlled trials.⁶⁴ Rates of morbidity also differ between the 2 procedures: 25.7% with RYGB and 11.3% with LAGB in a recent review.¹²⁶ Table 4 summarizes the rates of various classes of postoperative complications as reported in a recent study and a recent meta-analysis.^{64,133}

Surgical complications are uncommon in both RYGB and LAGB and can often be corrected laparoscopically.

One study compared complications resulting from bariatric procedures using a retrospective analysis of a prospective database of 780 bariatric procedures performed at a single institution.¹²⁵ The procedures were LAGB (n=480), RYGB (n=235), and BPD (n=65). Complication rates were 8.8% for LAGB, 23.0% for RYGB, and 24.6% for BPD for all complications ($P<.001$ for LAGB vs RYGB

Table 3: Perioperative Characteristics of RYGB and LAGB

	RYGB	LAGB	P Value
Mortality (as reported in case series studies) ⁶⁴	0.3% (95% CI, 0.2-0.4)	0.02% (1-sided 97.5% CI, 0-0.78)	NA
Early complications ¹²⁵	9.4%	3.3%	<.001
Major complications ^{126,129,132}	<ul style="list-style-type: none"> • Pulmonary emboli • Bleeding • Anastomotic leaks • Wound infection 	<ul style="list-style-type: none"> • Pulmonary emboli • Access port infection/obstruction • Prolapse/slippage • Pouch or esophageal dilation 	
Mean operating time (min) ¹²⁷⁻¹³⁰	162-209	42-66	NA
Mean length of stay (d) ^{128-131,133,134}	2.3-4.0	1.1	NA

RYGB, Roux-en-Y gastric bypass; LAGB, laparoscopic adjustable gastric banding; CI, confidence interval; NA, not available.

and BPD). Major complication rates were 0.2% for LAGB, 2.1% for RYGB, and 4.6% for BPD ($P < .001$ for LAGB vs RYGB and BPD). The difference between LAGB and the other 2 techniques was maintained for both early and late complications.¹²⁵

The most common perioperative complication for LAGB is infection of the access port, although this occurs in a minority of patients (1%-2%).¹²⁶ Other uncommon but more serious complications include obstruction of the band, esophageal puncture, and pulmonary emboli.¹³⁵⁻¹³⁹ For RYGB, the most common perioperative complications include anastomotic leaks, bleeding, and wound infection. Of these, anastomotic leakage and the resulting peritonitis cause the most concern.

Surgical complications are uncommon in both RYGB and LAGB and can often be corrected laparoscopically. Long-term surgical complications of RYGB occurred in 13.6% (91/668) of patients in the study by Parikh and colleagues.¹²⁵ Reported long-term surgical complications of RYGB include stomal stenosis, ulceration, staple line disruption (rarely seen now with laparoscopic transection of the stomach), and internal hernias.⁶

Long-term surgical complications of LAGB are also uncommon, occurring in approximately 5% of patients when the

band is implanted with the pars flaccida approach. The pars flaccida approach is currently the standard technique for LAGB placement because it provides a considerable reduction in rates of long-term band-related complications compared with the perigastric technique. When complications of LAGB occur, they usually involve the implanted device. Reported complications include access port problems and tube breakage, stomal obstruction, gastric prolapse, band slippage and/or erosion, and pouch or esophageal dilation.^{6,132} Access port problems can generally be managed without major surgery. Stomal obstruction can often be resolved by enlarging the aperture of the LAGB, although this is likely to cause weight regain. The other complications are closely related to the stability of the band positioning.

FAQ: Are there other long-term complications of RYGB and LAGB?

