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Bariatric Surgery vs Lifestyle Intervention for Diabetes Treatment: 5-Year Outcomes From a Randomized Trial

Anita P Courcoulas,[1] James W Gallagher,[1] Rebecca H Neiberg,[2] Emily B Eagleton,[1] James P DeLany,[3] Wei Lang,[4] Suriya Punchai,[1,5] William Gourash,[6] and John M Jakicic[7]

[1] Department of Surgery, University of Pittsburgh, Pittsburgh, Pennsylvania
[2] Department of Biostatistics and Data Sciences, Wake Forest School of Medicine, Winston-Salem, North Carolina
[3] Translational Research Institute for Metabolism and Diabetes, AdventHealth, Orlando, Florida
[4] UniversitätsSpital Zürich Zentrum Alter und Mobilität, Zürich, Switzerland
[5] Department of Surgery, Faculty of Medicine, Khon Kaen University, Khon Kaen, Thailand
[6] Department of Surgery, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania
[7] Physical Activity and Weight Management Research Center, Department of Health and Physical Activity, University of Pittsburgh, Pittsburgh, Pennsylvania

Correspondence and Reprint Requests: Anita P. Courcoulas, MD, MPH, Department of Surgery, University of Pittsburgh, 3380 Boulevard of the Allies, Suite 390, Pittsburgh, PA 15213. E-mail: courcoulasap@upmc.edu.

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Abstract

Context

Questions remain about bariatric surgery for type 2 diabetes mellitus (T2DM) treatment.

Objective

Compare the remission of T2DM following surgical or nonsurgical treatments.

Design, setting, and participants

Randomized controlled trial at the University of Pittsburgh, in the United States. Five-year follow-up from February 2015 until June 2016.

Interventions

61 participants with obesity and T2DM who were initially randomized to either bariatric surgical treatments (Roux-en-Y gastric bypass [RYGB] or laparoscopic adjustable gastric banding [LAGB]) or an intensive lifestyle weight loss intervention (LWLI) program for 1 year. Lower level lifestyle weight loss interventions (LLLIs) were then delivered for 4 years.

Main Outcomes and Measures

Diabetes remission assessed at 5 years.

Results

The mean age of the patients was 47 ± 6.6 years, 82% were women, and 21% African American. Mean hemoglobin A1c level 7.8% ± 1.9%, body mass index (BMI) 35.7 ± 3.1 kg/m^2, and 26 participants (43%) had BMI < 35 kg/m^2. Partial or complete T2DM remission was achieved by 30% (n = 6) of RYGB, 19% (n = 4) of LAGB, and no LWLI participants (P = .0208). At 5 years those in the RYGB group had the largest percentage of individuals (56%) not requiring any medications for T2DM compared with those in the LAGB (45%) and LWLI (0%) groups (P = .0065). Mean reductions in percent body weight at 5 years was the greatest after RYGB 25.2% ± 2.1%, followed by LAGB 12.7% ± 2.0% and lifestyle treatment 5.1% ± 2.5% (all pairwise P < .01).

Conclusions

Surgical treatments are more effective than lifestyle intervention alone for T2DM treatment.

Keywords: Obesity, type 2 diabetes mellitus, bariatric, randomized controlled trial

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Obesity and type 2 diabetes mellitus (T2DM) are closely correlated chronic conditions with an increasing prevalence worldwide (1). There is growing literature and observational and randomized control trials (RCTs) demonstrating bariatric/metabolic surgery can be a safe, effective, and durable treatment for both obesity and T2DM (2–4). A consensus statement from the 2nd Diabetes Surgery Summit (DSS-II) published a treatment algorithm recommending bariatric/metabolic surgery as treatment for T2DM for patients with class III obesity (BMI [body mass index] ≥ 40 kg/m^2) and in patients with class II obesity (BMI 35–39.9 kg/m^2) when hyperglycemia is not sufficiently controlled with lifestyle and medical treatments (5). DSS-II also recommended the consideration of bariatric/metabolic surgery for treatment of T2DM in class I obesity (BMI 30–34.9 kg/m^2) if hyperglycemia is inadequately controlled despite optimal treatment with either oral or injectable medications. Despite these recommendations, even more data are needed about the long-term effectiveness, safety, and durability of surgical versus nonsurgical treatments for T2DM in those with class I obesity (6). To date, published RCTs have shown bariatric surgery of all types is significantly superior to medical or lifestyle interventions in achieving and maintaining remission of T2DM but all studies are relatively small and more longer-term data are needed to address durability and longer-term safety of these comparative outcomes (3,4,7–9).

