

2004 ASBS Consensus Conference

## Consensus Conference Statement

# Bariatric surgery for morbid obesity: Health implications for patients, health professionals, and third-party payers

Henry Buchwald, M.D., Ph.D., F.A.C.S.

*For the Consensus Conference Panel*

This Consensus Statement on the state of bariatric surgery for morbid obesity has been prepared by a panel of broadly based and experienced experts based on presentations by investigators working in areas relevant to current questions in this field during a 1½-day public session; questions and statements from conference attendees during open discussion periods that were part of the public sessions; and closed deliberations by the panel. This statement is an independent report of the panel and is not a policy statement of the American Society for Bariatric Surgery or any of the sponsors or endorsers of the Consensus Conference. Though the Consensus Conference is modeled on the format used by the National Institutes of Health (NIH), the planning, execution, and development of the conference and preparation of this statement were carried out without any relationship with the NIH. In addition, although the Conference was addressed by the Honorable Tommy Thompson, Secretary of Health and Human Services, this report is not a policy statement of the federal government.

This statement reflects the panel's assessment of medical knowledge available at the time it was written. Knowledge about bariatric surgery and morbid obesity is dynamic, and

this assessment is made with the realization that new knowledge, recommendations, and procedures will continue to emerge through medical research.

The Consensus Conference was convened and this Consensus Statement was prepared to update the 1991 NIH Consensus Statement on "Gastrointestinal Surgery for Severe Obesity."

Findings and conclusions of the Consensus Panel include:

1. Bariatric surgery is the most effective therapy available for morbid obesity and can result in improvement or complete resolution of obesity comorbidities.
2. Types of operative procedures for morbid obesity have increased since 1991 and are continuously evolving; there are currently four types of procedures that can be used to achieve sustained weight loss: gastric bypass (standard, long-limb, and very long-limb Roux), alone or in combination with vertical banded gastroplasty; laparoscopic adjustable gastric banding; vertical banded gastroplasty; and biliopancreatic diversion and duodenal switch.
3. Both open and laparoscopic bariatric operations are effective therapies for morbid obesity and represent complementary state-of-the-art procedures.
4. Bariatric surgery candidates should have attempted to lose weight by nonoperative means, including self-directed dieting, nutritional counseling, and commercial and hospital-based weight loss programs, but should not be required to have completed formal nonoperative obesity therapy as a precondition for the operation.
5. The bariatric surgery patient is best evaluated and subsequently cared for by a multidisciplinary team.

This consensus statement is from the participants and in no way is an endorsement by the *Journal of the American College of Surgeons* or the American College of Surgeons.

Cosponsored by the American Society for Bariatric Surgery and the American Society for Bariatric Surgery Foundation.

Members of the Consensus Conference Panel are listed in the Appendix at the end of the article.

Henry Buchwald, MD, PhD, FACS provides consultative services to Ethicon Endo-Surgery, Inc., a Johnson & Johnson Company, and to Transneuronix, Inc.

Presented at the Georgetown University Conference Center, Washington, DC, May 2004.

\*Correspondence address: Henry Buchwald, 420 Delaware St SE, University of Minnesota, Mayo Mail Code 290, Minneapolis, MN 55455.

6. Bariatric surgery candidates should have a comprehensive medical evaluation before the operation; evaluation by subspecialists (eg, cardiologists, psychiatrists, and psychologists) is not routinely needed but should be available if indicated.
7. Bariatric surgery, performed only by experienced centers, should be considered in morbidly obese adolescents.
8. Extending bariatric surgery to patients with Class I obesity (body mass index [BMI] 30 to 34.9 kg/m<sup>2</sup>), who have a comorbid condition that can be cured or markedly improved by substantial and sustained weight loss, may be warranted and requires additional data and longterm risk and benefit analyses.
9. Bariatric surgery can be cost effective before the 4th year of followup.
10. Bariatric surgery offers rich opportunities for both basic and translational patient-oriented research to provide a better understanding of the factors involved in the regulation of food intake, pathophysiology of obesity, metabolic and clinical effects of sustained weight loss, and best treatment options for obese persons.

There is a world epidemic of overweight, defined as a BMI  $\geq 25$  to 29.9 kg/m<sup>2</sup>, and obesity, defined as a BMI  $\geq 30$  kg/m<sup>2</sup>, that is estimated to encompass 1.7 billion people. According to the Worldwatch Institute, the number of overweight people is approximately equal to the number of underweight people in the world.

Approximately two-thirds of the US population is overweight, and of these, about one-half are obese; one of four adults, or over 50 million people, in the United States are obese. Prevalence of obesity is particularly high in many ethnic minority women, such as African, Mexican, Native, and Pacific Islander American women.

In children and adolescents, overweight is defined by gender- and age-specific BMI  $\geq 95$ th percentile on growth charts determined by the National Center of Health Statistics. In the United States, overweight tripled in children between 1970 and 2000. Approximately, 15% of children and adolescents (6 to 19 years old) are overweight. An estimated 250,000 children and adolescents have a BMI  $\geq 95$ th percentile. Overweight children and adolescents have a higher risk of becoming obese adults.

Morbid obesity, also referred to as “clinically severe obesity” or “extreme obesity,” was defined as the criteria for bariatric surgery by the 1991 NIH Consensus Conference Statement on Gastrointestinal Surgery for Severe Obesity as a BMI  $\geq 40$  kg/m<sup>2</sup> or a BMI  $\geq 35$  kg/m<sup>2</sup> in the presence of high-risk comorbid conditions. Obesity was further classified in the 1998 NIH Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults into Class I (BMI 30.0 kg/m<sup>2</sup> to 34.9 kg/m<sup>2</sup>),

Class II (BMI 35.0 kg/m<sup>2</sup> to 39.9 kg/m<sup>2</sup>), and Class III (BMI  $\geq 40$  kg/m<sup>2</sup>).

Morbid obesity is estimated to afflict 20% of the obese population or over 8 million of the US population. Indeed, the relative rise of morbid obesity over the already exponential rise of obesity in the past 25 years can be characterized as an epidemic within an epidemic. Between 1986 and 2000, prevalence of obesity (BMI  $\geq 30$  kg/m<sup>2</sup>) doubled, morbid obesity (BMI  $\geq 40$  kg/m<sup>2</sup>) quadrupled, and super obesity (BMI  $\geq 50$  kg/m<sup>2</sup>) increased fivefold in US adults. A similar pattern of increasing degrees of obesity has been demonstrated in the pediatric population.

