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Journal
Annals of Surgery, 268(1)

ISSN
0003-4932

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Publication Date
2018-07-01

DOI
10.1097/sla.0000000000002348

Peer reviewed

HHS Public Access

Author manuscript

Ann Surg. Author manuscript; available in PMC 2019 July 01.

Published in final edited form as:

Ann Surg. 2018 July ; 268(1): 106–113. doi:10.1097/SLA.0000000000002348.

Ten-year Outcomes of a Prospective Randomized Trial of Laparoscopic Gastric Bypass Versus Laparoscopic Gastric Banding

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Abstract

Objective—The primary endpoints of this study were long-term weight loss, morbidity, and changes in comorbidities and quality of life.

Background—Bariatric surgery is an effective option for the treatment of severe obesity and its related comorbidities. However, few studies have reported on the long-term outcome (>5 yrs) of bariatric surgery.

Methods—Between 2002 and 2007, 250 patients with a body mass index (BMI) of 35 to 60 kg/m^2 were randomly assigned to undergo laparoscopic gastric bypass or laparoscopic gastric banding. After exclusions, 111 patients underwent gastric bypass and 86 patients underwent gastric banding. Factors predictive of improved weight loss were analyzed using multiple logistic regressions.

Results—At baseline, the mean age was 43 ± 10 years and the mean BMI was 46.5 ± 5.6 kg/m^2. At 10-year follow-up, the mean total body weight loss for the entire cohort was −37.5 ± 19.4 kg, −42.4 ± 19.6 kg for gastric bypass versus −27.4 ± 14.5 kg for gastric banding. Late reoperation was significantly higher after gastric banding compared with the gastric bypass group (31.4% vs. 8.1%, respectively, $P < 0.01$). For the entire cohort, improvement or remission of diabetes occurred in 68%; 61% for hypertension; and 57% for dyslipidemia. The long-term mortality for the entire cohort was 1.0% at a mean follow-up of 9.5 ± 0.4 years. Factors predictive of improved weight loss included the type of operation (ie, gastric bypass), female sex, and the absence of diabetes at baseline. At long-term follow-up, quality of life continues to be improved from baseline for both the groups.

Conclusions—Bariatric surgery is an effective treatment for severe obesity with durable 10-year weight loss and improvement in comorbidities and quality of life. Compared with gastric banding, gastric bypass was associated with better long-term weight loss, lower rate of late reoperation, and improved remission of comorbidities.

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The authors report no conflicts of interest.

Keywords

bariatric surgery; gastric banding; gastric bypass; long-term follow-up

Bariatric surgery has been shown to be an effective treatment for severe obesity and type 2 diabetes mellitus. However, the literature is scarce regarding the long-term outcome (>5 yrs follow-up) after bariatric surgery. In a multidisciplinary workshop convened by the National Institutes of Health in 2014 aimed to summarize the current state of knowledge of bariatric surgery, the researchers reviewed research findings on the long-term outcomes of bariatric surgery and concluded that more information was needed on the long-term durability of comorbidity control, complications after bariatric surgery, and predictors of outcomes.[1] The researchers identified only 4 long-term studies on bariatric surgery outcomes. Two studies involved prospective observation with matched controls, and 2 studies utilized a retrospective observation with matched controls design.[2–5] They also reviewed 5 published randomized controlled trials comparing bariatric surgery to nonsurgical treatment for obesity and type 2 diabetes, and only 1 of these studies had follow-up greater than 5 years.[6]

We previously published the 4-year follow-up results of our prospective, randomized trial comparing laparoscopic Roux-en-Y gastric bypass versus laparoscopic adjustable gastric banding for the treatment of severe obesity.[7] We found that gastric bypass resulted in improved weight loss at 4-year follow-up but was associated with higher rates of perioperative complications. The current study reports the 10-year follow-up data from our randomized trial of laparoscopic gastric bypass versus laparoscopic gastric banding, with the aims to examine the long-term morbidity, durability of weight loss, predictors of weight loss, comorbidities control, and changes in quality of life.

METHODS

Study Design

The study design and methods have been previously described.[7] In brief, patients were eligible for the trial if they had a body mass index (BMI) between 40 and 60 kg/m^2 or 35 kg/m^2 with associated comorbidities, had acceptable operative risk, and were between the ages of 18 and 60 years. Exclusion criteria included patients with a large ventral hernia, large hiatal hernia, or those who had previous gastric or bariatric surgery. Written informed consent to participate in the study was obtained from all patients who agreed to undergo randomization. After written consent, patients were randomly assigned to laparoscopic gastric bypass or laparoscopic gastric banding by the use of sealed envelopes. The randomized assignment was discussed with the patient at the second office visit, when the patient had the right to withdraw from the study protocol. The study was performed with approval of the Institutional Review Board and was registered on the ClinicalTrials.gov with an identifier of NCT00247377.