We have previously reported at 1 and 3 years for bariatric surgery (Roux-en-Y gastric bypass [RYGB] and laparoscopic adjustable gastric band [LAGB]) plus low-level lifestyle intervention (LLLI) are superior to intensive lifestyle weight loss intervention (LWLI) alone for T2DM remission and other glycemic control endpoints (9,10). In this longer-term study, we now report 5-year results evaluating the outcome of 2 types of bariatric surgery (RYGB, LAGB) and an LWLI for 1 year, followed by 4 years of LLLI for all 3 treatment groups that were modeled after the Look AHEAD (Action for Health in Diabetes) and Diabetes Prevention Program trials (11,12). This report addresses comparative efficacy of surgical and nonsurgical treatments for T2DM remission and reports other glycemic control outcomes, weight change, lipids, blood pressure, and adverse events. These results will contribute additional high-level evidence about the relative efficacy of different surgical versus nonsurgical treatments for T2DM, particularly in lower BMI individuals.

Materials and Methods

Study design

The design, methods, and rationale of this study have been previously reported (9,10). The study protocol was reviewed and approved by the University of Pittsburgh Institutional Review Board. Briefly, the trial was a prospective, single institution, randomized clinical trial with stratification by gender and baseline BMI. There were 3 treatment arms that compared the efficacy for treating T2DM: RYGB or LAGB followed by LLLI in years 2 to 5, and LWLI in year 1 then 4 years of LLLI. The inclusion criteria were adults aged 25 to 55 years with a BMI of 30 to 40 kg/m^2 and a diagnosis of T2DM confirmed by fasting plasma glucose (FPG) level of greater than 125 mg/dL *and/or* treatment with at least 1 glucose-lower medication (10). All patients provided written informed consent. The 61 participants randomized, treated, and followed (20 RYGB + LLLI, 21 LAGB + LLLI, 20 LWLI + LLLI) in the initial and second phase of the trial were also eligible and included in this third phase of the study.

Intervention

After conducting 1-year follow-up (initial phase) (10), the study participants provided informed consent for an additional 2 years (second phase) (9) of annual visits and a structured LLLI, which was subsequently extended an additional 2 years for 5 years of total follow-up for all 3 groups (RYGB + LLLI, LAGB + LLLI, and LWLI + LLLI) in this third phase of the study. While the study physician monitored all laboratory data including glucose levels for safety according to protocol guidelines, the management all individuals' T2DM was driven by their original treating endocrinologist or primary care physician. The first year of the intensive lifestyle LWLI arm and the LLLI for all 3 arms were developed from the Diabetes Prevention Program and the Look AHEAD trial, customized for patients treated with a surgical intervention (11–13). After the first year of follow-up, the postsurgical patients (RYGB and LAGB) were provided instruction on the behavioral changes for weight control that participants in the LWLI were taught during their year 1 intervention. The LLLI for all groups comprised an in-person session (approximately 30–40 minutes) and a brief telephone call (less than 10 minutes) per month plus regular refresher group meetings. At each meeting, a specific behavioral change concept related to weight loss was targeted. If a participant was unable to attend the in-person session, a telephone call was utilized, and relevant materials were mailed to the individual.

Study outcomes

The priori-defined primary and secondary endpoints for this trial was to conduct a 1-year feasibility study (initial phase) (10). Subsequent follow-up assessments after the first year were therefore exploratory. The primary outcomes in this 5-year follow-up report mirrored those reported in the 3-year outcomes paper and include either partial or complete remission of T2DM (9). Remission of T2DM was defined by the American Diabetes Association criteria, which classifies partial remission as absence of any medications for diabetes with hemoglobin A1c (HbA1c) level < 6.5% and FPG ≤ 125 mg/dL (14). Complete remission was defined as absence of medications with HbA1c <5.7% and FPG ≤ 100 mg/dL (14). Secondary outcomes included glycemic control and medications, weight change, lipid profile changes, blood pressure, and adverse events. Glycemic control (defined by same FPG and HbA1c), and the use of glucose-lowering medications (4 categories: none, insulin only, insulin/other medication, oral/other medication) were recorded prior to initial treatment and then at each annual follow-up visit. Baseline measurements of weight, including calculation of BMI (weight in kilograms divided by square of height in meters) and waist circumference. Blood was drawn for a lipid profile (high- and low-density lipoproteins, triglycerides, and total cholesterol) at each visit. Blood pressure was measured twice at each visit and averaged. Adverse events of any type requiring medical treatment were also recorded in detail at each visit.

Statistical analysis

Statistical analyses were performed using SAS (version 9.4) with the type I error rate fixed at 0.05 (2-tailed). Categorical variables are summarized using frequencies and percentages. Continuous variables with normal distributions are presented as mean (±standard deviation); continuous variables with non-normal distributions are presented as medians and interquartile ranges. Differences in baseline characteristics among the RYGB, LAGB, and LWLI groups were examined using the Pearson's chi-square test or Fisher's exact test for categorical variables and analysis of variance or Kruskal–Wallis test for continuous variables.

