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Laparoscopic Adjustable Gastric Banding in Severely Obese Adolescents

A Randomized Trial

Paul E. O'Brien, MD, FRACS
Susan M. Sawyer, MBBS, MD, FRACP
Cheryl Laurie, RN, BHSc
Wendy A. Brown, MBBS, PhD, FRACS
Stewart Skinner, MBBS, PhD, FRACS
Friederike Veit, MBBS, MD, FRACP
Eldho Paul, MSc
Paul R. Burton, MBBS, FRACS
Melanie McGrice, BSc, M Nutr Diet
Margaret Anderson, BHIM, Grad Dip HA
John B. Dixon, MBBS, PhD, FRACGP

Context Adolescent obesity is a common and serious health problem affecting more than 5 million young people in the United States alone. Bariatric surgery is being evaluated as a possible treatment option. Laparoscopic adjustable gastric banding (gastric banding) has the potential to provide a safe and effective treatment.

Objective To compare the outcomes of gastric banding with an optimal lifestyle program on adolescent obesity.

Design, Setting, and Patients A prospective, randomized controlled trial of 50 adolescents between 14 and 18 years with a body mass index (BMI) higher than 35, recruited from the Melbourne, Australia, community, assigned either to a supervised lifestyle intervention or to undergo gastric banding, and followed up for 2 years. The study was performed between May 2005 and September 2008.

Main Outcome Measures Weight loss. Secondary outcomes included change in metabolic syndrome, insulin resistance, quality of life, and adverse outcomes.

Results Twenty-four of 25 patients in the gastric banding group and 18 of 25 in lifestyle group completed the study. Twenty-one (84%) in the gastric banding and 3 (12%) in the lifestyle groups lost more than 50% of excess weight, corrected for age. Overall, the mean changes in the gastric banding group were a weight loss of 34.6 kg (95% CI, 30.2-39.0), representing an excess weight loss of 78.8% (95% CI, 66.6%-91.0%), 12.7 BMI units (95% CI, 11.3-14.2), and a BMI *z* score change from 2.39 (95% CI, 2.05-2.73) to 1.32 (95% CI, 0.98-1.66). The mean losses in the lifestyle group were 3.0 kg (95% CI, 2.1-8.1), representing excess weight loss of 13.2% (95% CI, 2.6%-21.0%), 1.3 BMI units (95% CI, 0.4-2.9), and a BMI *z* score change from 2.41 (95% CI, 2.21-2.66) to 2.26 (95% CI, 1.91-2.43). At entry, 9 participants (36%) in the gastric banding group and 10 (40%) in the lifestyle group had the metabolic syndrome. At 24 months, none of the gastric banding group had the metabolic syndrome ($P=.008$; McNemar χ^2) compared with 4 of the 18 completers (22%) in the lifestyle group ($P=.13$). The gastric banding group experienced improved quality of life with no perioperative adverse events. However, 8 operations (33%) were required in 7 patients for revisional procedures either for proximal pouch dilatation or tubing injury during follow-up.

Conclusions Among obese adolescent participants, use of gastric banding compared with lifestyle intervention resulted in a greater percentage achieving a loss of 50% of excess weight, corrected for age. There were associated benefits to health and quality of life.

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ADOLESCENT OBESITY IS A serious health challenge globally affecting both high- and middle-income countries.[1] More than 17.4%, or more than 5 million, adolescents in the United State were obese in 2004, an increase from 14.8% in 2000.[2] It is associated with both immediate and late health effects.[3,4] Type 2 diabetes in adolescents has increased more than 10-fold in prevalence over the last 2 decades.[5] Diseases commonly associated with the metabolic syndrome, such as obstructive sleep apnea, hypertension, dyslipidemia, polycystic ovary syndrome, and nonalcoholic steatohepatitis, were previously almost unknown in adolescence but are now commonplace,[3-6] as are serious psychosocial disabilities.[6,7] Life expectancy for obese adolescents is reduced.[7,8]

See also p 559 and Patient Page.

CME available online at www.jamaarchivescme.com and questions on p 568.

Author Affiliations are listed at the end of this article.
Corresponding Author: Paul E. O'Brien, MD, FRACS, Centre for Obesity Research and Education, Monash University Medical School, Alfred Hospital, Melbourne, 3004, Australia (paul.obrien@med.monash.edu.au).

