Threshold for Bariatric Surgery in Teens Lowered

BY MITCHEL L. ZOLER

The criteria for selecting obese adolescents as candidates for bariatric surgery have loosened in recent years, say some surgeons, while other surgeons had already applied the looser criteria for several years. Now that the adolescent field has converged on a roughly uniform body mass index standard that's the same as for adults—at least 35 kg/m^2 with serious comorbidities or at least 40 kg/m^2 in other patients—surgeons have begun to consider testing an even more aggressive approach to bariatric surgery in teenagers.

The goal, they agree, is to offer bariatric surgery to adolescents (usually defined as patients aged 13-17 years) safely but at a stage when the surgery has the best potential to normalize patients' weight so that comorbidities improve and possibly resolve.

An aggressive approach may also help avoid another problem. "No one can explain why, but there is a plateauing effect of all bariatric surgery, be it gastric bypass, gastric sleeve, or gastric banding. Patients lose about 15 BMI [body mass index] points but no more," said Dr. Evan P. Nadler, director of the bariatric surgery program at Children's National Medical Center in Washington. 'The chances of getting patients near a normal body weight once they reach a BMI of 45 or 50 are quite small."

The reasons behind this limit to the effect of bariatric surgery remain elusive. Many surgeons believe that the adaptable human body kicks in a thermostatlike resetting that maintains a certain body weight starting about a year after the large initial loss following surgery. Another factor may be that many patients have lifestyle regression at some point after surgery.

Regardless of the cause, the apparent limit to weight loss for most patients suggests to pediatric surgeons that bariatric surgery has the greatest potential to normalize BMI, and thereby prevent comorbidities, when applied relatively early, before BMI grows too high and before end-organ damage is irreversible.

"If you get to younger patients, they may still be in a window of opportunity for their end-organ disease to essentially be reversed," Dr. Marc P. Michalsky said. "Our hope is that perhaps in adolescents, without decades of cardiac disease, hypertension, and liver disease, once their weight is off you may see more resolution of that disease than in adults. That's the hypothesis, but we haven't proven it yet," said Dr. Michalsky, surgical director of the center for healthy weight and nutrition at Nationwide Children's Hospital in Columbus, Ohio.

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DR. HOLTERMAN

"It's a new concept to think of surgery as preventive medicine, but it is preventive in the sense that patients have more severe comorbidities if you wait," said Dr. Ai-Xuan Holterman, director of pediatric surgery at Rush University Medical Center in Chicago.

"You could argue that in a 14-year-old who is obese but has no comorbidities, there is no urgency to do surgery. But we know what the natural trajectory of these patients will be. If a patient is older than 14 and morbidly obese, even if their comorbidities are relatively minor, I think that surgery is an appropriate option," Dr. Nadler said in an interview.

Another benefit of early surgery is that "the risk of operating on a patient at a BMI of 45 is a lot different than operating on someone with a BMI of 60," he added.

Still, U.S. studies have yet to report outcomes from bariatric surgery in adolescents at more than 3 years of follow-up.

A series of 61 patients, with an average age of 17, underwent gastric bypass surgery (Roux-en-Y) at Cincinnati Children's Hospital Medical Center between August 2002 and January 2007. The analysis showed that the average percentage of lost BMI was about 37% across all weight categories, and that two-thirds of the variance in BMI 1 year after surgery was attributable to the variance in baseline BMI (J. Pediatr. 2010;156:103-8).

The shift in surgical criteria for adolescents means that most surgeons now follow the same guidelines that have been standard for adult patients for nearly 2 decades. Serious comorbidities that lower the threshold to 35 kg/m^2 are type 2 diabetes, severe steatohepatitis, pseudotumor cerebri, or moderate to severe obstructive sleep apnea.