Obesity should be considered a chronic disease that has serious health consequences. An expert panel convened by the National Heart, Lung and Blood Institute stated that, “obesity is a complex multifactorial chronic disease that develops from an interaction of genotype and the environment.” In 1997, the World Health Organization defined obesity as “a disease in which excess fat is accumulated to an extent that health may be adversely affected.” WHO has listed obesity as a disease condition in its *International Classification of Disease* since 1979. In the United States, the National Center for Health Statistics and the Centers for Medicare and Medicaid Services have assigned obesity a specific ICD-9, clinical modification code of #278.00, and morbid obesity, #278.01.

Morbid obesity is the harbinger of many other diseases that affect essentially every organ system: cardiovascular (hypertension, atherosclerotic heart and peripheral vascular disease with myocardial infarction and cerebral vascular accidents, peripheral venous insufficiency, thrombophlebitis, pulmonary embolism); respiratory (asthma, obstructive sleep apnea, obesity-hypoventilation syndrome); metabolic (type 2 diabetes, impaired glucose tolerance, hyperlipidemia); musculoskeletal (back strain, disc disease, weight-bearing osteoarthritis of the hips, knees, ankles, feet); gastrointestinal (cholelithiasis, gastroesophageal reflux disease, nonalcoholic fatty liver disease [steatotic steatohepatitis], hepatic cirrhosis, hepatic carcinoma, colorectal carcinoma); urologic (stress incontinence); endocrine and reproductive (polycystic ovary syndrome, increased risk of pregnancy and fetal abnormalities, male hypogonadism, cancer of the endometrium, breast, ovary, prostate, pancreas); dermatologic (intertriginous dermatitis); neurologic (pseudotumor cerebri, carpal tunnel syndrome); and psychologic (depression, eating disorders, body image disturbance). Nearly 30% of overweight adolescents in the United States meet the criteria for metabolic syndrome, which increases risk of type 2 diabetes and coronary heart disease.

The impact of obesity on longevity has been well documented. In the world, over 2.5 million deaths annually can be attributed to obesity; in the United States, over 400,000, second only to cigarette smoking. There is a direct relationship between increasing BMI and relative risk of dying prematurely as evidenced in the Nurses’ Health Study with

a > 100% increase in relative risk as BMI increased from < 19 kg/m<sup>2</sup> to ≥ 32 kg/m<sup>2</sup>. Annual risk of death can be as high as 40-fold that of an age- and gender-matched nonobese cohort. The Framingham data revealed that for each pound gained between ages 30 to 42 years, there was a 1% increased mortality within 26 years, and for each pound gained thereafter, there was a 2% increased mortality. Only one in seven obese individuals will reach the US life expectancy of 76.9 years. In the morbidly obese population, average life expectancy is reduced by 9 years in women and 12 years in men.

Obesity, in particular morbid obesity, is also a social and economic problem. Obesity bias and discrimination starts in the earliest social contacts of preschool children and progresses through childhood and adolescence into adulthood. This prejudice may contribute to depression, eating disorders, body image disturbance, and other suffering. Practical social implications of morbid obesity are manifold, eg, inability to ambulate, limited selection in clothing, stress incontinence, and difficulty with personal hygiene. A direct consequence of social bias is economic disadvantage with decreased monetary and educational opportunities. In estimating the total national financial burden of obesity, the intangible socioeconomic costs must be considered in addition to the calculable health care costs, which are in excess of \$117 billion annually in the United States.

Bariatric surgery is the most effective therapy available for the morbidly obese population. It markedly lowers body weight, reverses or ameliorates the myriad of obesity comorbidities, and improves quality of life.

The 1991 NIH Consensus Conference Panel recommended:

1. Patients seeking therapy for severe obesity for the first time should be considered for treatment in a nonsurgical program with integrated components of a dietary regimen, appropriate exercise, and behavioral modification and support.
2. Gastric restriction or bypass procedures should be considered for well-informed and motivated patients with acceptable operative risks.
3. Patients who are candidates for surgical procedures should be selected carefully after evaluation by a multidisciplinary team with medical, surgical, psychiatric, and nutritional expertise.
4. The operation should be performed by a surgeon substantially experienced with the appropriate procedures and working in a clinical setting with adequate support for all aspects of management and assessment.
5. Life-long medical surveillance after surgical therapy is a necessity.

Many of these guidelines are viable today, others have been modified, and new guidelines are needed in the dynamic field of morbid obesity management by bariatric

surgery. Certain critical events have occurred over the past 13 years since the 1991 NIH Consensus Conference that mandated conducting a new Consensus Conference to develop a new Consensus Statement as a national directive in bariatric surgery. These events include:

1. Marked increase in the incidence of obesity, in particular, morbid obesity.
2. Expansion of available operative procedures.
3. Improved safety of bariatric procedures with an acceptable operative mortality and morbidity (less than comparable operative procedures), reoperation rate, and longterm complications.
4. Introduction of laparoscopic minimally invasive techniques to bariatric surgery.
5. Increased experience with a team management approach.
6. Increased experience with bariatric surgery in adolescent and elderly patients.
7. A more complete elucidation and verification of obesity comorbidity outcomes with demonstration of reversal or improvement in diabetes, hypertension, hyperlipidemia, obstructive sleep apnea, gastroesophageal reflux disease, cardiac function, osteoarthritic orthopaedic conditions and bone fractures, nonalcoholic fatty liver disease, intertriginous dermatitis, stress incontinence, and symptoms of depression.
8. Documentation that delaying bariatric surgery diminishes the chances for full reversal of diabetes.
9. Demonstration that bariatric surgery improves the life expectancy of patients.
10. Data demonstrating that bariatric surgery can be costeffective less than 4 years after bariatric surgery (ie, less expensive than the care of a morbidly obese patient who has not had bariatric surgery).

#### **2004 Consensus Conference conclusions, future directions, and recommendations**

##### *Nonsurgical treatment options*

Few studies have specifically examined the effects of nonsurgical treatment in patients with morbid obesity, so conclusions about nonsurgical therapy in this population are based on inference. In studies of Class I (minimal) and Class II (moderate) obesity, medical therapy can achieve > 10% body weight loss (equivalent to > 25% excess body weight loss) in 10% to 40% of patients depending on study design, use of medications, and duration of the intervention. Duration of the weight-loss response increases with duration of treatment and with use of medications and behavior modification. Moderate weight loss of as little as 5% of body weight can have considerable health benefits. Longterm weight loss is difficult to achieve with diet, exercise, and pharmacotherapy. Most patients who present for bariatric

surgery have already failed multiple attempts to achieve a sustained weight loss by using nonsurgical treatment options.

