CLINICAL THERAPEUTICS

Bariatric Surgery for Morbid Obesity

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This Journal *feature begins with a case vignette that includes a therapeutic recommendation. A discussion of the clinical problem and the mechanism of benefit of this form of therapy follows. Major clinical studies, the clinical use of this therapy, and potential adverse effects are reviewed. Relevant formal guidelines, if they exist, are presented. The article ends with the author's clinical recommendations.*

A 44-year-old obese woman (height, 1.7 m [65 in.]) has seen her primary care physician for the past 10 years for management of conditions related to her obesity, including diabetes, hypertension, and gastroesophageal reflux disease. Despite efforts to lose weight, her body weight has increased from 109 to 127 kg (240 to 280 lb), and her body-mass index (BMI) — the weight in kilograms divided by the square of the height in meters — from 40.0 to 46.6. During a routine office visit, the patient asks her physician whether bariatric surgery might be a treatment option for her. The physician does not recommend referral for surgical evaluation, citing concerns about the variable effectiveness of the procedure and the associated risks, as well as the lack of long-term outcome data. The patient then seeks a specialist in bariatric surgery for evaluation, without the assistance of her physician.

THE CLINICAL PROBLEM

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Obesity has become an epidemic condition in the United States and around the world. In the United States, the percentage of adults who are obese (defined as having a BMI of 30 or more) increased from 15.3% in 1995 to 23.9% in 2005.[1] Approximately 4.8% are considered to be extremely or morbidly obese (having a BMI of 40 or more).[2] Worldwide, it is estimated that more than 300 million people are obese.[3]

Obesity, particularly abdominal obesity, is associated with increased risks of hypertension, diabetes, hyperlipidemia, sleep apnea, coronary heart disease, and stroke.[3,4] In the United States, health care expenditures related to obesity and associated medical conditions amount to $100 billion annually,[5] and in 2000, obesity was estimated to contribute to approximately 400,000 deaths.[6] It has been suggested that in the 21st century, increasing rates of obesity may lead to a decline in overall life expectancy in the United States.[7]

PATHOPHYSIOLOGY AND EFFECT OF THERAPY

The pathophysiology of obesity is complex and poorly understood, but it includes genetic, behavioral, psychological, and other factors.[8] Family studies suggest that heredity may explain 67% of the population variance in BMI.[9] However, genetic factors are unlikely to account fully for the rapid increase in the prevalence of obesity. Declining rates of physical activity[10] and increases in the consumption of energy-dense foods[11] may play a role.

Bariatric surgical procedures reduce caloric intake by modifying the anatomy of the gastrointestinal tract. These operations are classified as either restrictive or malabsorptive. Restrictive procedures limit intake by creating a small gastric reservoir with a narrow outlet to delay emptying. Malabsorptive procedures bypass vary-

ing portions of the small intestine where nutrient absorption occurs.

Restrictive procedures include gastric stapling (gastroplasty), adjustable gastric banding (wrapping a synthetic, inflatable band around the stomach to create a small pouch with a narrow outlet), or a combination of these two approaches. Adjustable gastric banding is a relatively new operation that includes the insertion of a subcutaneous reservoir so that gastric restriction can be adjusted by means of saline injections. The procedure can be performed laparoscopically, and the band can be removed in an outpatient setting without anesthesia (Fig. 1A).[12] Another recently developed procedure is the vertical restrictive (sleeve) gastrectomy (Fig. 1B), in which resection of much of the gastric body leaves a narrow tube of stomach as an alimentary conduit.

Proximal Roux-en-Y gastric bypass (Fig. 1C) is often referred to as a combination restriction–malabsorption procedure. It involves stapling of the stomach to create a small (≤30.0 ml) upper gastric pouch. The small intestine is then divided at the midjejunum, and the distal portion (called the alimentary, or Roux, limb) is anastomosed to the gastric pouch. The distal portion of the stomach and proximal small intestine (the biliopancreatic limb) are anastomosed end to side farther down the jejunum. Food comes into contact with pancreatic and biliary secretions only below this anastomosis, in the segment of small intestine called the common channel. The shorter the common channel (and the longer the Roux limb), the less nutrient absorption will occur.[13]

Malabsorptive procedures that introduce less gastric restriction than the Roux-en-Y procedure include biliopancreatic diversion, commonly done by means of a procedure called duodenal switch, which includes sleeve (vertical) gastrectomy (Fig. 1D). Some surgeons perform a sleeve gastrectomy (Fig. 1B) as the initial part of a staged operation, performing a Roux-en-Y procedure after initial weight loss has made surgery less difficult and reduced the operative risk.

