Original Investigation

Weight Change and Health Outcomes at 3 Years After Bariatric Surgery Among Individuals With Severe Obesity

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IMPORTANCE Severe obesity (body mass index [BMI] ≥35) is associated with a broad range of health risks. Bariatric surgery induces weight loss and short-term health improvements, but little is known about long-term outcomes of these operations.

OBJECTIVE To report 3-year change in weight and select health parameters after common bariatric surgical procedures.

DESIGN AND SETTING The Longitudinal Assessment of Bariatric Surgery (LABS) Consortium is a multicenter observational cohort study at 10 US hospitals in 6 geographically diverse clinical centers.

PARTICIPANTS AND EXPOSURE Adults undergoing first-time bariatric surgical procedures as part of routine clinical care by participating surgeons were recruited between 2006 and 2009 and followed up until September 2012. Participants completed research assessments prior to surgery and 6 months, 12 months, and then annually after surgery.

MAIN OUTCOMES AND MEASURES Three years after Roux-en-Y gastric bypass (RYGB) or laparoscopic adjustable gastric banding (LAGB), we assessed percent weight change from baseline and the percentage of participants with diabetes achieving hemoglobin A_{1c} levels less than 6.5% or fasting plasma glucose values less than 126 mg/dL without pharmacologic therapy. Dyslipidemia and hypertension resolution at 3 years was also assessed.

RESULTS At baseline, participants (N = 2458) were 18 to 78 years old, 79% were women, median BMI was 45.9 (IQR, 41.7-51.5), and median weight was 129 kg (IQR, 115-147). For their first bariatric surgical procedure, 1738 participants underwent RYGB, 610 LAGB, and 110 other procedures. At baseline, 774 (33%) had diabetes, 1252 (63%) dyslipidemia, and 1601 (68%) hypertension. Three years after surgery, median actual weight loss for RYGB participants was 41 kg (IQR, 31-52), corresponding to a percentage of baseline weight lost of 31.5% (IQR, 24.6%-38.4%). For LAGB participants, actual weight loss was 20 kg (IQR, 10-29), corresponding to 15.9% (IQR, 7.9%-23.0%). The majority of weight loss was evident 1 year after surgery for both procedures. Five distinct weight change trajectory groups were identified for each procedure. Among participants who had diabetes at baseline, 216 RYGB participants (67.5%) and 28 LAGB participants (28.6%) experienced partial remission at 3 years. The incidence of diabetes was 0.9% after RYGB and 3.2% after LAGB. Dyslipidemia resolved in 237 RYGB participants (61.9%) and 39 LAGB participants (27.1%); remission of hypertension occurred in 269 RYGB participants (38.2%) and 43 LAGB participants (17.4%).

CONCLUSIONS AND RELEVANCE Among participants with severe obesity, there was substantial weight loss 3 years after bariatric surgery, with the majority experiencing maximum weight change during the first year. However, there was variability in the amount and trajectories of weight loss and in diabetes, blood pressure, and lipid outcomes.

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Bariatric surgery results in large, sustained weight loss in severely obese populations. Although generally accepted as the most effective means for inducing weight loss in very heavy patients, few studies exist reporting outcomes longer than 2 years after the surgery was performed. Long-term outcome studies that do exist are mostly case series, are from limited geographical areas, or report surgical procedures no longer performed.[1-5] For example, high-quality long-term outcomes from the Swedish Obesity Study are well described, but most of the participants underwent a vertical banded gastroplasty procedure, an operation no longer used.[6-8] Six-year follow-up after Roux-en-Y gastric bypass (RYGB) was reported, but these data may not be generalizable because all the participants were from 1 surgical practice in Utah.[9] Even though surgically induced weight loss is much more effective than nonsurgical treatments for seriously obese patients, surgery is still not universally accepted because of incomplete knowledge of long-term outcomes from the procedures.

The Longitudinal Assessment of Bariatric Surgery (LABS) Consortium was formed to acquire long-term data on the safety, effectiveness, and durability of bariatric surgical procedures currently performed in the United States using standardized data collection practices. LABS is a multicenter, observational cohort study with standardized and detailed data collection protocols. LABS has 3 phases; LABS-1, LABS-2, and LABS-3.[10] The 30-day safety of bariatric surgery was reported in LABS-1.[11] LABS-2 focused on longer-term safety, outcomes, and durability of health changes. The major priorities for LABS-2 were to determine weight, medical, surgical, and behavioral outcomes, including incidence and remission of comorbid conditions, and to evaluate patient, procedure, and other characteristics that were associated with these outcomes. LABS-3 included 2 substudies that examined mechanisms of diabetes change and psychosocial aspects in more detail.

We now report the major clinical outcomes from LABS-2, including 3-year weight change from baseline and diabetes, lipid, and hypertension outcomes after RYGB and laparoscopic adjustable gastric band (LAGB) procedures.