#### *Surgical treatment options and criteria for selection*

Four operative procedures (in three classes of procedures), are currently in general use in the United States and worldwide: gastric bypass with a standard, long-limb, or very long-limb Roux (restrictive and malabsorptive), alone or in combination with vertical banded gastroplasty; laparoscopic adjustable gastric banding (restrictive); vertical banded gastroplasty (restrictive); and biliopancreatic diversion and duodenal switch (primarily malabsorptive). Certain surgeons perform one operation exclusively; other surgeons offer the full range of operations. There is an everincreasing effort to match a particular patient to a particular operation. To this end, several selection approaches or algorithms have been suggested; randomized trials that test these algorithms have not been conducted.

#### *Gastric bypass*

Gastric bypass is currently the most popular procedure performed in the United States and worldwide. Gastric bypass was the first of the gastric procedures for morbid obesity and the first of the combined restrictivemalabsorptive operations. The restrictive element of the operation consists of the creation of a small gastric pouch with a small outlet that, on distention by food, causes the sensation of satiety. This restrictive element is combined with a gastrointestinal bypass as the malabsorptive element. The extent of the bypass of the intestinal tract determines the degree of macronutrient malabsorption. The minimal amount of intestinal tract bypassed consists of the distal stomach, the entire duodenum, and about 40 cm of the proximal jejunum. The standard Roux limb is about 75 cm. More extensive malabsorptive variations consist of gastric bypasses with a 150-cm Roux limb (long-limb) or with a very longlimb (distal gastric bypass).

*Current techniques:* Gastric bypass can be performed by both open and laparoscopic techniques. In the United States, the laparoscopic technique has become the more popular approach. The upper pouch is constructed horizontally or vertically to be 15 to 25 mL in capacity, with the distal stomach separated from this pouch by four rows of staples, or totally divided from the upper gastric pouch. The anastomotic outlet to the retrocolic or antecolic Roux limb of jejunum is fashioned to be 0.75 to 1.25 cm in diameter. A hybrid gastric bypass—vertical banded gastroplasty has also been introduced using a divided vertical gastric bypass with a gastric ring proximal to the gastrojejunostomy. In the laparoscopic approach, the gastrojejunostomy can be performed with the end-to-end stapler, the linear stapler, or it can be hand-sewn (Fig. 1).

*Weight loss:* Weight loss after a standard 75 cm Roux gas-

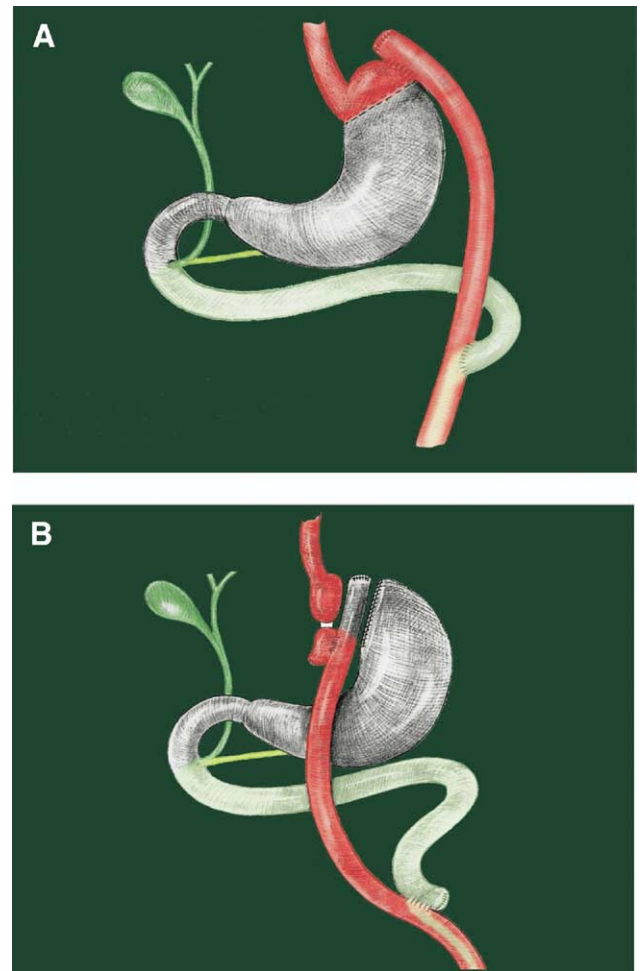


Figure 1. (A) Gastric bypass: horizontal gastric stapling with Roux gastrojejunostomy. (B) Gastric bypass: vertical gastric division with interposed Roux gastrojejunostomy and proximal silicone elastomer ring. (Reprinted from Buchwald H, Buchwald J. Evolution of operative procedures for the management of morbid obesity 1950 to 2000. *Obes Surg* 2002;12:705–717, with permission.)

tric bypass usually exceeds 100 lb, or about 65% to 70% of the excess body weight (EBW) and about 35% of the BMI. The longer-limb bypasses are used to obtain comparable weight reductions in super obese (BMI  $\geq$  50 kg/m<sup>2</sup>) patients. Weight loss generally levels off in 1 to 2 years, and a regain of up to 20 lb from the weight loss nadir to a longterm plateau is common.

*Operative mortality and morbidity:* Operative (30-day) mortality for gastric bypass when performed by skilled surgeons is about 0.5%. Operative morbidity (eg, pulmonary emboli, anastomotic leak, bleeding, wound infection) is about 5%. Compared with open procedures, laparoscopic gastric bypass has a higher rate of intraabdominal complications; whereas duration of hospitalization is shorter, wound complications are lower, and postoperative patient comfort is higher.

**Longterm complications:** Gastric bypass can be associated with the dumping syndrome, stomal stenosis, marginal ulcers, staple line disruption, and internal hernias. Life-long oral or IM vitamin B<sub>12</sub> supplementation, and iron, vitamin B, folate, and calcium supplementation is recommended to avoid specific nutrient deficiency conditions, such as anemia. Ventral hernia formation is more prevalent after open gastric bypass than after the laparoscopic approach. A unique complication of gastric bypass is dilation of the bypassed distal stomach in the event of a small bowel obstruction, which can lead to rupture and death if not rapidly managed by distal gastric decompression.