Changes in continuous outcomes from baseline to 12, 24, 36, 48, and 60 months were analyzed using mixed effects models with covariate adjustment for randomization stratification factors (gender and baseline BMI). Percent change in weight was adjusted for baseline weight. Inferences focused on the overall treatment effect, time, and treatment by time interaction. Pairwise comparisons were made between treatment groups at 60 months. For each outcome, 3 pairwise comparisons were made among the 3 treatment groups at 60 months, with the significance level set at .0167 (=.05/3) using the Bonferroni correction to account for multiple comparisons. Least-square means, along with their standard errors, were obtained from the models. Intent-to-treat analyses were conducted using multiple imputation using SAS PROC MI and PROC MIANALYZE. For each outcome, 10 datasets were imputed, and results were combined. For the primary endpoints of partial T2DM remission and complete remission, as well as other categorical data such as medication category usage, the Fisher's exact test was used to compare differences among groups at given time point. The intention-to-treat approach was used in analyses of the primary endpoint assuming no remission for participants that did not return for follow-up.

Results

Study participants

Of the 69 participants who underwent randomization from October 2009 to March 2012, 7 (10%, 3 RYGB, 1 LAGB, 3 LWLI) declined to undergo their assigned treatment and 1 patient was excluded on the day of the scheduled operation (RYGB) due to current smoking. Of these 61 participants, 82% were women and 21% were African American. The mean values for age were 47.3 ± 6.6 years, 35.7 ± 3.1 kg/m^2 for BMI, and 100.5 ± 13.7 kg for baseline weight. Forty-three percent of the participants (26 people) had had a baseline BMI less than 35 kg/m^2 (class I obesity). The mean duration of T2DM prior to randomization was 6.5 ± 4.8 years, with a mean baseline HbA1c level of 7.8% ± 1.9% and fasting plasma glucose of 171.3 ± 72.5 mg/dL. The baseline characteristics of all three groups can be found in Table 1.

Primary endpoints

Of these 61 participants, there were 2 participants from RYGB and 5 participants from LWLI had no follow-up data at all; there were another 2 participants from RYGB, 1 participant from LAGB, and 1 participant from LWLI had no year 5 data. At 5 years, 6 (30%) RYGB participants attained at least partial T2DM remission, compared to 4 (19%) in LAGB, and none in LWLI (P = .0208) (Fig. 1). For RYGB, 4 of the 6 experienced at least partial remission continuously at each annual visit over years 1 to 5, and 2 of the 6 were in any (partial or complete) remission years 1 to 3 and then again at year 5. Complete remission of T2DM at 5 years was achieved by only 1 (5.0%) RYGB participant and none in either LAGB or LWLI groups (P = .66). Fig. 1 also shows a decline in T2DM remission (either partial or complete) over time in both surgical intervention arms: from 60% at 1 year to 40% at 3 years and 30% at 5 years for RYGB and from 29% at 1 and 3 years to 19% at 5 years for LAGB. No one in the LWLI group experienced remission at any of the annual time points.

Glycemic control and medications

At 5 years, both surgical procedures plus LLLI were superior to lifestyle intervention alone (LWLI) in achieving glycemic control defined by HbA1c and fasting plasma glucose levels (15). The RYGB group achieved the largest improvement in both HbA1c, (mean [SD], −1.46% [0.39]), and FPG (−49.1 mg/dL [15.96]), comparing baseline to 5 year levels (HbA1c: $P < .0001$ for RYGB vs LWLI; FPG: P = .0919 for RYGB vs LWLI) (15). The LAGB group showed improvements in HbA1c (−0.62% [0.35]) at 5 years (P = .0078 for LAGB vs LWLI) and FPG improved an average of 35.4 mg/dL [15.08] (P = .2602 for LAGB vs. LWLI). At 5 years, the RYGB group had the largest share of participants (56%) who no longer required any medications compared with those in the LAGB (45%) and LWLI (0%) groups (P = .0065) (Fig. 2).

Body weight

At 5 years, reductions in body weight, BMI, and waist circumference were greatest in patients treated with RYGB followed by LAGB and finally LWLI. (Table 2) These reductions in the RYGB were significantly greater than the LAGB group (all $P < .0005$). Fig. 3 shows the adjusted mean percent weight change from baseline to year 5 by treatment group. By year 5, RYGB demonstrated (mean [SD]) −25.2% [2.09%] change in weight compared with baseline, while LAGB (−12.7% [1.98%]) and LWLI (−5.14% [2.46%]) showed smaller changes (all $P < .009$). Similarly, the mean of weight loss in kilograms from baseline to year 5 was highest in RYGB (−24.9 kg [2.12]) compared with LAGB (−12.6 kg [2.01], $P < .001$) and LWLI (−4.5kg [2.51], $P < .001$) (Table 2).