Study Interventions

Laparoscopic Gastric Bypass—Laparoscopic gastric bypass was performed using 5 abdominal ports. A 30 mL gastric pouch was constructed by stapling the stomach starting on

the lesser curvature and exiting through the angle of His. The ligament of Treitz was identified and the jejunum was divided 30 cm distal to the ligament of Treitz. The Roux limb was measured 75 to 150 cm whereby a stapled side-to-side jejunojejunostomy was constructed using a 60 mm linear stapler. The remaining enterotomy and mesenteric defect were closed with interrupted sutures. The Roux limb was routed retrocolic. A gastrojejunostomy was constructed using a circular stapler and reinforced with interrupted sutures. The gastrojejunostomy was inspected endoscopically and tested for air leaks.

Laparoscopic Adjustable Gastric Banding—Laparoscopic gastric banding was performed using 5 abdominal ports. The dissection began with mobilization of the right crus of the diaphragm posterior to the esophagus and a retroesophageal tunnel was developed toward the angle of His. A 9.75-mm, 10-mm Lap-Band, or the Lap-Band VG system was used. The gastric band was positioned at the level of the gastric cardia and securely closed. To minimize slippage, 3 anterior gastrogastric sutures were placed and a single gastrogastric suture was placed on the gastric lesser curvature below the band. The access port was implanted subcutaneously and secured to the rectus fascia.

Postoperative Care and Follow-up—An intensive multidisciplinary aftercare program was utilized for all the patients. Gastric banding patients underwent regular adjustment at the clinic. Criteria for adjustment were based on achievement of the ideal weight loss (1–2 lbs. per week), the presence of restriction and satiety with meals, and the lack of dysphagia, reflux, or vomiting symptoms. Follow-up was carried out on an outpatient basis every 3 months in the first year and every 4 months thereafter. For patients who did not attend their regular interval clinic appointment, phone call and emails were sent to encourage follow-up. Data were also obtained from patient telephone interviews and from records of all physicians caring for the patient.

Study End Points

The endpoints of the study were long-term morbidity, total body weight loss, changes in comorbidities and quality of life, and analysis of factors predictive of improved weight loss. The mean follow-up was calculated based on the time interval between the patient’s date of index bariatric operation and the date of last followup. Some patients within the band group required band removal for complications or were converted to another bariatric operation for poor weight loss. Data for these patients were included within the band group in an intention-to-treat analysis.

Long-term Morbidity and Mortality

Long-term complications were recorded and a single patient could have multiple unrelated complications. Long-term complication was defined as any complications occurring after 90 days following the index bariatric operation. Death occurring at any time period was recorded. Late reoperation (>90-d) was defined as any reoperation related to the index operation. Since our main interest was any reoperation specifically related to the operative procedures, patients requiring a laparoscopic cholecystectomy were not recorded in the rate of reoperation.

Weight Loss

Weight loss was expressed as changes in 1) mean total body weight (kg) loss and 2) mean body mass index (BMI, kg/m^2) loss after gastric bypass and after gastric banding.

Changes in Comorbidity

Comorbidities analyzed included diabetes, hypertension, dyslipidemia, and gastroesophageal reflux disease (GERD). The rate of improvement or remission of the comorbidity was calculated based on the patient's utilization of medications as managed by their medical physicians. Improvement of diabetes was defined as reduction in dosage or the number of diabetic medications prescribed. Remission of diabetes occurred when the patient no longer required the use of diabetes medications. Improvement of hypertension was defined as reduction in dosage or the number of hypertensive medications. Remission of hypertension occurred when the patient no longer required the use of hypertensive medications prescribed. Improvement of dyslipidemia was defined as reduction in dosage or the number of lipid medications prescribed. Remission of dyslipidemia occurred when the patient no longer required the use of lipid medications. Improvement/remission of GERD was defined as reduction in GERD symptoms based on the GERD-health related quality of life questionnaire.

Quality of Life

Quality of life was measured by the 36-item Health Survey (SF-36) questionnaire form (RAND Corp, Santa Monica, CA). The SF-36 forms were administered to patients before surgery and at long-term follow-up. The SF-36 measures the following 8 health domains: physical functioning, role-physical, role-emotional, body pain, vitality, social functioning, mental health, and general health. The SF-36 also can be grouped into physical and mental health components. The physical health component includes physical functioning, role-physical, body pain, and general health. The mental health component is comprised of role-emotional, social functioning, mental health, and vitality.

Statistical Analyses

All data are expressed as mean ± standard deviation. Analyses of differences between groups in demographic and operative data were performed using 2-sample *t* tests or Fisher exact tests for categorical data. Comparisons of comorbidities and complications were made using chi-square test tests for independence. Comparison of changes in percent of total body weight loss across time was performed using repeated measures analysis of variance. After the initial analysis, a series of stratified models was run to look for significant differences between groups at each time point using unpaired *t* tests. The SF-36 scores were compared between groups using unpaired *t* tests. Multivariate analysis was performed to determine predictors of improved weight loss. All statistical analyses were conducted using SAS 9.1 (SAS Institute Inc, Cary, NC). A *P* value less than 0.05 was considered significant. Data for patients with gastric banding that were converted to another bariatric operation were analyzed within the gastric banding group based on an intention-to-treat basis. Patients who did not undergo their randomized assignment were excluded from the analysis.

