Annals of Internal Medicine | ARTICLE

Treatment of Mild to Moderate Obesity with Laparoscopic Adjustable Gastric Banding or an Intensive Medical Program

A Randomized Trial

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Background: Obesity is a major, growing health problem. Observational studies suggest that bariatric surgery is more effective than nonsurgical therapy, but no randomized, controlled trials have confirmed this.

Objective: To ascertain whether surgical therapy for obesity achieves better weight loss, health, and quality of life than nonsurgical therapy.

Design: Randomized, controlled trial.

Setting: University departments of medicine and surgery and an affiliated private hospital.

Patients: 80 adults with mild to moderate obesity (body mass index, 30 kg/m^2 to 35 kg/m^2) from the general community.

Interventions: Patients were assigned to a program of very-low-calorie diets, pharmacotherapy, and lifestyle change for 24 months (nonsurgical group) or to placement of a laparoscopic adjustable gastric band (LAP-BAND System, INAMED Health, Santa Barbara, California) (surgical group).

Measurements: Outcome measures were weight change, presence of the metabolic syndrome, and change in quality of life at 2 years.

Results: At 2 years, the surgical group had greater weight loss, with a mean of 21.6% (95% CI, 19.3% to 23.9%) of initial weight lost and 87.2% (CI, 77.7% to 96.6%) of excess weight lost, while the nonsurgical group had a loss of 5.5% (CI, 3.2% to 7.9%) of initial weight and 21.8% (CI, 11.9% to 31.6%) of excess weight ($P < 0.001$). The metabolic syndrome was initially present in 15 (38%) patients in each group and was present in 8 (24%) nonsurgical patients and 1 (3%) surgical patient at the completion of the study ($P < 0.002$). Quality of life improved statistically significantly more in the surgical group (8 of 8 subscores of Short Form-36) than in the nonsurgical group (3 of 8 subscores).

Limitations: The study included mildly and moderately obese participants, was not powered for comparison of adverse events, and examined outcomes only for 24 months.

Conclusions: Surgical treatment using laparoscopic adjustable gastric banding was statistically significantly more effective than nonsurgical therapy in reducing weight, resolving the metabolic syndrome, and improving quality of life during a 24-month treatment program.

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The development of a safe and effective treatment for obesity is a leading challenge in health care today. Obesity is an increasing health problem across the world with a prevalence of more than 20% among the adult population in Western countries and more than 30% in the United States (1, 2). The increasing prevalence is associated with a parallel increase of several obesity-related diseases, in particular, the diseases of the metabolic syndrome (3, 4), which include type 2 diabetes, hypertension, and dyslipidemia, and are linked to nonalcoholic steatohepatitis, obstructive sleep apnea, and the polycystic ovary syndrome.

For obese individuals, the options are limited. Behavioral therapies of reduced energy intake, improved eating practices, and increased exercise and activity, supplemented by pharmacotherapy, generally achieve only modest and often transient effects (5, 6). Observational studies have shown that bariatric surgical therapies involving gastric restriction by various forms of stapling with or without diversion of the gut to generate malabsorption of food are effective in achieving major weight loss and clinically significant improvements in health and quality of life (7–11).

Strong direct evidence from randomized, controlled trials of the relative benefits of nonsurgical and surgical therapies is lacking. We are aware of only a single study, performed in the 1980s, in which 60 morbidly obese patients were randomly assigned, without informed consent, to diet plus an early form of gastric stapling or to diet alone (12). The maximum weight losses did not differ between the groups. However, the weight regain was greater in the diet-only group.

The advent of the laparoscopic adjustable gastric band has provided a new bariatric surgical option, which has proved to be safe, minimally invasive in its application, gentle in its use through its adjustability and easy reversibility, and similarly effective to the other bariatric procedures (10, 13, 14). **Figure 1** shows the LAP-BAND System

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Context

Observational studies have shown sustained weight loss after surgery for extreme obesity. No randomized trial of contemporary surgical methods has been performed.

Contribution

The authors randomly assigned 80 mildly to moderately obese (body mass index, 30 to 35 kg/m^2) adults to laparoscopic placement of an adjustable gastric band or to an intensive nonsurgical weight loss program. After 2 years, the surgical group had lost 21.6% of initial weight, and the nonsurgical group had lost 5.5% of initial weight. Four patients required laparoscopic revision of the gastric band.

Cautions

The study was not designed to detect uncommon adverse events.

Implications

Laparoscopic gastric banding is effective treatment for mild to moderate obesity.

—The Editors

(INAMED Health, Santa Barbara, California) and demonstrates the key feature of adjustability of the area within the band through which it induces satiety (15). Patients require no more than an overnight hospital stay, and the procedure has been shown to be markedly safer than gastric bypass surgery (13).

