Bariatric Surgery

Shared Decision Making and Dialogue Tool for the Patient and Physician

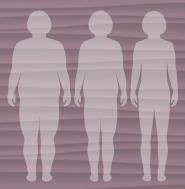
weight loss and other comorbidities. Results following bariatric surgery may vary.

Bariatric surgery may be appropriate for some patients, and not for others depending on their specific weight, age, and medical history. Patients and doctors should review all available information on non-surgical and surgical options in order to make an informed treatment decision. This brochure was developed by Ethicon, a device manufacturer that markets general surgical instruments used in bariatric surgery.

Overview

What is bariatric surgery?

Bariatric surgery—also known as weight loss surgery—makes surgical changes to your stomach and/or digestive system. These changes limit how much food you can eat and how many nutrients you absorb, leading to weight loss. By making these changes, bariatric surgery may also reset your body's "set point," or weight regulation system, by affecting hormonal signals, resulting in decreased appetite, increased feelings of fullness, increased metabolism, and healthier food preferences.



Depending on the type of bariatric surgery, the average patient loses between

55-75%

of excess body weight by 3 years post-surgery.¹⁻³

Bariatric surgery

- Limits the amount of food you eat, causing your body to stop storing excess calories and start using its fat supply for energy
- Causes changes in gut hormones which may impact hunger, satisfaction, and blood sugar control⁴
- Allows the body to adjust to its new, healthier set point, which enables sustained weight loss, may reduce appetite, and may improve obesity-related conditions
- Your body's metabolic set point is the weight range that your body is programmed to function at its best. As your body adapts to a higher-than-normal weight, it establishes and attempts to maintain a higher set point. Bariatric surgery intervenes in this cycle

There are four main types of bariatric surgery

- Sleeve Gastrectomy
- Gastric Bypass
- Biliopancreatic Diversion
- Gastric Banding

Most bariatric surgeries today are performed using minimally invasive techniques, called laparoscopic surgery.⁵ Laparoscopic surgery is done with video cameras and thin instruments inserted through small incisions in the abdomen.

Health benefits of bariatric surgery

Many patients with severe obesity continue to struggle with managing their weight and related health conditions. Bariatric surgery has been shown to be an effective means of achieving lasting weight loss, and can improve many obesity-related health conditions. People who have bariatric surgery also experience improvements in many areas of their life, including physical functioning and appearance and social and economic opportunities.

Potential risks of bariatric surgery

With more bariatric procedures being performed in recent years, safety has improved significantly. The overall death rate is 0.1%—less than gallbladder (0.7%) and hip replacement (0.93%) surgery. The overall likelihood of major complications is 4%.6

The risk for serious complications depends on the type of surgery, your medical condition, and your age, as well as the surgeon's and anesthesiologist's experience.

The long-term commitment to weight loss, and the decision to have bariatric surgery

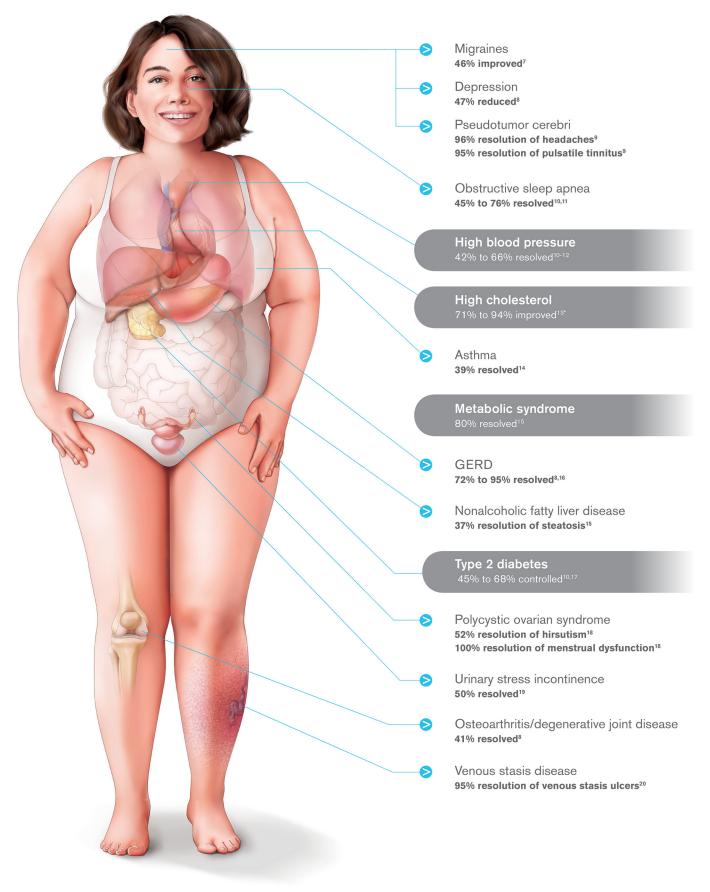
The decision to have bariatric surgery is an important one. It shouldn't be made quickly or without weighing the health risks and benefits.