Methods

Participants

LABS-2 participants were at least 18 years old and underwent first-time bariatric procedures with a surgeon participating in the LABS consortium at 1 of 10 hospitals at 6 clinical centers in the United States.[12] All participants provided written informed consent and underwent surgery between March 2006 and April 2009. Follow-up for this report ended September 2012. Sociodemographic characteristics were self-reported. Race and ethnicity were considered missing for participants not self-reporting their race or ethnicity as at least 1 of the following: white or Caucasian, black or African American, Asian, American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, or Latino.

Participants whose initial bariatric surgery was subsequently revised or reversed are included in the 3-year results because they represent the natural history of the participant's postsurgical course.

The institutional review board at each center approved the protocol and consent forms.

Assessments and Outcome Measures

LABS-certified trained personnel collected study outcome data. Weights and other clinical data were collected within 30 days before surgery. If the original operation date had to be changed, biospecimen samples collected within 180 days before the bariatric operation were used. At 6 months after surgery, a brief clinical assessment was performed, with a complete evaluation performed annually after surgery.

Weight change is reported as the percent change from baseline.[10,13,14] During in-person follow-up visits, weight was measured ("in-person" weight) on a study-purchased standard scale (Tanita Body Composition Analyzer, model TBF-310).[10] If an in-person weight was not obtained, weight was measured by research or medical personnel on a nonstudy scale and is referred to as a "clinical" weight. If neither an in-person nor clinical weight was available, a participant self-reported weight was used. Differences between in-person and self-reported weights in this cohort were small and did not systematically differ by measured body mass index ([BMI] calculated as weight in kilograms divided by height in meters squared) or degree of postoperative weight change. The average degree of underreporting by self-report was 0.7 kg for women and 1.0 kg for men.[15] Weights of women in their second or third trimester of pregnancy and those up to 6-month postpartum were excluded from analyses (**Figure 1**).

Diabetes was defined as currently taking diabetes medication or having a glycated hemoglobin (HbA_{1c}) measure of 6.5% or greater or, if HbA_{1c} level was not available, then fasting plasma glucose value of 126 mg/dL or greater[16] as measured by a central laboratory used for all the study sites. (To convert glucose to mmol/L, multiply by 0.0555.) Participants reporting having polycystic ovarian syndrome who did not meet laboratory criteria for diabetes and were not taking a diabetes medication other than metformin were not considered to have diabetes.[12]

Hypertension was defined as having systolic blood pressure of at least 140 mm Hg or diastolic blood pressure of at least 90 mm Hg from a single measurement or taking an antihypertensive medication when evaluated.[12]

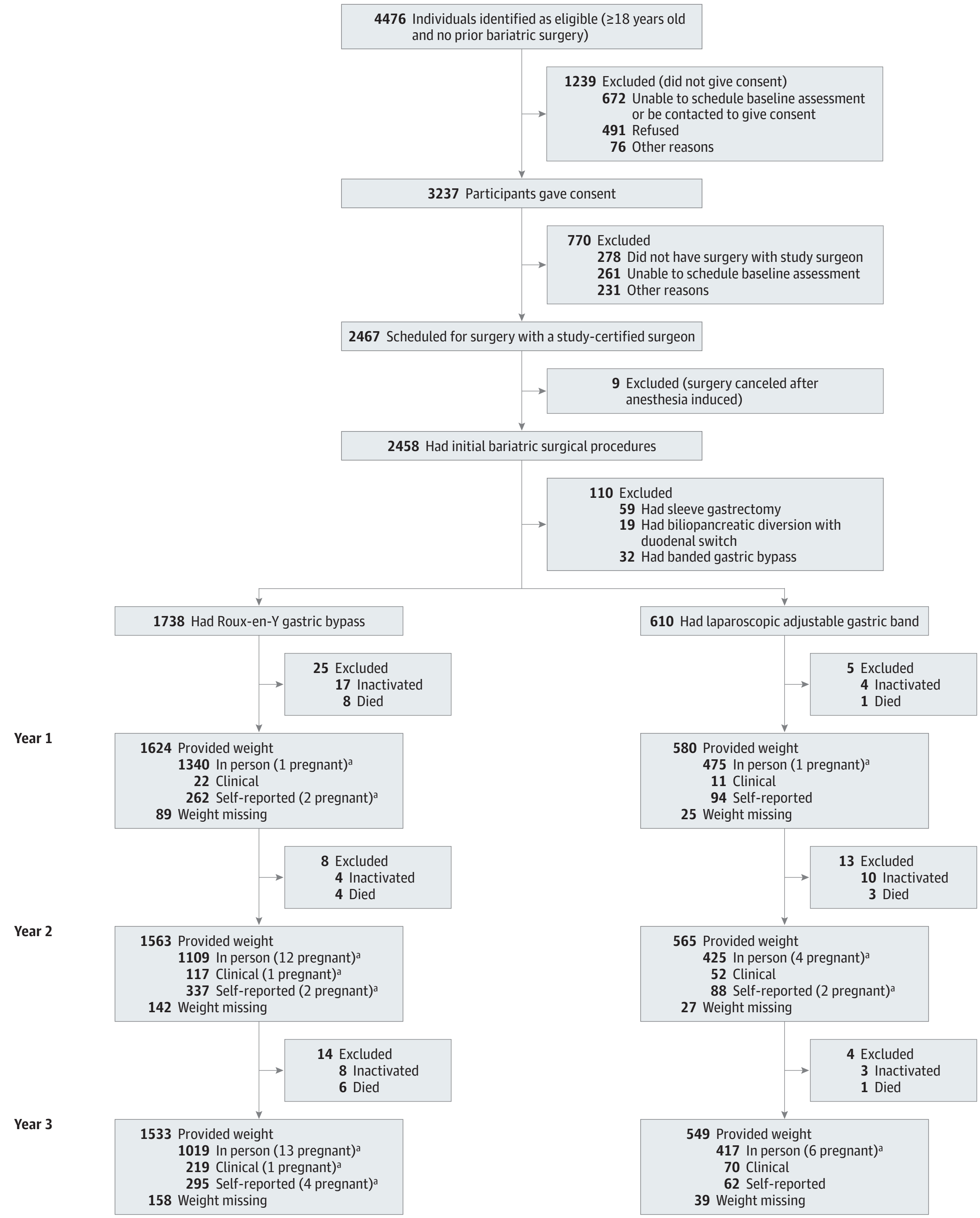
Dyslipidemia was defined as having either a low-density lipoprotein cholesterol (LDL) level of 160 mg/dL or greater, high-density lipoprotein cholesterol (HDL) level of less than 40 mg/dL, or fasting triglycerides level of 200 mg/dL or greater or currently taking a lipid-lowering medication.[12] (To convert LDL or HDL to mmol/L, multiply by 0.0259; to convert triglycerides to mmol/L, multiply by 0.0113.) Hyperlipidemia was defined as currently taking a lipid-lowering medication or having LDL of 160 mg/dL or greater. Low HDL was defined as less than 40 mg/dL and high triglycerides as fasting level of 200 mg/dL or greater.[12]

