Bariatric Surgery for Obese Adolescents

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On April 16, 2007, National Institutes of Health (NIH) launched an observational study to evaluate the benefits and risks of bariatric surgery for obese adolescents.¹ The purpose of bariatric surgery is to restrict stomach size and decrease the amount of calories and nutrients the body absorbs. The Teen Longitudinal Assessment of Bariatric Surgery (LABS) study will help determine if it is an appropriate treatment option for extremely overweight teens. The information obtained from this multicenter study, called Teen-LABS, will help determine whether adolescence is a good time to intervene in obesity with this surgical therapy.

Body mass index (BMI) is a number calculated from a person's weight and height. For children and teens, BMI is age and sex specific and is often referred to as BMI for age.² BMI is intended to be an indicator of body fatness. This number is often used as an inexpensive and easy-to-perform method of screening for weight categories that may lead to health problems.

Using age- and gender-adjusted growth charts for children, overweight is defined as BMI (weight in kg/height in m²) $\geq$ 95th percentile and at risk for overweight is defined as BMI $\geq$ 85th and <95th percentile (http://www.cdc.gov/nccdphp/dnpa/bmi/childrens_BMI/about_childrens_BMI.htm). There is no agreed-upon definition for obesity in

children, although the term is often used. Healthy weight ranges cannot be provided for children and teens because healthy weight ranges change with each month of age for each sex and healthy weight ranges change as height increases.

According to the National Health and Nutrition Examination Survey, the percentage of children and teens aged 6–19 years in the United States who are overweight nearly tripled to 16% during the period of 1980–2002.³ Overweight and obese children and teens are at greater risk for many comorbid conditions, both immediate and long term. Their risk is approximately 10 times greater than that of normal weight children for hypertension in young adulthood, three to eight times greater for dyslipidemias, and more than twice as great for diabetes mellitus.⁴

In one series, approximately 60% of overweight children had a least one cardiovascular risk factor, such as elevated serum cholesterol or high blood pressure, but only 10% of children with healthy weight had at least one such risk factor. Furthermore, 25% of overweight children had two or more risk factors.⁵ Social consequences of obesity include poor self-esteem and social discrimination. Finally, in addition to the health problems they may suffer in their youth, overweight children and teens have an increased risk of developing

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Abbreviations: (BMI) body mass index; (LABS) Longitudinal Assessment of Bariatric Surgery; (NIH) National Institutes of Health

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many chronic diseases when they become adults. These chronic diseases include hypertension, type 2 diabetes, and coronary heart disease and adult obesity.⁶

In the Teen-LABS study, between 2007 and 2012, researchers will enroll 200 adolescents scheduled for bariatric surgery and compare their data to 200 adults who had bariatric surgery after being obese since their teen years. Teen-LABS will collect information on the preoperative and 2-year postoperative status of the study participants. The study will focus on outcomes of bariatric surgery in 10 areas: (1) cardiovascular risk factors and fitness; (2) metabolic markers of endocrine function; (3) sleep disorders; (4) weight loss, body fat, and body composition; (5) renal function; (6) liver function; (7) nutrient deficiencies; (8) eating habits and adherence to nutritional supplements; (9) psychosocial factors and quality of life; and (10) surgical risks. The investigators will also store serum, plasma, urine, and genetic samples for future studies.

The Teen-LABS study will not pay for the costs of bariatric surgery or patient care. Study participants must be able to support the cost of their surgery and related care through medical insurance or self-payment. To be included in this study, a subject must be an adolescent whose age is between 14 and 19 years. Younger patients might also be included.

Teen-LABS is based on the ongoing adult LABS study, which is examining the benefits and risks of bariatric surgery in extremely obese adults and its impact on their health and well-being. The LABS study was launched in 2003 at six sites and is expected to continue through 2008. This study has enrolled over 4000 subjects to date into a series of short- and long-term studies that are collecting information on patient characteristics, outcomes, and economic factors. The LABS study consists of three parts. LABS-1 includes all subjects greater than or equal to 18 years of age who have undergone bariatric surgery by LABS-certified surgeons, and this study will evaluate the short-term safety of bariatric surgery. LABS-2 includes a subset of approximately 2400 of the LABS-1 subjects, and this study will evaluate the relationship of patient and surgical characteristics to the longer term safety and efficacy of bariatric surgery. LABS-3 includes a subset of the LABS-2 subjects, and this study will examine mechanisms involved in surgical weight loss.⁷

The Teen-LABS study is being conducted by a consortium of researchers at four medical centers: Cincinnati Children's Hospital Medical Center (the Data Coordinating Center and Clinical Center); Texas

Children's Hospital, Houston; Children's Hospital of Alabama in Birmingham; and University of Pittsburgh, Pennsylvania. The consortium also intends to work with nonconsortium investigators on ancillary studies. The consortium investigators expect to test additional hypotheses that are not part of the NIH-funded core protocols by utilizing subject data from what they expect will be a large and well-characterized sample of obese adolescents.

An analysis of recent nationwide trends in the use of adolescent (age under 20 years) bariatric surgery was reported in 2007.⁸ Data were derived from the Nationwide Inpatient Sample from 1996 to 2003. The population-based annual adolescent bariatric case volume varied little between 1996 and 2000 but more than tripled from 2000 to 2003. Despite this trend, only 771 bariatric procedures were performed in adolescents in 2003, representing less than 0.7% of bariatric procedures performed nationwide. No in-hospital deaths were observed in any adolescents, whereas the investigators observed a mortality rate of 0.2% in the adult population. The authors endorsed the alignment of bariatric surgery programs for adolescents initially with high volume programs for adults.

Major complications of bariatric surgery can include obstruction, leakage, or death.⁹ The benefits of bariatric surgery in adults are that these patients typically lose more than 50% of their excess weight postoperatively and their obesity-related diseases improve markedly, leading to an increased life expectancy.¹⁰ After bariatric surgery in adults, clinical improvement or resolution has been reported in 64 to 100% of patients with diabetes mellitus, 62 to 69% of patients with hypertension, 85% of patients with obstructive sleep apnea, 60 to 100% of patients with dyslipidemia, and up to 90% of patients with nonalcoholic fatty liver disease.¹¹

It is possible that risks of bariatric surgery are lower for teens than for adults because obesity has had fewer decades to damage vital organ systems in the body. Because it appears that the surgery can be done safely in this population does not mean, however, that the surgery should be done. It has been only recently that the United States and the rest of the world as well have been confronted by an unexpected major public health threat.¹² We have experienced first a marked increase in the incidence of adolescent obesity and then we have witnessed a marked increase in the incidence of type 2 diabetes in adolescents, and now we are beginning to become aware of a newly emerging trend of utilizing bariatric surgery for reversing morbid obesity and possibly type 2 diabetes in adolescents. The benefits

of bariatric surgery for adolescents with obesity and metabolic diseases must be shown to exceed the potential morbidity and expense of this approach. Federally funded studies such as Teen-LABS are necessary to provide answers to clinical and economic questions about the benefits and drawbacks of bariatric surgery in adolescents. It will be critical to carefully monitor short- and long-term outcomes after such procedures in adolescents to ensure their safety and effectiveness.

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