It is important to recognize that bariatric surgery is a complement, not an alternative, to lifestyle changes. The modifications made to your gastrointestinal tract will require permanent changes to your eating habits that must be adhered to for successful weight loss.

Having bariatric surgery entails a lifetime commitment to following dietary restrictions, adhering to an exercise program, taking dietary supplements, and complying with follow-up recommendations. The surgery is one step in a lifelong journey towards better overall health.

In order to reach a decision that both you and your doctor feel good about, you should have an open conversation about the surgery you are considering, and make sure your doctor has answered any questions you may have.



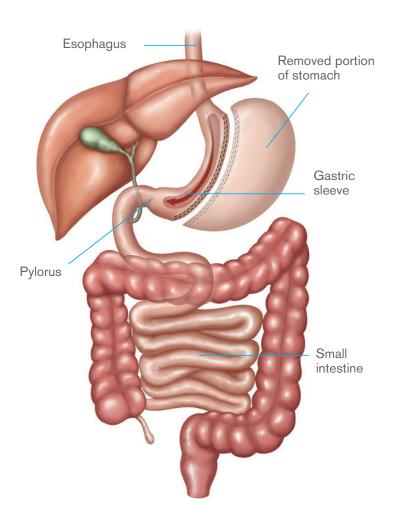


Outcomes for obesity-related health conditions based on data for sleeve gastrectomy, gastric bypass, and gastric banding.

* Figure is for hyperlipidemia. Hyperlipidemia is a general term for high fats in blood, which may include cholesterol and/or triglycerides.

IMPORTANT SAFETY INFORMATION: This procedure is for the treatment of patients suffering from severe obesity only. Patients should consult their physicians to determine if this procedure is appropriate for their condition. All surgery presents risk. Risk of bariatric surgery are generally low and similar to other commonly performed procedures like gallbladder surgery. Risks include adverse reactions to medications, problems with anesthesia, problems with breathing, bleeding, blood clots, inadvertent injury to nearby organs and blood vessels, nutritional deficiency, even death.

Sleeve Gastrectomy







66% Total % of excess weight lost at 3 years

The procedure

The surgeon creates a small stomach "sleeve" using a stapling device.

The sleeve is about the size of a banana.

The rest of the stomach is removed.

An estimated 58% of bariatric procedures in 2016 were sleeve gastrectomies.²⁴

How it works

Permanently reduces the size of your stomach, which limits how much food you can eat.

Food passes normally through your digestive tract, allowing vitamins and nutrients to be fully absorbed.

Potential complications

You may develop stomach ulcers.

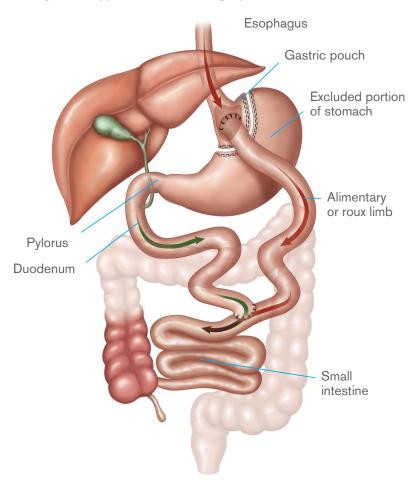
Stomach staples may cause complications such as leaks from staple lines or separation of tissue that was stapled or stitched together.

Stomach-related discomfort may occur, such as heartburn, nausea or belching.

Irregular contractions of your esophagus may cause complications with swallowing (also known as esophageal dysmotility).

Gastric Bypass

Also referred to as Roux-en-Y gastric bypass (RYGP) surgery





The procedure

The surgeon creates a small stomach pouch using a stapling device that significantly reduces the overall stomach size.