Deaths were adjudicated by committee using all available information (eg, death certificate, medical record, autopsy report). Subsequent bariatric procedures were identified by medical record review or participant self-report. Deaths and subsequent bariatric procedures within 3 years of the initial bariatric surgery are reported.

Statistical Analysis

Descriptive statistics summarize baseline characteristics for each procedure. Frequencies and percentages are reported for

Figure 1. Flow of Participants Through Recruitment, Follow-up, and Weight Measurements



[a]Weights of women in their second or third trimester and those up to 6-months postpartum were excluded from analyses.

categorical data. Medians and interquartile ranges (IQRs) are reported for continuous data.

The median and IQR of the observed percent weight change and the modeled mean percent weight change from a normal mixed model with only indicators for time after surgery are reported separately for RYGB and LAGB at each follow-up time point. The modeled values are used to account for missing weights due to missed visits.

Growth mixture models[17] were used to estimate weight change trajectories for each participant and to classify participants with similar modeled trajectories into groups. We required that the smallest trajectory group include at least 1% of the sample. With this constraint, the best fitting model was determined using the Bayesian information criterion. The modeled trajectories of each group are plotted, with bars indicating the IQR of the observed percent weight change for the participants within a group. Separate trajectories were derived for participants undergoing RYGB and LAGB.

Normal mixed models and growth mixture models assume weights are missing at random. To address this assumption, the baseline characteristics of participants with follow-up weights at every time point were compared with participants missing at least 1 follow-up weight value. Statistical significance was tested using the Wilcoxon rank sum test for continuous data and Pearson χ^2 test for categorical data. Furthermore, normal mixed models were used to test whether those missing weight values at a particular time point differed significantly from those with weight recorded with respect to percent weight change at the preceding and next time points. Because the results were not statistically significant for percent weight change at time points when they were available for those with missing weights, the assumption that data were missing at random was considered reasonable.

The percentage of participants with a comorbidity at baseline who did not have the comorbidity at year 3 was used to determine remission rates. The incidence rate was defined as the percentage of participants without the comorbidity at baseline who newly developed the comorbidity at year 3.

To determine the similarity of participants missing outcomes data at year 3 to those having the outcomes information, baseline characteristics of participants were compared using the Wilcoxon rank sum test for continuous data and Pearson χ^2 test for categorical data. In addition, the prevalence of each comorbidity at baseline and at years 1 and 2 was compared between participants with known and missing comorbidity data at year 3 using a logistic model adjusting for baseline characteristics found to be significantly associated with missing 3-year data.

Weighted percentages for incidence and remission were calculated using inverse proportional weighting to account for missing clinical information.[18] Participants with comorbidity information at both baseline and year 3 were weighted by the inverse of the probability of having follow-up data at year 3. These probabilities were estimated separately for remission and incidence percentages using a logistic regression model adjusting for age and site, stratified by procedure. In the weighted estimates, the individuals with complete data represent themselves as well as similar participants who had missing data.