Factors frequently associated with complications in bariatric surgery include weight, age, gender, and hypertension. Elevated weight increases the difficulty of the bariatric procedures and is generally considered to increase the risk of complications.^{48-50,86,87,91} Male gender also

increases the risk of complications,^{47,49,87} with superobese (BMI >50 kg/m²) male patients at highest risk for serious, life-threatening complications.⁸⁷ More specifically, those who are superobese at a BMI ≥ 60 kg/m² are considered to be a part of this high-risk population.¹³³ Several studies found that the risk of complications is higher in elderly patients.⁴⁷⁻⁵⁰ In one study, mortality among older individuals (>55 years) was triple that among younger patients, although the complication rates were not significantly different, suggesting better tolerance of complications by young patients.⁸⁷

RYGB and LAGB have different surgical and GI adverse event and complication profiles. Potential GI complications include the dumping syndrome in RYGB and vomiting in both RYGB and LAGB. These complications frequently stem from inappropriate patient eating habits and can usually be prevented by effective patient education. Vomiting can occur after both RYGB and LAGB, usually when the patient consumes more food than the small gastric pouch can contain.⁷⁴ Among LAGB patients, vomiting can be minimized by appropriate adjustment of the band aperture. The dumping syndrome, which occurs in some patients after RYGB, occurs in response to the consumption of sugary foods or simultaneous consumption of fluids and solids among patients who undergo gastric bypass procedures.⁷⁴ Symptoms include nausea, dizziness, diaphoresis, cramping, diarrhea, and malaise. These symptoms can be viewed as somewhat beneficial because they tend to discourage sweet-eating behavior.¹⁰⁶ Although the dumping syndrome usually resolves within 2 to 3 years postoperatively, many RYGB patients experience at least a few dumping syndrome episodes.¹⁰⁶

Table 4a: Percentage of postoperative complications after LAGB or RYGB procedures from a study by Jan and colleagues¹³³

Jan et al, 2007*	RYGB	LAGB	P Value
Total complications (%)	32	24	.002
Life threatening adverse events requiring urgent intervention (%)	9	5	.05

N=898 (n=492 for RYGB; n=406 for LAGB)

*In Jan et al, 27 cases of chronic band slippage/pouch dilation were reported.

Table 4b: Percentage of patients experiencing postoperative complications after LAGB or RYGB procedures from a meta-analysis by Maggard and colleagues⁶⁴

Maggard et al, 2005		GI	Nutritional	Surgical	Leak	Stenosis	Bleeding	Reoperation	Medical
Patients (%)	RYGB	17	17	19	2	5	2	2	5
	LAGB	7	0	13.2	0	0	0.3	7.7	0.7

N=128 studies

RYGB, Roux-en-Y gastric bypass; LAGB, laparoscopic adjustable gastric banding; GI, gastrointestinal. GI includes reflux, vomiting, dysphagia, dumping syndrome, and others; nutritional includes mineral, vitamin, and protein deficiencies; surgical includes bleeding, anastomotic and stoma-related problems, reoperations, wound problems and others; leak includes anastomotic, pouch, or duodenal complications; stenosis includes anastomotic or stomal stenosis; reoperation includes those related to anastomosis, band, bleeding, and revision; medical includes cardiac episodes, stroke, or hypertension.

FAQ: What are the nutritional impacts of RYGB and LAGB?

RYGB and LAGB have different effects on the digestive system and therefore have had different GI and nutritional impacts. Nutritional deficiencies are common after malabsorptive procedures such as RYGB because of impaired nutrient absorption.¹³⁸ Thus, RYGB patients require careful monitoring to avoid nutritional problems.¹³⁸ Iron and vitamin B₁₂ deficiencies are the most common, occurring in approximately 33% and 37% of patients, respectively, who have undergone RYGB procedures and resulting in anemia in 30% of patients.¹⁴⁰ The prevalence of iron and vitamin B₁₂ deficiencies increases with time after surgery, with iron and vitamin B₁₂ deficiencies reported in up to 48.6% and 70.1% of patients, respectively, 7 years after gastric bypass surgery.¹⁴⁰ When deficiencies occur, they are usually mild and can be effectively treated with nutritional supplementation, although standard multivitamins may not be sufficient.^{74,141} Bariatric surgery patients may develop severe and persistent nausea and vomiting, which can produce a profound thiamin (vitamin B₁) deficiency associated with a Wernicke-Korsakoff encephalopathy or peripheral neuropathy that may not be reversible.¹⁴² This occurs more commonly with RYGB. It is less common with LAGB, but may occur if there is band slippage or obstruction, or if the band is too tight,^{143,144} situations which may be avoided with appropriate follow-up. It is extremely important that all bariatric patients take a multivitamin and, should persistent nausea and vomiting occur, the patient must be given large doses of intravenous B vitamins without glucose. Severely obese patients frequently have vitamin D insufficiency preoperatively as well as postoperatively. However, the risk of nutritional deficiencies after RYGB is often underestimated, and metabolic bone disease resulting from insufficiencies in calcium and vitamin D is a concern.¹⁴⁵ Although the available data are scant, recent studies report rates of preoperative vitamin D insufficiency (serum 25-hydroxyvitamin D ≤ 20 mg/mL) ranging from 21.1% to 68.1% among severely obese bariatric surgery candidates.¹⁴⁶⁻¹⁴⁸ Several observational studies and case reports suggest