A sample size calculation was performed with the assumption that the mean percent of excess weight loss after gastric bypass was 60% ± 29% at 2 years and the mean percent of excess weight loss after gastric banding was 46% ± 39%. A difference of 14% in excess weight loss between the 2 groups was considered statistically significant. A minimum of 96 patients in each group was necessary to detect this difference using a 2-tailed *t* test with the probability of a type I error (α) of 0.5 and the probability of a type II error (β) of 0.2 (power of 80%). Due to the potential drop-out rate, 250 patients were accrued for this study.

RESULTS

Study Patients

Between November 2002 and September 2007, 250 patients were randomly assigned to undergo laparoscopic gastric bypass or laparoscopic gastric banding. Fourteen patients in the gastric bypass group and 39 patients in the gastric banding group were excluded because the patients were unwilling to undergo the randomly assigned procedure or were unable to obtain insurance coverage for the bariatric operation. After exclusion, 111 patients underwent gastric bypass and 86 patients underwent gastric banding (Fig. 1). For baseline characteristics of the 2 groups, the mean BMI was higher in the gastric bypass group (47.5 ± 5.5 kg/m^2 for gastric bypass vs. 45.5 ± 5.4 kg/m^2 for gastric banding, $P = 0.01$), while the mean age was higher in the gastric banding group (45.8 ± 9.8 vs. 41.4 ± 11.0 yrs respectively, $P < 0.01$). Preoperative weight, comorbidities, and history of prior abdominal surgery were similar between the 2 groups. At 5 years, follow-up data were available for 78% of the entire cohort (70% for gastric bypass and 86% for gastric banding). At 6 years, follow-up was available for 67% of the cohort (56% for gastric bypass and 79% for gastric banding). At 7 years, follow-up was available for 52% of the cohort (44% for gastric bypass and 60% for gastric banding). At 8 years, follow-up was available for 42% of the cohort (35% for gastric bypass and 49% for gastric banding). Of the patients with 9 years of data, follow-up was available for 46% (41% for gastric bypass and 57% for gastric banding). Of the patients with 10 years of data, follow-up was available for 50% (43% for gastric bypass and 61% for gastric banding).

Long-term Morbidity, Mortality, and Late Reoperation

Late complications (>90 d after index operation) for gastric bypass and gastric banding are shown in Table 1. The most frequent late complication after gastric banding was band erosion, slippage, or obstruction, often requiring revisional surgery with band explant or band revision. In contrast, the most frequent late complication after gastric bypass was marginal ulceration requiring medical management. Two patients within the gastric bypass group died from alcohol-related complications. Five patients within the gastric banding group required conversion to a sleeve gastrectomy (n = 4) or gastric bypass (n = 1) for poor weight loss. Late reoperation occurred in 18.3% of the entire cohort with a significantly higher rate of reoperation in the gastric banding compared with the gastric bypass group (31.4% vs. 8.1%, respectively, $P < 0.01$).

Weight Loss

Change in total body weight and BMI loss after gastric bypass and gastric banding are depicted in Figure 2A and B respectively. The mean total body weight reduced significantly from baseline after gastric banding and gastric bypass but weight loss was significantly greater after gastric bypass than gastric banding at all follow-up time periods (Fig. 2A). At 10-year follow-up, the mean total body weight loss for the entire cohort was −37.5 ± 19.4 kg (−42.4 ± 19.6 kg for gastric bypass vs. −27.4 ± 14.5 kg for gastric banding). At 10-year follow-up, the mean percent total body weight loss was −27.0 ± 12.8% for the entire cohort (−32.7 ± 13.6% for gastric bypass vs. −21.2 ± 11.9% for gastric banding). Figure 2B represents the mean BMI reduction after gastric bypass versus gastric banding. At 10-year follow-up, the mean BMI reduction was −13.5 ± 7.1 kg/m^2 for the entire cohort (−15.3 ± 7.1 kg/m^2 after gastric bypass vs. −9.9 ± 5.5 kg/m^2 for gastric banding).

Table 2 details various preoperative factors that may predict improved weight loss after bariatric surgery. The patient's age, baseline BMI, dyslipidemia, and hypertension were not predictive of long-term weight loss. However, female sex, gastric bypass operation, and the absence of diabetes at baseline were significant predictors for improved long-term weight loss.

Changes in Comorbidities

Figure 3 depicts the rate of improvement or remission of diabetes, hypertension, and dyslipidemia after gastric bypass and gastric banding. At follow-up, the rate of improvement or remission of diabetes was 68.2% for the entire cohort (86.4% for gastric bypass vs. 50.0% for gastric banding). For hypertension, the rate of improvement or remission was 61.2% for the entire cohort (78.8% for gastric bypass vs. 44.1% for gastric banding). For dyslipidemia, the rate of the improvement or remission was 57.1% for the entire cohort (73.9% for gastric bypass vs. 42.3% for gastric banding). Figure 4 depicts the changes in GERD symptoms based on the GERD health-related quality of life questionnaire. The rate of the improvement or remission of GERD at follow-up was 82.0% overall (86.0% for gastric bypass vs. 76.0% for gastric banding). Rate of GERD symptoms worsening occurred in 5.0% of gastric banding patients.