CLINICAL EVIDENCE

No large, randomized trials have compared current bariatric surgical techniques with medical management of severe obesity. A 2005 Cochrane Review identified only two small, randomized, controlled trials and three cohort studies, all of which were considered to have a high risk of bias in their design.[14] Nonetheless, their summary assessments, as well as those of two meta-analyses, suggest a typical weight loss of 20 to 50 kg (44 to 110 lb) with various bariatric procedures as compared with a modest weight gain in medically treated patients.[14-16]

The only large, well-controlled prospective study of bariatric surgery is the Swedish Obese Subjects (SOS) trial.[17] A total of 2010 surgically treated obese patients (BMI, 34 or more for men and 38 or more for women) were compared with 2037 control subjects who were matched for 18 variables, including age, sex, weight, and several cardiac risk factors. Weight changes were significantly greater in the surgical group than in the control group among 3505 patients followed for 2 years (23.4% of body weight lost vs. 0.1% gained) and among 1268 patients followed for 10 years (16.1% of body weight lost vs. 1.6% gained). In a study of 1035 patients who underwent bariatric surgery, the mean BMI decreased from 50.0 to 32.6 at a median of 2.0 years of follow-up.[18] In general, weight loss with malabsorptive procedures tends to be greater than weight loss with solely restrictive procedures.[15]

Improvement in the conditions that are often associated with obesity has been consistently reported after bariatric surgery. In a meta-analysis by Buchwald et al., 77% of patients with preoperative diabetes no longer required medication after surgery. Similar improvements were seen for patients with hyperlipidemia (83%), hypertension (66%), and sleep apnea (88%).[15] The SOS data suggest that some of these benefits are less marked at 10 years than at 2 years, although they are still significant.[17]

It has not been clearly established whether bariatric surgery results in reduced mortality as compared with medical management of obesity, although such a benefit is suggested in the results of several matched cohort studies.[18-20] Sjostrom has presented data from the SOS trial[21] showing that unadjusted overall mortality was reduced by 31.6% in the surgery group as compared with the control group, which was a significant reduction.

CLINICAL USE

In 1991, the National Institutes of Health (NIH) convened a Consensus Development Conference on gastrointestinal surgery for severe obesity.[22]

The recommendations resulting from the conference included the following criteria for bariatric surgery: a BMI of 40 or higher, or a BMI of 35 or higher in a patient with a high-risk condition such as severe sleep apnea, obesity-related cardiomyopathy, or severe diabetes mellitus. Additional criteria included failure of medical weight control and an absence of medical or psychological contraindications, as well as the patient's understanding of the procedure and its risks and strong motivation to comply with the postsurgical regimen. These criteria make clear the need for a multidisciplinary approach that includes medical, surgical, nutritional, and psychological assessment.

Evaluation of the surgical candidate should include a comprehensive nutritional and weight history, covering weight trends, previous weight-loss efforts, and perceived obstacles to successful weight management.[23] Current weight, height, and BMI should be determined. Although measurement of waist circumference provides additional information regarding health risks, this information is not particularly useful in persons with a BMI above 40.[23]

Secondary causes of obesity should be considered, although they do not usually account for severe obesity. Routine screening for Cushing's syndrome and hypothyroidism is not necessary unless clinical suspicion is high.[24] A medication history should be obtained; antidepressants, oral contraceptives, oral hypoglycemic agents, and other drugs can be associated with weight gain.[3]

The medical evaluation should include assessment for the conditions that commonly accompany severe obesity, including diabetes, hypertension, hyperlipidemia, coronary artery disease, sleep apnea, pulmonary hypertension, and musculoskeletal disease.[3,4,25] Careful selective investigation of these conditions serves several purposes. It facilitates optimal medical management before surgery, identifies problems that may influence the perioperative and postoperative course, and provides a baseline set of clinical data for evaluating the benefit of surgery.