In 2004, a group of surgeons who at the time primarily favored gastric bypass for their adolescent patients published recommendations that called for limiting bariatric surgery for adolescents to those with a BMI of at least 40 kg/m^2 with a serious, obesity-related comorbidity or a BMI of at least 50 kg/m^2 with less severe comorbidities (Pediatrics 2004;114:217-23). Last year, a surgeon from that group, Dr. Thomas H. Inge of Cincinnati Children's Hospital, worked with a different group of collaborators to write revised criteria, which set their threshold BMI at 35 or 40 kg/m^2 depending on comorbidities (Obesity 2009;17:901-10).

All children with a BMI above the 99th percentile after age 10 had BMIs greater than 35 kg/m^2 when they were adults.

DR. PRATT

Dr. Nadler and his associates published their own endorsement for applying the adult BMI criteria for bariatric surgery to adolescents in another paper that appeared last year (J. Pediatr. Surg. 2009;44:1869-76).

"What is crucial is that you're not operating just because of BMI or weight, but that there is a compelling health indication," said Dr. Inge, surgical director of the surgical weight loss program for teens at Cincinnati Children's. He cited preliminary evidence collected by his collaborators that, for example, "the pediatric heart may be more resilient to remodeling" than an adult's heart, and more likely to return to normal following significant weight loss. "There may be a window of opportunity to act before there is more permanent damage to the heart," Dr. Inge said in an interview.

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Comorbidities that are "more or less reversible" with bariatric surgery in adolescents and are the most common indications for surgery are diabetes, sleep apnea, and nonalcoholic steatohepatitis. Others in this category include hypertension, pseudotumor cerebri, gastroesophageal reflux disease, asthma, and poor self-esteem, said Dr. Janey S.A. Pratt, a bariatric surgeon at Massachusetts General Hospital in Boston. However, she noted, other obesity-linked conditions are generally not reversible, including glomerulosclerosis of the kidney, gallstones, flat feet, major orthopedic deformities, precocious puberty, and some body-image issues.

"The most important reason to operate on obese adolescents is ... to treat or prevent the comorbidities associated with excess weight," Dr. Pratt said. "Will all of the adolescents we operate on be obese as adults?" Dr. Pratt cited results from a recent study in which 100% of children with a BMI above the 99th percentile after age 10 years had BMIs greater than 35 kg/m^2 when they were adults. ■

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Counterfeit Alli Poses Risks to Consumers, FDA Warns

BY ELIZABETH MECHCATIE

Counterfeit versions of Alli, the over-the-counter formulation of the lipase inhibitor orlistat, contain sibutramine, another weight loss agent, and could be "potentially harmful" for consumers, the Food and Drug Administration announced last month.

A statement posted on the agency's MedWatch site said orlistat manufacturer GlaxoSmithKline (GSK) had identified counterfeit versions of Alli 60-mg capsules in the 120-count refill kit that do not contain orlistat. The counterfeit products contain sibutramine, a controlled substance that is marketed as Meridia by Abbott Laboratories. Sibutramine's therapeutic effects result from norepinephrine, serotonin, and dopamine reuptake inhibition, according to the label.

Suspected reports of counterfeit Alli products were first made in December 2009. GSK has determined that the counterfeit products have been sold over the Internet and that there is no evidence the counterfeit product has been sold through retail stores or other channels.

The differences between the counterfeit product and the real product include the lot code, packaging, and expiration date: The counterfeit product does not have a "Lot" code on the outer cardboard packaging and the plastic bottle has a slightly taller and wider cap, with "coarser ribbing" than the authentic product.

In addition, the expiration date on the counterfeit product includes the month day and year—such as 06162010–while the authentic product includes the month and year only—such as 06/10. The foil that seals the opening of the counterfeit bottle has no printed words, but this safety seal on the authentic product seal is printed with "SEALED for YOUR PROTECTION." Finally, the counterfeit product contains a white powder, while the authentic capsules contain small white pellets.

Prescription orlistat is marketed as Xenical, and is available in a 120-mg dose. Alli, 60-mg, was approved for over the counter use in 2007. ■

People who believe they have a counterfeit Alli product should contact the FDA's Office of Criminal Investigations at 800-551-3989 or www.fda.gov/OCI. Adverse events should be reported to the FDA's MedWatch Program at 800-332-1088 or www.fda.gov/medwatch.