Lipids and blood pressure

At 5 years, the RYGB group demonstrated the greatest improvements in triglyceride levels ($P = .0003$) and high-density lipoprotein levels ($P = .0042$) compared with LWLI. (Table 2) The RYGB group had the greatest improvements in systolic blood pressure compared to LAGB and LWLI ($P < .009$ for both) and significantly improved diastolic blood pressure compared with LAGB ($P = .0078$) (Table 2). The results for RYGB compared with LAGB for other lipids and LAGB compared with LWLI for blood pressure and lipid measures were inconsistent and not significant (Table 2).

Adverse events

For events and complications occurring more than 30 days after randomization, participants in the LWLI experienced primarily orthopedic related events with 10 individuals undergoing orthopedic procedures in the 5-year follow-up period. There were orthopedic events and procedures for participants in the RYGB (5) and LAGB (8) cohorts as well. There were no deaths in any of the groups, 1 cardiovascular event in the RYGB group requiring a coronary stent placement and 2 cardiovascular/blood pressure-related events (hypertension and hypotension) in LAGB participants. One participant in LWLI underwent a crossover bariatric surgical procedure to LAGB. One RYGB participant developed an anastomotic ulcer requiring an operation, and 2 LAGB participants underwent a revisional bariatric procedures. The complete list of 65 adverse events in 32 participants can be found in Table 3.

Discussion

The results of this study show that at 5-year follow-up RYGB + LLLI was the most effective treatment, followed by LAGB plus LLLI, for T2DM remission and other glycemic control endpoints. Remission rates for T2DM declined over the 5 years of the study but were greatest for RYGB. Nearly 60% of those in the RYGB group and half of the LAGB group did not require any medications for T2DM treatment at 5 years compared with none of those in the lifestyle intervention-only group. The surgical intervention groups both had significantly higher probability of achieving and maintaining glycemic control when compared with the intensive lifestyle therapy alone group, in people with both class I and II obesity in this study. The safety of the procedures was acceptable with no deaths and very few adverse events overall in both surgical groups and the lifestyle-only group. Secondary outcomes of this study, including body weight, blood pressure, and lipids, also demonstrated the greatest improvements in the RYGB group, followed by LAGB then LWLI.

Three other RCTs with 5-year results comparing surgical with nonsurgical treatments have been published (3,4,7). In the study by Mingrone et al., 60 patients who underwent biliopancreatic diversion (BPD) or RYGB were compared with a medical treatment group. The remission rate of T2DM (FPG level of less than 100 mg per deciliter (5.6 mmol/L) and a glycated hemoglobin level of less than 6.5% for at least 1 year without active pharmacologic therapy) was 63% in BPD group, 37% for RYGB, and none in the medically treated patients (16). However, relapse of diabetes occurred in 37% of BPD patients and 53% of RYGB patients who had achieved 2-year remission (16). There was one fatal myocardial infarction in the medical arm and no late complications or deaths occurred in the surgery groups and nutritional side-effects were noted mainly after biliopancreatic diversion (7). Further, Schauer et al. reported 5-year outcomes comparing RYGB or sleeve gastrectomy (SG) to intensive medical therapy alone. Their results showed a remission of T2DM (HbA1C ≤ 6.0%, *on or off* medications) in 29% of RYGB, 23% SG, and 5% of nonsurgical patients (3). If the criterion to be off glycemic control medications was added in the Schauer study, the remission rate dropped to 22% RYGB, 15% SG, and 0% for medical therapy with a good safety profile for all groups. In the multicenter trial by Ikramuddin et al. comparing RYGB to medical treatment with a triple primary endpoint, 13 participants (23%) in the gastric bypass group and 2 (4%) in the lifestyle-intensive medical management group had achieved the composite triple end point and 31 patients (55%) in the gastric bypass group versus 8 (14%) in the lifestyle-medical management group achieved an HbA1c level of less than 7.0%. The surgery group had more serious adverse events than did the lifestyle–medical management intervention in that trial and most were gastrointestinal events and surgical complications such as strictures, small bowel obstructions, and leaks (4). It is clear from these 3 other longer-term RCTs that the definitions of diabetes remission varies between studies, making direct comparisons difficult. Nevertheless, the remission rate in this study was similar to that of the RYGB group in the Mingrone study at 5 years with comparable remission definitions. The results of the current study are also comparable to the Schauer and Ikramuddin reports, given the different thresholds used for remission of diabetes.