We hypothesized that surgical therapy would induce more weight loss, health benefit, and improvement in quality of life than nonsurgical therapy and have conducted a randomized, controlled trial comparing the effectiveness of current nonsurgical therapy with laparoscopic adjustable gastric banding in a group of mildly to moderately obese adults (body mass index, 30 kg/m^2 to 35 kg/m^2).

We did not study patients with a body mass index greater than 35 kg/m^2 because current observational data suggest that outcomes after nonsurgical treatment were unlikely to be equal to those after surgical care for these patients. The principal outcome measures were weight change, health, quality of life, and complications of therapy.

METHODS

Patient Recruitment

We recruited patients for the study through a newspaper advertisement. All patient assessments and outpatient treatments were conducted at a community clinic dedicated to obesity management or in the clinics of a university department of surgery. Surgical procedures were conducted at a private community hospital experienced in the care of bariatric surgical patients. Patients in both groups did not pay any medical costs generated by the study. The human ethics committees of The Alfred Hospital and The Avenue Hospital approved the study in accordance with the guidelines of the National Health and Medical Research Council (www.nhmrc.gov.au/publications/synopses/e35syn.htm) and with the Helsinki Declaration of 1975, as revised in 2000 (www.wma.net/e/ethicsunit/pdf/draft_historical_contemporary_perspectives.pdf).

Inclusion Criteria

We considered patients to be eligible if they were between 20 and 50 years of age; had a body mass index of 30 kg/m^2 to 35 kg/m^2; had identifiable problems, including an obesity-related comorbid condition (such as hypertension, dyslipidemia, diabetes, obstructive sleep apnea, or gastroesophageal reflux disease), severe physical limitations, or clinically significant psychosocial problems associated with their obesity; had attempted to reduce weight over at least the previous 5 years; could understand the options offered and the randomization process; and were willing to comply with the requirements of each program.

Exclusion Criteria

We excluded candidates with a history of bariatric surgery or medical problems that contraindicated treatment in either study group, such as impaired mental status, drug or alcohol addiction, or portal hypertension. In addition, we excluded participants if they had undergone an intensive, physician-supervised program that used very-low-calorie diets or pharmacotherapy or if they did not attend the 2 initial patient information visits.

Assessment

We provided detailed information about the problems of obesity and about the 2 study groups through at least 2 discussion periods and a patient information booklet. Initial assessment included anthropometric measures; identification of medical, physical, or psychosocial problems (both weight-related and other); and a discussion of previous weight loss efforts. The assessment included a detailed dietary history by the trial dietitian and a review by a specialist physician to determine the presence and severity of associated medical conditions. Initial investigations included measurements of fasting blood glucose level; serum insulin level; and a lipid profile, including HDL cholesterol and LDL cholesterol levels.

After initial assessment, we instituted a program of advice on appropriate eating patterns and exercise and followed each patient on a monthly basis for 3 months. During this time, we assessed the patients' fulfillment of tasks, such as completion of a food diary, and overall adherence to appointments.

Randomization Process

We randomly allocated eligible patients to receive a conventional, intensive, nonsurgical program or laparo-

scopic adjustable gastric banding. A computer-derived random allocation sequence, without blocking or stratification, performed the randomization. This was prepared at the trial office. The trial coordinator enrolled participants and informed them of the trial allocation. After assessment had confirmed a participant's suitability for randomization, the coordinator contacted the trial office by telephone for allocation. The study was not blinded.

Description of Nonsurgical and Surgical Interventions

Common Program

We instructed and encouraged all patients to follow appropriate lifestyle behavior of good eating practices and increased exercise and activity. We also encouraged them to exercise for at least 200 minutes per week.