The psychological evaluation of the candidate for bariatric surgery is one of the most important and difficult elements of the clinical assessment. A majority of patients presenting for bariatric procedures have one or more psychiatric disorders[26]; some studies suggest that patients with a diagnosis of an Axis I or Axis II disorder (according to the *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition[27]) are likely to lose less weight after surgery than those without such diagnoses.[28] Other psychosocial factors that have been associated with a suboptimal surgical outcome include disturbed eating habits (e.g., binge eating), substance abuse, low socioeconomic status, limited social support, and unrealistic expectations of surgery.[28,29]

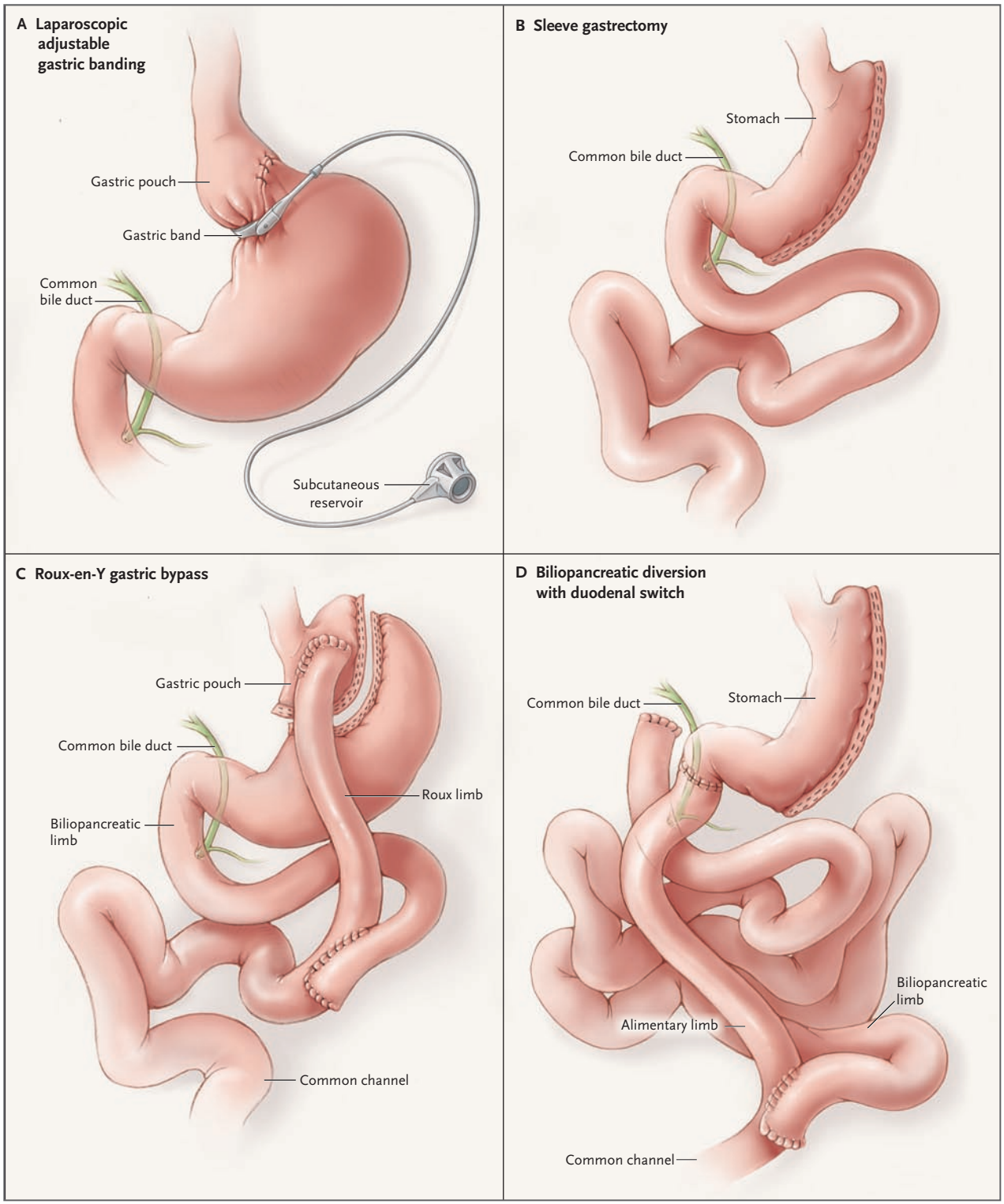
Figure 1 (facing page). Common Surgical Procedures for Weight Loss.

Restrictive operations for the treatment of morbid obesity and its coexisting conditions, popular today particularly because of laparoscopic surgical approaches, include adjustable gastric banding (Panel A) and vertical (sleeve) gastrectomy (Panel B). Roux-en-Y gastric bypass (Panel C), a procedure that combines restriction and malabsorption, is considered by many to be the gold standard because of its high level of effectiveness and its durability. More extreme malabsorption accompanies biliopancreatic diversion procedures, commonly performed with a duodenal switch (Panel D), in which a short, distal, common-channel length of small intestine severely limits caloric absorption. This procedure also includes a sleeve gastrectomy.