Systematic reviews of lifestyle programs addressing changes in diet, exercise, and behavior to promote weight loss have found mostly poor results.[9] A recent Cochrane[10] collaboration meta-analysis that included 17 randomized controlled trials (RCTs) of lifestyle programs involving adolescents suggested that adolescents experienced modest weight reduction for up to 12 months and weight regain afterward. Methodological heterogeneity, inadequate sample size, and short-term follow-up reduced the quality of the studies precluding a calculation of an estimated mean effect.

Bariatric surgery is now extensively used for adults and is being evaluated for adolescents.[11] The most common procedures are laparoscopic adjustable gastric banding (gastric banding) and Roux-en-Y gastric bypass (gastric bypass) surgery. Randomized controlled trials involving adults have shown gastric banding to be more effective and cost-effective than optimal lifestyle treatment.[12-14] Gastric banding has been proposed for treating obese adolescents.[15] A systematic review of bariatric surgery—8 studies involving 352 adolescents who underwent gastric banding and 6 studies involving 131 adolescents who underwent gastric bypass—reported observational data, which by its nature precludes making definitive conclusions about whether adolescents would benefit from bariatric surgery.[15] Thus, a need exists for appropriately controlled RCTs to investigate whether surgical procedures would benefit adolescents.[11,16]

We hypothesized that gastric banding would induce more weight loss and would provide greater health benefits and better improvement in the quality of life of obese adolescents than the optimal application of the currently available lifestyle approaches. To test this hypothesis, we conducted a prospective, randomized controlled trial in a group of severely obese adolescents.

METHODS

Participants

The trial was conducted between May 2005 and September 2008 in Melbourne, Australia. Participants were recruited from the community through newspaper advertisements. Eligibility criteria included age between 14 and 18 years; body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) greater than 35; identifiable medical complications such as hypertension, metabolic syndrome, asthma, back pain; physical limitations such as an inability to play a sport, difficulties with activities of daily living; or psychosocial difficulties such as isolation or low self-esteem, subject to bullying that stems from obesity and evidence of attempts to lose weight by lifestyle means for more than 3 years. Participants and their parents were informed of the 2 study groups and consented to randomization to either treatment program. We excluded 3 applicants with intellectual disability and 1 with Prader Willi syndrome.

Consultations and adjustments of the gastric banding were carried out at a community clinic dedicated to obesity management or at a special clinic at the Centre for Adolescent Health, Royal Children's Hospital. Gastric banding procedures were conducted at a private hospital. Patients did not pay any medical costs. The study was approved by the human ethics committees of Monash University, the Royal Children's Hospital, and the Avenue Hospital, in accordance with the guidelines of the National Health and Medical Research Council of 1999, as revised in 2007 (available at http://www.nhmrc.gov.au/publications/synopses/e35syn.htm).

Assessment, Initial Program, and Randomization

At initial telephone contact, potential participants and their families were invited to attend a patient information session followed by a clinical assessment by 2 physicians experienced in the management of obesity in adolescents. At this time, the nature of the study and the proposed management of the 2 study groups was carefully explained, and the suitability of the participant was clarified. Participants were asked to complete a 2-week food diary, record activity for 2 weeks using a pedometer, and complete several questionnaires. A second consultation occurred no less than 4 weeks later with a detailed clinical assessment, confirmation of satisfactory completion of the tasks, and further discussion of the trial methods. Clinical assessment included measurement of weight and height, neck, waist, and hip circumference; history of the weight disorder; and diet and weight loss efforts. Clinical features of comorbidities of obesity were sought. Laboratory analyses included fasting blood glucose, serum insulin, C-peptide, hemoglobin A_{1c}, iron status, liver function tests, lipids, and thyroid function tests.

Potential participants undertook a 2-month program that involved best practice recommendations around eating and physical activity. At a third clinical appointment, the randomization process was again explained and the consent form was signed by the participant and the parent or guardian. After a cooling-off period of 7 days, the desire to enter the study was reconfirmed and randomization was performed using a computer-derived random allocation sequence to allow orderly admission into both programs. There was no stratification or blocking, and the study was not blinded.

Lifestyle Program

This program centered on reduced energy intake (individualized diet plans ranging between 800 and 2000 kcal/d, depending on age and weight status), increased activity (target of >10 000 steps per day on pedometer) with a structured exercise schedule of at least 30 minutes a day and behavioral modification. Compliance was monitored intermittently with food diaries and step counts. Consultation occurred approximately every 6

weeks throughout the 24-month study period by an adolescent physician and a dietitian or exercise consultant, the study nurse coordinator, and a sports medicine physician.