that vitamin D insufficiency leads to hyperparathyroidism and metabolic bone disorders. However, it is unclear how vitamin D malabsorption and metabolism are affected by RYGB versus a deficiency being pre-existing or caused by weight loss.¹⁴⁵ Patients who undergo RYGB or other malabsorptive procedures need lifelong nutritional supplementation and regular medical follow-up to maintain and monitor nutrient levels. The dramatic postoperative reductions in nutritional intake can also cause nutritional deficiencies. However, these are usually short-term. Nutritional deficiencies are unlikely in patients who have received LAGB because the purely restrictive operation does not affect nutrient absorption.

FAQ: What were the results of comparative clinical trials of RYGB and LAGB?

As previously mentioned, a recent randomized, prospective trial noted a significantly greater weight loss with RYGB than with LAGB. However, there have also been several comparative studies that reported and showed variable results. The variability could result from several factors, including selection bias due to the lack of randomization, differences in the experience of the surgeons performing the procedures, differences in the duration of follow-up, and variations in their definitions of complications. This section summarizes several recent reports (Table 5).^{38,121,129,140-152}

In the sole randomized trial comparing RYGB and LAGB to date, Angrisani and colleagues⁷¹ compared 51 patients who were randomly allocated to RYGB or LAGB with a minimum follow-up of 5 years. Patients were permitted to opt out of the trial before it began. In the RYGB group, 20 of 24 (83%) patients were female, the mean age was 34.1 \pm 8.9 years, and the mean preoperative weight and BMI were 118.2 \pm 13.2 kg and 43.8 \pm 4.1 kg/m², respectively. In the LAGB group, 22 of 27 (81%) patients were female, the mean age was 33.8 \pm 9.1 years, and the mean preoperative weight and BMI were 117.1 \pm 12.8 kg and 43.4 \pm 4.2 kg/m², respectively. At 5 years, mean weight loss was significantly greater in the RYGB group than in the LAGB group (%EWL,

66.6 and 47.5, respectively; $P < .001$). The follow-up in the surgeon's office was scheduled every 3 months for the first year and every 6 months for subsequent years for both RYGB and LAGB patients. There were 3 serious complications in RYGB patients: an intraoperative pouch leak, a jejunal perforation at 3 days, and an internal hernia at 15 months with hospital stays of 6 days, 6 months and 11 days, respectively. In the LAGB group, 2 patients required band removal with hospital stays of 2 and 3 days, respectively. As mentioned previously, the researchers concluded that RYGB provides greater weight loss than LAGB but has a higher risk of complications and longer operative times. They currently perform both techniques depending on the patient's desires, expectations, and needs.⁷¹

Both RYGB and LAGB produce substantial weight loss and comorbidity resolution with some morbidity and low mortality.

