

Original Investigation

Perioperative Outcomes of Adolescents Undergoing Bariatric Surgery

The Teen-Longitudinal Assessment of Bariatric Surgery (Teen-LABS) Study

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IMPORTANCE Severe obesity in childhood is a major health problem with few effective treatments. Weight-loss surgery (WLS) is being used to treat severely obese adolescents, although with very limited data regarding surgical safety for currently used, minimally invasive procedures.

OBJECTIVE To assess the preoperative clinical characteristics and perioperative safety outcomes of severely obese adolescents undergoing WLS.

DESIGN, SETTING, AND PARTICIPANTS This prospective, multisite observational study enrolled patients from February 28, 2007, through December 30, 2011. Consecutive patients aged 19 years or younger who were approved to undergo WLS (n = 277) were offered enrollment into the study at 5 academic referral centers in the United States; 13 declined participation and 22 did not undergo surgery after enrollment, thus the final analysis cohort consisted of 242 individuals. There were no withdrawals.

MAIN OUTCOMES AND MEASURES This analysis examined preoperative anthropometrics, comorbid conditions, and major and minor complications occurring within 30 days of operation. All data were collected in a standardized fashion. Reoperations and hospital readmissions were adjudicated by independent reviewers to assess relatedness to the WLS procedure.

RESULTS The mean (SD) age of participants was 17.1 (1.6) years and the median body mass index (calculated as weight in kilograms divided by height in meters squared) was 50.5. Fifty-one percent demonstrated 4 or more major comorbid conditions. Laparoscopic Roux-en-Y gastric bypass, vertical sleeve gastrectomy, and adjustable gastric banding were performed in 66%, 28%, and 6% of patients, respectively. There were no deaths during the initial hospitalization or within 30 days of operation; major complications (eg, reoperation) were seen in 19 patients (8%). Minor complications (eg, readmission for dehydration) were noted in 36 patients (15%). All reoperations and 85% of readmissions were related to WLS.

CONCLUSIONS AND RELEVANCE In this series, adolescents with severe obesity presented with abundant comorbid conditions. We observed a favorable short-term complication profile, supporting the early postoperative safety of WLS in select adolescents. Further longitudinal study of this cohort will permit accurate assessment of long-term outcomes for adolescents undergoing bariatric surgery.

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Obesity threatens the health and welfare of millions of children and adolescents, particularly the estimated 4% to 7% of youth who are considered severely obese.^{1,2} Nonsurgical weight-loss interventions rarely result in a substantial and sustained reduction in body mass index (BMI, calculated as weight in kilograms divided by height in meters squared) or resolution of comorbidities for those who are severely obese.³ The increased prevalence of obesity in children has been accompanied by an increased prevalence of obesity-related comorbidities at much younger ages than in the past including diabetes mellitus, hypertension, dyslipidemia, and nonalcoholic fatty liver disease.^{4,5} The increase in severe obesity-related comorbidities in adolescents, coupled with the present ineffectiveness of nonsurgical therapies, has resulted in increased acceptance of weight-loss surgery (WLS) as a treatment option during adolescence.^{6,7}

The volume of adolescent WLS in the United States tripled from the late 1990s to 2003 and shows no decline.^{8,9} Initial data suggest that WLS can be offered to adolescents with a reasonable expectation of safety.^{8,10-12} However, to our knowledge, few prospective or comprehensive studies have been performed to define the comorbidities, outcomes, and safety of bariatric surgery in adolescents.^{6,13} Existing reports detailing the risks of adolescent bariatric surgery have been almost exclusively retrospective analyses of large administrative data sets,^{8,10-12,14} retrospective small single-institution studies,¹⁵ and small prospective studies,^{6,13,16} all without standardization of outcome definitions and research methods.³

To address important knowledge gaps pertaining to the outcomes of adolescent bariatric surgery, the Teen-Longitudinal Assessment of Bariatric Surgery (Teen-LABS) Study (NCT00474318) was designed to collect standardized prospective preoperative and postoperative clinical and laboratory data longitudinally on adolescents undergoing WLS at 5 US centers. In this report, baseline clinical characteristics and 30-day complications were analyzed.