**Reversal and revision:** Gastric bypass can be functionally totally reversed, though this is rarely required. For all bariatric procedures, pure reversal without conversion to another bariatric procedure is almost certainly followed by a return to morbid obesity. A standard Roux gastric bypass with failed weight loss can be revised to a very long-limb Roux-en-Y procedure.

#### *Laparoscopic adjustable gastric banding*

Gastric banding is the least invasive of the purely restrictive bariatric surgery procedures. It consists of a small pouch and a small stoma created by a band high on the stomach. The stomach is not cut or crushed by staples, and no anastomoses are made.

Laparoscopic adjustable gastric banding was first introduced in the early 1990s. Though there was an open surgery history with gastric banding, currently this procedure is essentially a laparoscopic operation. Today, there are six adjustable bands available worldwide and one approved by the FDA (June 2001) for use in the United States.

Laparoscopic adjustable gastric banding is the most common procedure performed outside of the United States, primarily in continental Europe, Australia, and South America. It is the second most commonly performed procedure worldwide. Since its introduction in the United States, it has gained greater acceptance in this country and its relative use in the United States is increasing.

**Current techniques:** After a period of evolution of technique, certain operative principles have been established: The upper gastric pouch is made very small (the “virtual pouch”), approximately 15 mL in volume, and placed primarily anteriorly. The dissection on the lesser curvature of the stomach includes the neurovascular bundle of the lesser omentum—the *pars flaccida* approach. Suture fixation of the anterior wall of the stomach, with at least four gastrogastric sutures, completely imbeds the anterior band. The system is assembled and the port for inflation and deflation of the band is secured onto the rectus fascia of the anterior abdominal wall.

Adjustment of the band through the access port is an essential part of laparoscopic adjustable gastric banding



Figure 2. Gastric band: laparoscopic adjustable silicone elastomer. (Reprinted from Buchwald H, Buchwald J. Evolution of operative procedures for the management of morbid obesity 1950 to 2000. *Obes Surg* 2002;12:705–717, with permission.)

therapy. Appropriate adjustments, performed up to six times annually, are critical for successful outcomes (Fig. 2).

**Weight loss:** Weight loss after laparoscopic adjustable gastric banding is about 50% of the EBW and about 25% of the BMI at 2 years. Because weight loss with this procedure may be progressive over time, these figures may represent an underestimation.

**Operative mortality and morbidity:** Operative (30-day) mortality for laparoscopic adjustable gastric banding when performed by skilled surgeons is about 0.1%. Operative morbidity is about 5%.

**Longterm complications:** There are unique longterm complications of laparoscopic adjustable gastric banding, which include gastric prolapse, stomal obstruction, esophageal and gastric pouch dilation, gastric erosion and necrosis, and access port problems. Experience has markedly reduced the incidence of these complications. Use of a prosthetic device introduces additional potential problems of malfunction and infection.

**Reversal and revision:** Laparoscopic adjustable gastric banding can be completely reversed with removal of the band, tubing, and port. For failed weight loss, revision procedures include removal of the device and performance of a restrictive-malabsorptive procedure (eg, gastric bypass) or a primarily malabsorptive procedure (eg, biliopancreatic diversion and duodenal switch).

#### *Vertical banded gastroplasty*

The vertical banded gastroplasty, introduced in the early 1970s, is a relatively fast and simple operation to perform. It consists of the creation of a small upper gastric pouch with a restricted orifice to the rest of the stomach. It has the

advantage of not bypassing, resecting, or rearranging any part of the gastrointestinal tract.

Since 1991, the percentage of patients undergoing vertical banded gastroplasty has decreased, but the operation is still performed at centers in the United States and worldwide. For the most part, vertical banded gastroplasty is performed by open procedure, but is also feasible laparoscopically.

**Current techniques:** There are two distinct techniques used in the construction of an open vertical banded gastroplasty. Both involve forming a linear pouch the size of a finger (15 to 25 mL) along the lesser curvature of the stomach. For the silicone elastomer ring gastroplasty, this pouch is created by a specially designed notched stapler; the outlet of the pouch is then encircled with a silicone elastomer ring. For the Marlex mesh band gastroplasty, this pouch is created by a linear stapler placed through a hole in the stomach made with an end-to-end stapler; the outlet is encircled with a mesh collar sewed to itself. Comparable with the gastric bypass, the outlet is created to be 0.75 to 1.25 cm in diameter. With some modifications of technique, gastroplasty procedures can be performed laparoscopically as well (Fig. 3).

**Weight loss:** Weight loss after vertical banded gastroplasty is about 50% to 60% of EBW, and about 25% to 30% of BMI. A plateau in weight loss is generally reached at 2 years after a slight weight increase from the weight response nadir.

**Operative mortality and morbidity:** Operative mortality for vertical banded gastroplasty when performed by skilled surgeons is about 0.1%. Operative morbidity is about 5%.

**Longterm complications:** Comparable with other restrictive bariatric surgery procedures, vertical banded gastroplasty may be associated with vomiting, usually early in the post-operative period and in relation to the patient's learning curve in appreciating the tolerated size of a meal. The most notable complication of vertical banded gastroplasty is lodging of a food particle, or a large pill or capsule, within the band or ring. If this problem is not relieved spontaneously within 24 hours by antegrade or retrograde passage of the obstructing item, endoscopic removal becomes necessary. Outlet obstruction resulting from adhesion formation and twisting of the ring or band can occur and requires operative intervention because neither the ring nor the band can be endoscopically dilated.

**Reversal and revision:** Vertical banded gastroplasty can be functionally reversed by removal of the ring or the band, allowing the outlet to dilate. Revision of vertical banded gastroplasty for failed weight loss can be achieved by conversion to a gastric bypass or to a duodenal switch.