The remaining stomach area is stapled shut and divided from the smaller pouch.

The pouch is surgically attached to the middle of the small intestine, thereby bypassing the rest of the stomach and the upper portion of the small intestine (duodenum).

An estimated 19% of bariatric procedures in 2016 were gastric bypasses.²⁴

How it works

Creating a smaller stomach pouch limits the amount of food you can eat, so you feel full sooner and stay full longer.

Bypassing part of the intestine limits calorie absorption.

Potential complications

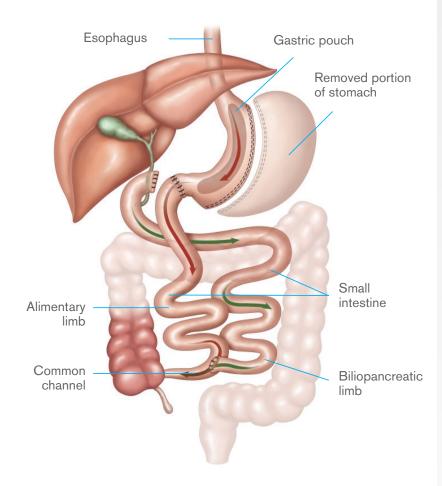
Because the duodenum is bypassed, poor absorption of iron and calcium can lead to vitamin deficiencies and anemia.

To combat this, you'll need to take dietary supplements (including daily multivitamin, calcium, and sometimes vitamin B12 and/or iron).

You may experience discomfort as food moves rapidly through your small intestine. This is called "dumping syndrome" and is a warning sign that you're consuming too much sugar or food.

Understand Your Surgical Options

Biliopancreatic Diversion/ Duodenal Switch (BPD/DS)







The procedure

The surgeon removes part of the stomach, leaving a sleeve with the beginning of the duodenum intact.

The small intestine is then divided with one end attached to the stomach pouch to create what is called an "alimentary limb."

All the food moves through this segment; however not much is absorbed. The digestive juices move through the alimentary limb. This separates digestive juices until they join at a common channel.

BPD/DS is the least common bariatric surgery, with less than 1% performed in 2016.²⁴

How it works

This surgery permanently alters the normal digestive process.

Food bypasses most of the small intestine where calories and nutrients are normally absorbed.

It also limits the amount of food that can be eaten by reducing the size of the stomach.

Potential complications

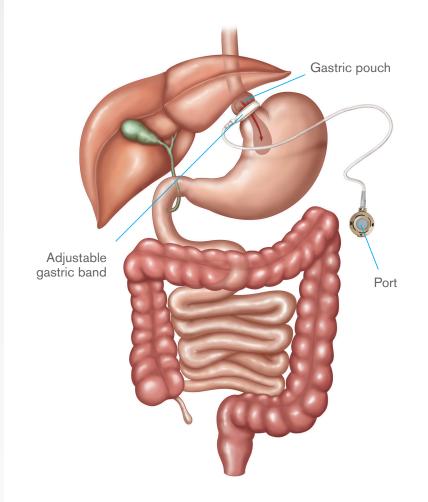
There is a period of intestinal adaptation when bowel movements can be very liquid and frequent. This condition may lesson over time, but may be a permanent condition. You may also experience bloating, gas, and malodorous stool.

Lifelong vitamin supplementation is required, and close lifelong monitoring for protein malnutrition, anemia and bone disease is recommended.

Changes to the intestinal structure can result in the increased risk of gallstone formation and the need for removal of the gallstone.

You may experience "dumping syndrome" as food moves rapidly through your small intestine.

Gastric Banding





The procedure

A silicon band is placed at the top of your stomach dividing it into two parts: a small upper pouch and a lower stomach.

Saline is added to the band to restrict food passage. The saline is delivered through a port that is connected to the band and attached to the abdominal wall.

The surgery can be reversed. No part of the stomach or digestive system is stapled, cut or removed.

An estimated 3% of bariatric procedures in 2016 were gastric banding procedures.²⁴

How it works

The degree of band tightness affects how much food you can eat and the length of time it takes for food to leave the smaller stomach pouch.

Your health care team will determine when adjustments to your band are needed.

Does not significantly alter normal digestion and absorption. Food passes through the digestive tract in the usual order, allowing it to be fully absorbed in the body.