As summarized at a recent World Conference on Interventional Therapies for Diabetes (WCITD) (17) there are currently 874 patients in total included in randomized studies comparing bariatric/metabolic surgery to nonsurgical treatment worldwide; 3 published studies with 5-year follow-up, 3 published studies with 3-year follow-up (including this one), and several with 1- to 2-year follow-up. All except one, show superiority of surgical to medical treatment for T2DM treatment consistent with the current additional 5-year data from this study (18,19). In all these studies, including the current one, the remission rates for T2DM with surgery do decrease with increasing follow-up. In the WCITD summary, there were very few cardiovascular events or deaths in either surgical or medical group and the most common adverse events after bariatric surgery were anemia (15%), gastrointestinal disturbances (5–10%), and reoperation (8%). The rates of adverse events in the current study were also low, consistent with the WCITD summary.

Also, of note was a broader enrollment for people with varying diabetes severity in our study, with an initially lower average baseline HbA1c in our cohort of 7.8 ± 1.9%, versus 9.2 ± 1.5% in the Schauer trial and over 8.0% in the Ikramuddin study. Our study also included a large proportion of people (40%) with a BMI of 30 to 35 kg/m^2 (class I obesity), for whom data are still lacking, thus contributing to filling that gap in knowledge. The results from this study continue to support the literature and algorithm for considering bariatric/metabolic surgery as an alternative treatment for people with class I obesity and T2DM in whom medical management is unsuccessful in achieving glycemic control (5).

This study is also the first RCT with 5-year results that include the LAGB as a surgical treatment group. The use of LAGB has declined dramatically worldwide (20), but the LAGB may still have a limited role for the management of selected lower BMI/class I obesity patients as results for glycemic control are superior to nonsurgical treatment in this trial. There are also a few previous RCTs utilizing LAGB which have reported results at 2 years after surgery and demonstrated about 20% initial weight loss (21,22). The results from the current study demonstrate less weight loss (12.7%) at 5 years and a remission rate for T2DM of 19% at 5 years. The LAGB diabetes remission rate in this study is somewhat lower than results from the Longitudinal Assessment of Bariatric Surgery Study, which was an observational, multicenter study in the United States that showed significant heterogeneity of weight loss (median, 15%) and 29% T2DM remission at the 5-year timepoint for LAGB (23).

This study has several strengths including a relatively large proportion of participants with class I obesity, therefore expanding the evidence within this specific population. We show a detailed collection of all adverse and other events with a low rate of reoperation and complications in the longer term. These results may be more generalizable to people with obesity and various degrees of T2DM severity due to inclusion of people with lower average baseline HbA1c in this study. A limitation of this study may be in the behavioral approach that was undertaken in LWLI. This study implemented a behavioral intervention that was based primarily on the approach from the Look AHEAD Study, which included modest energy restriction, physical activity, and behavioral counseling. This approach was shown to result in weight loss, enhanced glycemic control, and reduction in medication usage compared with diabetes support and education intervention. However, this approach may not be effective for all participants undertaking a LWLI. Thus, other dietary or physical activity approaches focused on weight loss and glycemic control in patients with type 2 diabetes may warrant examination for comparison with bariatric surgery. Additional limitations of this study include the small sample size in a single center, which may affect generalizability. However, larger RCTs are unlikely to be carried out due to the significant financial costs of such trials and the great difficulty with recruitment into surgical vs medical treatment trials, as seen in the first phase of this trial and other feasibility trials (10,24,25). Given these obstacles to a large trial, the alternative is to pool the data from smaller trials together into a larger study which has been done in forming the Alliance of Randomized Trials of Medicine vs Metabolic Surgery in Type 2 Diabetes Collaborative (3,8,9,26,27). This study will pool the data from four separate and smaller trials (including this one) to yield 7 to 10 year durability and safety results on approximately 300 people with class I and II obesity who underwent randomization to surgical and medical/lifestyle treatments.

In conclusion, surgical treatments including RYGB and then LAGB are safe and more effective than lifestyle intervention alone for long-term diabetes remission and glycemic control in people with obesity, including those with a BMI between 30 and 35 kg/m^2. Bariatric surgery should be considered in the treatment algorithm for type 2 diabetes treatment for all obesity classes.

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Author Contributions: Dr. Courcoulas had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Courcoulas, Jakicic. Acquisition, analysis, or interpretation of data: Courcoulas, DeLany, Eagleton, Neiberg, Lang, Jakicic. Drafting of the manuscript: Courcoulas, Punchai, Gallagher. Critical revision of the manuscript for important intellectual content: All authors. Statistical analysis: Neiberg, Lang. Obtained funding: Courcoulas, Eagleton. Administrative, technical, or material support: Courcoulas, Eagleton, Jakicic. Study supervision: Courcoulas, DeLany, Jakicic, Gourash

Glossary

Abbreviations

BMI	body mass index
BPD	biliopancreatic diversion
FPG	fasting plasma glucose
LAGB	laparoscopic adjustable gastric banding
LLLI	low-level lifestyle intervention
LWLI	lifestyle weight loss intervention
RCT	randomized control trials
RYGB	Roux-en-Y gastric bypass
SG	sleeve gastrectomy
T2DM	type 2 diabetes mellitus
WCITD	World Conference on Interventional Therapies for Diabetes

Additional Information

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Data Availability: All data generated or analyzed during this study are included in this published article or in the data repositories listed in References.