The participant's family was included in activities and education where appropriate. Exercise and activity recommendations included decrease of sedentary activities with a limit of 2-hour computer or television screen time, increase of formal exercise including bicycle riding, walking, and swimming plus informal individual and group activities. Group outings to fun parks, bike rides, hiking trips, walking, jogging, kickboxing, indoor bowling, and outdoor reunions were scheduled. A personal trainer was provided to each participant for a 6-week period. Parents were invited to participate in a specific educational program that included sports motivational talks, nutritional education, and discussions of the psychological aspects of adolescence.

Gastric Banding Program

Participants in the gastric banding group had the procedure performed within a month of randomization. The LAP-BAND Adjustable Gastric Banding system (Allergan, Irvine, California) was used in all cases. Detailed instructions on the requirements for correct eating and exercise after gastric banding were provided by discussion as well as in written form before the procedure. Eating rules centered on having 3 or fewer small (approximately 125 mL), protein-containing meals per day, eaten slowly (1 min/bite) and chewed well. Each participant was encouraged to undertake at least 30 minutes of formal exercise per day and to maintain a high level of activity through the day. Clinical reviews were conducted approximately every 6 weeks for 2 years by experienced medical staff. Adjustments to the volume of fluid in the band were conducted in the office, without use of x-ray imaging, based on weight loss, sense of satiety, and eating pattern and symptoms.[17]

Outcome Measures

The primary end point of the study was whether participants could lose 50% excess weight. We used the Centers for Disease Control and Prevention (CDC) growth charts[18] and defined excess weight as the weight above the 85th percentile of BMI for age and sex. We calculated the total weight loss (kg), percentage of total weight lost, percentage of excess weight lost, change in BMI, and BMI *z* score.[19] BMI *z* scores are the number of standard deviations that a patient's BMI deviates from the reference mean BMI for that age group. Anthropometric measures included neck, waist, and hip circumference. Adjustment for change in height was made when appropriate. Secondary end points were health, quality of life, and adverse events resulting from treatment or from failure of compliance with the protocol. Health status was documented by clinical assessment and investigations at the initial assessment before randomization, and at 12 and 24 months after randomization.

We defined the metabolic syndrome by the age-specific adolescent criteria of Joliffe and Janssen[20] linked to the Adult Treatment Panel III[21] criteria. The definition of hypertension was adjusted for age.[22] Insulin sensitivity and pancreatic β-cell function were measured to estimate risk of diabetes, and we used the homeostatic model assessment (HOMA)[23] incorporating computer-derived nonlinear solutions.[24] HOMA correlates closely to insulin resistance as measured by euglycemic clamp.[25] We used a HOMA insulin resistance value of 2.6 as the upper limit of normal.[26] Adverse events included perioperative complications, revisional or other gastric banding procedures, protocol violations, adverse drug or treatment effects, hospitalizations, new disease diagnoses, and loss to follow-up.

We measured quality of life using the Child Health Questionnaire (CHQ CF-50).[27] This has been tested and standardized in more than 17 countries including Australia.[28] The questionnaire was administered to each adolescent alone, prior to randomization, and at 2 years after entry. The CHQ CF-50 has 11 validated subscores.[29] Each item was scored and transformed into 10 final subscores with values ranging from 0 to 100, and 1 subscore (change of health) with 5 levels.

Statistical Analysis

Sample Size. The study was powered assuming that, using an intention-to-treat analysis, more than 60% of patients of the gastric banding group would achieve an excess weight loss of more than 50% at 2 years[30] and that less than 10% of the lifestyle group would achieve this weight loss. Using these expected proportions, we required 17 participants in each the study group to provide an 80% power and a 2-sided *P* value of .05. On the basis of a possible loss of 30% after randomization, 50 adolescents were recruited.