Quality-of-life

Figure 5 shows the polar graph for the SF-36 scores for all patients at baseline (preoperative) and at follow-up for gastric bypass and gastric banding patients. The SF-36 scores improved from baseline in all 8 health domains for both gastric bypass and gastric band, and reached that of the US normal population. Figure 6 separates the SF-36 into the physical and mental health components. At follow-up, the physical health component and the mental health component improved significantly from baseline for both gastric bypass and gastric banding patients (Fig. 6A and B).

DISCUSSION

Contemporary bariatric surgery for the treatment of severe obesity originated in the mid-1960s with Dr. Edward Mason performing the first gastric bypass for the treatment of

obesity.[8] Over the past 4 decades, the field of bariatric surgery has gone through revolutionary changes including various technical modifications of the gastric bypass, development of the laparoscopic approach to bariatric surgery, FDA approval of 2 laparoscopic gastric bands, and development of a relatively new bariatric operation—the sleeve gastrectomy.[8] A significant amount of research has been published regarding the mechanisms and medium-term outcomes of bariatric surgery.[5,6] However, there is a paucity of data regarding the long-term outcomes (>5 yrs) of bariatric surgery. In this prospective, randomized trial of laparoscopic gastric bypass versus laparoscopic gastric banding with a mean follow-up of 9.5 ± 0.4 years, we found durable weight loss after bariatric surgery. Factors predictive of improved weight loss were the type of bariatric operation (gastric bypass as compared with gastric banding), female sex, and the absence of diabetes at baseline. At 10-year follow-up, patients who underwent gastric bypass maintained 33% reduction of their total body weight while patients who underwent gastric banding had a 21% reduction of their total body weight. There was a higher rate of late reoperation associated with gastric banding, with a small subset of patient (5.8%) requiring conversion to another bariatric operation for complications or poor weight loss. Improvement or remission of diabetes, hypertension, dyslipidemia, and GERD were significantly better after gastric bypass compared with gastric banding. However, quality of life remains improved after both gastric bypass and gastric banding at long-term follow-up.

In this study, we found durable weight loss at long-term follow-up. Although both gastric bypass and gastric banding were associated with significant weight loss, long-term weight loss continues to be better after gastric bypass compared with gastric banding. At 10-year follow-up, the mean total body weight loss for our entire study cohort was −37.5 kg with a mean BMI reduction of −13.5 kg/m^2. In the Swedish Obesity Subjects (SOS) study, which analyzed weight loss in patients who underwent bariatric surgery compared with a control population, the bariatric surgery group lost a mean of −19.7 kg of total body weight with a reduction of −6.7 kg/m^2 BMI at 10-year followup.[9] Improved weight loss in our study is likely related to the higher proportion of patients who underwent gastric bypass, which has been shown to be associated with better weight loss compared with gastric band operation. The majority of patients in the SOS study underwent vertical banded gastroplasty (68%), an operation that is not currently performed at most bariatric centers.[5,9] In one of the most rigorous medical weight loss programs for diabetes participants, the Look AHEAD (Action for Health in Diabetes) research group reported −8.6% total body weight loss at 1-year follow-up and −6% total body weight loss at a median follow-up of −9.6 years through intensive lifestyle intervention with weekly sessions or meetings.[10] As a comparison, the mean percent long-term total body weight loss for the entire bariatric surgery cohort in this study was −29%. Another important finding in our study was the improved weight loss after gastric bypass compared with gastric banding. The SOS study similarly reported improved weight loss after gastric bypass compared with gastric banding patients.[11]

Bariatric surgery has been shown to improve or cause remission of obesity-related comorbidities. In our study, we examined both improvement and remission of diabetes together as a single category, which occurred in 68% of subjects. Other studies, however, looked specifically at remission of diabetes. In a randomized trial comparing bariatric surgery versus conventional medical treatment for obese patients with type 2 diabetes,

Mingrone et al[6] reported remission of diabetes in 50% of patients who underwent gastric bypass or biliopancreatic diversion versus 0% remission in the medical control group at 5 years. In the 3-year results of the STAMPEDE trial, the primary endpoint of glycated hemoglobin level of 6% or less occurred in 5% of patients in the medical group as compared with 38% in the gastric bypass group and 24% in the sleeve gastrectomy group.[12] In the SOS study, 36% of patients in the bariatric surgery group had recovery from diabetes compared with 13% of patients in the control group at 10 years.[11]

Although our study does not have enough power to examine the perioperative safety of bariatric surgery, there was no 30-day or 90-day mortality within our cohort of 197 patients. Late reoperation was significantly higher after gastric banding compared with gastric bypass relating to band slippage, obstruction, or erosion. However, these late complications were not life-threatening or associated with residual disability. One complication that is of concern is the alcohol-related complication. In our study, both deaths within this study occurred as a result of alcohol-related complications. The issue of alcohol-related death after bariatric surgery has been examined previously. In a retrospective cohort study of 7925 patients who underwent bariatric surgery compared with 7925 severely obese control subjects, Adams et al[3] reported that the rates of death not caused by disease, such as accidents, poisoning, and suicide, were 58% higher in the bariatric surgery group. This issue of deaths related to alcohol needs to be further examined in larger studies.