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Figures and Tables

Table 1.

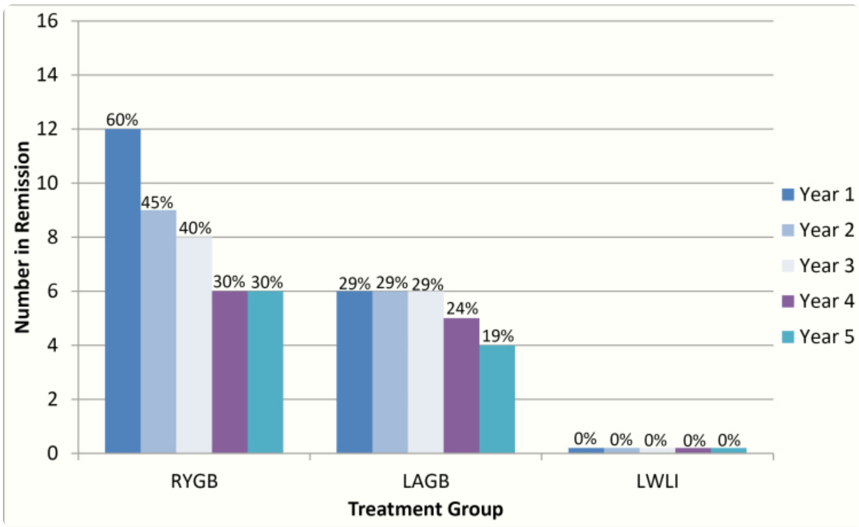
Baseline Sample Characteristics

	Intervention Assignment				**P** [a]
	Overall N = 61	**RYGB N = 20**	**LAGB N = 21**	**LWLI N = 20**	
Male sex, n (%)	11 (18.0)	4 (20.0)	4 (19.0)	3 (15.0)	1.0000
Age (years)	47.3 ± 6.6	45.4 ± 7.5	47.7 ± 7.0	48.9 ± 4.7	.2322
African American race, n (%)	13 (21.3)	6 (30.0)	3 (14.3)	4 (20.0)	.4602
Weight (kg)	100.5 ± 13.7	99.3 ± 13.4	100.2 ± 14.0	102.0 ± 14.3	.8171
BMI (kg/m^2)	35.7 ± 3.1	35.7 ± 2.7	35.6 ± 3.4	35.7 ± 3.3	.9867
Waist circumference (cm)	112.3 ± 10.0	110.6 ± 8.2	114.5 ± 11.9	111.8 ± 9.5	.4546
Total cholesterol (mg/dL)	190.5 ± 45.7	200.2 ± 40.3	189.5 ± 55.8	182.0 ± 39.0	.4542
High-density lipoprotein (mg/dL)	41.9 ± 12.2	41.8 ± 8.7	40.0 ± 9.3	44.1 ± 17.1	.5599
Low-density lipoprotein (mg/dL)	112.4 ± 34.7	124.3 ± 38.8	107.4 ± 29.7	105.5 ± 33.3	.1871
Triglycerides (mg/dL), median (IQR)[b]	125 (85–251)	115.5 (92.5–241.5)	139 (91–253)	119.5 (74.5–232.5)	.6988
Blood pressure (mmHg)					
Systolic	135.4 ± 16.0	139.7 ± 12.3	134.5 ± 17.0	132.0 ± 17.9	.3033
Diastolic	78.2 ± 9.4	81.3 ± 9.6	77.1 ± 8.6	76.3 ± 9.6	.1968
History of hypertension, n/total n (%)	36 (59.0)	10 (50.0)	13 (61.9)	13 (65.0)	.6465
History of dyslipidemia/High cholesterol, n/total (%)	41 (67.2)	12 (60.0)	16 (76.2)	13 (65.0)	.5504
Duration of T2DM (years)	6.5 ± 4.8	7.6 ± 4.6	6.1 ± 4.3	5.7 ± 5.6	.4566
FPG (mg/dL)	171.3 ± 72.5	191.5 ± 82.0	180.0 ± 85.4	142.1 ± 28.0	.0759
Median (IQR)[b]	147 (120–188)	173 (127.5–255)	134 (116–262)	142 (124–	.2623

[a]Fisher's exact test for categorical, analysis of variance F-test for continuous.