Potential complications

There are risks of band erosion, leakage, migration/slippage, or displacement from the port.

There could also be tubing-related complications, such as kinking of disconnection from the port.

There is also the risk of port-site infection.

Understand Your Surgical Options —

Estimates of Bariatric Surgery Benefits



^{*}Results achieved with combination of bariatric surgery and intensive medical therapy as defined by American Diabetes Association guidelines. Intensive medical therapy included frequent glucose monitoring, lifestyle counseling, weight management, and treatment with antidiabetic, lipid-lowering and antihypertensive medications.

Preparing for surgery

Your bariatric healthcare team will be there for you as you undertake this life-changing event. Your healthcare team includes not only your surgeon and nurses, but also other health professionals, such as a dietitian, psychologist or counselor, exercise physiologist, and your primary care physician. This team will help you prepare you for surgery, and guide you throughout your recovery and for the long term.

Since bariatric surgery is a complement to lifestyle changes such as diet and exercise, it's important that you are mentally and behaviorally prepared. Your healthcare team may work with you prior to surgery to start healthy lifestyle changes that will help you succeed in the long term. Often, patients are required to be on a diet prior to their surgery.³² The length of the diet depends on your surgeon's suggestions as well as the requirements of your insurance provider.



Throughout preparation and recovery, you'll be supported by a dedicated healthcare team



Recovery after surgery

After surgery, you will remain in the hospital for a few days, where you will consume a clear liquid diet and be monitored for any immediate complications. Upon discharge, you will be given strict dietary instructions. Depending on the type of surgery you have, about 10 to 14 days after surgery, you will be allowed to add soft or pureed protein sources to your liquid diet and will then gradually build up to a solid food diet at 5 to 6 weeks after your surgery.

In addition to the health benefits of bariatric surgery, keep in mind that you may experience some unwanted changes to your body after surgery, such as scarring or loose skin. Your scars can be various sizes or shapes, depending on the type of surgery you have. Talk to your healthcare team if you are worried about scarring, and they may be able to recommend tips to limit scarring.

Most patients who have bariatric surgery experience loose skin as they lose weight. For some, this may be temporary. The amount of loose skin depends on many factors, including how much weight you lose, your genetics, age, smoking history, and whether you exercise. Clothing or compression garments can often hide loose skin. But, if the extra skin bothers you, discuss options with your healthcare team to see if plastic surgery may be an option for you.

As you begin to lose weight and gain strength, members of your team will help you take the next steps to full health and recovery. They may refer you to support groups or exercise facilities in your community. Studies have shown that patients who have frequent, face-to-face contact with their healthcare team are most successful in achieving and maintaining their goals.³³

You will most likely need to see your healthcare team for follow-up appointments every 3 to 6 months, and then every 1 to 2 years after that. It's important to remember that the decision to have bariatric surgery is the first step in a lifelong commitment to your health, so follow-up care is recommended for life.



Insurance coverage

Insurance plans differ in their coverage requirements. In addition to being medically fit for surgery, you may need documentation that you have tried other weight loss methods, are mentally healthy and able to understand what is involved and are free of drug and alcohol dependencies.

Talk to your doctor's office staff about your health insurance options. They may be able to help guide and inform your conversations with your healthcare provider.

Physician and Patient Conversation Guide and Checklist

The best way for patients and doctors to make a shared decision about surgery is to have an open discussion about treatment options and concerns. Your doctor should help you understand how the latest research can influence recommendations about your surgery, and you should help the doctor understand what aspects of your surgery and recovery are most important to you.



The benefits of shared decision making

Today, more studies show that patients who are more actively involved in their healthcare experience have better health outcomes and incur lower costs.³⁷

During your conversation, use this checklist to ensure the following topics have been covered to your and your doctor's satisfaction:

TOPIC TO DISCUSS: The risks of obesity, including the relationship between other health conditions and my weight
DID YOU KNOW
 Obesity can increase the risk of medical conditions such as diabetes, chronic heart disease, stroke and cancer³⁴
 Bariatric surgery can help reduce medication use for diabetes and other obesity-related diseases³⁵
■ In the US, an estimated 112,000 excess deaths per year are associated with obesity ³⁶
TOPIC TO DISCUSS: The health benefits of bariatric surgery, including reduction or resolution of obesity-related health conditions DID YOU KNOW
 Bariatric surgery can cause changes in gut hormones which impact hunger, satisfaction, and blood sugar control⁴
 Bariatric surgery can improve many obesity-related health conditions⁶
TOPIC TO DISCUSS: The available bariatric surgery options, the differences between the surgeries, and the risks and benefits of each
DID YOU KNOW
 Bariatric surgery is an accepted treatment option for patients with severe obesity who do not respond to non-surgical treatment
 There are 4 main types of bariatric surgery procedures: sleeve gastrectomy, gastric bypass, biliopancreatic diversion, and gastric banding. There are risks and benefits with each type of surgery

TOPIC TO DISCUSS: The surgical team's experience with bariatric surgeries, affiliation with an accredited bariatric surgery program, how your surgery will be performed (laparoscopically or open) and who will be assisting with your surgery (resident, surgical assistant, or another surgeon)
■ DID YOU KNOW ■ More than 90% of bariatric surgeries are performed laparoscopically ■ In addition to your surgeon, your healthcare team may include psychologists and dietitians
TOPIC TO DISCUSS: Preparation for surgery, including behavioral and mental readiness; dietary or lifestyle changes to be made; other special considerations or actions to prepare for this life-changing event
 PID YOU KNOW For 2 to 3 weeks prior to bariatric surgery, most surgeons require patients to be on a special diet in order to help with surgery. But remember, bariatric surgery entails a lifetime commitment to following dietary restrictions, adhering to an exercise program, taking dietary supplements, and complying with follow-up recommendations The surgery is one step in a lifelong journey towards better overall health
TOPIC TO DISCUSS: Recovery after surgery, including how long my hospital stay will be, how often I will have follow-up care, and what to expect during recovery
 DID YOU KNOW Most patients stay in the hospital for a few days following surgery and then follow-up with their healthcare team every few months as needed, and then every 1-2 years A bariatric healthcare team will be there to support you during recovery and for the long term

By the end of your discussion, you should feel confident that you understand all the factors involved and that, together with your doctor, you've made the best decision.

Questions and Notes	Questions and Notes

Resources

www.thehealthpartners.com
www.asmbs.org/patients
www.cdc.gov/obesity
www.ethicon.com/obesity
www.mbsaqip.org
www.obesity.org/publications/obesity-journal.htm
www.obesityaction.org
www.stopobesityalliance.org
www.win.niddk.nih.gov/publications/gastric.htm

Statements about bariatric surgery from leading associations

American Association of Clinical Endocrinologists 2015

The beneficial effect of surgery on reversal of existing diabetes and prevention of its development has been confirmed in a number of studies.³⁸

American College of Physicians 2005

Surgery should be considered as a treatment option for patients with a BMI of 40kg/m² or greater who instituted but failed an adequate exercise and diet program...and who present with obesity-related comorbid onditions, such as hypertension, impaired glucose tolerance, diabetes mellitus, hyperlipidemia and obstructive sleep apnea.³⁹

American Diabetes Association 2017

The 2017 ADA recommendations for bariatric surgery and type 2 diabetes patients who met surgical qualifications⁴⁰:

- 40+ BMI: Surgery recommended regardless of glycemic control
- 35-39.9 BMI: Surgery recommended with poor glycemic control and considered with glycemic control
- 30-34.9 BMI: Surgery considered with treated and poor glycemic control (down to BMI of 27 for Asians)

American Heart Association 2011

When indicated, surgical intervention leads to significant improvements in decreasing excess weight and comorbidities that can be maintained over time.⁴¹

Department of Veterans Affairs, U.S. Department of Defense 2014

Bariatric surgery to reduce body weight, improve obesity-associated comorbidities and improve quality of life may be considered in adult patients with a BMI >40kg/m² and those with a BMI >35kg/m² with at least one obesity-associated chronic health condition (ie, hypertension, type 2 diabetes, dyslipidemia, metabolic syndrome and sleep apnea).⁴²

International Diabetes Federation 2011

Bariatric surgery is an appropriate treatment for people with type 2 diabetes and obesity not achieving recommended treatment targets with medical therapies.⁴³