Another important variable to examine at long-term follow-up is the quality of life. At baseline, we found a depressed quality of life in 7 of 8 heath domains in our patient population as measured by the SF-36 survey. At long-term follow-up, quality of life after in patients who underwent bariatric surgery improved and reached that of US norms. Mingrone et al[6] reported that quality of life based on the SF-36 survey for bariatric surgical patients were improved compared with the control group. The SOS intervention study similarly reported their 10-year trends in health-related quality of life and showed that surgical patients had significantly better outcomes compared with the conventional treatment group.[9]

Our study has several limitations. The baseline BMI was significantly higher (47 vs. 45 kg/m^2, respectively) and age was significantly lower (41 vs. 45 yrs, respectively) in the gastric bypass group than in the gastric banding group. Although statistically different, a BMI difference of 2 kg/m^2 and a mean age difference of 4 years between groups are not considered of clinical significance. This study lacks a nonsurgical control population that would be important to determine the extent of differential in weight loss and improvement in comorbidities compared with a control cohort. This study did not evaluate the sleeve gastrectomy operation that currently is the most common bariatric operation being performed in the United States since it was initiated prior to the introduction of the sleeve gastrectomy. Our study also has a small sample size that limits our ability to evaluate the risk of mortality associated with bariatric surgery. Last, improvement or resolution of comorbidities was based only on reduction in medication and not based on objective laboratory parameters such as HbA1C, lipids, or fasting glucose levels. Despite these limitations, this study is one of few to provide data on long-term weight loss, changes in comorbidities, and quality of life data for a group of patients who underwent bariatric surgery.

CONCLUSIONS

Bariatric surgery is an effective treatment for severe obesity with durable, long-term weight loss and improvement in comorbidities and quality of life. Compared with gastric banding, gastric bypass was associated with better long-term total body weight loss, lower rate of late reoperation, and improved remission of comorbidities.

Acknowledgments

Funding for this study was obtained from the Department of Surgery at the University of California, Irvine Medical Center, Orange, CA.

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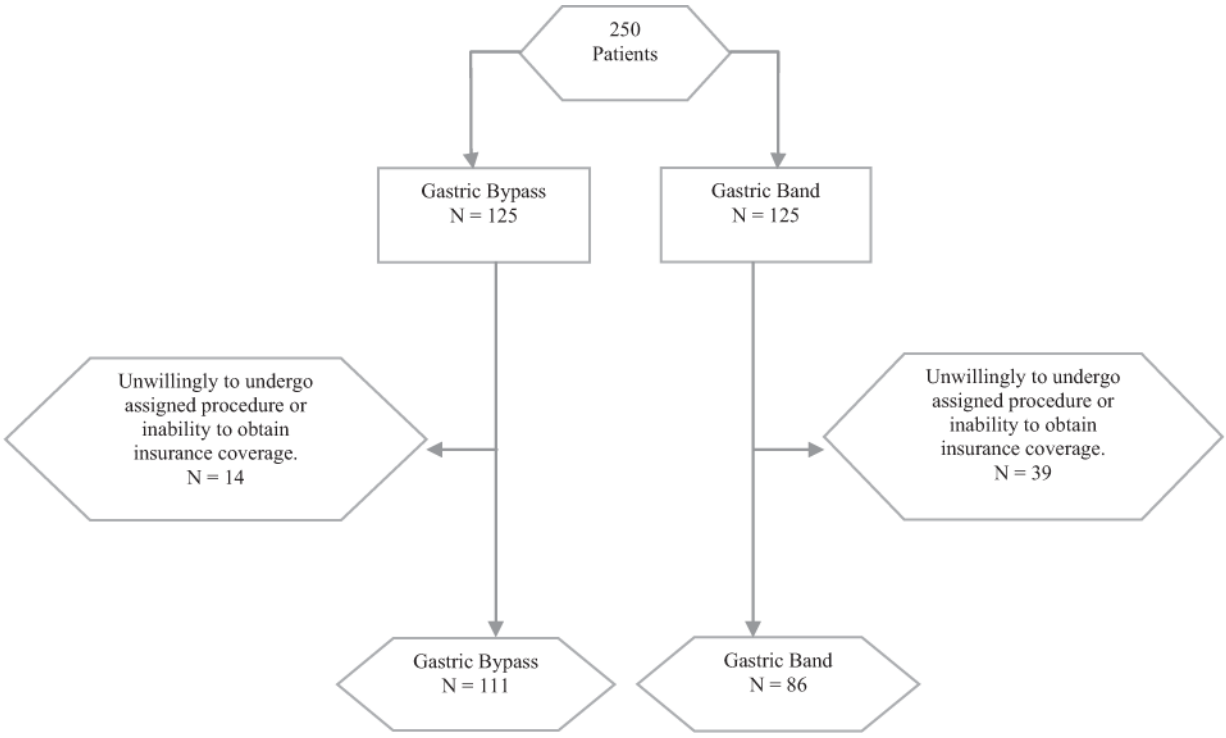

FIGURE 1.