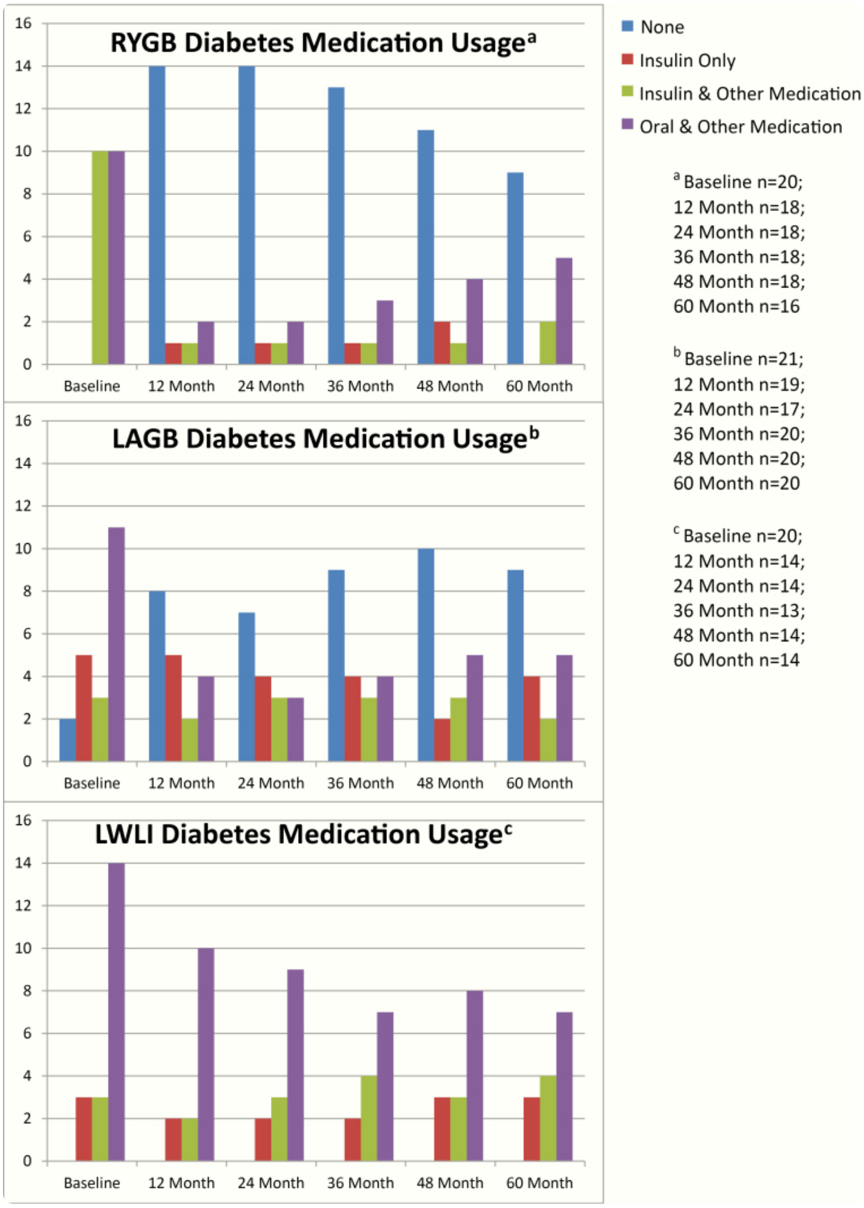
[b]Wilcoxon Rank Sum Test for skewed data.

Figure 1.



Prevalence of any remission (partial or complete) by treatment group and year*. *Results calculated using the intention to treat (ITT) analysis.

Figure 2.



Diabetes medication usage by treatment group.

Table 2.

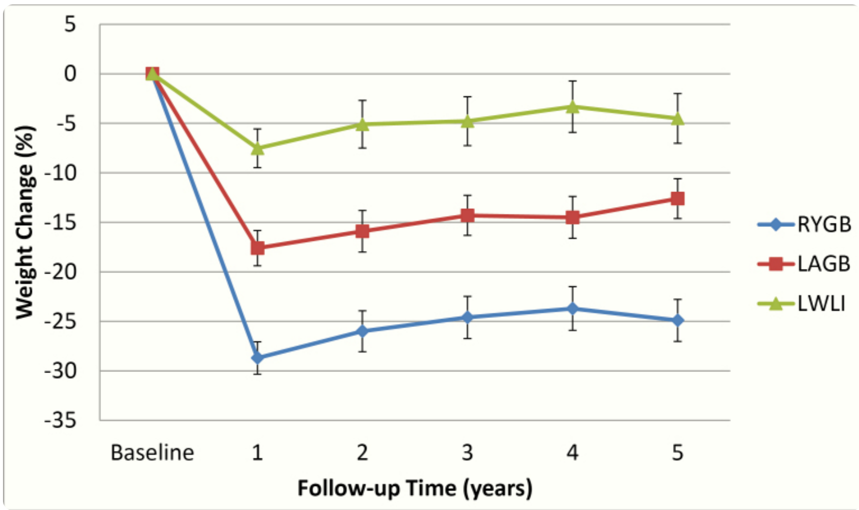
Multiple imputation results for change in continuous variables by intervention condition