Patients undergoing bariatric surgery often believe they will lose more weight than is consistent with clinical experience and may think that minimal personal effort or risk is involved. Unfortunately, such ideas are increasingly fostered by inaccurate information obtained from unreliable sources on the Internet and elsewhere.[30,31] Preoperative education is important in improving the patient's understanding of the anticipated consequences of the procedure.[24]

Specific contraindications to bariatric surgery are few. They include mental or cognitive impairment that limits the patient's ability to understand the procedure and thus precludes informed consent. Very severe coexisting medical conditions, such as unstable coronary artery disease or advanced liver disease with portal hypertension, may in some instances render the risks of surgery unacceptably high.

Perioperative care of patients undergoing bariatric surgery requires specialized expertise and



facilities. Studies have demonstrated that the likelihood of postoperative complications is significantly associated with annual surgical experience. The risks are greatest when surgeons perform fewer than 25 operations and hospitals host fewer than 50 operations per year, and the risks are lowest when surgeons perform more than 100 operations and hospitals host more than 150 operations per year.[32-34]

The University HealthSystem Consortium evaluated 1143 bariatric surgical procedures performed between October 2003 and March 2004 at 29 institutions in the United States.[35] Roux-en-Y gastric-bypass operations accounted for 1049 (92%) of the procedures. Among the patients who underwent these procedures, the mean time in the operating room was 3.8 hours, 7.7% required intensive care, and the mean hospital stay was 3.5 days. Ninety-four (8%) of the procedures were restrictive. In the group of patients who underwent restrictive operations, the mean time in the operating room was 2.3 hours, only 1.1% required intensive care, and the mean hospital stay was 1.6 days.

A comprehensive plan for long-term patient care is necessary for bariatric surgery to have a reasonable chance of being both safe and successful. The operation should not be performed unless systematic follow-up is available and unless the patient has made a commitment to participate in such care. As in the preoperative evaluation, postoperative management requires a coordinated approach involving expertise in medicine, surgery, psychology, and nutrition.[36] Unfortunately, many patients do not receive systematic postoperative care, and they may have suboptimal outcomes as a result.[37,38]

Estimates of the median hospital costs for bariatric surgery range from approximately $10,000 to $14,000.[39] The Medicare physician fees for 2007 are $800 to $1,000 for laparoscopic adjustable gastric banding and $1,300 to $2,000 for Roux-en-Y gastric bypass and for biliopancreatic diversion with duodenal switch.[40] Longer-term costs are more difficult to determine, but one analysis suggested that lifetime medical costs could be $59,000 to $75,000.[41]

ADVERSE EFFECTS

In several large series, the mortality rate associated with bariatric surgery was 0.1% to 2.0%.[20,42-45] In the meta-analysis by Buchwald et al., operative mortality rates were 0.5% for gastric bypass, 0.1% for gastric banding, and 1.1% for malabsorptive procedures.[15] Common causes of death among patients undergoing bariatric surgery include pulmonary embolism and anastomotic leaks. Factors that have been found to contribute to increased mortality include lack of experience on the part of the surgeon or the program, advanced patient age, male sex, severe obesity (BMI ≥50), and coexisting conditions.[20,32,42,44-50]

Nonfatal perioperative complications include venous thromboembolism, anastomotic leaks, wound infections, bleeding, incidental splenectomy, incisional and internal hernias, and early small-bowel obstruction. In the SOS trial, postoperative complications occurred in 13% of patients, including bleeding in 0.5%, embolism or thrombosis in 0.8%, wound complications in 1.8%, and pulmonary complications in 6.1%.[17]

Postoperative gastrointestinal complications of bariatric surgery are common. Nausea and vomiting occur in more than 50% of patients undergoing restrictive procedures, partly as a result of eating too much or too rapidly but sometimes because of anastomotic stricture or other mechanical consequences of the operation.[36] The dumping syndrome, a complex of neurohormonally mediated symptoms that include facial flushing, lightheadedness, palpitations, fatigue, and diarrhea, occurs in as many as 70% of patients after Roux-en-Y gastric bypass.[24] Typically triggered by the ingestion of concentrated sugar, this syndrome may discourage patients from eating foods with a high sugar content, thus contributing to the beneficial effects of the operation.[51] Deficiencies of iron, calcium, folate, vitamin B_{12}, and other nutrients occur after procedures with a component of malabsorption, such as gastric bypass. With the more extensive procedures, such as biliopancreatic diversion, protein malnutrition and deficiencies of the fat-soluble vitamins (A, D, E, and K) may occur. All of these deficiencies require regular monitoring and replacement.[24,36] Other gastrointestinal complications include dehydration, bowel obstruction, anastomotic leaks, strictures, erosions, ulcers, adhesions, internal and incisional hernias, and cholelithiasis.[16,36,52]