Data Analysis. We analyzed the weight change data according to the patient's randomly assigned program (intention-to-treat analysis) and used completer's analysis for the health and quality of life data. Demographic data were compared using the χ^2 test, independent sample *t* test, or Wilcoxon rank-sum test, as appropriate. Comparative outcomes of follow-up data of anthropometry, blood pressure, quality of life, and biochemistry were analyzed using the McNemar χ^2 test for categorical data and *t* test for paired samples for continuous data. All tests were 2-sided. The laboratory and questionnaire represent data provided by only those who completed. SPSS statistical software 16 (SPSS Inc, Chicago, Illinois) and SAS software version 9.1 (SAS Institute Inc, Cary, North Carolina) were used for statistical analysis.[31] No adjustments were made to account for multiple secondary outcome comparisons. A 2-tailed *P* value of less than .05 was considered significant.

Longitudinal data analysis was performed using SAS software to estimate weight measures allowing for missing data. This analysis was performed using the PROC MIXED procedure in SAS

Figure 1. Participant Flowchart

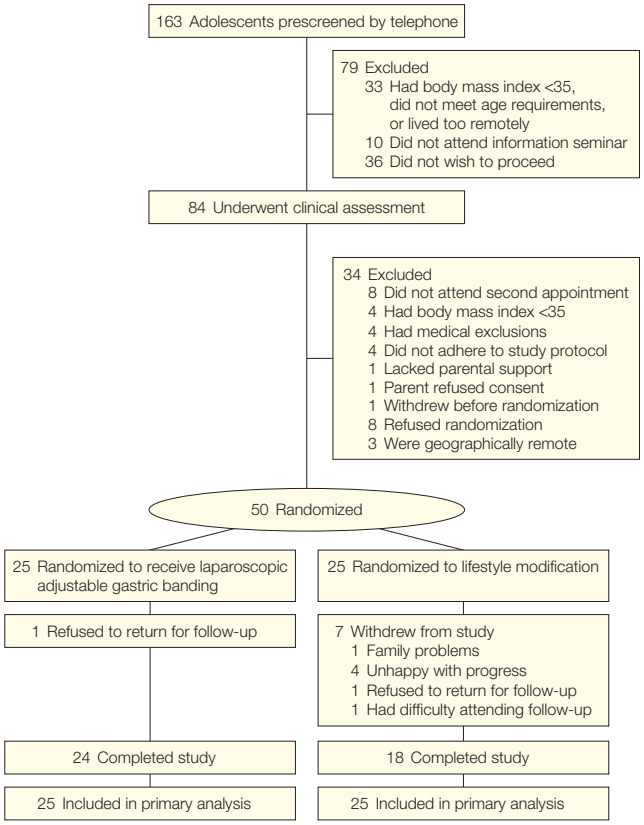


Table 1. Baseline Characteristics of Participants[a]

Characteristic	Laparoscopic Adjustable Gastric Banding Group (n = 25)	Lifestyle Group (n = 25)	*P* Value
Age, y	16.5 (1.4)	16.6 (1.2)	.78
Male sex, No. (%)	9 (36.0)	7 (28.0)	.54
BMI	42.3 (6.1)	40.4 (3.1)	.18
BMI percentile	99.25 (0.51)	99.20 (0.43)	.19
z Score	2.54 (0.31)	2.46 (0.22)	.37
Weight, kg	120.7 (25.3)	115.4 (14.0)	.37
Waist circumference, cm	120.8 (14.2)	118.1 (10.6)	.45
Blood pressure, mm Hg			
Systolic	122.0 (13.9)	132.8 (15.9)	.01
Diastolic	72.4 (7.5)	76.5 (10.5)	.12
Plasma glucose, mg/dL	89 (20)	82 (7.2)	.07
Plasma insulin, μIU/mL	23.4 (10.6)	26.1 (13.3)	.43
HOMA, median (IQR), %			
Insulin sensitivity	35 (29.9-49.4)	35.5 (23.5-50.6)	.59
β-Cell function	210 (13.7)	255 (17.1)	.048
Total cholesterol, mg/dL	173 (27)	178 (27)	.53
Triglycerides, mg/dL	124 (44)	141 (141)	.50
HDL-C, mg/dL	46 (12)	46 (8)	.82
Metabolic syndrome, No. (%)	9 (36)	10 (40)	.77

Abbreviations: BMI, body mass index, calculated as weight in kilograms divided by height in meters squared; HDL-C, high-density lipoprotein cholesterol; HOMA, homeostasis model assessment; IQR, interquartile range.
SI conversion factors: to convert total cholesterol and HDL-C from mg/dL to mmol/L, multiply by 0.0259 and triglycerides from mg/dL to mmol/L, multiply by 0.0113.
[a]Data are presented as mean (SD), unless otherwise indicated.