Methods

Study Design and Patients

The Teen-LABS Study was designed as an ancillary study to the Longitudinal Assessment of Bariatric Surgery Study (NCT00465829) and study methods have been briefly described.¹⁷ Consecutive adolescents (aged ≤ 19 years) undergoing bariatric surgery at each of 5 Teen-LABS centers between February 28, 2007, and December 30, 2011, were offered enrollment. Medical and surgical care were provided for each patient as specified by patient care pathways at each institution. No attempts were made to standardize or alter care within this observational research protocol. However, clinical decision making at the centers followed accepted guidelines including indications for operation and preoperative and postoperative management.¹⁸ All bariatric procedures were performed by surgeons who were specifically trained for study data collection (Teen-LABS-certified surgeons). The study protocol, assent/consent forms, and data and safety monitoring plans were approved by the institutional review boards of each

institution and by the independent data and safety monitoring board prior to study initiation.

Collection of Data

The standardized methods developed for the LABS-2 Study by the LABS Consortium^{19,20} were modified for an adolescent cohort. Written, informed consent was obtained from patients who were 18 or 19 years of age; written permission was obtained from caregivers and assent from the adolescent if the patient was younger than 18 years. The participants self-reported race/ethnicity. Preoperative data were collected within 30 days of operation at an in-person visit with trained study personnel. A Teen-LABS-certified clinical coordinator or surgical investigator followed standard definitions to determine the presence or absence of each comorbid condition using medical records, physical examination, patient interview, and laboratory values. Detailed descriptions of study methods, comorbidity and other data definitions, case report forms, and laboratory testing are included in the eAppendix (Supplement).

Complications

Perioperative Period

Events designated as major complications in the perioperative period included those that were life-threatening, had potential for permanent harm, resulted in organ loss (eg, splenic injury resulting in splenectomy), led to reoperation or blood transfusion, or represented a major deviation in anesthetic or operative management. Minor complications included unplanned perioperative events (eg, liver or splenic laceration, mesenteric hematoma, anastomotic revision at the time of primary operation, and injury to adjacent structures), additional testing, specific medical management, nonoral enteral feedings at the time of hospital discharge, or use of any parenteral nutrition at the time of discharge.

Discharge to 30 Days Postoperative Period

Between discharge and 30 days following surgery (postoperative), events that were life-threatening, had potential for permanent harm (eg, anticoagulation for pulmonary embolus or deep vein thrombosis), or required abdominal reoperation (including contained gastrointestinal leaks) were considered major complications. In contrast, events requiring outpatient percutaneous or endoscopic intervention, any use of nonoral enteral feeds or parenteral nutrition at 30 days after operation, or any event requiring readmission for inpatient management (without reoperation/intervention) were considered minor complications.

All reoperations and readmissions were analyzed by the Teen-LABS Adjudication Committee by review of the medical records and study data to determine relationship to the WLS (eAppendix in Supplement).

Statistical Analyses

Categorical descriptive measures were presented using frequencies and percentages. Continuous variables were summarized using measures of central tendency and dispersion. The rates of minor and major events were calculated as the number of participants with such complications within 30 days

of surgery, divided by the total number of patients (multiplied by 100%). Patients with major and minor events were only included in major complication calculations. Event estimates were calculated for the entire cohort and by procedure type. Exact binomial 95% CIs were calculated for these measures. Event counts of each complication were also tabulated. Statistical analyses were conducted using SAS version 9.3; all reported *P* values were 2-sided.

Results

Baseline Characteristics

Two hundred seventy-seven patients were offered enrollment in this study. However, 13 declined participation and 22 did not undergo operation by the study-imposed deadline, leaving a final analysis cohort of 242 participants. The 242 final study participants were similar in terms of BMI, age, and race/ethnicity to the 35 who were not studied. However, compared with the 35 not studied, the final analysis cohort was more likely to be female (*P* = .04). The 242 patients who underwent a primary WLS procedure had a mean age of 17.1 years at surgery, a median BMI of 50.5, and a median waist circumference of 145.9 cm at baseline (Table 1). Twenty-one percent had a BMI greater than 60 at the time of study enrollment. The cohort was primarily non-Hispanic (93%), white (72%), and female (76%).