Nonsurgical Program

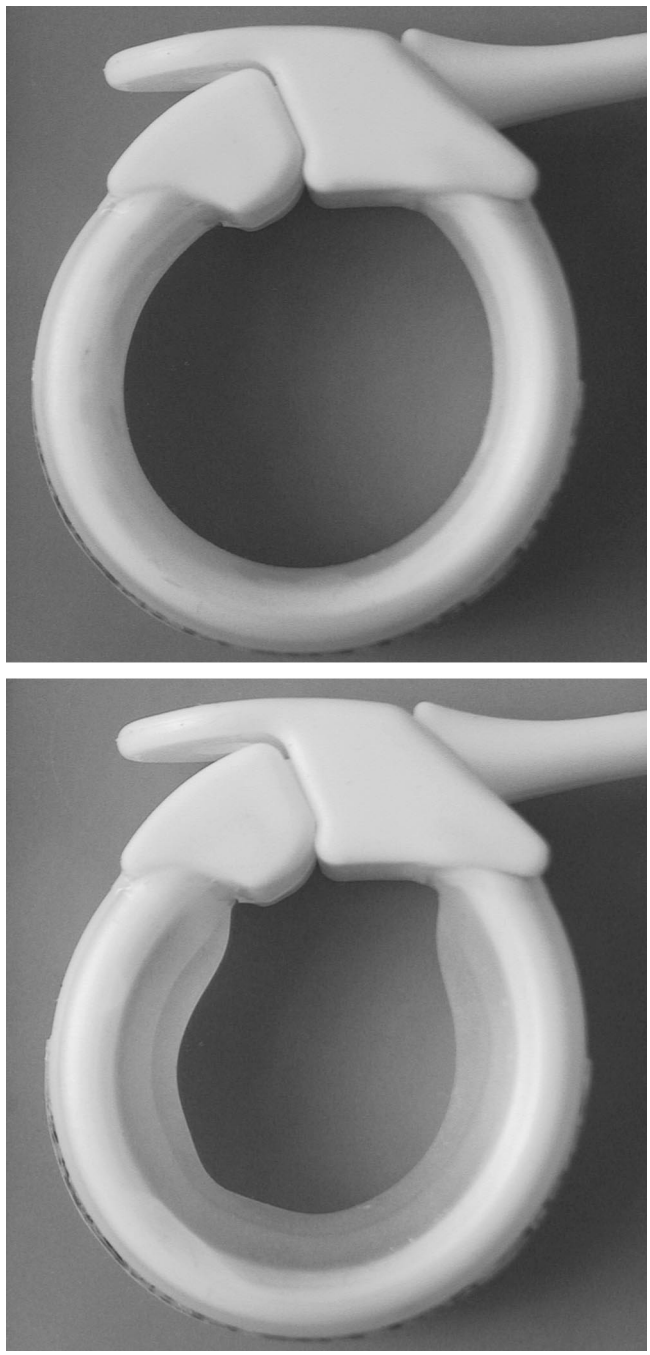
This program centered on the use of behavioral modification, very-low-calorie diet, and pharmacotherapy with education and professional support on appropriate eating and exercise behavior. During the 2-year period, 3 trained physicians developed a program using all the available modalities for each individual on the basis of guidelines prepared and continually reviewed by a panel of experienced bariatric physicians.

The program began with an intensive 6-month period of very-low-calorie diet (500 to 550 kcal/d) using 1 to 3 packets of Optifast (Novartis, Fremont, Michigan) daily for 12 weeks, followed by a transition phase over 4 weeks combining some very-low-calorie meals with 120 mg of orlistat before non–very-low-calorie diet meals, and then 120 mg of orlistat before all meals until the completion of the intensive phase. This intensive 6-month program was followed by further courses of very-low-calorie diets or orlistat as tolerated, as well as continual behavioral, dietary, and exercise advice to assist the participant in maintaining weight loss over a prolonged period. Sibutramine was not approved for use in Australia during the first 12 months of the study and, therefore, was not incorporated into the medical program. The management program for each individual was designed to reflect good clinical practice. A physician saw each patient every 2 weeks during the very-low-calorie diet program and every 4 to 6 weeks during the rest of the study. All patients were seen at least every 6 weeks.

Surgical Program

Two experienced surgeons performed the laparoscopic adjustable gastric band (LAP-BAND System) procedure, by a standardized method (14), within 1 month of randomization. The band was placed along the perigastric pathway in all cases (16). The treating surgeon reviewed patient progress every 4 to 6 weeks during the study period and made adjustments to the volume of saline within the band in the office by using standard clinical criteria (17).

Figure 1. **The laparoscopic adjustable gastric band (LAP-BAND System, INAMED Health, Santa Barbara, California) with no added fluid (*top*) and with 2 mL of fluid added (*bottom*).**