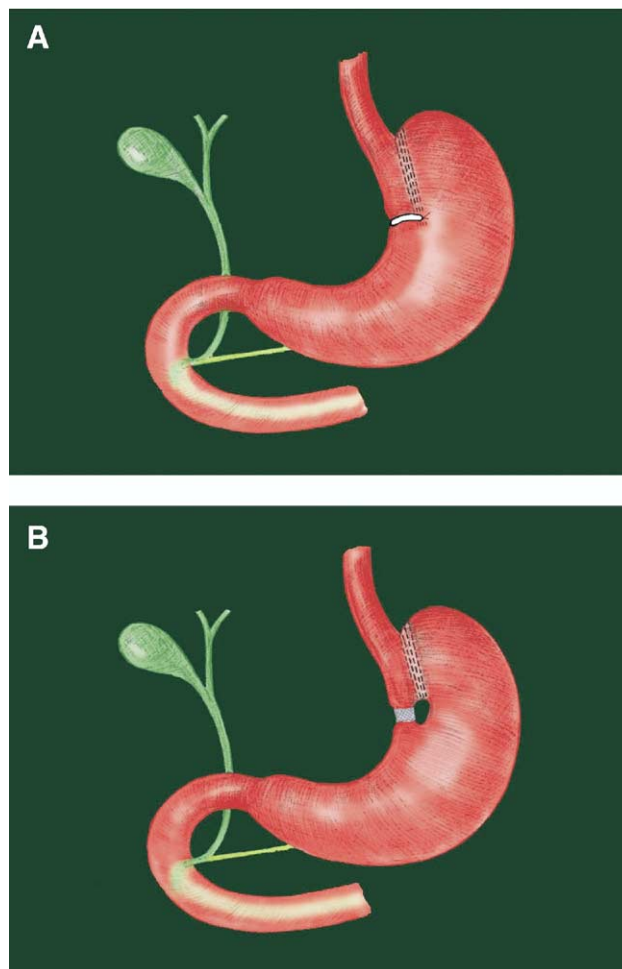


Figure 3. (A) Gastroplasty: silicone elastomer ring vertical gastroplasty using notched stapler. (B) Gastroplasty: vertical banded gastroplasty. (Reprinted from Buchwald H, Buchwald J. Evolution of operative procedures for the management of morbid obesity 1950 to 2000. *Obes Surg* 2002;12:705–717, with permission.)

#### *Biliopancreatic diversion and duodenal switch*

Biliopancreatic diversion and duodenal switch are primarily malabsorptive procedures. The biliopancreatic diversion originated in Genoa, Italy and is widely used in Europe and sparingly in the United States. The duodenal switch is a US adaptation of the biliopancreatic diversion and is gaining popularity in this country. Both procedures involve a partial gastrectomy leaving a gastric pouch of 100 to 150 mL, which is considerably larger than that of gastric bypass or the restrictive procedures and, thereby, allows larger meals in comparison with those of the other bariatric operations. Both procedures avoid leaving a nonfunctioning intestinal segment by dividing the intestine into a long enteric limb joining a long biliopancreatic limb to form a common channel 50 to 150 cm from the ileocecal valve. This modification avoids the toxic problems seen with the old jejunoileal bypass procedure.

**Current techniques:** For the biliopancreatic diversion, a horizontal gastrectomy is performed with a retrocolic gastrojejunostomy. This long Roux limb, carrying enteric contents, is anastomosed to the biliopancreatic limb emanating from the closed postpyloric duodenum. For the duodenal switch, a pylorus-sparing vertical sleeve gastrectomy is performed with anastomosis of the proximal duodenal cuff to the retrocolic enteric limb. Comparable with biliopancreatic diversion, the enteric limb of the duodenal switch is anastomosed to the biliopancreatic limb emanating from the postpyloric duodenum. Length of the common channel formed by joining of the enteric and biliopancreatic limbs governs the malabsorptive outcomes of these procedures.

Open biliopancreatic diversion and duodenal switch are long and difficult procedures requiring skilled surgeons and adequate experience. Both procedures have been performed by total or by handassisted laparoscopic techniques. A two-stage laparoscopic duodenal switch with initial subtotal gastrectomy has been used in high-risk, extremely obese (BMI  $\geq 60$  kg/m<sup>2</sup>) patients (Fig. 4).

**Weight loss:** Weight loss after biliopancreatic diversion and duodenal switch is about 70% of the EBW and about 35% of the BMI. Weight loss with these procedures is at the upper end of the efficacy range. Weight loss may be sustained without a rise from the weight nadir.

**Operative mortality and morbidity:** Operative mortality for biliopancreatic diversion and duodenal switch when performed by skilled surgeons is about 1%. Operative morbidity is about 5%.

**Longterm complications:** On occasion, these procedures are associated with diarrhea. Some patients report malodorous stools and flatus. Long-range complications can consist of vitamin, mineral, and nutrient deficiencies, in particular, protein deficiency. These contingencies need to be anticipated and properly managed by dietary supplements with about 75 to 80 g of dietary protein and B vitamins, calcium, and iron. Biliopancreatic diversion may be associated with postoperative dumping; the duodenal switch is not.

**Reversal and revision:** Normal intestinal continuity can be restored, but the partial gastrectomy cannot be reversed. For failed weight loss after these procedures, shortening of the common channel has produced a desired result in some, but not all, patients.

#### Overview

There is no single or standard procedure for management of morbid obesity and, probably, there never will be. There never was a single procedure for peptic ulcer disease, and there is no standard inguinal hernia repair. Ingenuity and investigation will lead to changes in the procedures used, eg, the current work-in-progress testing the efficacy of gastric pacing. The next bariatric surgery consensus conference on the state-of-the-art will, undoubtedly, discuss new pro-