Approximately one-half of participants (49%) presented with 3 or fewer comorbid conditions (conditions listed in Table 2), 39% presented with 4 or 5, and 12% presented with 6 or more. The most commonly observed comorbidities were dyslipidemia (74%), sleep apnea (57%), back and joint pain (46%), hypertension (45%), and fatty liver disease (37%) (Table 2). The most common abnormal laboratory values (not adjusted for medication use) were elevated C-reactive protein (75%), hyperinsulinemia (71%), low high-density lipoprotein (64%), and hypertriglyceridemia (40%) (eTable 1 and eTable 2 in Supplement).

Microalbuminuria was detected in 17.7% of patients, while 13.4%, 2.7%, and 3.1% met criteria²¹ for chronic kidney disease stages 1, 2, and 3, respectively. No patient met criteria for chronic kidney disease stages 4 or 5.

Surgical Findings

The most common operative procedure performed was Roux-en-Y gastric bypass (RYGB) followed by vertical sleeve gastrectomy (VSG), and adjustable gastric banding (AGB) (Table 1). There was a shift in procedure use over time, with a relative increase in patients undergoing VSG and decrease in AGB (Figure).

Within 30 days of surgery, a total of 19 patients (7.9%) experienced 20 major complications and 36 (14.9%) experienced 47 minor complications. There were no deaths. Procedure-specific rates of patients with major complications were as follows: RYGB = 9.3% (95% CI, 5.3-14.9); VSG = 4.5% (95% CI, 0.9-12.5); and AGB = 7.1% (95% CI, 0.2-33.9). Comparable rates for minor events were as follows: RYGB = 16.8% (95% CI, 11.4-23.5); VSG = 11.9% (95% CI, 5.3-22.2); and AGB = 7.1% (95% CI, 0.2-33.9).

Table 1. Demographic, Anthropometric, and Procedural Characteristics for the 242 Participants

Characteristic	No. (%)
Age at operation, mean (SD), y	17.1 (1.56)
Age group, y	
13-15	65 (26.9)
16-17	91 (37.6)
18-19	86 (35.5)
BMI, median (IQR) [range]	50.5 (45.2-58.3) [34.0-87.7]
BMI group	
<40	6 (2.5)
40-49	109 (45.0)
50-59	77 (31.8)
≥60	50 (20.7)
Female	183 (75.6)
Race/ethnicity	
White	174 (71.9)
Black	54 (22.3)
Asian	1 (0.4)
American Indian or Alaskan Native	1 (0.4)
>1 race/ethnicity	12 (5.0)
Hispanic	17 (7.0)
Waist circumference, median (IQR) [range], cm	145.9 (136.3-157.8) [112.8-194.0]
Sagittal abdominal diameter, mean (SD), cm	31.7 (4.01)
Surgical procedure	
RYGB	161 (66.5)
AGB	14 (5.8)
VSG	67 (27.7)

Abbreviations: AGB, adjustable gastric band; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); IQR, interquartile range; RYGB, Roux-en-Y gastric bypass; VSG, vertical sleeve gastrectomy.

Most of the major and minor complications occurred prior to discharge from the hospital (perioperatively; Table 3). Twelve patients (5.0%) experienced 13 major perioperative complications including 1 intraoperative splenic injury requiring conversion to an open procedure for splenectomy; 7 of these 12 underwent early reoperation for intestinal obstruction, bleeding, and confirmed or suspected gastrointestinal leak (Table 3). Nineteen patients (7.9%) experienced 20 minor perioperative complications including 4 minor injuries to solid organs at operation and 6 urinary tract events (infections and complications of urethral catheterization).

