Surgery for Obesity

Demand Soars Amid Scientific, Ethical Questions

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As bariatric surgery for the treatment of patients with morbid obesity surges in popularity in the United States, ethical and scientific questions about the approach are mounting.

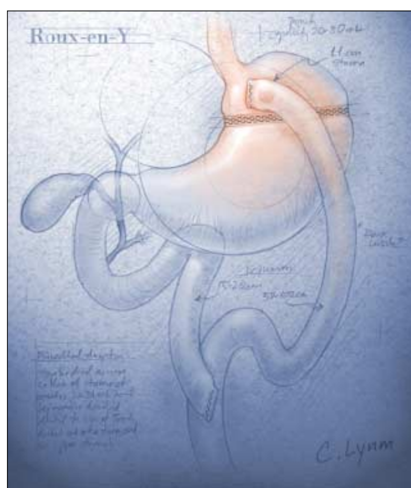
While bariatric surgery has been performed since the 1960s, improvements in laproscopic methods and a 1991 Consensus Statement by the National Institutes of Health (NIH) that established criteria for eligibility for surgical treatment of morbid obesity opened the door for insurance coverage and set the stage for an explosive increase in its use.

According to the American Society for Bariatric Surgery (ASBS), about 47 000 surgeries for treatment of morbid obesity were performed in 2001. Last year about 63 000 bariatric surgeries were performed and this year an estimated 98 000 will be done. The majority of procedures are: Roux-en-Y gastric bypass, stapled gastroplasty, and adjustable gastric banding—all of which are designed to reduce stomach size and thus control calorie intake (*JAMA*. 2002;288:2793-2796).

The NIH criteria for obesity surgery eligibility are a well informed and motivated patient with a body mass index (BMI) of greater than 40, or a patient with less severe obesity (BMI greater than 35) who has high-risk, comorbid conditions such as type 2 diabetes and cardiopulmonary problems.

YEAR-LONG WAITING LISTS

The demand for the surgery is so great that many hospitals have year-long waiting lists of hundreds of patients. In this environment, many surgeons are increasingly interested in learning the techniques to treat a patient population that is desperate for help. But coupled with this growth are scientific questions about safety and effectiveness and ethical issues such as potential conflicts of interest among surgeons.



With an estimated six million morbidly obese people in the United States—a number that continues to increase—the market for bariatric surgery is huge. Researchers last year estimated that the prevalence of extreme obesity (BMI of 40 or greater) in the United States increased from 2.9% in 1988-1994 to 4.7% by 1999-2000 (*JAMA*. 2002;288:1723-1727). The ASBS estimates that another 10 million people have BMIs between 35 and 40 with comorbidities.

Faced with this legion of patients with extreme obesity, some bariatric surgeons are performing up to 400 surgeries a year, typically receiving $1500-$2500 for the 2-hour procedures, the ASBS estimated. Anecdotally, it is reported that some surgeons are being paid $4000 for each procedure.

Also making the procedure lucrative is the willingness of people to pay cash if they do not have insurance or they have been denied coverage. However, coverage denial may becoming a thing of the past. Today, more and more insurers are covering the procedure, provided a physician determines it to be medically necessary, said a spokesperson with the Health Insurance Association of America, an industry trade association.

Add into this mix the element of advertising for patients, and some physicians begin to question whether the profession is handling this therapy properly.

"You have physicians advertising like crazy. You can't watch television without seeing an ad," said Edward H. Livingston, MD, a professor of surgery at the University of Texas Southwestern Medical Center in Dallas. "This is the highest-paying general surgical procedure there is, and a lot of patients will pay."

AVOIDING CONFLICTS OF INTEREST

To avoid conflicts of interest, bariatric surgeons should avoid self-referral of patients, and for patients they do treat, should play an active role in postoperative care, said Peter Angelos, MD, PhD, an associate professor of surgery and medical ethics and humanities at Northwestern University's Feinberg School of Medicine in Chicago.

"Every patient we [surgically] treat has been evaluated psychologically and medically by internal medicine at our wellness center before being recommended for an operation," said Angelos, who is a general surgeon, but does not perform bariatric procedures.

"I'm a little worried about any surgeon who can call himself a bariatric

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surgeon but who does not have the pre- and post-operation management and follow-up," he added. "I think this becomes a potential problem ethically."

Another crucial question in light of the explosive growth in bariatric surgery is whether the science is keeping pace with the popularity of the procedures.