Flow chart of patients randomized to undergo gastric banding vs. gastric bypass.

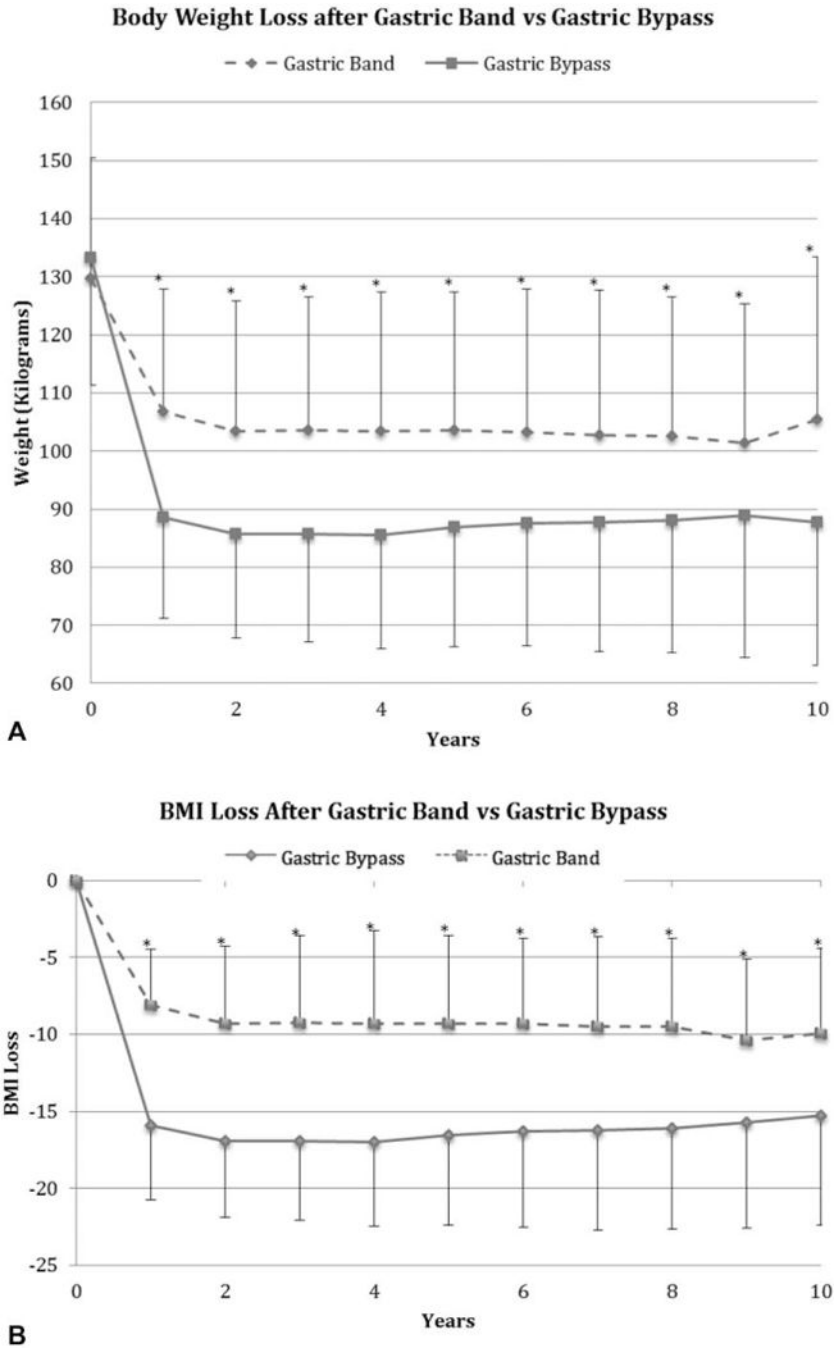

FIGURE 2.

(A) Mean total body weight (kg) loss after gastric banding vs. gastric bypass. (B) Mean body mass index (BMI) reduction after gastric banding vs. gastric bypass. *$P < 0.05$ for comparison between gastric band and gastric bypass.

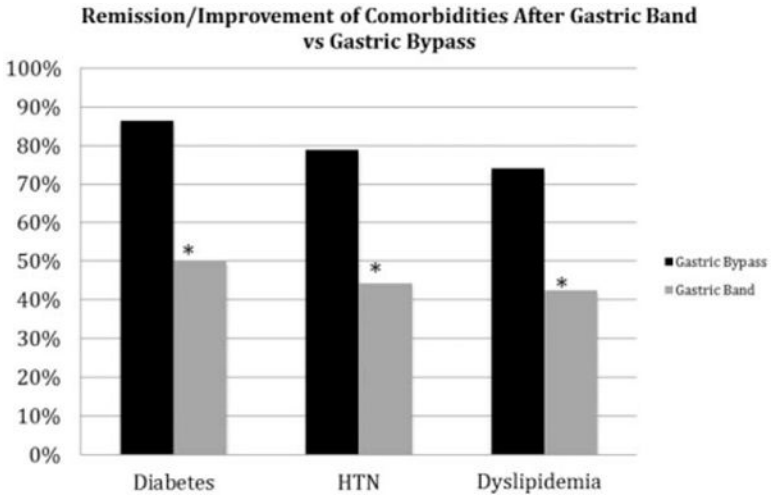

FIGURE 3.