Galvani and colleagues¹²⁹ described a case series of 590 patients treated with either laparoscopic RYGB or LAGB. Other than gender, demographic differences between groups were not significant. Complications occurred in both groups, varying in frequency and severity depending on the type of surgery. Among the major complications (>30 days) in the RYGB group, the most frequently occurring were stomal stenosis, marginal ulceration, small bowel obstruction, and one death due to Roux limb obstruction. The predominant LAGB complication was pouch enlargement—which was non-surgically managed for 77% (n=365) of the patients—and band slippage. Initial weight loss was greater for the RYGB group than for the LAGB group. Through the follow-up period, weight loss in the LAGB group continued and at 3 years was not significantly different from weight loss in the RYGB group. There were no significant differences in the resolution of comorbidities (eg, diabetes, hypertension, GERD, and sleep apnea).¹²⁹

The early outcomes of bariatric surgery were described by Kim and colleagues¹⁴⁹ for 232 patients who underwent RYGB and 160 who underwent LAGB. Mean weight loss was significantly greater for

Table 5: Summary of Selected Trials Comparing RYGB and LAGB (Pars Flaccida Technique)

Study	Galvani Cet al, 2006 ¹²⁹		Kim TH et al, 2006 ¹⁴⁹		Cottam DR et al, 2006 ¹⁵⁰		Jan JC et al, 2007 ¹³³		Parikh MS et al, 2005 ¹²¹		Biertho L et al, 2003 ¹⁵²		Sjostrom L et al, 2004 ³⁸	
	RYGB	LAGB	RYGB	LAGB	RYGB	LAGB	RYGB	LAGB	RYGB	LAGB	RYGB	LAGB	RYGB	LAGB
Patient population	120	470	232	160	181	181	219	406	97	192	456	805	34	156
% Female	91	80	89	75	89	80	87	78	78	70	79	79	69.4	
Age, y (mean±SD)	41±10	41±10	38.5	41.7	43±10	42±13	44±10	47±11	42	43	40.2±10.5	41.7±10.9	47.0±5.6	
BMI, kg/m ² (mean±SD)	46±5	47±8	47.2	47.1	47.2	47.2	49±8	51±9	54.8	55.3	49.4±8.3	42.2±4.9	41.9±4.2	
Operating time, min (mean±SD)	209±39	66±26	NS	NS	NS	NS	134±41	68±26	130	60	NS	NS	NS	
Length of stay, h (mean±SD)	55±17	22±25	NS	NS	NS	NS	2.5±3.5	1.1±1.1	72 (median)	24 (median)	72	120	NS	
Complication rate % (n) of patients	Early: 7.0 (8); 1 death Late: 14.0 (17)	Early: 3.6 (17) Late: 17.0 (82)	Early: 5.2 Late: 0.43	Early: 0.63 Late: 3.7	Reoperations Minor: 13 (25) Major: 5.3 (10)	Reoperations Minor: 15 (28) Major: 8.0 (15)	Any: 32.0 Urgent life-threatening: 9.0	Any: 24.0 Urgent life-threatening: 5.0	11.3	4.7	Major intraoperative: 2.0 Major postoperative: 4.2	Major intraoperative: 1.3 Major postoperative: 1.7	NS	
% EWL (mean)	63.0 (3 y)	55.0 (3 y)	68.0 (2 y)	47.5 (2 y)	74±25 (3 y)	51±23 (3 y)	66.0 (3 y; n=47/146)	34.9 (3 y; n=35/47)	56.8±21.1 (3 y)	49.5±18.6 (3 y)	74.6 (18 mo)	40.4 (18 mo) 56 (3 y)	-25.0 (10 y)*	-13.2 (10 y)*

RYGB, Roux-en-Y gastric bypass; LAGB, laparoscopic adjustable gastric banding; SD, standard deviation; BMI, body mass index; NS, not significant; %EWL, percentage of excess weight loss.

*% of total weight lost, not %EWL.

Note: The Swedish Obesity Subjects study focused on comparing bariatric surgery with nonsurgical weight loss and did not give demographic data by procedure.