The rates of death and of subsequent bariatric procedures, respectively, were estimated by dividing the number of events known to occur within 3 years of the initial bariatric surgery by the number of person-years of observation. We report the rates per 300 person-years, which corresponds to the number of events expected if 100 people were followed up for 3 years. Exact confidence intervals for rates were constructed using the Poisson distribution.

Analyses were conducted using SAS version 9.2 (SAS Institute), R version 2.15.2, and Mplus version 7 (Muthén & Muthén). All reported *P* values are 2-sided. *P* values less than .05 are considered to be statistically significant.

Results

This report includes the 1738 participants who underwent RYGB surgery and the 610 participants who underwent an LAGB procedure as their first bariatric operation. The 110 participants who underwent the less commonly performed procedures in LABS-2 are not included.

As shown in Figure 1, 3 years after surgery, a weight was obtained for 91% (91% RYGB and 93% LAGB) of the 2279 active participants (23 participants died and 46 were inactivated, 41 at the participants' request). Weights from in-person research visits were available for 66% of the RYGB participants and 76% of the LAGB participants at year 3 (Figure 1).

Details of the baseline characteristics of the LABS-2 cohort have been published.[12] Briefly, the median age was 46 years (range, 18-78 years), and the median BMI was 46 (range, 33-94); the majority of participants were female (79%), and 14% were nonwhite. **Table 1** presents select baseline characteristics of LABS-2 participants stratified by surgical procedure.

Weight Change

Weight was obtained at all 4 follow-up time points for 1365 RYGB participants (79%) and 521 LAGB participants (85%). Participants with a weight value at every time point were significantly older (RYGB, median age, 46 years [IQR, 38-55]; LAGB, median age, 48 years [IQR, 38-57]) compared with participants missing at least 1 follow-up weight measure (RYGB, median age, 41 years [IQR, 34-49], $P < .001$; LAGB, median age, 44 years [IQR, 33-53], $P = .01$). RYGB participants with a weight at every time point had a significantly lower baseline BMI (median BMI, 46.2 [IQR, 42.2-51.7]) and were more likely to be white (86%) than those missing at least 1 follow-up weight (median BMI, 48.0 [IQR, 43.0-52.9], $P = .002$; 81% white, $P = .02$). However, these differences in BMI were small. The percentages of RYGB and LAGB participants with complete weight data also varied significantly by clinical center ($P < .001$). For RYGB and LAGB participants, the percent weight change preceding a missed visit was not significantly different from those without a missed visit. Similarly, the percent weight change after a missed visit was not significantly different from those without a missed visit.

Figure 2 depicts both observed and modeled percent weight change by procedure and by time point. The modeled weight change (continuous lines) for both RYGB and LAGB show a close approximation to the observed medians at each time point. The IQR for observed weight change shows that there is substantial variability in weight change for participants at each time point; eg, at year 3, one-quarter of RYGB participants lost less than 25% of their baseline weight whereas one-quarter lost more than 38% of their baseline weight. At 3 years after surgery, the observed median percent weight loss for participants who underwent RYGB is 31.5% (IQR, 24.6%-38.4%; range, 59.2% loss to 0.9% gain) of baseline weight and 15.9% (IQR, 7.9%-23.0%; range, 56.1% loss to 12.6% gain) for LAGB. The actual median 3-year weight loss was 41 kg (IQR, 31-52; range, 110 loss to 1 gain) for RYGB and 20 kg (IQR, 10-29; range, 75 loss to 20 gain) for LAGB. As a group, participants experienced most of their total weight change in the first year after surgery. From years 2 to 3, modeled LAGB weight loss remained stable while RYGB weight loss began to demonstrate some modest erosion from 2-year levels.

To evaluate common patterns of weight change from baseline to 3 years among participants by procedure, 5 weight change trajectory groups were identified (**Figure 3**). The 5 RYGB trajectories (Figure 3A) all showed initial weight loss within the first 6 months after surgery. After 6 months, on average the participants in group 1 (2%) began to regain weight while those in groups 3, 4, and 5 continued to lose weight through 2 years. After 2 years of follow-up, the trajectories for groups 2, 3, 4, and 5 began to demonstrate some weight regain. However, in 76% of the RYGB participants represented (groups 3-5), the weight regain was small compared with the overall loss.

Figure 3B shows 5 weight change trajectory groups for those who underwent LAGB. Almost two-thirds (62%) of the participants were included in group 2, which showed the greatest average weight loss occurring in the first 6 months and then a slowing of weight loss and stabilization after 2 years. LAGB participants in group 1, the second most common trajectory (19%), experienced weight loss on average only during the first 6 months of follow-up, gaining weight on average through year 3. The group 5 trajectory (4%) showed continual weight loss throughout the 3-year period while group 3 (14%) showed steady weight loss for the first 2 years and then slight weight regain from years 2 to 3. Group 4 included only 7 participants who experienced substantial weight loss through year 2 with an increase in weight afterward.