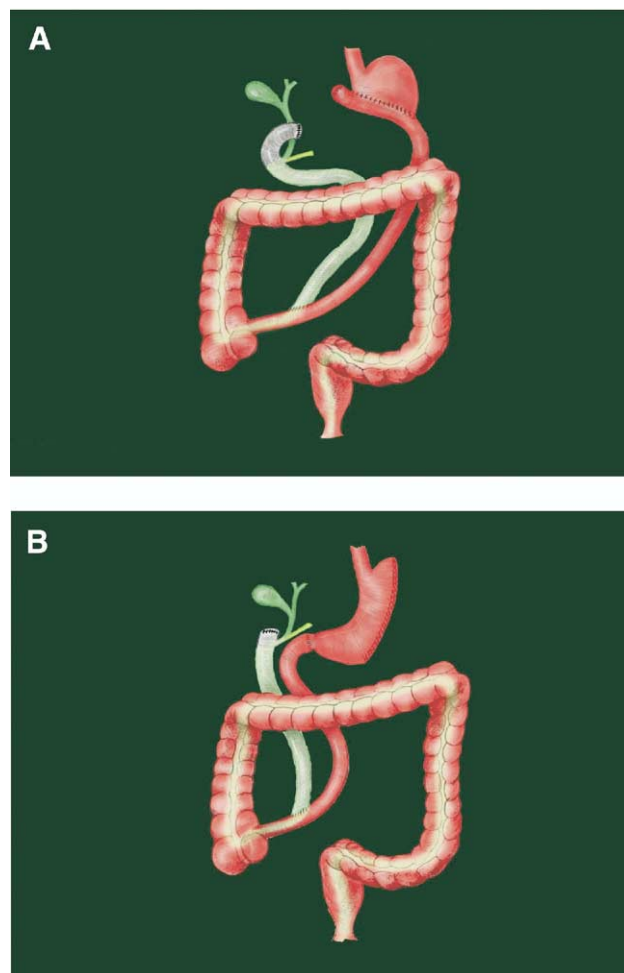


Figure 4. (A) Biliopancreatic diversion. (B) Duodenal switch with division of the duodenum. (Reprinted from Buchwald H, Buchwald J. Evolution of operative procedures for the management of morbid obesity 1950 to 2000. *Obes Surg* 2002;12:705–717, with permission.)

cedures and modifications of existing ones. This continuous evolution in operative approaches will result in continued improvement in patient management.

#### Introduction of laparoscopy

Laparoscopic procedures, primarily laparoscopic gastric bypass and laparoscopic adjustable gastric banding, were introduced to bariatric surgery in the early 1990s and so were not included in the 1991 NIH Consensus Conference Statement. By 2003, nearly two-thirds of bariatric procedures worldwide were performed laparoscopically. Laparoscopic bariatric surgery is not experimental or investigational.

Open bariatric operation has certain advantages over laparoscopic procedures. These include tactile control of dissection and the ability to palpate tissues, greater ease and speed for lysis of adhesions, freedom to use fine suture technique and materials, greater facility to perform ancillary procedures, possibly a lower incidence of certain perioper-

ative complications (eg, leaks, hemorrhage), and decreased risk of specific longterm complications (eg, anastomotic strictures, internal hernias, bowel obstructions). Laparoscopic bariatric surgery has certain advantages over open procedures, such as minimal incisional scars, less postoperative pain, increased mobility, shortened hospital stay, shorter convalescent time, and fewer late ventral hernias. Operative times vary between open and laparoscopic procedures from surgeon to surgeon. Costs are similar; the cost of additional operative equipment disposables needed for laparoscopic surgery equals the cost of longer hospital stay for open procedures. Longterm weight loss and amelioration of comorbid conditions are essentially the same for open and laparoscopic bariatric operations.

When the laparoscopic approach proves to be difficult (eg, adhesions, size of liver, size of patient), the surgeon should convert to an open operation. For certain conditions, the surgeon may initially select the open approach, eg, super (BMI  $\geq 50$  kg/m<sup>2</sup>) and central obesity, hepatomegaly, inability to tolerate pneumoperitoneum, presence of congenital anomalies, anticipated severe adhesions, certain abdominal wall hernias, management of complications, and some planned revision procedures. Open and laparoscopic bariatric operations are not competitive; they are complementary.

#### *Care of the bariatric surgery patient*

*Patient selection:* The 1991 NIH Consensus Conference weight criteria for bariatric surgery of a BMI  $\geq 40$  kg/m<sup>2</sup> or a BMI of 35.0 kg/m<sup>2</sup> to 39.9 kg/m<sup>2</sup> in the presence of severe comorbidities are still reasonable today. High-risk comorbid conditions that can justify reducing the BMI to 35 kg/m<sup>2</sup> include type 2 diabetes, life-threatening cardiopulmonary problems (eg, severe sleep apnea, Pickwickian syndrome, obesity-related cardiomyopathy), obesity-induced physical problems interfering with a normal lifestyle (eg, joint disease treatable but for the obesity), and body size problems precluding or severely interfering with employment, family function, and ambulation.

Certain data demonstrate that bariatric surgery can ameliorate obesity comorbidities (eg, type 2 diabetes) in patients with a BMI  $< 35$  kg/m<sup>2</sup>. Extending bariatric surgery to patients with Class I obesity (BMI 30 kg/m<sup>2</sup> to 34.9 kg/m<sup>2</sup>) who have a comorbid condition that can be cured or markedly improved by substantial and sustained weight loss may be warranted; this BMI change requires additional data and longterm risk-to-benefit analyses.

Successful and safe bariatric surgery has been performed in patients in their 70s and in adolescents. Patient variables of gender, race, and body habitus may influence outcomes and may dictate operative selection. Comorbidities, as a rule, are affirmative indicators for patient selection for bariatric operations.

Mental status is a difficult area in which to define standards for patient selection. Selected screening for severe

depression, untreated or undertreated mental illnesses associated with psychoses, active substance abuse, bulimia nervosa, and socially disruptive personality disorders may help avoid adverse postoperative outcomes. History of compliance with nonoperative therapy may be beneficial in assessing the risk-to-benefit ratio of bariatric surgery.

*Preoperative care:* The bariatric surgery patient needs to be well-informed, motivated, willing to participate in longterm care, change dietary patterns, and embrace a revised lifestyle.

The bariatric patient is best evaluated and subsequently cared for by a team approach involving the surgeon, a nurse practitioner or nurse, a dedicated dietician, office personnel (scheduling and triage), and other specialists when needed. In addition to a preoperative history, physical, and laboratory evaluation, a preoperative discussion or teaching seminar that provides information on postoperative recovery, dietary changes, activity, and clinical outcomes, by the dietician, the bariatric nurse, and the bariatric surgeon, is critical. Availability of a support group is recommended, as is distribution of literature describing procedures, postoperative diets, exercise, and so forth. Availability of a full spectrum of expert consultants (eg, cardiologists, pulmonologists, psychiatrists and psychologists) is mandatory.

*Perioperative care:* Expert anesthesiology support, knowledgeable in the specific problems of the bariatric patient, is necessary. The anesthesiology support includes an understanding of patient positioning, blood volume and cardiac output changes, airway maintenance, and drug pharmacokinetics in the morbidly obese. It is advisable to have preoperative, intraoperative, and postoperative written protocols. The bariatric surgeon must be able to manage, and have coverage to manage, the postoperative patient and any problems and complications that may occur.

A facility that practices bariatric surgery must be equipped with appropriate operating room equipment, including operating tables that can handle large patients; bariatric instruments, including large retractors, special staplers, long laparoscopic instruments; special equipment to transfer the patient; extra-large beds, commodes, chairs, and wheelchairs; and diagnostic facilities and equipment that can accommodate the morbidly obese patient.