RYGB than for LAGB at up to 18 months of follow-up. At 24 months, %EWL was 68.0 and 47.5 for RYGB and LAGB, respectively, a difference that was not statistically significant possibly because of the small number of patients. Rates of comorbidity resolution were also not significantly different at 2 years. The 2 procedures had similar overall complication rates of 5.6% for RYGB and 4.3% for LAGB, with early complications more frequent in the RYGB group and late complications more frequent in the LAGB group.¹⁴⁹

Cottam and colleagues¹⁵⁰ reported on a case-controlled study comparing RYGB with LAGB, with 181 case-matched patients in each arm. Weight loss and comorbidity resolution at 3 years were better for the RYGB group than the LAGB group. Rates of complications and reoperations were similar in both arms. This trial included the surgeon's initial experience with LAGB procedures and that the rates of LAGB complications and reoperations considerably decreased during the 3 years of the study. This further confirms other studies' findings that such events are

correlated with the surgeon's experience with LAGB. The authors concluded that RYGB was superior to LAGB in terms of weight loss, but that both procedures were effective and that LAGB was acceptable for patients who preferred it.¹⁵⁰

Jan and colleagues¹³³ recently reported on a single-institution study of 898 bariatric surgery patients, of whom 492 and 406 underwent RYGB and LAGB, respectively, over a 5-year period. Patients in the LAGB group were more likely than their respective counterparts in the RYGB group to be male, to be ≥60 years of age, and to have BMI ≥60 kg/m². Operative times and hospital stays were longer for patients undergoing RYGB than for those undergoing LAGB. %EWL in the LAGB group was significantly less ($P<.05$) than in the RYGB group at all time points except 5 years ($P=.84$), at which point only 3 and 5 patients, respectively, had been followed up. These results reflect current information regarding predictors of outcome for this highest-risk patient population. Complication rates were 32% for RYGB and 24% for LAGB ($P=.002$), with 9% of RYGB patients and 5% of

LAGB patients experiencing potentially life-threatening complications that required urgent intervention. Reoperation rates were 17% in both groups.¹³³

Parikh and colleagues¹²¹ reported on a case series involving superobese patients (BMI >50/kg/m²) who underwent LAGB (n=192), RYGB (n=97), or BPD (n=43). The BPD results are not discussed here. Levels of weight loss (%EWL) for RYGB versus LAGB, respectively, were 57.7±15.4 versus 35.3±12.6 at 1 year, 54.7±21.2 versus 45.8±19.4 at 2 years, and 56.8±21.1 versus 49.5±18.6 at 3 years. Operating time and length of stay were longer for RYGB than for LAGB. Morbidity rates for RYGB and LAGB, respectively, were 11.3% and 4.7% ($P=.02$).¹²¹

A comparative study published in 2003 by Biertho and colleagues¹⁵² reported results for 805 LAGB procedures and 456 RYGB procedures. At 18 months' follow-up, %EWL was 74.6 for RYGB and 40.4 for LAGB. Weight loss at longer durations was only reported for the LAGB group and reached a %EWL of 58 at 4 years. Early postoperative complication rates were 4.2% for RYGB and 1.7%

for LAGB ($P=.02$). Differences between techniques in perioperative complication and mortality rates were not significant.¹⁵²

The SOS study, already discussed, was a prospective case-matched study involving 4047 obese subjects who were treated with either customary nonsurgical treatment, VBG ($n=451$), gastric banding (adjustable or nonadjustable) ($n=156$), or RYGB ($n=34$).³⁸ Mean percentage weight loss (SD) at 1 year was -38% (7%) for RYGB, -21% (10%) for banding, and -26% (9%) for VBG. All 3 patient groups had regained some weight at 10 years, with mean (SD) weight loss of -25% (11%), -13.2% (13%), and -16.5% (11%), for RYGB, banding, and VBG, respectively. The course of weight change for the different groups is shown in **Figure 2**.³⁸ RYGB provided more weight loss than banding at all time points.

Overall, these studies make it clear that both RYGB and LAGB produce substantial weight loss and comorbidity resolution with some morbidity and low mortality. Differences between the procedures in terms of operative and recovery time, the extent and time course of weight

loss, and complication profiles appear to be considerable. More definitive data from randomized controlled trials comparing the 2 procedures is needed to better differentiate long-term outcomes.

FAQ: How is the appropriate surgical technique selected for individual patients?