Postdischarge, 7 patients (2.9%) experienced 7 major complications and 27 (11.2%) experienced 27 minor complications (Table 4). Major complications included 2 patients with pulmonary embolus, which were treated and resolved; 2 instances of gastrointestinal leak that did not require intervention; 1 leak that required drain/stent placement; 1 leak that required subsequent abdominal operations; and 1 instance of suicidal ideation without physical harm. Among the 27 minor complications, 11 patients had abdominal/gastrointestinal complaints and dehydration, while 5 patients required upper endoscopy (Table 4).

Details for all readmission events are provided in eTable 3 in Supplement. Independent adjudication determined that 85% of readmissions were related to the original WLS procedure. Fifteen percent of readmissions were related to abdominal pain (unrelated to WLS), medication error, and elective orthopedic surgery (eTable 3 in Supplement).

Discussion

The safety of WLS is a major area of concern for families and health care providers alike, particularly as these procedures become more common. The Teen-LABS Study is the first multicenter study to collect rigorously defined prospective preoperative and postoperative data in adolescent WLS patients to assess the risks and benefits of these procedures. The ongoing study will permit characterization of longer-term outcomes in this cohort.

These initial data allowed detailed description of the health status of adolescents undergoing WLS at 5 academic medical centers and provided estimates of major and minor complications observed in the first 30 days after operation. The meth-

ods used, including review by an external adjudication committee, resulted in a complete and objective assessment of the risks facing adolescents undergoing WLS.

These data demonstrated that 92% of the 242 severely obese adolescents who underwent WLS did so without major complications. This safety profile, including a 5% rate of major inpatient morbidity, was demonstrated despite the presence of significant comorbidities and severity of obesity that exceeded that of most published adult and adolescent bariatric studies.^{6,13,22} By comparison, this is consistent with complications in 409 adolescents who underwent RYGB in California,¹⁴ where inpatient morbidity, reoperation, and readmission rates of 5.9%, 2.9%, and 11.5%, respectively, were documented. Our data were also consistent with the inpatient morbidity rate of 5.5% for 309 adolescents who underwent predominantly RYGB,¹¹ and an analysis of 771 adolescent cases in the National Inpatient Sample data set that showed a 4.2% inpatient morbidity.⁸

While these previous studies all have strengths, especially those derived from relatively large numbers, the administrative nature of much of the data has inherent limitations. In addition to replicating the 5% major inpatient morbidity rate, the Teen-LABS Study also provides estimates of less-serious complications stratified by perioperative period, and objectively documents the relatedness of readmissions to the WLS through review and adjudication by experts who do not participate in the study.

The types of complications observed in our adolescents were similar to those which would be expected for WLS in severely obese adults. Indeed, a contemporaneous, prospective, randomized trial of RYGB and VSG in adults²³ reported 30-day complication rates for RYGB and VSG of 26.5% and 14.2%, respectively. Although the Teen-LABS Study was not originally designed to compare the risks of different WLS procedures, these adult trial data are in excellent agreement with our combined total major and minor complication estimates of 26.1% and 16.4% for RYGB and VSG, respectively, in adolescents.

The second important contribution of the Teen-LABS Study is the detailed baseline phenotyping of a large cohort of severely obese adolescents. Obesity in youth is associated with development of cardiovascular risk factors.⁵ To our knowl-

Table 2. Baseline Comorbidities and Conditions

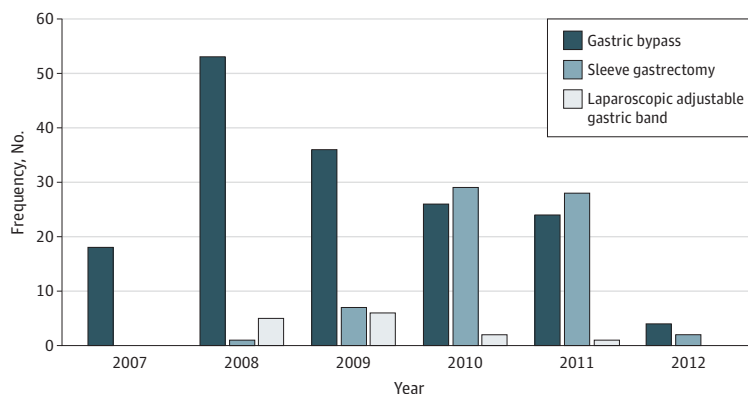
Comorbidity	No. (%)
Dyslipidemia	180 (74.4)
Sleep apnea	137 (56.6)
Joint pain ^a	110 (45.6)
Hypertension	109 (45.0)
Back pain ^a	109 (45.2)
Fatty liver disease ^a	89 (36.9)
PCOS, females only	38 (20.9)
Chronic kidney disease, any stage ^b	43 (19.2)
Diabetes mellitus	33 (13.6)
Blount disease	9 (3.7)
Pseudotumor cerebri	6 (2.5)