References

1. Fischer L, Hildebrandt C, Bruckner T, et al. Excessive weight loss after sleeve gastrectomy: a systematic review. Obes Surg. 2012 May;22(5):721-731. 2. Garb J. Bariatric surgery for the treatment of morbid obesity: A meta-analysis of weight loss outcomes for laparoscopic adjustable gastric banding and laparoscopic gastric bypass. Obes Surg. 2009;19(10):1447-55. 3. Baltasar A, Bou R, Bengochea M, et al. Duodenal switch: an effective therapy for morbid obesity—intermediate results. Obes Surg. 2001;11:54–58. 4. Shin AC, Zheng H, Townsend RL, Sigalet DL, Berthoud HR. Meal-induced hormo responses in a rat model of roux-en-Y gastric bypass surgery. Endocrinology. 2010;151 (4):1588-1597. 5. Beitner M, Luo Y, Kurian M. Procedural changes to decrease complications in laparoscopic gastric bypass. JSLS. 2015;19(1):e2014.00256. 6. American Society for Metabolic and Bariatric Surgery, Metabolic and Bariatric Fact Sheet. https://asmbs.org/wp/uploads/2014/05/Metabolic+Bariatric-Surgery, Detabolic and Bariatric Fact Sheet. Accessed December 19, 2017. 7. Bond DS, Vithiananthan S, Nash JM, et al. Improvement of migraine headaches in severely obese patients after bariatric surgery. Neurology. 2011 Mar 29;76(13):1135-8. 8. Schauer PR, Ikramuddin S, Gourash W, et al. Outcomes after laparoscopic Roux-en-Y gastric bypass for morbid obesity. Ann Surg. 2000 Oct;232(4):515-29. 9. Sugerman HJ, Felton WL III, Sismanis A, et al. Gastric surgery for pseudotumor cerebri associated with severe obesity. Ann Surg. 1999 May;229(5):634-40; discussion 640-2. 10. Tice JA, Karliner L, Walsh J, et al. Gastric banding or bypass? A systematic review comparing the two most popular bariatric procedures. Am J Med. 2008 Oct; 121(10):885-93. 11. Brethauer SA, Hammel JP, Schauer PR. Systematic review of sleeve gastrectomy as staging and primary bariatric procedure. Surg Obes Rel Dis. 2009;5:469-475. 12. EES analysis of data from US Clinical Trial PMA 070009. 13. Buchwald H, Avidor Y, Braunwald E, et al. Bariatric surgery: a systematic review and meta-analysis. JAMA. 2004 Oct 13;292(14):1724-37. 14. Reddy RC, Baptist AP, Fan Z, et al. The effects of bariatric surgery on asthma severity. Obes Surg. 2011 Feb;21(2):200-6. 15. Mattar SG, Velcu LM, Rabinovitz M, et al. Surgically-induced weight loss significantly improves nonalcoholic fatty liver disease and the metabolic syndrome. Ann Surg. 2005 Oct;242(4):610-17. 16. DeMaria EJ, Sugerman HJ, Kellum JM, et al. Results of 281 consecutive total laparoscopic Roux-en-Y gastric bypasses to treat morbid obesity. Ann Surg. 2002 May; 235(5):640-5. 17. Schauer PR Kashyap SR, Wolski K, et al. Bariatric surgery versus intensive medical therapy in obese patients with diabetes. N Engl J Med. 2012;366(17):1567-76. 18. Eid GM, Cottam DR, Velcu LM, et al. Effective treatment of polycystic ovarian syndrome with roux-en-Y gastric bypass. Surg Obes Relat Dis. 2005 Mar-Apr; 1(2):77-80. 19. Kuruba R, Almahmeed T, Martinez F, et al. Bariatric surgery improves urinary incontinence in morbidly obese individuals. Surg Obes Relat Dis. 2007 Nov-Dec;3(6):586-90. 20. Sugerman HJ, Sugerman EL, Wolfe L, et al. Risks and benefits of gastric bypass in morbidly obese patients with severe venous stasis disease. Ann Surg. 2001 Jul;234(1):41-6. 21. Fletcher R, Deal R, Kubasiak J, Torquati A, Omotosho P. Predictors of increased length of hospital stay following laparoscopic sleeve gastrectomy from the National Surgical Quality Improvement Program. J of Gastrointest Surg. 2018;22(2):274-278. 22. Armstrong J, O'Malley SP. Outcomes of sleeve gastrectomy for morbid obesity: a safe and effective procedure? Int J of Surg. 2010;8:69-71. 