At present, there are no objective, clinically proven methods for selecting between bariatric surgical techniques for a particular patient and no generally accepted algorithms for matching individual patients to the techniques. The few algorithms that have been proposed have not been evaluated in controlled trials.⁶ In the absence of objective methods, the overriding factors are the surgeon's experience with the technique and the surgeon's and patient's preferences.¹⁵³

When surgeon or patient preferences do not dictate the choice of procedure, the choice of procedure should aim to optimize the risk/benefit ratio for each patient. Several factors have been

proposed as selection criteria, including weight and comorbidities, age, and eating behaviors. Unfortunately, none of these factors is supported by strong evidence,¹⁵⁴ and some are controversial.

Weight and comorbidities: It has been argued that patients with extremely high BMIs, such as the superobese, should be treated with RYGB or BPD because of these procedures' greater efficacy for inducing initial weight loss.¹⁵⁵ The contrary argument suggests that LAGB is appropriate because of its greater safety and lower complication rate.¹¹⁹ However, it is likely that superobese patients who undergo LAGB may require a longer period to reach their target %EWL.¹¹⁹

Age: Increasing age decreases the effects of bariatric surgery on weight loss and comorbidities and increases the probability and severity of complications. This has led to suggestions of using RYGB in the belief that it causes more weight loss than LAGB and thereby reduces the risk of repeated surgeries being needed.¹⁵⁵ On the other hand, LAGB may be more appropriate for the elderly because of its safer complication profile. Further studies are warranted.

Eating behavior: Patients with high consumption of liquid or soft carbohydrates ("sweet eaters") are often allocated to RYGB, the idea being that the occurrence of the dumping syndrome will prompt avoidance of sweet foods.¹⁵⁶ However, recent studies have found that sweet-eating behavior does not affect the outcome of LAGB.^{104,108} In general, eating behavior appears to be of little value in selecting the procedure.¹⁵⁶

FAQ: What follow-up is needed after RYGB and LAGB?

Any bariatric surgery requires regular medical follow-up for the duration of the patient's lifetime. Follow-up has both medical and psychosocial functions. The medical functions include monitoring of weight loss, comorbidities, and nutritional status. For patients with LAGB, the status of the band is checked and the diameter adjusted as necessary. Both RYGB and LAGB techniques require follow-up regarding psychosocial functions, centering on education, reinforcement, and support related to the behavioral and dietary