Comorbid Conditions

Participants with missing comorbidity data at year 3 were significantly younger than participants with known 3-year comorbidity data. The percentage of participants with missing comorbidity data varied significantly by site. Percent weight change at year 3 was not significantly associated with miss-

Table 1. Baseline Characteristics of the LABS-2 Cohort by Procedure

	Overall (N = 2458)	Roux-en-Y Gastric Bypass (n = 1738)	Laparoscopic Adjustable Gastric Band (n = 610)	Sleeve Gastrectomy (n = 59)	BPDS (n = 19)	Banded Gastric Bypass[a] (n = 32)
Age, median (IQR), y	46 (37-54)	45 (37-54)	48 (37-56)	48 (36-55)	39 (35-46)	48 (40-54)
Range, y	18-78	19-75	18-78	21-73	26-60	21-69
Weight, median (IQR), kg	129 (115-147)	131 (116-150)	123 (111-139)	158 (134-180)	136 (123-151)	136 (116-157)
Range, kg	75-290	75-240	85-246	82-290	110-192	92-227
BMI, median (IQR)[b]	45.9 (41.7-51.5)	46.6 (42.4-51.9)	43.9 (40.4-48.0)	57.7 (46.8-64.1)	50.0 (44.9-52.3)	49.2 (42.5-54.1)
Range	33.0-94.3	33.7-81.0	33.0-87.3	35.5-94.3	37.9-62.6	36.2-76.0
Sex, No. (%)						
Female	1931 (78.6)	1389 (79.9)	465 (76.2)	39 (66.1)	14 (73.7)	24 (75.0)
Male	527 (21.4)	349 (20.1)	145 (23.8)	20 (33.9)	5 (26.3)	8 (25.0)
Race, No. (%)[c]						
White	2102 (86.4)	1463 (85.1)	543 (89.6)	47 (82.5)	18 (94.7)	31 (100.0)
Black	256 (10.5)	196 (11.4)	51 (8.4)	8 (14.0)	1 (5.3)	0 (0.0)
Other	75 (3.1)	61 (3.5)	12 (2.0)	2 (3.5)	0 (0.0)	0 (0.0)
Ethnicity, No. (%)[c]						
Hispanic	119 (4.8)	85 (4.9)	26 (4.3)	6 (10.2)	0 (0.0)	2 (6.2)
Non-Hispanic	2337 (95.2)	1652 (95.1)	583 (95.7)	53 (89.8)	19 (100.0)	30 (93.8)
Diabetes, No. (%)[c]	774 (33.4)	583 (35.4)	164 (28.8)	15 (28.8)	7 (38.9)	5 (17.2)
Dyslipidemia, No. (%)[c]	1252 (63.4)	901 (64.4)	291 (60.9)	33 (64.7)	9 (52.9)	18 (64.3)
Hyperlipidemia, No. (%)[c]	725 (36.6)	515 (36.7)	177 (36.7)	22 (43.1)	5 (29.4)	6 (21.4)
Low HDL, No. (%)[c]	883 (37.5)	648 (38.8)	194 (33.3)	21 (37.5)	5 (27.8)	15 (50.0)
High triglycerides, No. (%)[c]	462 (22.9)	339 (23.8)	103 (21.1)	12 (21.8)	5 (27.8)	3 (10.7)
Hypertension, No. (%)[c]	1601 (67.5)	1159 (68.9)	367 (62.7)	44 (80.0)	10 (52.6)	21 (67.7)

Abbreviations: BMI, body mass index; BPDS, biliopancreatic diversion with duodenal switch; HDL, high-density lipoprotein cholesterol; IQR, interquartile range.

[a] Banded gastric bypass is a gastric bypass with a nonadjustable band.

[b] Calculated as weight in kilograms divided by height in meters squared

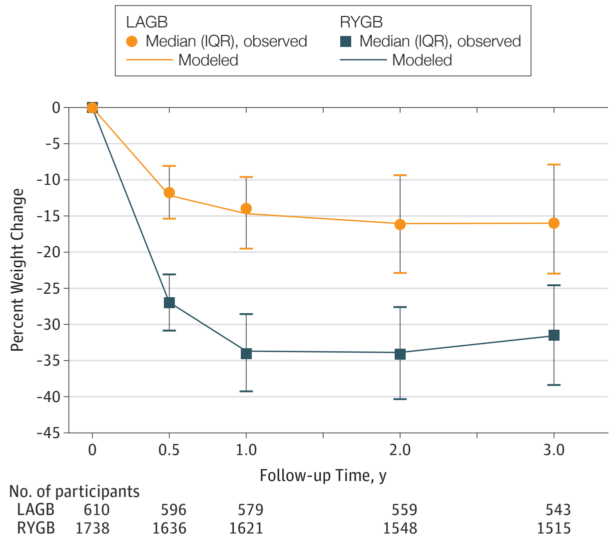
[c] Missing data: 25 race; 2 ethnicity; 144 diabetes; 484 dyslipidemia; 476 hyperlipidemia; 101 low HDL; 444 high triglycerides; 86 hypertension.

ing 3-year data for any of the comorbidities. Adjusting for age and site, the prevalence of each comorbid condition prior to year 3 did not differ significantly between participants with known and unknown 3-year comorbidity data using a Bonferroni-corrected significance level of .003. **Table 2** shows both observed and "weighted" remission and incidence of several important comorbid health conditions at 3 years after surgery. Only observed rates are reported in the text because observed and weighted values are similar.