*Postoperative care:* Care of the postoperative bariatric surgery patient is recommended for the lifetime of the patient with at least three followup visits with the bariatric surgery team within the first year. Laparoscopic adjustable gastric banding will require more frequent visits for band adjustment. Postoperative dietary (including vitamin, mineral, and possibly liquid protein supplementation), exercise, and lifestyle changes should be reinforced by counseling, support groups, and working with the family physician. Favorable outcomes of bariatric surgery can lead to socioeconomic advancement, which may require patient guidance. Postop-



erative care may include planning for reconstructive operations after weight stabilization for certain patients.

#### *Care of the adolescent patient*

Bariatric surgery has been performed in morbidly obese adolescents for more than a decade. In these small series, surgical weight loss resulted in considerable improvement, if not complete resolution, of most obesity-related comorbidities, supporting the position that bariatric surgery in adolescents is reasonable. Longterm efficacy, potential adverse consequences related to decreased absorption of nutrients, and degree of recidivism remains unknown.

BMI guidelines for adolescents should be identical to those advocated for adults. Deferring surgery to a higher BMI standard may increase operative mortality and morbidity, and possibly prevent reversal of comorbid conditions. To be considered for bariatric surgery, the adolescent's physiologic maturity should be complete and, ideally, the adolescent should have obtained  $\geq 95\%$  of predicted adult stature. Adolescents should indicate their desire for the operation and should have sufficient cognitive and psychologic development to participate in decision-making. The adolescent needs to have a general understanding of the procedure to be performed and its lifestyle consequences.

Adolescents considered for bariatric surgery should be referred to specialized centers with a multidisciplinary bariatric team capable of providing longterm followup care. These adolescents should first undergo a trial of dietary and behavior modification for at least 6 months. The bariatric team must be expert in the technical aspects of bariatric surgery, and capable of addressing the unique cognitive, psychosocial, and emotional needs of the adolescent prospectively, as well as the longterm nutritional consequences of bariatric surgery. Centers performing adolescent bariatric surgery should be committed to clinical data collection and participation in a central database or registry.

#### **Future directions for clinical investigation, basic research, and education**

##### *Clinic investigation*

Over the past 10 years, the field of bariatric surgery has been enriched by data from numerous clinical investigations and experience. Directions for future clinical investigations are manifold and include:

1. Controlled, prospective, intervention studies.
2. Establishment of a major prospective database to study bariatric surgery outcomes.
3. Establishment of a pediatric (adolescent) bariatric surgery registry.
4. Performance of randomized clinical trials to compare the safety and efficacy of different operative procedures.

5. Controlled studies of new operative modalities (eg, gastric pacing) and nonoperative modalities of treatment.
6. Study by metaanalysis of outcomes of comorbid conditions of morbid obesity.
7. Study of the socioeconomic outcomes of bariatric surgery.
8. Study by stratified risk assessment of the risk-to-benefit ratio of treating morbid obesity with bariatric surgery and without bariatric surgery.

##### *Basic research*

Availability of thousands of bariatric patients for basic research studies, involving minimal risk (eg, blood drawing), can considerably enhance our basic knowledge of the pathogenesis and pathophysiology of obesity. Directions for future basic research are manifold and include:

1. Study of the interrelationships among specific bariatric surgical procedures, marked weight loss, gastrointestinal hormones (eg, ghrelin), adipokines (eg, leptin), and inflammatory markers.
2. Exploring the mechanisms by which different types of bariatric procedures work (eg, purely restrictive, restrictive and malabsorptive, primarily malabsorptive); and application of new and safe technology in these studies (eg, brain PET scanning).
3. Learning the mechanisms by which various bariatric surgical procedures impinge on the comorbid conditions of morbid obesity.
4. Gaining insight into the basic cause(s) and mechanisms(s) of overweight, obesity, and morbid obesity.

##### *Education*

Bariatric surgery and bariatric surgery training is expanding. A recent survey of the 251 accredited surgery training institutions in the United States, with a 100% response rate to the survey, showed that 185 (73.7%) of the institutions perform bariatric surgery and that all of these 185 institutions teach bariatric operations in their residency training programs. Of 48 institutions that offer minimally invasive fellowships, 43 (89.5%) offer bariatric surgery training. Fellows in these programs assist in approximately 4,000 cases annually. In the future, these educational efforts will increase and bariatric surgery may well become the mainstay of general surgery.

#### **Summary**

Bariatric surgery, involving either open or laparoscopic techniques, is the most effective weight loss therapy available for patients with morbid obesity. Bariatric surgery results in marked and long-lasting weight loss and elimination or improvement of most obesity-related medical complications, including diabetes, hypertension, hyperlipid-

emia, obstructive sleep apnea, gastroesophageal reflux disease, cardiac dysfunction, osteoarthritis and low back pain, nonalcoholic fatty liver disease, intertriginous dermatitis, stress incontinence, symptoms of depression, and eating disorders; bariatric operations can also prevent obesity-related diseases (eg, type 2 diabetes). There is no single or standard surgical procedure for management of morbid obesity, and future studies will likely lead to modifications in current procedures and new surgical approaches.

## Recommendations

1. A multidisciplinary team including a surgeon, anesthesiologist, dietitian, nurse, and experienced office personnel should be used in the care of the bariatric surgery patient. Additional clinical expertise, such as a cardiologist, pulmonologist, or psychiatrist and psychologist, should be available if needed.
2. Candidates should have attempted to lose weight by self-directed dieting, nutrition counseling, and commercial and hospital-based weight loss programs, but should not be required to complete formal non-operative obesity therapy as a precondition for the operation.
3. Candidates should have a comprehensive medical evaluation before the operation; evaluation by subspecialists (eg, cardiologists, psychiatrists, psychologists) is not routinely needed but should be available if indicated.
4. Currently recommended operative procedures include: (a) gastric bypass with standard, long-limb, or very longlimb Roux, alone or in combination with vertical banded gastroplasty; (b) laparoscopic adjustable gastric banding; (c) vertical banded gastroplasty; and (d) biliopancreatic diversion and duodenal switch.
5. The surgical team should be receptive to change in selecting operative procedures and concepts and, contingent on thorough evaluation, the future introduction of new operative approaches.
6. Standard of care for bariatric surgery includes use of laparoscopic and open techniques.
7. Additional experience should be obtained with extending the benefits of bariatric surgery to adolescents under carefully defined conditions by a multidisciplinary team with the ability to perform longterm monitoring.
8. Consideration should be given to extending the benefits of bariatric surgery to patients with Class I obesity (BMI 30 kg/m<sup>2</sup> to 34.9 kg/m<sup>2</sup>), who have a condition that can be cured or markedly improved by substantial and sustained weight loss; this extension requires more data and longterm risk-to-benefit analysis.