Abbreviation: PCOS, polycystic ovary syndrome.

^a Denominator = 241 (<242 owing to missing data).

^b Denominator = 224 (<242 owing to missing laboratory data).

Figure. Surgical Procedure Type by Year



The graph shows the trend in use of the 3 surgical procedures over time.

Table 3. Characteristics and Complications in the Perioperative Period^a

Characteristic	No. (%)			
	Bypass (n = 161)	Band (n = 14)	Sleeve (n = 67)	Total (n = 242)
Length of stay, median (IQR), d	3.0 (2-4)	1.0 (1-2)	3.0 (3-4)	3.0 (2-4)
Operative technique				
Laparoscopic	160 (99.4)	14 (100.0)	67 (100.0)	241 (99.6)
Laparoscopic converted to open	1 (0.6)	0	0	1 (0.4)
Open	0	0	0	0
Perioperative complications				
Major complications			0	
Reoperation for bowel obstruction/bleeding	3 (1.9)	0	0	3 (1.2)
Reoperation for GI leak/sepsis	2 (1.2)	0	1 (1.5)	3 (1.2)
Reoperation for suspected sepsis	1 (0.6)	0	0	1 (0.4)
Postoperative bleeding, transfusion required	4 (2.5)	0	0	4 (1.7)
Anticoagulation therapy for DVT	1 (0.6)	0	0	1 (0.4)
Unplanned splenectomy for injury	1 (0.6)	0	0	1 (0.4)
Minor complications			0	
GI leak, minimal	1 (0.6)	0	0	1 (0.4)
Postoperative bleeding, no transfusion	2 (1.2)	0	0	2 (0.8)
Atelectasis/pneumonia	1 (0.6)	0	1 (1.5)	2 (0.8)
Urinary tract events	5 (3.1)	0	1 (1.5)	6 (2.5)
Bowel injury	1 (0.6)	0	0	1 (0.4)
Solid organ injury	1 (0.6)	1 (7.1)	2 (3.0)	4 (1.7)
Mesenteric bleeding/hematoma	2 (1.2)	0	0	2 (0.8)
Oversedation	0	0	1 (1.5)	1 (0.4)
Hypertension	0	0	1 (1.5)	1 (0.4)

Abbreviations: DVT, deep vein thrombosis; GI, gastrointestinal; IQR, Interquartile range.

^a Perioperative complications were categorized into major (life-threatening events) and minor (nonlife-threatening but unplanned events) types. The percentage of total participants with 1 or more of these complications is shown.

Table 4. Postoperative Characteristics and Complications Between Discharge and 30 Days^a

Characteristic	No. (%)			
	Bypass (n = 161)	Band (n = 14)	Sleeve (n = 67)	Total (n = 242)
Deaths	0	0	0	0
Discharged home	161 (100.0)	14 (100.0)	67 (100.0)	242 (100.0)
Major complications				
Anticoagulation therapy for pulmonary embolus	1 (0.6)	1 (7.1)	0	2 (0.8)
GI leaks not requiring reoperation	2 (1.2)	0	0	2 (0.8)
Suicidal ideation	0	0	1 (1.5)	1 (0.4)
GI leaks requiring reoperation	1 (0.6)	0	1 (1.5)	2 (0.8)
Minor complications				
Any TPN or enteral feeds after discharge	0	0	1 (1.5)	1 (0.4)
Gastrojejunal anastomotic stricture	6 (3.7)	0	0	6 (2.5)
Wound infection	3 (1.9)	0	2 (3.0)	5 (2.1)
Small-bowel obstruction/ileus	1 (0.6)	1 (7.1)	0	2 (0.8)
Abdominal pain/dehydration/diarrhea/nausea	9 (5.6)	0	2 (3.0)	11 (4.5)
Acute pancreatitis	1 (0.6)	0	0	1 (0.4)
Urinary tract infection	1 (0.6)	0	0	1 (0.4)