Rate of improvement or remission of diabetes, hypertension, and dyslipidemia after gastric banding versus gastric bypass. $*P < 0.05$ for comparison between gastric band versus gastric bypass. HTN indicates hypertension.

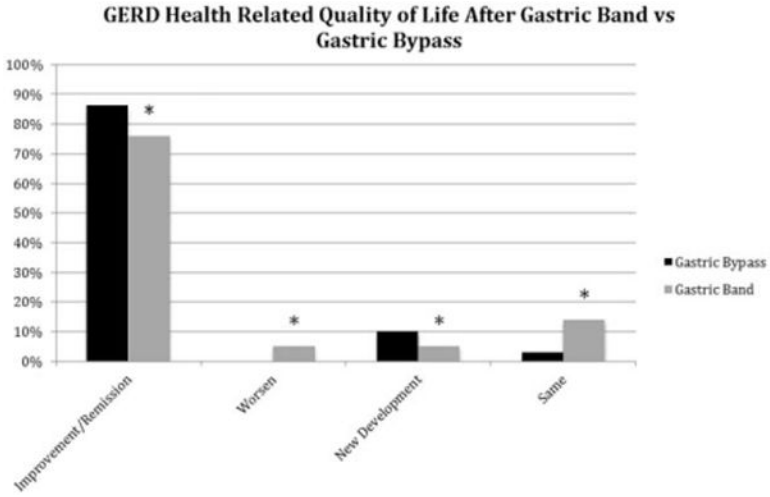

FIGURE 4.

Changes in gastroesophageal reflux symptoms based on the GERD health-related quality of life questionnaire after gastric banding versus gastric bypass. $*P < 0.05$ for comparison between gastric band and gastric bypass.

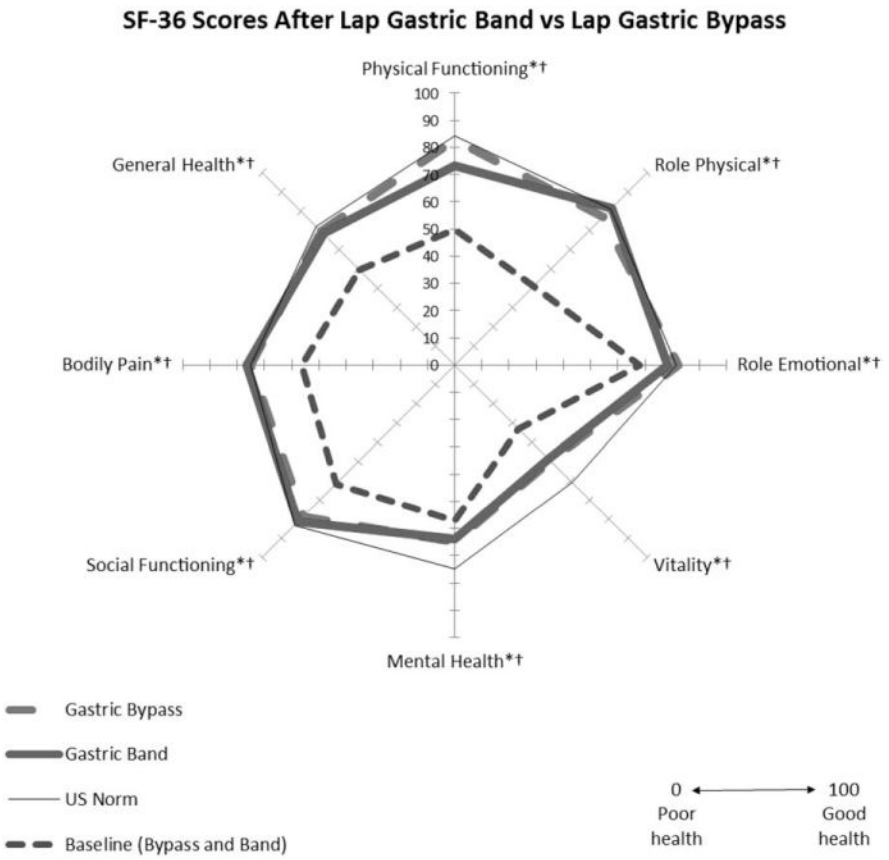

FIGURE 5.

Polar graph of SF-36 scores before surgery and at follow-up after gastric banding versus gastric bypass. $*P < 0.05$, comparison between gastric band at follow-up versus baseline. $^{\dagger}P < 0.05$, comparison between gastric bypass at follow-up versus baseline.