Three years after surgery, the percentages of participants experiencing at least partial diabetes remission were 67.5% and 28.6% for RYGB and LAGB, respectively, while the percentages of participants with new-onset (incident) diabetes were 0.9% and 3.2% for RYGB and LAGB, respectively.

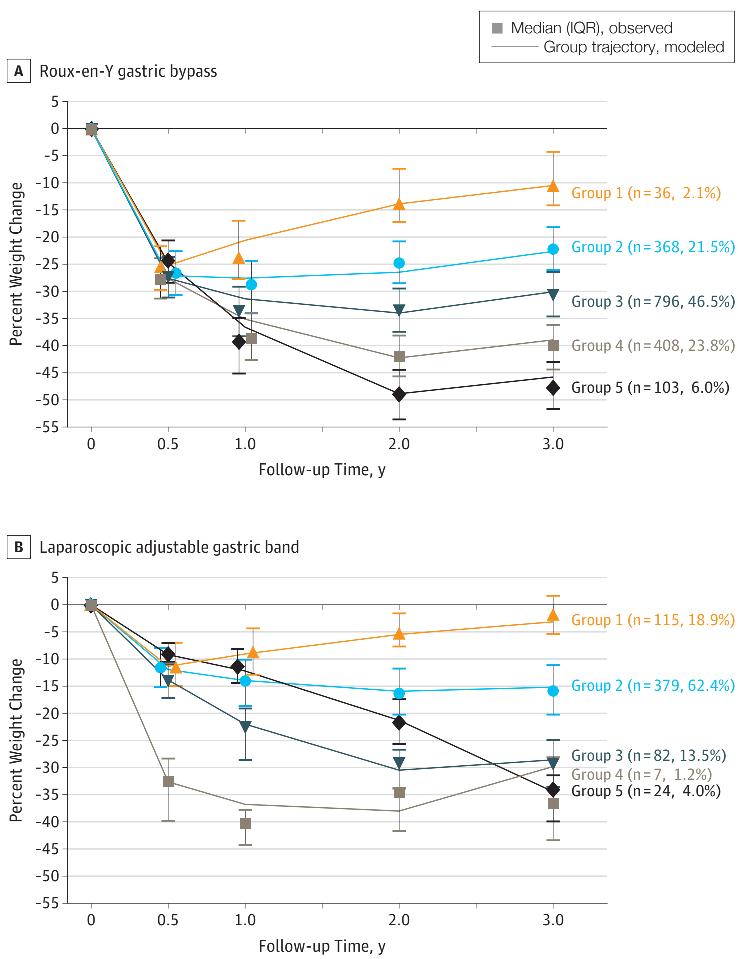
Dyslipidemia was in remission for 61.9% of RYGB participants and 27.1% of LAGB participants at 3 years. A new diagnosis of dyslipidemia was made in 3.2% of RYGB and 16.0% of LAGB participants. Changes in hyperlipidemia were similar. Low HDL remitted in 85.6% and 67.3% for RYGB and LAGB participants and high triglycerides remitted in 85.8% and 62.1%, respectively. Hypertension was in remission at 3 years in 38.2% of RYGB and 17.4% of LAGB participants, and incidence was 12.6% in RYGB and 18.1% in LAGB participants over 3 years.

Figure 2. Observed and Modeled Percent Weight Change by Time Point



Lines indicate modeled weight change; data markers, median values; bars, interquartile ranges.

Figure 3. Percent Weight Change Trajectories



Growth mixture models were used to estimate weight change trajectories for each participant and to classify participants with similar modeled trajectories into groups. Lines indicate modeled group trajectories; data markers, observed median values; bars, observed interquartile ranges.

Table 2. Observed and Weighted Remission and Incident Rates 3 Years After Bariatric Surgery by Procedure[a]

	Roux-en-Y Gastric Bypass (n = 1691)[b]		Laparoscopic Adjustable Gastric Band (n = 588)[b]	
	Observed No./Total No. (%)[c]	Weighted % (95% CI)[d]	Observed No./Total No. (%)[c]	Weighted % (95% CI)[d]
Diabetes				
Remission	216/320 (67.5)	68.9 (64.9-72.5)	28/98 (28.6)	29.4 (22.8-37.0)
Incidence	5/560 (0.9)	0.8 (0.4-1.6)	8/247 (3.2)	3.2 (1.8-5.5)
Dyslipidemia				
Remission	237/383 (61.9)	61.6 (58.2-64.8)	39/144 (27.1)	25.9 (21.0-31.5)
Incidence	7/221 (3.2)	3.2 (2.0-5.3)	15/94 (16.0)	16.9 (11.9-23.3)
Hyperlipidemia				
Remission	151/253 (59.7)	58.9 (54.4-63.2)	22/97 (22.7)	23.5 (17.7-30.7)
Incidence	9/353 (2.5)	2.4 (1.5-3.7)	21/143 (14.7)	14.3 (10.6-18.9)
Low HDL				
Remission	292/341 (85.6)	86.5 (83.6-89.0)	76/113 (67.3)	65.9 (58.6-72.4)
Incidence	9/616 (1.5)	1.4 (0.9-2.4)	10/266 (3.8)	3.5 (2.0-5.9)
High triglycerides				
Remission	139/162 (85.8)	83.9 (79.4-87.6)	36/58 (62.1)	60.4 (50.1-69.9)
Incidence	8/495 (1.6)	1.4 (0.8-2.3)	14/206 (6.8)	7.0 (4.8-10.1)
Hypertension				
Remission	269/705 (38.2)	41.0 (38.1-43.9)	43/247 (17.4)	18.8 (15.0-23.2)
Incidence	39/309 (12.6)	12.6 (10.0-15.8)	27/149 (18.1)	17.3 (12.7-23.2)