with each participant treated as a random effect. Main fixed effects of the treatment and time were fitted to the model with changes over time determined by an interaction between treatment and time. To facilitate specific comparisons, time was treated as a categorical variable. Age, sex, and baseline weight were considered as potential covariates, with baseline weight being the only variable found to be statistically significant. All observed data were considered for analysis, with the mixed-effects models assuming noninformative dropout such that the probability of dropout may depend on a participant's previous response but not on current or future responses.[32]

RESULTS

Study Participants

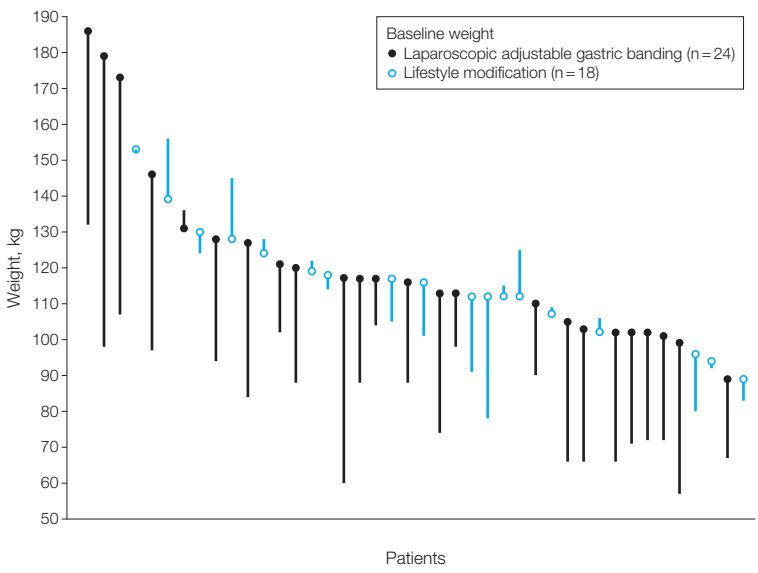
The flow of participants through each stage of the study is shown in FIGURE 1. Twenty-four of 25 participants in the gastric banding group and 18 of 25 in the lifestyle group completed the study. The baseline characteristics of the 2 groups are shown in TABLE 1. There were no statistically significant differences in demographics, anthropometric, clinical, or biochemical values except for higher systolic blood pressure and HOMA β-cell value in the lifestyle group (Table 1). The participants were at a mean of 99⅓ BMI percentile (range, 97.9-99.9) according to growth charts.[18] Extreme obesity (>99th percentile) was present in all but 4 participants. The participants showed physiological maturity with secondary sexual characteristics in all and most had completed bone growth. The mean increase in height during the 24-month study period was 1.4 cm. Recruitment began in May 2005. All patients were randomly assigned by August 2006. The final patient follow-up was completed in September 2008.

Weight Loss

The primary outcome of greater than 50% of excess weight loss was achieved by 21 of the 25 participants (84%) in the gastric banding group and 3 of 25

(12%) in the lifestyle group. The eFigure (available at http://www.jama.com) shows the weight loss, as change in BMI, percentage of total weight loss, and the BMI *z* score. At 2 years the gastric banding group had lost a mean of 34.6 kg (95% CI, 30.2-39.0). This represents an overall mean loss of 28.3% (95% CI, 24.9%-31.7%) total body weight, 78.8% (95% CI, 66.6%-91.0%) excess weight loss, and 12.7 BMI units (95% CI, 11.3-14.2). The BMI *z* score decreased from 2.39 to 1.32, a mean difference of 1.08 (95% CI, 0.86-1.31). The lifestyle group lost a mean 3.0 kg (95% CI, 2.1-8.1), which represents a mean 3.1% (95% CI, 0.7%-6.8%) total weight loss, 13.2% (95% CI, 2.6%-21.0%) excess weight loss, and 1.3 BMI units (95% CI, 0.4-2.9). The BMI *z* score for this group decreased from 2.41 to 2.26, a mean difference of 0.23 (95% CI, 0.05-0.39). The differences between groups was significant for all weight measures at 24 months ($P<.001$). All analyses are based on intention-to-treat model. FIGURE 2 shows the weight change of each participant that ranged from a loss of 81.4 kg to a weight gain of 17.0 kg.