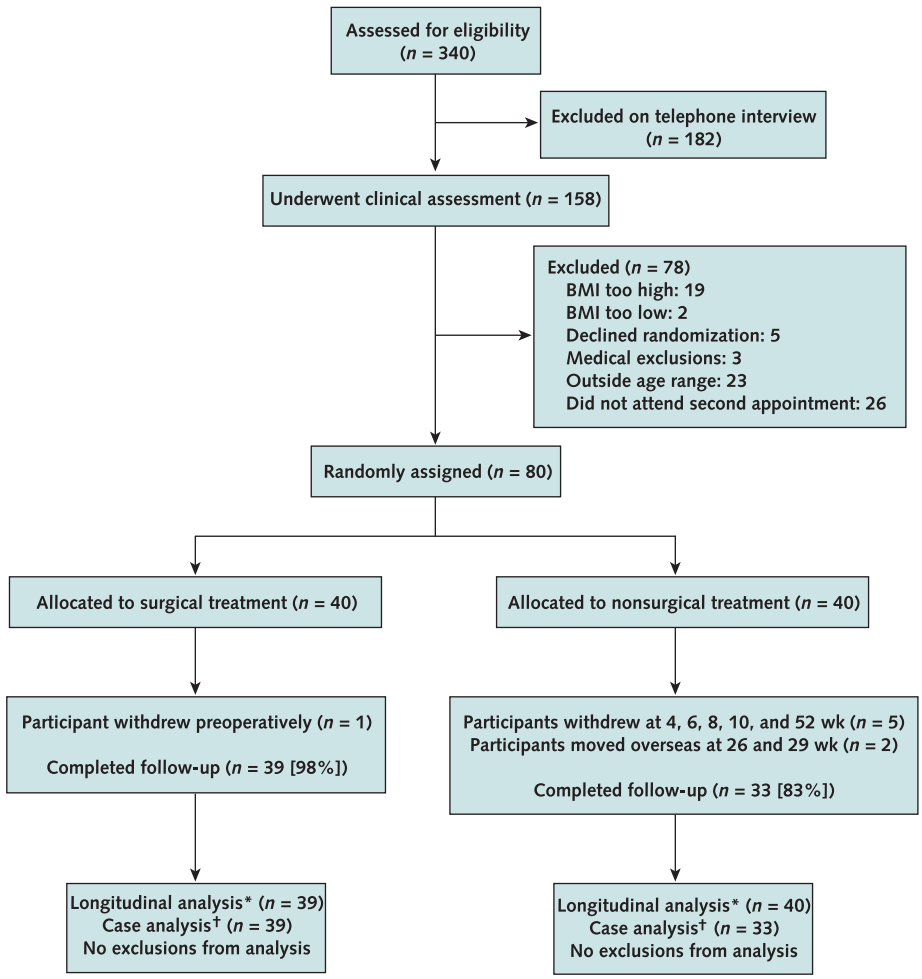


The band is placed laparoscopically around the most proximal region of the stomach. When saline is added to the subcutaneous access port, the balloon expands, thereby generating an increased feeling of satiety before meals and earlier satiety after eating.

Adverse Events

All patients in the study were questioned about the occurrence of adverse events at each consultation, and physicians recorded the results on the data sheets.

Figure 2. **Participant flow chart.**



BMI = body mass index. *Longitudinal analysis was used for weight changes. †Case analysis was used for changes in comorbid conditions and quality of life.

Primary and Secondary Outcomes

The primary end points of the study relate to weight change. We calculated preoperative excess weight as the amount in kg that weight exceeded a body mass index of 25 kg/m^2. We expressed weight change as the change in absolute weight (kg), body mass index, percentage of initial weight lost and excess weight lost, and the percentage of patients who lost more than 50% of excess weight at 2 years. Secondary end points were health, quality of life, and side effects of treatment. We documented health status by clinical and laboratory assessment. We formally documented each disease present at initial assessment with respect to disease activity and treatment status before randomization, and we reassessed these at 12 months and 24 months after randomization. We defined prevalence of the metabolic syndrome by the Adult Treatment Panel III (ATP III) criteria (18). We calculated insulin sensitivity indirectly by using the quantitative insulin sensitivity check index (QUICKI) (19). We measured quality of life at the start of treatment and at 12 and 24 months by using the Medical Outcomes Trust 36-Item Short Form General Health Survey (SF-36) questionnaire (20, 21). Side effects of treatment were adverse drug reactions, protocol violations, or the need for surgical treatments in the nonsurgical group and perioperative problems and need for revisional or other surgery in the surgical group. We classified patients as lost to follow-up when they declined to attend appointments for further consultations or tests. Major complications were those that required hospitalization or major outpatient therapy. Minor complications were those requiring simple outpatient therapy.

Statistical Analysis

Sample Size

We set the sample size on the basis of weight loss, expressed as percentage of excess weight lost, at 2 years after entry into the study. On the basis of our existing data, we expected that the mean excess weight lost for the sur-

gical program would be 54% (14). We determined that a difference of at least 20% (that is, <44% or >64%) would be clinically significant. To achieve 80% power of detecting such a difference (at a 2-sided significance level of 5%), 72 patients would need to be randomly assigned into the study. We planned for a total initial recruitment of 80 patients.