Abbreviations: HDL, high-density lipoprotein cholesterol.

[a] Remission is the percentage of participants with the comorbidity at baseline who did not have the comorbidity at year 3. Incidence is the percentage of participants without the comorbidity at baseline who did have the comorbidity at year 3.

[b] Active participants at year 3; participants not included in the denominator for remission or incidence are missing comorbidity data.

[c] Observed percentages for participants with comorbidity data at baseline and year 3.

[d] Model estimates from weighting the participants with comorbidity data at baseline and year 3 by the inverse of the estimated probability that the participant has comorbidity data at year 3 adjusting for age and site.

Deaths and Subsequent Procedures

Deaths and subsequent bariatric procedures within 3 years of initial bariatric surgery are detailed in **Table 3**. After RYGB procedures, 16 deaths were reported, with 3 occurring in the immediate 30-day postsurgical period. There were 2 RYGB revision procedures and 2 RYGB reversal procedures over the 3 years.

For LAGB procedures, there were 5 deaths, with none occurring during the 30-day postsurgical period. There were 77 subsequent bariatric procedures among the 610 LAGB participants over the 3-year period, the majority for band removal, revision to another bariatric procedure, or port revision.

Discussion

In 3-year follow-up after bariatric surgery, substantial weight loss was observed, with most of the change occurring during the first year. Compared with the very modest weight loss resulting from lifestyle intervention,[19,20] at 3 years, weight loss from bariatric surgery was substantial: 31.5% of baseline weight for RYGB participants and 15.9% for LAGB participants. There was great variability in the amount and trajectory of weight loss, as well as in diabetes, blood pressure, and lipid outcomes. Variability in weight change also indicates a potential opportunity to improve patient selection and education prior to surgery as well as enhance support for continued adherence to lifestyle adjustments in the postoperative years.

Weight loss from RYGB in LABS-2 was similar to that observed in the Utah Obesity Study.[9] Because our patient population was more diverse and our results were from a large number of surgeons and surgical centers, long-term, sustained weight loss can be expected from RYGB, and the results are likely generalizable. Our RYGB results were also similar to those observed for RYGB in the Swedish Obesity Study even though their participants were more homogenous than ours.[6] Weight loss associated with the LAGB procedure was less than anticipated in our study and less than what would be expected based on published series.[21-23] These studies reported 20% to 25% initial weight loss with weight loss continuing through and then reaching a plateau at 3 years. LABS-2 LAGB participants experienced different weight loss trajectories than previously reported, with less than 20% of participants experiencing much weight loss after the first year. The differences between our results and those of prior publications and the extreme heterogeneity in outcomes we found highlight the need to better understand factors contributing to individual differences in weight loss results.

Health improvements in diabetes, blood pressure, and lipids also showed variability in response. The diabetes partial remission rate for RYGB in LABS-2 (67.5%) is comparable with the 6-year remission rate in the Utah Obesity Study (62%) but is somewhat lower than the 75% to 80% remission rates observed in other retrospective reviews[1-5,24,25] and randomized controlled single-site studies/trials of RYGB with shorter (1- and 2-year) follow-up periods.[26,27] This is perhaps due to at least 2 factors including the duration of follow-up and the definitions of diabetes and diabetes remission that were used (quite similar in LABS-2 and the Utah Obesity Study) as well as other differences in the nature of follow-up (standardized vs clinical vs administrative data collection). The partial remission rate of diabetes among LAGB participants in LABS-2, 28.6%, is considerably lower than the 73% rate after 2 years as reported by Dixon et al,[28] although participants in that trial had mild diabetes by study design and experienced more consistent weight loss. In contrast, the LABS-2 participants were not selected based on diabetes status but recruited from all eligible and consenting participants for bariatric surgery at the clinical sites and represent a group of participants with diabetes over the entire spectrum of disease severity. The range of disease severity and the relatively modest weight change of LAGB participants in LABS-2 likely account for the lower rates of diabetes improvement.