Abbreviations: GI, gastrointestinal; TPN, total parenteral nutrition.

^a Postoperative complications were categorized into major (life-threatening, potential for permanent harm, abdominal reoperation required) and minor (outpatient percutaneous or endoscopic intervention, supplemental nutrition required, or any event requiring readmission for inpatient management [without reoperation/intervention]) types. The percentage of total participants with 1 or more of these complications is shown.

edge, few prior studies have been able to shed light on the objective laboratory measures of cardiovascular risk and general health status of adolescents who are on average greater than 2-fold heavier than ideal weight. Nationally representative data demonstrate prevalence rates of hypertension, high low-density lipoprotein cholesterol, and low high-density lipoprotein cholesterol of 3%, 8%, and 3%, respectively, in

adolescents.²⁴ In comparison, our data suggest that in the setting of severe obesity in a select, referral population, these conditions may be expected in as many as 45%, 8.5%, and 64% of patients, respectively.

An unexpected but concerning finding of this study was the high prevalence of other factors that were not considered clinical selection criteria. For instance, we found evidence of

systemic inflammation (elevated high-sensitivity C-reactive protein) in more than three-quarters of our participants, a finding thought to be a potential link between obesity, cardiovascular disease, and a prothrombotic state.²⁵ In addition, 19% of participants demonstrated objective evidence of abnormal kidney function. Although ascertainment of urine protein was not done with the first morning void, these data are concerning, especially in light of other data suggesting that obesity is an independent risk factor for kidney impairment,²⁶ even in pediatric age groups.²⁷ Further studies are needed to assess predictors of renal dysfunction in severely obese youth.

The strengths of the Teen-LABS Study included multisite enrollment of consecutive patients, standardized prospective data collection by trained research staff during current clinical practice in 5 centers using several bariatric surgical procedures, an infrastructure that facilitated ancillary investigation of questions about severe pediatric obesity and surgical intervention, and the ability to compare outcomes with a large adult cohort with the same study design. In addition, this study suggests hypotheses and provides preliminary data for future, focused projects. The sample size and observational design without standardization of surgical technique and clinical care restrict interpretation of infrequent complications, while the study's lack of ethnic diversity limits generalizabil-

ity. However, the study does provide information about the types of complications to be expected with frequency estimates for the procedures used.

In conclusion, we prospectively and comprehensively characterized the baseline phenotype and described the safety of WLS procedures when performed in severely obese adolescents. The findings highlight the presence of both overt comorbidities and less-obvious indicators of organ dysfunction at baseline, and they indicate that WLS procedure selection has evolved over time. The fact that major, life-threatening complications were infrequently observed documents the short-term safety of these procedures in this patient population. Clinical data and saved biospecimens from this cohort²⁸ will provide materials for more in-depth ancillary studies of obesity-related disease and response to surgical therapy in adolescents. Furthermore, the psychosocial health and behaviors of the adolescent patient are important considerations and, as such, the Teen-LABS Consortium is also addressing key psychosocial questions, which will be published separately. These studies should help to inform patient evaluation and management. Longitudinal data from this cohort will inform us about the effects of surgery on comorbidities, physical/metabolic health and health-related quality-of-life changes, nutritional effects, and durability of weight loss.

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Author Contributions: Dr Jenkins had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Study supervision: Inge, Zeller, Brandt, Michalsky, Harmon, Xanthakos, Dolan, Barnett.

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