Figure 2. Individual Weight Change at 2 Years



Each line segment indicates the weight change for each study participant and are ordered by baseline weight (highest to lowest). Baseline weight is indicated by a round data marker; final weight, by the opposite end of the line segment.

Markers of Increased Health Risk

At study entry, 19 of the 50 participants (38%) had the metabolic syndrome. Nine (36%) of these were in the gastric banding group and 10 (40%) in the lifestyle group. All participants had central obesity, 27 (54%) had hypertension, 22 (44%) had an abnormally low level of high-density lipoprotein cholesterol, 13 (26%) had elevated triglyceride levels, and 1 had an elevated fasting blood glucose level. The values for these measures are shown for each group in Table 1. At 24 months, none of the 24 completers in the gastric banding group had the metabolic syndrome ($P<.008$; McNemar χ^2). Four of the 18 completers in the lifestyle group still had metabolic syndrome. The proportions with metabolic syndrome were different between groups at 24 months ($P=.025$, Fisher exact test).

HOMA insulin resistance, the reciprocal of HOMA insulin sensitivity percentage and an established estimate of insulin resistance,[25] was abnormally high in 28 participants (56%) at study commencement, with a mean (SD) of 3.06 (1.5). After 2 years, the gastric banding group reduced this to 1.04 (0.6) with no abnormal values, while the lifestyle group reduced to 2.06 (1.3) with 11% still elevated at study completion. The improvement of insulin sensitivity in the gastric banding group (TABLE 2) was greater than in the lifestyle group ($P<.001$). β-Cell function or insulin secretion, as estimated by total HOMA β-cell function, was elevated at study entry in both groups and decreased in line with improved insulin sensitivity (Table 2).

Clinical and Adverse Events

Gastric Banding Group. The gastric banding placement occurred without any complications during the perioperative period or within 30 days. The mean length of hospital stay was 26 hours (range, 23-32 hours). The gastric banding group had a mean of 20.4 visits (range, 10-31) during the 2-year follow-up and had 9.5 adjustments made to the volume of saline in the band (range, 5-18). Twelve participants (48%) experienced a total of 13 adverse events in the gastric banding group (TABLE 3), 8 of which required a revisional procedure among 7 patients (28%) during the 2-year period. Six proximal pouch dilatations caused symptoms of heartburn, reflux, or vomiting, and 2 needlestick injuries to tubing. Revision consisted of removal and replacement of the band or replacement of the access port. These procedures occurred without complication, and the length of stay was less than 24 hours. This subgroup had a mean (SD) weight loss of 83.3% (9.9%) of excess weight loss at 2 years, which did not differ from the 77.7 % (37%) excess weight loss among the rest of the members of the gastric banding group. One patient developed acute cholecystitis treated by cholecystectomy. Another patient, who had depression and trichotillomania at study entry, required hospital admission for depression at 8 months of follow-up, subsequent to parental divorce. There were 2 pregnancies. One ended at 6 weeks from spontaneous abortion, while the other

delivered a healthy infant after completion of the study. There was 1 loss to follow-up.

Lifestyle Group. Adolescents visited the adolescent physician, study dietitian, study nurse practitioner, or other physicians a mean 15.5 (range, 7-31) times. There was also a mean of 5 telephone consultations per patient and each participant had 6 sessions with a personal trainer. Eighteen adverse events occurred in 11 participants (44%; Table 3). Seven patients withdrew from the study (Figure 1). Six had gained weight at the time of withdrawal.

One patient had 8 hospital admissions for headache, depression, and tonsillitis. After multiple psychiatric assessments and 3 lumbar punctures, the diagnoses of bipolar disorder and benign intracranial hypertension were made just prior to completion of the study. One patient required cholecystectomy for cholelithiasis. There were 2 pregnancies. One had a termination of pregnancy, while the other delivered a healthy infant.