Data Analysis

We analyzed data according to the patients' randomly assigned program (intention-to-treat analysis). We compared demographic data by using the chi-square test, independent sample *t*-test, or Mann–Whitney U test, as appropriate. We analyzed comparative outcomes of follow-up data of anthropometry, blood pressure, biochemistry, and quality-of-life measures by using the chi-square test for categorical data and the *t*-test for paired samples for continuous data. All tests were 2-sided. The laboratory and questionnaire data presented are for only those patients who remained in the study for 2 years. All continuous variables were expressed as means (SDs). We used the SPSS statistical software, version 12.01 (SPSS Inc, Chicago, Illinois), for statistical analysis. A *P* value less than 0.05 was considered significant.

We performed a longitudinal analysis by using SAS, version 8.2 (SAS Institute Inc., Cary, North Carolina), to estimate weight measures, allowing for missing data. We performed the analysis by using the PROC MIXED procedure in SAS, with each patient treated as a random effect. We fitted main fixed effects of the treatment and time to the model with changes over time determined by an interaction between treatment and time. To facilitate specific comparisons, we treated time as a categorical variable. We considered age, sex, and baseline weight to be potential covariates, with baseline weight being the only variable that we found to be statistically significant. We considered all observed data for analysis, with the mixed-effects models assuming noninformative dropout such that the probability of dropout may depend on a patient's observed previous response but not on current or future unobserved responses (22).

Role of the Funding Source

The study was funded by Monash University. The laparoscopic adjustable gastric bands (INAMED Health), laparoscopic ports (U.S. Surgical Corp.), and Optifast (Novartis) were provided by the manufacturers. These sources had no role in the design, conduct, analysis, or reporting of the study or in the decision to submit the manuscript for publication.

RESULTS

Participant Flow

Figure 2 shows the participant flow. One patient who was randomly assigned to surgery withdrew from the study on the evening before the scheduled operation and declined to be followed further. The remaining 39 (98%) treated surgical patients and 33 (83%) nonsurgical patients completed the 2-year follow-up program.

Table 1. **Baseline Characteristics of Participants***

Characteristic	Nonsurgical Group (*n* = 40)	Surgical Group (*n* = 40)
Age, *y*	40.7 (7.0)	41.8 (6.4)
Men, %	22.5	25
Hypertension, %	17.5	22.5
Metabolic syndrome, %	37.5	37.5
Coronary artery disease, %	0	0
BMI, *kg/m²*	33.5 (1.4)	33.7 (1.8)
Weight, *kg*	93.6 (11.9)	96.1 (11.2)
Waist circumference, *cm*	99.4 (9.4)	103.3 (10.0)
Waist–hip ratio	0.85 (0.08)	0.86 (0.08)
Neck circumference, *cm*	38.5 (3.5)	39.2 (3.6)
Systolic BP, *mm Hg*	130.3 (13.5)	131.4 (14.0)
Diastolic BP, *mm Hg*	81.0 (9.1)	83.2 (11.7)
Plasma glucose level		
mmol/L	5.0 (0.6)	5.3 (1.9)
mg/dL	90.1 (10.8)	95.4 (34.2)
Median plasma insulin level (IQR), *pmol/L*	75.7 (60.4–104.1)	61.1 (35.7–86.1)
Total cholesterol level		
mmol/L	5.56 (1.60)	5.40 (1.60)
mg/dL	215.7 (62.8)	208.8 (62.7)
Triglyceride level		
mmol/L	1.40 (0.90)	1.45 (0.85)
mg/dL	123.9 (79.6)	128.3 (75.2)
HDL cholesterol level		
mmol/L	1.40 (0.65)	1.30 (0.41)
mg/dL	54.1 (25.9)	50.2 (15.8)
LDL cholesterol level		
mmol/L	3.50 (1.70)	3.50 (1.35)
mg/dL	135.1 (65.6)	135.1 (52.10)
Total cholesterol–HDL cholesterol ratio	4.3 (1.5)	4.3 (1.3)

* Values are means (SDs), unless otherwise indicated. There were no statistically significant differences between the groups (*P* values not shown). BMI = body mass index; BP = blood pressure; HDL = high-density lipoprotein; IQR = interquartile range; LDL = low-density lipoprotein.

Table 1 shows the baseline characteristics of the groups. The demographic characteristics or the values that contributed to the study outcomes did not statistically significantly differ between the groups.

The recruitment for the study began in May 2000, and all patients had been randomly assigned by November 2001. Final patient follow-up at 2 years after entry was completed by November 2003.