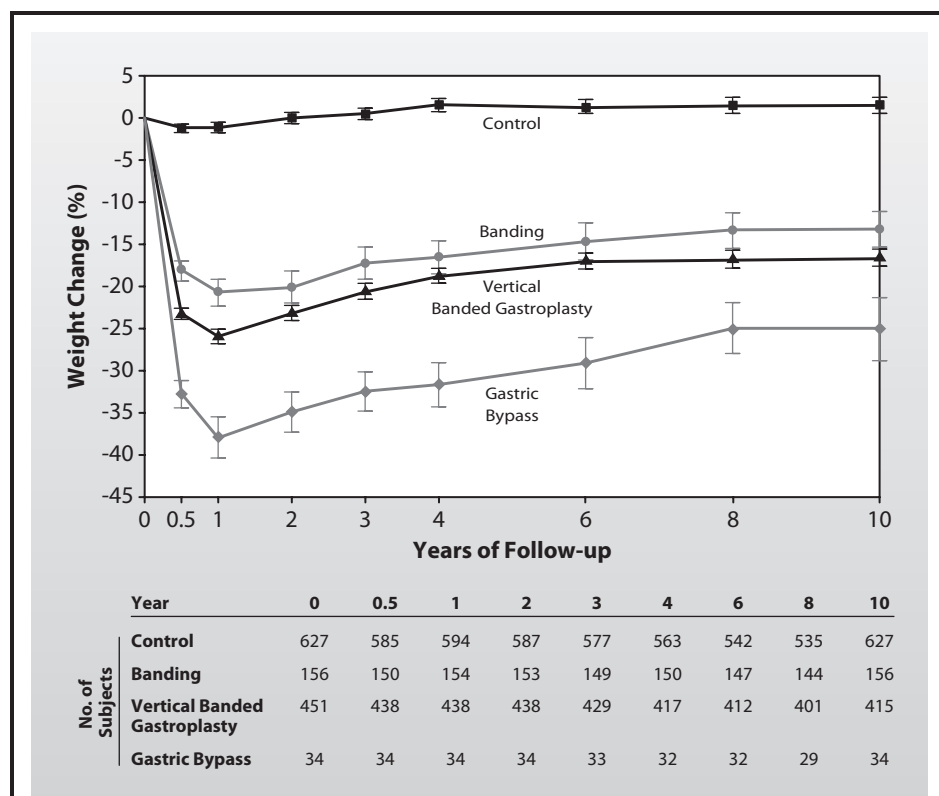


Figure 2: Weight changes in the Swedish Obesity Study by type of therapy.³⁸

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changes needed to lose and maintain weight after the surgery, along with assistance in coping with the psychologic and social changes that often occur with bariatric surgery.⁶

In the immediate postoperative period, LAGB requires more frequent follow-up visits than RYGB because of the potential need for band adjustment. Follow-up visits that provide an opportunity for band adjustment are recommended every 4 to 6 weeks during the first year, every 3 to 6 months during the second and third years, and annually thereafter. A follow-up visit should be scheduled within 1 month of any band adjustment.¹⁵⁷ These adjustments may often be performed by trained allied healthcare professionals, including nurse practitioners, physician's assistants, and registered nurses. **Table 6** shows a suggested schedule for postoperative follow-up.^{74,157}

Table 6: Recommendations for Follow-up With the Obesity Management Team After Bariatric Surgery

Years Postprocedure	RYGB ⁷⁴	LAGB ¹⁵⁷
1	Months 1, 3, 6, 12	Every 4-6 wk
2	Every 6 mo	Every 3-6 mo
3	Annually	Every 3-6 mo
Ongoing	Annually	Annually

RYGB, Roux-en-Y gastric bypass; LAGB, laparoscopic adjustable gastric banding.

CONCLUSION

Bariatric surgery has been shown to be the only available effective therapy for severe obesity. Patients who undergo bariatric surgery typically experience substantial weight loss and resolution of obesity-related comorbidities. However, surgery alone is not sufficient to cause this weight loss. For successful and prolonged weight loss, the patient must fully commit to and participate in lifelong changes in his or her dietary habits and lifestyle. Without effective lifestyle management, the patient may not reach reported levels of weight loss regardless of bariatric technique. Effective management is a multifaceted process that includes medical,

psychosocial, and nutritional factors. Management should begin preoperatively and continue throughout the patient's lifespan. Because of the multiple factors involved, effective management is best performed by a multidisciplinary team that includes the patient, the surgeon, nutritional or dietary counselors, psychologic counselors, a nurse practitioner or coordinator, and the patient's primary care physician. With effective management, bariatric surgery patients can achieve considerable, prolonged weight loss with the attendant reductions in comorbidities and improvements in quality of life.

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Note: The topics discussed in this white paper will be addressed more fully in upcoming educational initiatives that will include several multimedia activities. The initiative began with a multidisciplinary scientific roundtable that included surgeons, other physicians specializing in obesity, psychologists, registered dietitians, registered nurses, and allied healthcare professionals involved in the treatment of severely obese patients. A number of enduring materials are being planned. Please continue to check www.MedCME.org over the coming months for access to these CME programs. You can also contact SynerMed® Communications at 908-832-4142 and reference "Obesity Programs" to request additional CME materials on this topic.