Patients who have undergone bariatric surgery may require subsequent readmission or reoperation. In the study by the University HealthSystem Consortium, the rate of repeat operation was

3.7%, and the rate of readmission at 30 days 6.4%.[35] In one study of Roux-en-Y gastric-bypass procedures, more patients were readmitted within 12 or 36 months after the procedure (19.3% and 40.4%, respectively) than had been admitted for hospital care 12 or 16 months before the procedure (7.9% and 19.4%, respectively).[53] Some of the postoperative readmissions were required for complications, but others were for treatment of coexisting conditions (e.g., joint replacement and abdominoplasty) that could be managed more definitively after weight loss.

AREAS OF UNCERTAINTY

The potential benefit of bariatric surgery for patients with mild obesity (BMI of 30 to 35) remains unclear. In a recent randomized, controlled trial, patients in this range who underwent laparoscopic adjustable gastric banding had more weight loss, greater resolution of the metabolic syndrome, and greater improvement in the quality of life than did patients who received medical therapy.[54] However, this remains an area of controversy.

It is likewise uncertain whether patients with extremely severe obesity are appropriate candidates for bariatric surgery. There are reasons for concern that the operative risk may be increased for such patients, partly because of technical difficulties in performing the procedure and practical management issues.[55] At least one report has suggested that mortality rates may be increased among patients with a BMI of 70 or more.[56] However, there is also a lack of comparison data with which to determine risk and longevity in patients who have not had surgery.

The role of bariatric procedures in patients outside the commonly defined age range (18 to 60 years) is not well established. It has been demonstrated that the levels of risk and benefit among obese adolescents who undergo surgery are similar to those among older patients. However, many younger patients may not have sufficient insight to appreciate the consequences of the decision to undergo surgery or to cooperate fully with follow-up care.[57] In addition, the long-term consequences of surgery are less clear in this population. For the elderly, at least one report has indicated that the benefits in terms of weight loss and improvement in coexisting conditions, although significant, are not as great as in younger patients.[58]

The changing popularity of specific bariatric surgical procedures over time suggests that the ideal procedure has not been definitively established. In the United States, the Roux-en-Y gastric bypass (open or laparoscopic) is the most common operation, but in Europe, laparoscopic adjustable gastric banding is performed more frequently.[59] Comparative studies indicate that laparoscopic gastric bypass is similar to open surgery in terms of weight loss, with fewer complications and less postoperative pain, but specific training in laparoscopic techniques is required.[60,61]

GUIDELINES

Most clinical guidelines regarding the role of bariatric surgery have followed the lead of the 1991 NIH Health Consensus Development Conference in concluding that such procedures should be considered for patients who have a BMI of 40 or more or for those who have a BMI of 35 or more with coexisting medical conditions.[22] These criteria are endorsed by the National Heart, Lung, and Blood Institute in guidelines for the treatment of obesity published in 1998[62]; they are also endorsed in more recent guidelines published by the Institute for Clinical Systems Improvement,[63] the American Society for Bariatric Surgery,[64] the European Association for Endoscopic Surgery,[65] and other organizations.[16,66-68] The American College of Physicians has adopted a somewhat more conservative approach, recommending that surgery be considered only in patients with a BMI of 40 or more who also have coexisting conditions.[69] All these guidelines generally concur that patients should have made previous attempts to lose weight, should be free of medical and psychological contraindications, and should be cared for by a multispecialty team with experience in bariatric surgery and perioperative care.

RECOMMENDATIONS

The patient described in the vignette is a candidate for bariatric surgery on the basis of her BMI and coexisting medical conditions. She should be evaluated by an experienced surgeon at a center with established expertise in bariatric procedures and should undergo a comprehensive medical, surgical, nutritional, and psychological assessment. It is important that her expectations for surgery be discussed in advance and that she re-

ceive full information about the anticipated risks and results of the operation. She should be required to make a commitment to an appropriate postoperative regimen of diet, exercise, and medical and surgical follow-up care. On the basis of my own experience, I would recommend that she undergo a laparoscopic Roux-en-Y gastric bypass, with some discussion and consideration of other surgical options. The detailed plan for her care should be discussed with her primary care physician, who should be recruited in the effort to provide the patient with appropriate preoperative and postoperative medical and psychological support.

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