Weight Loss

Table 2 shows weight loss estimates for both groups, using longitudinal analysis, as absolute weight loss, change in body mass index, and percentage of excess weight lost, and **Figure 3** shows the percentage of initial weight lost. Both groups had identical weight loss at 6 months, with 13.8% of initial weight lost. The surgical group continued to lose weight at each study point during the follow-up period with means of 21.6% (95% CI, 19.3% to 23.9%) of initial weight lost and 87.2% (CI, 77.7% to 96.6%) of excess weight lost at 2 years. The nonsurgical group

Table 2. **Estimated Weight, Body Mass Index, and Percentage of Excess Weight Loss at Baseline and at 6, 12, 18, and 24 Months on the Basis of Longitudinal Analysis***

Variable	Time Point				
	Baseline	6 mo	12 mo	18 mo	24 mo
Weight, *kg*					
Surgical group	95.0 (94.1–95.9)	81.6 (79.4–83.7)	76.3 (74.1–78.5)	75.2 (73.1–77.4)	74.5 (72.4–76.7)
Medical group	94.8 (93.9–95.7)	81.6 (79.4–83.7)	85.3 (83.0–87.5)	87.7 (79.9–83.0)	89.5 (80.5–83.6)
P value	0.88	0.99	<0.001	<0.001	<0.001
BMI, *kg/m²*					
Surgical group	33.7 (32.9–34.4)	28.9 (28.1–29.7)	27.0 (26.2–27.8)	26.7 (25.9–27.5)	26.4 (25.6–27.2)
Medical group	33.5 (32.7–34.3)	28.7 (27.9–29.6)	29.9 (29.1–30.8)	30.9 (30.0–31.8)	31.5 (30.6–32.4)
P value	0.71	0.73	<0.001	<0.001	<0.001
Excess weight lost, %					
Surgical group		57.2 (47.8–66.6)	78.6 (69.2–88.1)	83.6 (74.2–93.1)	87.2 (77.7–96.6)
Medical group		57.4 (47.6–66.4)	41.1 (31.2–50.9)	29.0 (19.0–38.9)	21.8 (11.9–31.6)
P value		0.98	<0.001	<0.001	<0.001

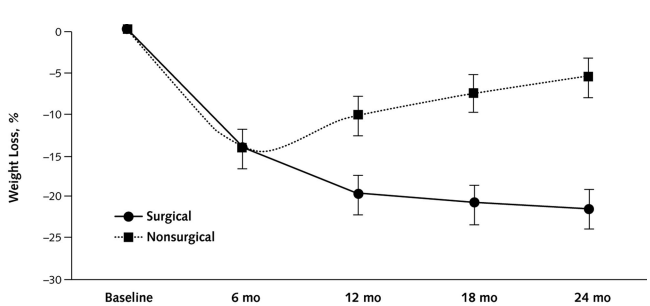
* Values are means (95% CI). *P* values are for the differences between groups. A mixed-effects model was used for longitudinal analysis, with age, sex, and baseline weight as covariates. BMI = body mass index.

showed progressive weight regain after the 6-month point with means of 5.5% (CI, 3.2% to 7.9%) initial weight lost and 21.8% (CI, 11.9% to 31.6%) of excess weight lost at 2 years ($P < 0.001$). Thirty-three of 39 (85%) surgical patients and 8 of 31 (26%) nonsurgical patients lost more than 50% of excess weight at 2 years (chi-square; $P < 0.001$). All 39 of the 40 (98%) surgical patients who actually had surgery and 14 of the 40 (35%) nonsurgical patients achieved satisfactory weight loss (>25% of excess weight lost) ($P < 0.001$).

Health Outcomes

Table 3 shows the percentage change of a range of clinical and laboratory measures of health at 24 months. The resolution of the metabolic syndrome statistically significantly differed between the 2 groups. The surgical group had a statistically significantly greater improvement at 2 years for diastolic blood pressure, fasting plasma glucose level, insulin sensitivity index, and HDL cholesterol level. The metabolic syndrome, as defined by ATP III criteria, was present in 15 (37.5%) patients in each group before treatment and in 1 of 39 (2.7%) patients in the surgical group and 8 of 33 (24%) patients in the medical group at 2 years ($P = 0.006$). The reduction in the proportion of patients with the metabolic syndrome during the study period was significant for the surgical group ($P < 0.001$) but not for the nonsurgical group ($P = 0.22$).

Figure 3. **Mean (±SE) percentage of initial weight lost with initial data carried forward for missing values.**



Changes in Quality of Life

The baseline SF-36 domain scores did not statistically significantly differ between the nonsurgical and surgical groups. At 2 years, the nonsurgical group had statistically significant improvements in 3 domain scores: physical function, vitality, and mental health. The surgical group had statistically significant improvements in all 8 domain scores (**Figure 4**). The change in domain scores between baseline and 2 years show a statistically significant greater improvement in 5 of the 8 domains in the surgical group than in the nonsurgical group.