Table 2. Changes in Cardiovascular Risk End Points at 2 Years[a]

Change in Variable	Laparoscopic Adjustable Gastric Banding Group (n = 24)	Lifestyle Group (n = 18)	Between-Group Difference, Mean (95% Confidence Interval)	*P* Value[b]
Waist circumference, cm	−28.2 (12.4)	−3.5 (14.6)	−24.7 (−33.1 to −16.3)	<.001
P value	<.001	.32		
Blood pressure systolic, mm Hg	−12.5 (17.6)	−20.3 (21.7)	7.8 (−4.5 to 20.1)	.21
P value	<.002	<.001		
Diastolic, mm Hg	−6.0 (9.4)	−6.9 (12.5)	0.9 (−5.9 to 7.7)	.79
P value	<.01	<.03		
Plasma glucose, mg/dL	−6.8 (20)	2.8 (9)	−9.6 (−18.6 to 2.3)	.13
P value	.11	.46		
Plasma insulin, μIU/mL	−15.2 (10.1)	−11.2 (11.0)	−4.0 (−10.8 to 2.8)	.24
P value	<.001	<.001		
HOMA insulin sensitivity, %	89 (71)	14.6 (48)	74.6 (116 to 33)	.001
P value	<.001	.26		
HOMA β-cell function, %	−95.4 (70)	−74.9 (88,5)	−20.5 (31 to −72)	.43
P value	<.001	.006		
Triglycerides, mg/dL	−52 (38)	−32 (83)	−20 (59 to 18)	.29
P value	<.001	.12		
HDL cholesterol, mg/dL	9.3 (14.7)	3.9 (6)	5.4 (3.5 to 14)	.22
P value	<.005	.18		
Metabolic syndrome, No.	0	4	78	.03
P value	.008	.12		

Abbreviations: HDL, high-density lipoprotein; HOMA, homeostasis model assessment.
SI conversion factors: to convert HDL cholesterol from mg/dL to mmol/L, multiply by 0.0259 and triglycerides from mg/dL to mmol/L, multiply by 0.0113.
[a]Data are presented as mean (SD) unless otherwise indicated. See Table 1 for baseline values.
[b]*P* values are for the difference between groups. All other *P* values are for within group differences.

Table 3. Adverse Events

Adverse Event	No. of Events (% of Patients)
Laparoscopic adjustable gastric banding group (n = 25)	
Total No. of events/participants (%)	13/12 (48)
Event	
Proximal gastric enlargements	6 (24)
Needle stick injury to tubing	2 (8)
Cholecystectomy	1 (4)
Hospital admission for depression	1 (4)
Lost to follow-up	1(4)
Unplanned pregnancy	2 (8)
Lifestyle group (n = 25)	
Total No. of events/participants (%)	18/11 (44)
Event	
Hospital admission for depression and intracranial hypertension event/No. of participants (%)	8/1 (4)
Cholecystectomy	1 (4)
Loss to follow-up	7 (28)
Unplanned pregnancy	2 (8)

Quality of Life Measures

Eight of the subscores of the CHQ are shown in the eTable (available at http://www.jama.com) in which values are compared with community norms derived from Australian data.[33] The subscores for behavioral, emotional, and physical limitations are not shown because these did not differ from community values at entry into the study and were not different within or between groups over the 2-year follow-up period. No significant differences existed in any measures between groups at the commencement of the study. At follow-up, the gastric banding group showed improvements in physical functioning, general health, self-esteem, family activities, and change in health. Both groups experienced significant improvement in general health. Both groups had 6 subscores below the community norm at commencement. At 2 years, members of the lifestyle group scored lower than the community norm for general behavior, general health, physical functioning, and self-esteem, whereas the gastric banding group remained below the community mean for general behavior and family cohesion but significantly higher for change in health and family activities. No changes occurred for either group in general behavior, mental health, or family cohesion during the study.

COMMENT

In this randomized controlled trial of treatment with the gastric banding procedure vs a lifestyle weight loss pro-

gram for adolescents with severe obesity, weight measures and health status improved in both study groups. However, the extent of the weight loss was substantially greater for those in the gastric banding group, which also showed improved health with complete resolution of the metabolic syndrome and insulin resistance and quality of life as measured by the CHQ.

Despite a comprehensive, behaviorally focused intervention, those in the lifestyle group were not able to achieve substantial weight loss. Indeed, keeping adolescents and their parents involved in the trial for its 2-year duration proved challenging. The extent of weight loss in this group is consistent with published literature, although most studies have only 1 year of follow-up.[13]

In contrast, there was substantial weight loss in the gastric banding group. All but 1 lost more than 10% of their total body weight and 84% achieved more than 50% of excess weight loss. The effect was durable over the 2 years of follow-up (eFigure).

A key end point of the study was evidence of better current and future health. The study was not powered to enable evaluation of any single health problem but did demonstrate reduction of the risk factors for cardiovascular disease and diabetes through measurement of the metabolic syndrome and insulin resistance. Both became normal for all gastric banding participants. There was also an improvement in quality of life for the physical activity, self-esteem, and general health domains.