9. Because bariatric surgery can be cost-effective in less than 4 years, in comparison with nonoperative management, critical examination of the cost-to-benefit ratio of bariatric surgery is indicated.
10. Increased clinical investigation, basic research, and education in the obesity field are strongly recommended.

## Appendix

### *Consensus conference panel*

Chair: Henry Buchwald, MD, PhD, Owen H and Sarah Davidson Wangenstein Chair in Experimental Surgery, Professor of Surgery and Biomedical Engineering, University of Minnesota, Minneapolis, MN; Charles J Billington, MD, Professor of Medicine, VA Medical Center, Minneapolis, MN; Katherine M Detre, MD, PhD, Distinguished Professor of Epidemiology, Principal Investigator, Liver Transplantation Data Base, University of Pittsburgh, Pittsburgh, PA; Victor Garcia, MD, Professor of Surgery and Pediatrics, Cincinnati Children's Hospital, Cincinnati, OH; Michael D Jensen, MD, Endocrine Research Unit, Mayo Clinic, Rochester, MN; David E Kelley, MD, Professor of Medicine, Director, Obesity and Nutrition Research Center, University of Pittsburgh School of Medicine, Pittsburgh, PA; Samuel Klein, MD, William H Danforth Professor of Medicine and Nutritional Science, Washington University School of Medicine, St Louis, MO; J Patrick O'Leary, MD, Professor and Chair of Surgery, Louisiana State University Medical Center, New Orleans, LA; George F Sheldon, MD, Professor of Surgery and Social Medicine, University of North Carolina, Chapel Hill, NC; Thomas Wadden, PhD, Professor of Psychology, University of Pennsylvania School of Medicine, Philadelphia, PA; Alan Wittgrove, MD, (American Society for Bariatric Surgery President), Center for Surgical Weight Control, San Diego, CA; Bruce M Wolfe, MD, Sacramento Bariatric Medical Associates, Carmichael, CA, Emeritus Professor of Surgery, UC Davis Medical Center, Sacramento, CA.

### *Consensus conference speakers*

Organizer and Moderator: Walter J Pories, MD, Professor of Surgery and Biochemistry, Brody School of Medicine, East Carolina University, Greenville, NC; Host and Welcome Address: Stephen RT Evans, MD, Professor and Chairman, Department of Surgery, Georgetown University Hospital, Washington, DC; Keynote Speaker: Tommy Thompson, Secretary, Health and Human Services, US Department of Health and Human Services, Washington, DC; Steven Belle, PhD, MScHyg, Principal Investigator, Longitudinal Assessment of Bariatric Surgery (LABS) Consortium Coordinating Center, University of Pittsburgh Graduate School of Public Health, Pittsburgh, PA; Robert E Brolin, MD, Director of Bariatric Surgery, University Med-

ical Center, Princeton, NJ, Professor of Surgery, University of Pittsburgh Medical Center, Pittsburgh, PA; J Kenneth Champion, MD, Clinical Professor of Surgery, Mercer University School of Medicine, Director of Bariatric Surgery, Emory-Dunwoody Medical Center, Atlanta, GA; George SM Cowan, Jr, MD, Professor Emeritus of Surgery, University of Tennessee, Memphis, TN; David E Cummings, MD, Associate Professor of Medicine, Division of Metabolism, Endocrinology and Nutrition, University of Washington, Seattle, WA; John B Dixon, MD, Senior Research Fellow, Centre for Obesity Research and Education, Monash University, Department of Surgery, Alfred Hospital, Melbourne, Australia; G Lynis Dohm, PhD, Professor of Physiology, Brody School of Medicine, East Carolina University, Greenville, NC; David R Flum, MD, MPH, Assistant Professor, Department of Surgery, Division of General Surgery, Adjunct, Assistant Professor Department of Health Services, University of Washington, Seattle, WA; Mal Fobi, MD, Center for Surgical Treatment of Obesity, Hawaiian Gardens, CA; Michel Gagner, MD, Professor of Surgery, Chief, Division of Bariatric Surgery, Weill College of Medicine, Cornell University, New York, NY; Douglas S Hess, MD, Wood County Hospital, Bowling Green, OH; Thomas Inge, MD, Assistant Professor of Surgery, University of Cincinnati, Cincinnati, OH; Kenneth B Jones, Jr, MD, Clinical Assistant Professor of Surgery, Louisiana State University Medical Center, Shreveport, LA; John G Kral, MD, PhD, Professor of Surgery and Medicine, SUNY Downstate

Medical Center, Brooklyn, NY; Robert Kushner, MD, Professor of Medicine, Northwestern University, Feinberg School of Medicine, Medical Director, Wellness Institute, Northwestern Memorial Hospital, Chicago, IL; Kenneth G MacDonald, MD, Professor of Surgery, Brody School of Medicine, East Carolina University, Greenville, NC; Edward E Mason, MD, PhD, Professor Emeritus of Surgery, University of Iowa Hospitals and Clinics, Iowa City, IA; Ingmar Naslund, MD, PhD, Associate Professor, Department of Surgery, Örebro University Hospital, Örebro, Sweden; Jaime Ponce, MD, Medical Director for Bariatric Surgery, Hamilton Medical Center and, Dalton Surgical Group, Dalton, GA; Philip R Schauer, MD, Director of Advanced Laparoscopic and Bariatric Surgery, Cleveland Clinic Foundation, Cleveland, OH; Nicola Scopinaro, MD, Professor of Surgery, DICMI—University of Genoa, Ospedale San Martino, Genova, Italy; Scott A Shikora, MD, Associate Professor of Surgery, Tufts University School of Medicine, Tufts-New England Medical Center, Boston, MA; Harvey J Sugerman, MD, Emeritus Professor of Surgery, Virginia Commonwealth University, Richmond, VA.

*Consensus conference staff*

Georgeann N Mallory, RD, LD, Executive Director, American Society for Bariatric Surgery, Gainesville, FL; Pat Watson, Convention Manager, American Society for Bariatric Surgery, Gainesville, FL.