Adverse Events

Table 4 lists the adverse events that occurred in both groups. In the surgical group, 1 patient developed an infection of a 5-mm port site, which was treated by the patient's general practitioner with antimicrobial agent therapy. Four patients developed prolapse of the posterior gastric wall through the band at 4, 10, 12, and 22 months after placement. The principal symptom in each case was the onset of gastroesophageal reflux, especially at night. All patients with this symptom were treated with laparoscopic revision. The length of hospital stay for each revisional procedure was less than 24 hours, and no perioperative complications occurred. One patient developed acute cholecystitis at 23 months and had an elective uncomplicated laparoscopic cholecystectomy.

In the nonsurgical group, 1 patient could not tolerate the very-low-calorie diet, 8 patients could not tolerate orlistat, and 3 others chose not to use orlistat. Four patients

Table 3. **Percentage Change in Variables Associated with the Metabolic Syndrome and Metabolic Risk***

Variable	Nonsurgical Group (n = 31)	Surgical Group (n = 39)	95% CI of Between-Group Differences
Weight loss	6.1 (8.5)	20.5 (6.4)	–18.9 to –11.6
Waist circumference	–1.4 (8.1)	–15.2 (6.7)	–18.2 to –10.3
Systolic BP	–7.2 (9.7)	–10.8 (10.8)	–9.9 to 1.9
Diastolic BP	–1.58 (11.2)	–10.9 (12.5)	–17.0 to –3.4
Plasma glucose level	0.35 (8.3)	–7.3 (15.2)	–13.0 to –0.7
Plasma insulin level	–8.5 (22.4)	–22.2 (26.8)	–29.3 to 1.00
Insulin sensitivity†	6.2 (21.1)	26.3 (26.7)	–25.7 to –4.7
Total cholesterol level	–3.0 (17.0)	–0.4 (18.1)	–5.9 to 11.2
Triglyceride level	–3.7 (39.4)	–19.1 (35.7)	–33.7 to 2.9
HDL cholesterol level	6.9 (18.9)	30.0 (28.9)	10.6 to 35.4
LDL cholesterol level	–5.2 (21.6)	–6.5 (19.0)	–11.3 to 8.8
Total cholesterol–HDL cholesterol ratio	–8.0 (15.7)	–21.3 (15.0)	–20.9 to –5.5

* Data are only for those who completed the study. Values are mean (SD) percentages for participants who remained in the study at the given time period. P values were calculated by using independent t-test. BP = blood pressure; HDL = high-density lipoprotein; LDL = low-density lipoprotein.
† Insulin sensitivity was calculated indirectly by using the quantitative insulin sensitivity check index (QUICKI) (19).

developed acute cholecystitis at 6, 7, 10, and 23 months and had uncomplicated laparoscopic cholecystectomy performed electively.

DISCUSSION

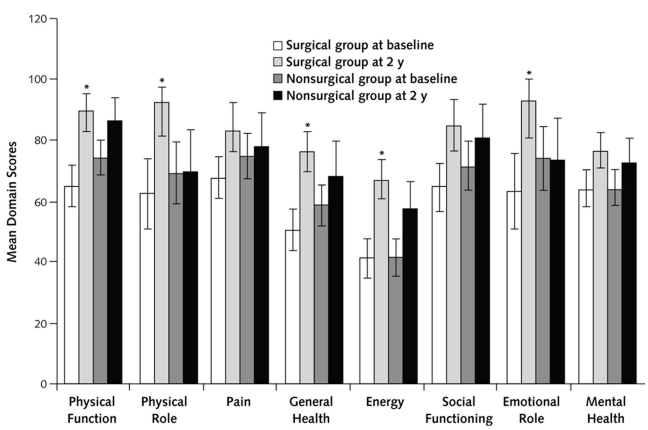
In our randomized, controlled trial of surgical and nonsurgical intervention, both groups showed improvement in weight, health, and quality of life. Patients in the surgical group had statistically significantly better outcomes in each area than those in the nonsurgical group. The extent of weight loss was equal for the 2 groups at 6 months. The nonsurgical group regained weight at 2 years, whereas the surgical patients continued to lose weight. Therapy did not fail in any surgical patient, except for the patient who withdrew before surgery.