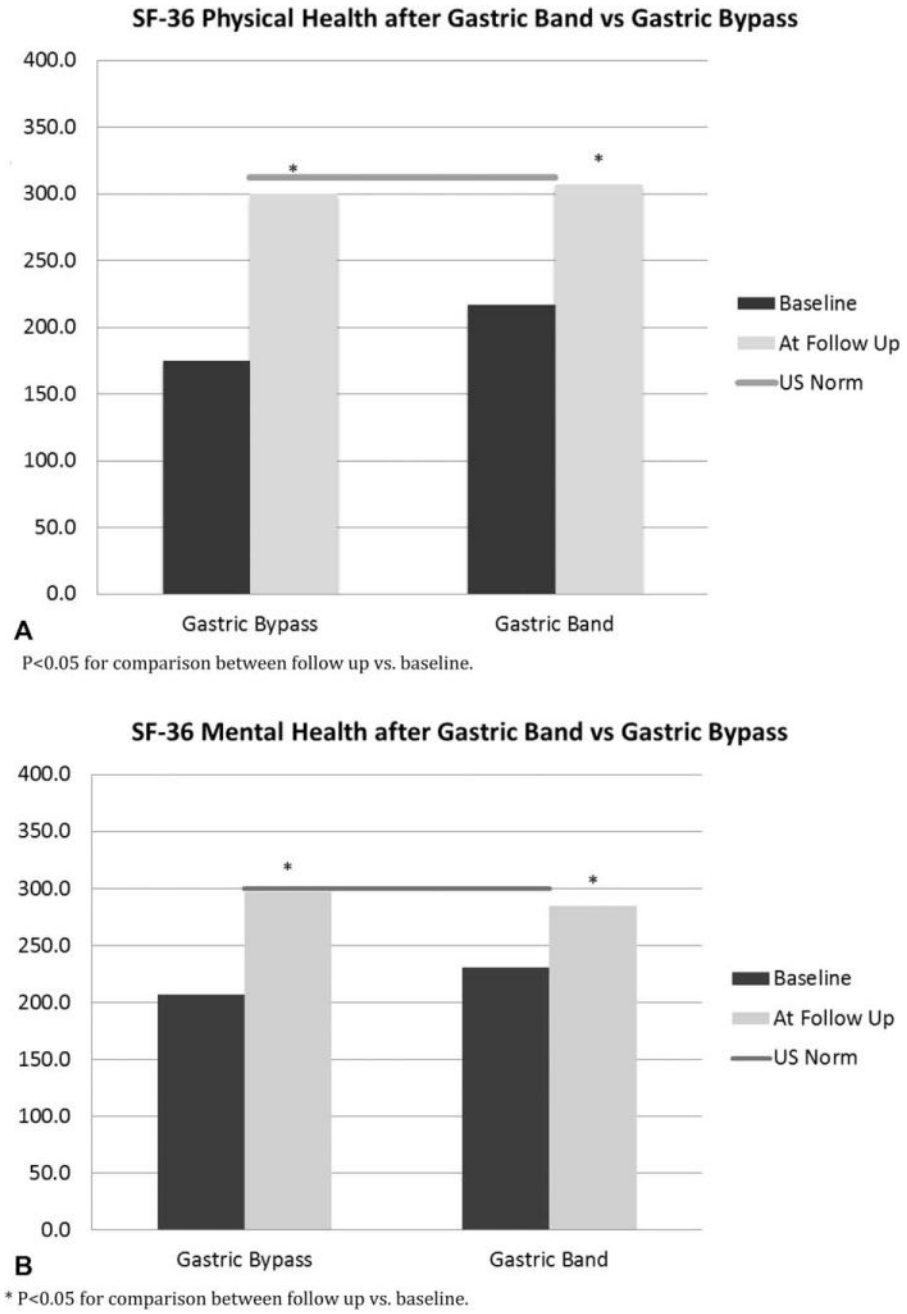

FIGURE 6.

SF-36 physical (A) and mental (B) health scores at baseline and at follow-up after gastric banding and gastric bypass.

TABLE 1

Late Complications (>90 d After Index Operation) After Gastric Banding Versus Gastric Bypass

Late Complications	Gastric Bypass	Gastric Band
Port revision	0	3
Internal hernia	0	0
Band erosion/slippage/obstruction	0	17
Ventral hernia	2	0
Marginal ulcer requiring revision of anastomosis	1	0
Bowel obstruction	1	0
Peripheral neuropathy	1	0
Marginal ulcer require medical management	15	0
Severe iron deficiency requiring iron infusion	4	0
Alcohol/drug abuse	4	1
Kidney stones	0	1
Poor weight loss requiring revisional surgery	0	5
Cancer	1	1
Cholecystitis	11	4
Death	2	0

TABLE 2

Multivariate Regression Analyses for Improved Weight Loss After Gastric Banding and Gastric Bypass

Baseline Factors (Reference)	Coefficient (95% CI)	*P* Value
Type of procedure (gastric bypass)	11.92 (8.62, 15.22)	<0.001
Sex (male)	−4.68 (−7.65, 1.72	0.002
Diabetes (presence of disease)	−4.24 (−8.43, 0.06)	0.047
Age	−0.08 (−0.24, 0.09)	0.379
BMI	0.11 (−0.30, 0.52)	0.607
Dyslipidemia	−0.15 (−4.43, 4.14)	0.947
Hypertension	0.02 (−4.03, 4.07)	0.992

CI indicates confidence interval.