The RYGB rates of hypertension remission (38.2%) in LABS-2 are consistent with the Swedish Obesity Study remission rates of all surgery participants of 34% and 19% at 2 and 10 years of follow-up, respectively.[6] The Utah Obesity Study of RYGB reported hypertension remission of 53% and 42% at 2 and 6 years' follow-up,[9] slightly better than that observed in LABS-2. The remission of hypertension is a complex measurement that requires frequent monitoring and longer-term follow-up as many hypertensive participants experience a period of remission while not receiving medication, but many eventually relapse.[29] In addition, the relapse in blood pressure after surgical weight loss appears to be related more to aging and recent small weight increases than to baseline weight or the type of initial weight loss after a procedure.[30] Among the LAGB participants, remission rates of hypertension were lower than previously reported, again perhaps due to either initial disease severity or the more modest weight loss.[31,32]

Remission of any dyslipidemia in LABS-2 was 61.9% for RYGB and 27.1% for LAGB, consistent with prior studies for RYGB but lower than other LAGB reports.[33,34] Hyperlipidemia was in remission in 59.7% of RYGB participants in LABS-2, which is consistent with the 2- and 6-year rates of 57% and 53%, respectively, for RYGB in the Utah Obesity Study.[9] High triglyceride levels improved after both RYGB and LAGB participants in LABS-2 with remission in 85.8% and 62.1%, respectively. High resolution rates were also observed for triglycerides in both the Utah and Swedish obesity studies[6,7,9] at the reported time points.

The primary strength of the LABS-2 study is that data were collected on a large sample using standardized definitions and procedures by trained evaluators in a multicenter, geographically diverse cohort.[10] These factors should make the results of the LABS-2 study generalizable to clinical practice. In addition, longer-term and detailed complication data are being collected in LABS-2. At this time, fewer than 1 in 100 participants followed up for 3 years after RYGB or LAGB surgery died. Subsequent bariatric procedures were rare within 3 years after RYGB and were more common after LAGB.

Conclusions regarding the long-term efficacy of bariatric surgery are limited because many studies have incomplete long-term follow-up rates, with completeness of data collection declining below 50% after 1 to 2 years.[5,35] As a longitudinal study, LABS-2 has a strong emphasis on retention with resources devoted to obtaining high ascertainment rates.[36] A strength of the current study is that it reports follow-up weights in more than 90% of active participants at 3 years. Despite its commitment, LABS-2 did not accomplish complete in-person follow-up required for measures of comorbid health outcomes. However, the results presented here are based on a thorough analysis of the missing data to provide an estimate of comorbid health at 3 years after RYGB and LAGB. This highlights one of the significant challenges to large, multicenter, clinical observational studies in bariatric surgery[36] and stresses the need for sustained efforts to maximize retention and follow-up.

Another weakness to consider in interpreting differences in weight loss and comorbidity improvement between procedures is that as an observational study, participants underwent specific procedures based on clinical decision making, including individual or surgeon preference. Thus, baseline differences, both measured and unmeasured, between participants undergoing differing procedures may have had an effect on both weight and health outcomes.

Table 3. Deaths and Subsequent Bariatric Surgery Procedures Within 3 Years of Initial Bariatric Surgery

	No. of Participants	Rate[a] (95% CI)
Roux-en-Y Gastric Bypass (n = 1738)		
Deaths	16[b]	0.9 (0.5-1.5)
Within 30 days of surgery	3	0.2 (0.04-0.5)
Sepsis	1	
Cardiovascular disease	1	
Pulmonary embolism	1	
More than 30 days after surgery	13	0.8 (0.4-1.3)
Bowel obstruction	1	
Sepsis	1	
Respiratory failure	1	
Cardiovascular disease	3	
Suicide/substance abuse	2	
Cancer	1	
Indeterminate after adjudication	4	
Subsequent bariatric surgery procedures	4	0.3 (0.1-0.9)
Revision	2	
Reversal	2	
Laparoscopic Adjustable Gastric Band (n = 610)		
Deaths	5	0.8 (0.3-1.9)
Within 30 days of surgery	0	0 (0-0.6)
More than 30 days after surgery	5	0.8 (0.3-1.9)
Organ failure	2	
Respiratory failure	1	
Cancer	1	
Indeterminate after adjudication	1	
Subsequent bariatric surgery procedures	77	17.5 (13.8-21.9)
Band replacement	7	
Port revision	19	
Other revision	10	
Band removal	21	
Revision to another bariatric procedure	20	

[a] Estimated number of events per 300 person-years (ie, estimated number of events if 100 participants were followed up for 3 years).

[b] The 16 deaths reported in Table 3 occurred within 3 calender years after surgery. The 18 deaths in Figure 1 occurred within study visit windows, which extend slightly beyond 3 years.

In conclusion, LABS-2 data confirm in a heterogeneous population with a high degree of follow-up that RYGB and LAGB were associated with significant weight and health improvements at 3 years after surgery. Reduction in weight and improvements in comorbid conditions with LAGB were less than reported in previous studies and not as large as those seen with RYGB. Longer-term follow-up of this cohort will determine the durability of these improvements over time and factors associated with variability in effect.

ARTICLE INFORMATION

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