The adverse events that occurred are in line with the expectations of the 2 treatment programs. The surgical group had no clinically significant perioperative problems, but 4 patients required late revision of the band position because of posterior prolapse of the gastric wall through the band. This was corrected laparoscopically, and these patients continued to have a good overall outcome. The perigastric pathway (16) was used for all of the surgical patients in our study. In a randomized, controlled trial subsequent to our study, we showed that posterior prolapse can be avoided by the pars flaccida pathway (23). Four patients in the nonsurgical group required cholecystectomy, which may be linked to the very-low-calorie diet.

Several limitations of our study need to be recognized. First, the weight range of body mass index that we chose for our study (30 kg/m^2 to 35 kg/m^2) may seem inappropriate for surgical treatment. We chose this weight category because it represents a "gray zone" between the generally accepted domains for nonsurgical and surgical treatment. We recognize that principal guidelines for bariatric surgery (24, 25) do not include criteria for this group of patients; however, inclusion of the group makes our study important. Revision of those guidelines can only occur once data from this group are published. Furthermore, given the extensive observational data on relative effectiveness of bariatric surgery when the body mass index is greater than 35 kg/m^2, we did not study severely obese patients.

Second, the experience of the surgical team may not reflect general community surgical competence in the care of patients with laparoscopic adjustable gastric bands. Both surgeons had performed several hundred of these procedures and were experienced in providing follow-up and adjustment. A systematic review showed inverse correlation

Figure 4. **Mean (95% CI) Short Form-36 quality-of-life domain scores for the surgical and nonsurgical groups at baseline and at 2 years.**



Mean age- and sex-matched general community domain scores are physical function, 88 (SD, 17); physical role, 83 (SD, 32); pain, 75 (SD, 23); general health, 74 (SD, 19); energy, 59 (SD, 19); social function, 83 (SD, 23); emotional role, 81 (SD, 34); and mental health, 73 (SD, 17) (data from Ware et al. [20, 21]). *Statistically significantly greater improvement in the surgical group at 2 years compared with the nonsurgical group.

Table 4. **Adverse Events in the Surgical and Nonsurgical Groups**

Adverse Event	Value, *n* (%)
Nonsurgical group (*n* = 31)	
Total events	18 (58)
Intolerance to very-low-calorie diet	1 (3)
Intolerance to orlistat	8 (26)
Acute cholecystitis (laparoscopic cholecystectomy)	4 (13)
Loss to follow-up	5 (12.5)
Operative interventions	4 (13)
Surgical group (*n* = 39)	
Total events	7 (18)
5-mm port site infection	1 (2.6)
Acute cholecystitis	1 (2.6)
Prolapse, posterior (laparoscopic revision)	4 (10)
Loss to follow-up	1 (2.6)
Operative interventions	5 (13)

between the experience of the surgical team and incidence of early and late complications after band placement (13).

Third, the incidence of adverse events, including the need for surgical intervention, was similar in both groups. However, we cannot conclude that the 2 programs were equally safe because the study was not powered to validly compare the groups for this variable.

Laparoscopic adjustable gastric banding has been shown to be safe and effective in achieving weight loss, health benefits, and improved quality of life. A systematic review of literature published up to September 2001 on the safety and efficacy of this procedure showed a mortality rate of 0.05% (26). When compared with that of gastric stapling procedures, the mortality rate was 10 times greater for Roux-en-Y gastric bypass (0.5%) and 6 times greater for vertical banded gastroplasty (0.31%). The systematic review reported median percentages of 61%, 56%, and 54% of excess weight lost at 3, 4, and 5 years, respectively (26). Comparative figures for Roux-en-Y gastric bypass, as reported from the systematic review, were 69%, 58%, and 59%, respectively. The differences in effect between the 2 operations on weight loss at 5 years were not statistically significant. After laparoscopic adjustable gastric banding, major improvements have been described for type 2 diabetes, asthma, sleep apnea, hypertension, dyslipidemia, gastroesophageal reflux, and depression, and durable improvement occurs in the quality of life (27).

Very few studies that compare nonsurgical and surgical therapies are available. Although it did not involve random allocation, the Swedish Obese Subjects Study (28) is a major nonrandomized, comparative study in which 2000 matched patient pairs have been followed for 10 years. The ongoing study has already demonstrated better weight loss (20 kg vs. 0.7 kg at 8 years) and benefits to health and quality of life in the surgical group (28). However, the surgical group was treated by open gastric restrictive stapling operations because the laparoscopic approach and adjustable forms of gastric banding were not available at the commencement of the study.

Our study demonstrates that surgical treatment with the laparoscopic adjustable gastric band provides greater benefits than nonsurgical therapy for mild to moderate obesity and supports the findings of current observational studies of more severely obese patients. The procedure has been shown to be safe and effective in morbidly obese (29, 30) and superobese (31) patients. A broader application of the approach for the serious and common problem of obesity warrants consideration.

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