The gastric banding approach to weight loss is not a quick fix. For optimal effectiveness, it requires long-term supportive follow-up by trained health professionals. The need for revisional procedures for enlargement of the stomach above the band or injury to the tubing is intrinsic to the gastric banding procedure and was required in 28% of the patients in that treatment group. Although this incidence is within the range of other studies,[34,35] it is higher than what has been reported in recent articles.[36] Eating small meals slowly is central to avoiding this problem after the gastric banding procedure. This was repeatedly stressed during the study. For adolescents, additional education and supervision of eating may help reduce the need for revision. The need for a revisional procedure did not compromise the weight loss outcome or lead to additional adverse events. The incidence of pregnancies was higher than we anticipated and suggests sexual counseling may be appropriate in association with weight loss programs.[37]

There are several limitations of the study. We cannot be sure how well the participants reflect those of the general obese adolescent population in the community. The recruitment methods were used to minimize bias toward one or other treatment but may have drawn on a subset of the community attracted by the availability of free treatment. The study was powered to measure differences in weight outcomes rather than differences in other health measures or adverse events. We used an intention-to-treat analysis for the primary outcome of weight change but have used the completer's analysis for secondary outcomes. The 2-year duration of the study may not be sufficient to measure the durability of the gastric banding approach. However, previous experience with adults followed up for as many as 8 years[30,38] and adolescents followed up for as many as 5 years[39] provides a reasonable expectation that the effect at 2 years will be durable.

It has been argued that adolescents with severe obesity need treatment during adolescence rather than deferring until adulthood.[40] Severe obesity in adolescents is associated with multiple serious diseases, impaired quality of life, and an increased risk for later cardiovascular and other diseases that would reduce life expectancy.[7,41] This study confirms that lifestyle treatments can achieve weight loss and improvement in health for some. Diligent application of these approaches should remain the first option for obese adolescents.

However, if these measure fail, should gastric banding be considered for adolescents with severe obesity? Recent reviews[16,40] and health surveys of adolescent obesity[11,41] support the consideration of bariatric surgery during adolescence for those above the 99th percentile if nonsurgical approaches have failed. Laparoscopic adjustable gastric banding was selected as the bariatric surgical procedure of choice for this study because it is an effective procedure[12] that is safer than Roux-en-Y gastric bypass surgery[42] and is adjustable and reversible. With a final outcome of 79% excess weight loss in the gastric banding group, the present study contributes data on the efficacy of 1 of the candidate bariatric options.[15] Reversibility is important because better therapies are likely to become available during the active life of the adolescent.

In this study, gastric banding proved to be an effective intervention leading to a substantial and durable reduction in obesity and to better health. The adolescent and parents must understand the importance of careful adherence to recommended eating behaviors and of seeking early consultation if symptoms of reflux, heartburn, or vomiting occur. As importantly, they should be in a setting in which they can maintain contact with health professionals who understand the process of care. This study indicates that, in such a setting, the laparoscopic adjustable gastric banding process can achieve important improvements in weight, health, and quality of life in severely obese adolescents.

Author Affiliations: Centre for Obesity Research and Education (Drs O'Brien, Brown, Skinner, Burton, and Dixon and Mss Laurie, McGrice, and Anderson); Obesity Research Unit, Department of General Practice (Dr Dixon); and Department of Epidemiology and Preventive Medicine, Monash University (Mr Paul); Centre for Adolescent Health, Royal Children's Hospital (Drs Sawyer and Veit); Department of Paediatrics, University of Melbourne, and Murdoch Children's Research Institute (Dr Sawyer), Melbourne, Australia.
Author Contributions: Dr O'Brien 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.
Study concept and design: O'Brien, Sawyer, Laurie, Dixon.
Acquisition of data: O'Brien, Sawyer, Laurie, Brown, Skinner, Veit, Burton, McGrice, Anderson, Dixon.

Analysis and interpretation of data: O'Brien, Sawyer, Brown, Paul, Burton, Anderson, Dixon.
Drafting of the manuscript: O'Brien, Sawyer, Burton.
Critical revision of the manuscript for important intellectual content: O'Brien, Sawyer, Laurie, Brown, Skinner, Veit, Paul, Burton, McGrice, Anderson, Dixon.
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