Outcome variable	Intervention group	Baseline	Change from baseline to 1 year	Change from baseline to 2 years	Change from baseline to 3 years	Change from baseline to 4 years	Change from baseline to 5 years	Group *P*	Time *P*
Weight (kg)	RYGB	99.27 ± 2.99	−28.7 ± 1.64	−26.0 ± 2.07	−24.6 ± 2.13	−23.7 ± 2.21	−24.9 ± 2.12	<.0001	.0060
	LAGB	100.2 ± 3.06	−17.6 ± 1.78	−15.9 ± 2.10	−14.3 ± 2.02	−14.5 ± 2.11	−12.6 ± 2.01		
	LWLI	102.0 ± 3.19	−7.52 ± 1.95	−5.09 ± 2.41	−4.78 ± 2.47	−3.32 ± 2.60	−4.50 ± 2.51		
Percent weight change	RYGB		−29.1 ± 1.62	−26.3 ± 2.04	−25.0 ± 2.05	−24.1 ± 2.09	−25.2 ± 2.09	<.0001	.0059
	LAGB		−17.6 ± 1.73	−15.9 ± 2.07	−14.4 ± 1.96	−14.8 ± 2.01	−12.7 ± 1.98		
	LWLI		−7.94 ± 1.92	−5.72 ± 2.38	−5.52 ± 2.38	−4.44 ± 2.45	−5.14 ± 2.46		
Body mass index (kg/m^2)	RYGB	35.67 ± 0.61	−10.2 ± 0.57	−9.19 ± 0.72	−8.69 ± 0.73	−8.36 ± 0.76	−8.75 ± 0.76	<.0001	.0063
	LAGB	35.58 ± 0.75	−6.13 ± 0.62	−5.46 ± 0.72	−4.97 ± 0.69	−5.05 ± 0.72	−4.38 ± 0.71		
	LWLI	35.75 ± 0.73	−2.40 ± 0.65	−1.66 ± 0.81	−1.60 ± 0.81	−1.11 ± 0.85	−1.20 ± 0.85		
Waist (cm)	RYGB	110.6 ± 1.83	−26.9 ± 1.58	−22.3 ± 1.92	−21.1 ± 1.88	−19.5 ± 2.10	−18.9 ± 1.80	<.0001	<.0001
	LAGB	114.5 ± 2.59	−16.0 ± 1.67	−12.4 ± 1.99	−12.0 ± 1.88	−12.9 ± 2.03	−10.4 ± 1.75		
	LWLI	111.8 ± 2.13	−5.42 ± 1.80	−3.51 ± 2.16	−4.24 ± 2.13	−3.22 ± 2.30	−6.02 ± 2.02		
Fasting plasma glucose (FPG)	RYGB	191.5 ± 18.33	−69.5 ± 10.33	−50.3 ± 11.28	−65.6 ± 10.97	−61.9 ± 12.86	−49.1 ± 15.96	.0307	.2879

Models adjusted for gender, BMI < 35 or ≥35 kg/m^2, and repeated measures.

Baseline values are raw means and standard errors.

Figure 3.



Percent weight change from baseline by treatment group.

Table 3.

Adverse events and complications through 5 years

Complication	RYGB (N = 16)	LAGB (N = 20)	LWLI (N = 14)
< 30 days			
Prolonged postoperative hospital stay (+1 night)	2	4	0
Incisional pain	0	1	0
Abdominal pain	0	1	0
> 30 days			
Cardiovascular	0	1	0
Vertigo and hypertension resulting in hospital admission			
Hypotension and lightheadedness	0	1	0
Stent	1	0	0
Respiratory—pneumonia	1	0	0
Nutritional and metabolic			
Dehydration	1	2	0
Anemia with transfusion	1	0	0
Neurologic	2	0	0
Urology			
Stent	0	1	0
Stone	1	1	0
Plastic surgery	1	3	0
Orthopedic procedures			
Surgery	1	6	5
Injection	2	2	4
Fracture	2	0	0
Joint replacement	0	0	1
Bariatric reoperations			
Bariatric	1	1	0
Port malposition	0	1	0
Crossover procedure	0	0	1
Bariatric complications			
Anastomotic ulcer	1	0	0
Overfilled gastric band resulting in hospital admission	0	2	0
Appendectomy	1	0	0

There were 65 complications in 32 participants.