23. Novikov AA, Afanch C, Saumoy, et al. Endoscopic sleeve gastroplasty, laparoscopic sleeve gastrectomy, and laparoscopic band for weight loss: how do they compare? J Gastrointest Surg. 2018;22(2):267-273. 24. American Society for Metabolic and Bariatric Surgery. Estimate of Bariatric Surgery Numbers, 2011-2016. https://asmbs.org/ resources/estimate-of-bariatric-surgery-numbers. Accessed January 11, 2018. 25. Schauer P, Ikramuddin S, Hamad G, Gourash W. The learning curve for laparoscopic roux-en-Y gastric bypass is 200 cases Surg Endosc. 2003;17:212-215. 26. Baker MT, Lara MD, Larson CJ, et al. Length of stay and impact on readmission rates after laparoscopic gastric bypass. Surg Obes Relat Dis. 2006;2(4):435-439. 27. Mayo Clinic Staff. Gastric bypass surgery. https://www.mayoclinic.org/tests-procedures/bariatric-surgery/basics/what-you-can-expect/ prc-20019138. Accessed January 16, 2018. 28. Resa JJ, Solano J, Fatas JA, et al. Laparoscopic biliopancreatic diversion: technical aspects and results of our protocol. Obes Surg. 2004;Mar; 14(3): 329-33; discussion 333. 29. Edholm D, Axer S, Hedberg J, Sundbom M. Laparoscopy in duodenal switch: safe and halves length of stay in a nationwide cohort from the Scandinavian Obesity Registry. Scandinavian Journal of Surgery. 2017;106(3):230-234. 30. Søvik TT, Taha O, Aasheim ET, et al. Randomized clinical trial of laparoscopic gastric bypass versus laparoscopic duodenal switch for superobesity. BJS. 2010;97:160-166. 31. Weiner RA, Weiner S, Pomhoff I, et al. Laparoscopic sleeve gastrectomy—influence of sleeve size and resected gastric volume. Obes Surg. 2007;12:1297-1305. 32. American Society for Metabolic and Bariatric Surgery. Bariatric Surgery FAOs. https://asmbs.org/patients/bariatric-surgery-faqs. Accessed January 11, 2018. 33. Steffen R, Potoczna N, Bieri N, Horber F. Successful multi-intervention treatment of severe obesity: a 7-year prospective study with 96% follow-up. Obes Surg. 2009;19:3-12. 34. American Society for Metabolic and Bariatric Surgery. Obesity in America Fact Sheet. http://www.asbs.org/ Newsite07/media/asmbs_fs_obesity.pdf. Accessed December 14, 2017. 35. Segal JB, Clark JM, Shore AD, et al. Prompt reduction in use of medications for comorbid conditions after bariatric surgery. Obes Surg. 2009;19(12):1646-56. 36. Flegal KM, Graubard BI, Williamson DF, Gail MH. Excess deaths associated with underweight, overweight, and obesity. JAMA. 2005;293(15):1861-1867. 37. James J. Health Policy Brief: Patient Engagement. Health Affairs. February 14, 2013. https://www.healthaffairs.org/do/10.1377/hpb20130214.898775/full/ Accessed January 24, 2018. 38. Handelsman Y, Bloomgarden ZT, Grunberger G, et al. American Association of Clinical Endocrinologists and American College of Endocrinology—Clinical practice guidelines for developing a diabetes mellitus comprehensive care plan—2015. Endocrine Practice. 2015;21(suppl1):1-87. 39. Snow V, Barry P, Fitterman N, et al. Pharmacologic and surgical management of obesity in primary care: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2005;142:525-531. 40. American Diabetes Association. Standards of medical care in diabetes—2017. Diabetes Care. 2017;40(supple1):1. 41. Poirier P, Comier MA, Mazzone T, et al. Bariatric surgery and cardiovascular risk factors: a scientific statement from the American Heart Association. Circulation. 2011;123(15);1683-1701. 42. Department of Veterans Affairs, Department of Defense. VA/DoD clinical practice guideline for screening and management of overweight and obesity (2014). https://www.healthqualitywa.gov/guidelines/CD/obesity/ CPGManagementOfOverweightAndObesityFINAL041315.pdf Accessed January 12, 2018. 43. Dixon JB, Zimmet P, Alberti KG, Rubino F. Bariatric surgery: an IDF statement for obese type 2 diabetes. Diabet Med. 2011;28(6):628-642.