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Identification and Treatment of Extreme Obesity—Considering Surgical Options: Frequently Asked Questions

Release Date: August 2007
Expiration Date: August 31, 2008

METHOD OF PARTICIPATION

Continuing medical education (CME) credit will be awarded to physicians who successfully complete this activity. Participation should take approximately 1 hour. To complete this activity and receive credit, the participant should:

- Read the educational objectives
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POSTTEST

1. Approximately how many US adults are extremely obese (body mass index ≥ 40.0 kg/m²)?
A. 5 million B. 9 million C. 14 million D. 25 million
2. Which of these disorders is most strongly associated with obesity?
A. Type 2 diabetes C. Rheumatoid arthritis
B. Chronic kidney disease D. Chronic rhinitis
3. Which type of therapy provides the greatest degree of maintained weight loss in severely obese patients?
A. Lifestyle changes C. Lifestyle changes with concomitant
(diet, exercise, behavioral therapy) pharmacotherapy
B. Pharmacotherapy D. Bariatric surgery
4. According to the NIH guidelines, which of these patients would be the most appropriate candidate for bariatric surgery?
A. Male, 17 years of age, 6'0", 350 lb (BMI 47.5 kg/m²), with a severe learning disability
B. Female, 65 years of age, 5'4", 270 lb (BMI 46.3 kg/m²), with angina, diabetes, and hypertension
C. Female, 37 years of age, 5'6", 210 lb (BMI 33.9 kg/m²), with severe depression
D. Male, 45 years of age, 5'9", 260 lb (BMI 38.4 kg/m²), with diabetes, hypertension, and hypercholesterolemia
5. What type of procedure is Roux-en-Y gastric bypass (RYGB)?
A. Restrictive B. Malabsorptive C. Combined
6. Which of these factors has consistently been found to be an important predictor of low percentage of excess weight loss (%EWL)?
A. Diabetes B. High initial weight C. Male sex D. Depression
7. Approximately what percentage of bariatric surgery candidates require preoperative psychological or psychiatric therapy?
A. 15% B. 25% C. 40% D. 80%
8. Which of the following best describes the typical course of weight loss after LAGB?
A. Rapid weight loss to 70%-80% EWL
B. Rapid weight loss to 80%-90% EWL
C. Gradual weight loss to 35%-60% EWL
D. Gradual weight loss to 20%-30% EWL
9. What is the most common class of long-term complications after LAGB?
A. Dumping syndrome
B. Device-related problems (eg, band slippage or access port infection)
C. Micronutrient deficiencies
D. Reflux
10. For RYGB, the postoperative complications include:
A. Bleeding C. Anastomotic leak
B. Nutritional deficiencies D. All of the above

CME REGISTRATION/POSTTEST ANSWER FORM/EVALUATION

To ensure credit, type or print all information legibly.

Full name: _____

MD/DO/Other: _____

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Yes (address below) No, please send my certificate via US mail.

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Record your posttest answers by filling in the blank with the correct letter from the corresponding question:

1. _____ 2. _____ 3. _____ 4. _____ 5. _____
6. _____ 7. _____ 8. _____ 9. _____ 10. _____

NAASO, The Obesity Society, would appreciate your comments regarding the quality of the information presented. Later, via email, we would also like to send you a Web site link to an outcome survey regarding the material presented. (Your email address will be used only for educational purposes. It will not be sold or shared with anyone outside our organization.) May we contact you? (Please check one.)

Yes, via email (address above) No, please do not contact me.

1. The program objectives were fully met.
 Strongly Agree Agree Disagree Strongly Disagree
2. The quality of the educational process (method of presentation and information provided) was satisfactory and appropriate.
 Strongly Agree Agree Disagree Strongly Disagree
3. The educational activity has enhanced my professional effectiveness in treating patients.
 Strongly Agree Agree Disagree Strongly Disagree
 Not Applicable
4. The educational activity will result in a change in my practice behavior.
 Strongly Agree Agree Disagree Strongly Disagree
 Not Applicable
5. The information presented was without promotional or commercial bias.
(When answering this question, please refer to the following guidelines set forth by the ACCME regarding commercial bias and fair balance: Discussion of commercial products must be free of bias for or against any one product and must present objective information about each product discussed; only generic names of therapeutic options should be used; however, if trade names are used, those of several companies must be discussed in the activity.)
 Strongly Agree Agree Disagree Strongly Disagree

6. What new information did you learn during this program?

7. Recommendations for topics of future presentations.

If CME credit and a certificate are desired, please mail/fax this completed form or a copy of it. Keep a copy of this form for your records until you receive your certificate.