Short-term outcomes are impressive—patients undergoing bariatric surgery maintain more weight loss compared with diet and exercise. Comorbidities such as type 2 diabetes can be reversed. But long-term consequences remain uncertain. Issues such as whether weight loss is maintained and the long-term effects of altering nutrient absorption remain unresolved.

GETTING ANSWERS

Walter J. Pories, MD, president of the ASBS and a professor of surgery and biochemistry at the Brody School of Medicine at East Carolina University in Greenville, NC, laid out a number of issues that need to be addressed.

"The questions are who should be treated, which operation is the best, who should be doing them, and what kind of center should this work be performed in," said Pories.

To begin answering these questions, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is establishing a Bariatric Surgery Clinical Research Consortium. The consortium, expected to be announced in September, will consist of between four and six centers generating significant data over a 5-year period by treating a large number of bariatric surgery patients (http://grants1.nih.gov/grants/guide/rfa-files/RFA-DK-03-006.html).

The NIDDK noted that some of the research questions posed by the 1991 Consensus Panel remain unanswered a decade later. These include the mechanisms whereby surgical treatment results in weight reduction, mechanisms underlying improvement in comorbid risk factors or disease, safety and efficacy of bariatric surgery in defined subgroups, safety and efficacy of different surgical procedures, and the impact of bariatric surgery on subsequent pregnancy.

"The panel also noted the need for improved reporting of surgical results, and clearer outcomes assessment, including psychosocial outcomes," the NIDDK noted.

Pories called the creation of a consortium a major step towards bolstering the science.

"There will be a large enough patient population to determine what are the best outcomes, best operations and how they can be performed with the best results," he said. "Also, the consortium should provide good research on why diabetes goes away and why a patient's emotional health does not continue to improve."

SURGICAL VS NONSURGICAL APPROACHES

Livingston said the consortium is a long time in coming, noting it has been over a decade since the 1991 NIH Consensus Conference that, beyond establishing criteria for surgery, mentioned an inadequacy of research. He also speculated that long-term results may not be as dramatic.

"We need a prospective trial comparing medical treatment to surgical for a five-year follow-up," said Livingston, who has performed about 1500 bariatric procedures. "And I believe such a trial will show we've overestimated the benefits of surgery compared with medical [treatment]."

Using behavioral therapy alone, such as dieting, or in combination with physical activity, can lead to weight losses of about 5% to 10% over 4 to 6 months. But in the majority of cases, weight gain reoccurs and any improvements in obesity-related comorbidities such as hypertension, dyslipidemia, hyperinsulinemia, and progression to diabetes are not maintained.

With surgery, weight loss usually reaches a maximum between 18 and 24 months after surgery, with mean excess weight loss at five years ranging from 48% to 74% after gastric bypass and from 50% to 60% after vertical banded gastroplasty, said the ASBS. In a case-series study of more than 600 patients following gastric bypass with a 96% follow-up, mean excess weight loss still exceeded 50% at 14 years after surgery (http://www.asbs.org./html/rationale/rationale.html).

ELIGIBILITY CRITERIA

With these kinds of statistics, along with celebrity endorsements, many patients are pleading for the surgery. And while the criteria for eligibility appear straightforward, they are not, said Pories.

"BMI is a terrible indicator [of dangerous obesity]," Pories said, citing as an example a football running back who weighs 308 pounds but has only 7% body fat—yet his BMI classifies him as morbidly obese. "We need to start to define what is . . . harmful obesity. The distribution of fat is important, as are racial differences."

And if BMI is not a good indicator of "harmful obesity," then physicians face the ethically murkier region of treating patients whose BMI is just below 40, Livingston said.

"You end up with patients increasing their weight just to qualify," Livingston said. "I knew of one patient who actually went to her weigh-in with weights concealed under her clothes."

"From a physician's perspective, the hardest thing is to say 'no' to these patients," he noted. "And I can't criticize their ethics. When [surgeons are] under such pressure from these patients, you can see them throw up their hands and say they'll do it, make more money and treat patients who have fewer complications."

The ethical haze surrounding bariatric procedures is not unknown in surgery, said Laurence B. McCullough, PhD, a professor of medicine and medical ethics at Baylor College of Medicine in Houston, Texas.

"This is the classic problem in surgery—innovation without the research to guide it. So all this should be brought under experimental protocols," McCullough said. "That's how you handle the conflict of interest—make sure you tell the patient, 'The procedure is investigational; we don't know if it will help you.'" □

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