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End-of-Trial Health Outcomes in Look AHEAD Participants Who Elected to Have Bariatric Surgery

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Abstract

Objective: This study examined end-of-trial health outcomes in participants in the Look AHEAD (Action for Health in Diabetes) trial who had bariatric surgery during the approximately 10-year randomized intervention.

Methods: Data were obtained from the Look AHEAD public access database of 4901 individuals with type 2 diabetes and overweight/obesity who were assigned to intensive lifestyle intervention (ILI) or a diabetes support and education (DSE) control group. Changes in outcomes in participants who had bariatric surgery were compared with those in participants with a body mass index (BMI) ≥ 30 kg/m^2 who remained in the ILI and DSE groups.

Results: A total of 99 DSE and 97 ILI participants had bariatric surgery. At randomization, these 196 participants were significantly younger and more likely to be female and to have higher BMIs than the remaining ILI (N=1972) and DSE (N=2009) participants. At trial's end, surgically-treated participants lost 19.3% of baseline weight, compared with 5.6% and 3.3% for the ILI and DSE groups, respectively, and were more likely to achieve partial or full remission of their diabetes.

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This paper is dedicated to the memory of G. L. Blackburn, M.D., Ph.D.

Dr. Jakicic reports serving on a scientific advisory board for Weight Watchers, and Dr. Wadden serves on scientific advisory boards for Novo Nordisk and Weight Watchers. The other authors report no conflicts of interest.

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Conclusions: The large, sustained improvements in weight and diabetes observed in this self-selected sample of surgically-treated participants are consistent with results of multiple randomized trials.

Keywords

bariatric surgery; weight loss; lifestyle modification

INTRODUCTION

The Look AHEAD (Action for Health in Diabetes) study was a multi-center, randomized controlled trial of the effects of an intensive lifestyle intervention (ILI) on cardiovascular morbidity and mortality in participants with type 2 diabetes and overweight or obesity (1,2). The ILI was designed to decrease initial body weight by an average of 7% or more and to increase physical activity to ≥175 minutes/week (1,3), compared with a control group that received diabetes support and education (DSE) (4). Participants in the ILI generally achieved and sustained improvements in weight and physical activity over 8–11 years of intervention (2,5). However, the randomized trial was stopped in September 2012, based on a futility analysis that found no significant differences between the ILI and DSE groups on the study's primary outcome, a composite of death from cardiovascular causes, nonfatal myocardial infarction or stroke, or hospitalization for angina (2). Since the trial's termination in 2012, Look AHEAD has continued as an observational study (6).

Participants in the ILI and DSE groups were encouraged to adhere to the treatment condition to which they were randomly assigned. However, some participants ultimately pursued weight loss interventions that were not approved or provided by the study. Before the randomized trial ended in 2012, a total of 198 participants in the combined ILI and DSE groups reported they had undergone bariatric surgery.

Bariatric surgery is the most effective intervention for severe obesity. It is recommended for persons with a body mass index (BMI) ≥ 40 kg/m^2 who cannot lose weight satisfactorily with lifestyle intervention, as used alone or in combination with weight loss medication (7–9). It also is appropriate for persons with a BMI ≥35 kg/m^2 who have one or more obesity-related co-morbidities (7–9). An international panel recently recommended that it also be considered in persons with type 2 diabetes and a BMI as low as 30 kg/m^2 who are unable to achieve satisfactory glycemic control with oral or injectable medications (10). This latter recommendation is based on the superiority of Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG) in inducing long-term weight reduction and remission of diabetes, as compared with non-surgical weight loss interventions combined with anti-diabetic medications (10–14). Laparoscopic adjustable banding (LAGB) also is effective for managing type 2 diabetes (15) and is approved by the U.S. Food and Drug Administration (FDA) for persons with a BMI ≥ 30 kg/m^2, with co-morbidities. However, LAGB is no longer widely used in the U.S. because of lesser long-term benefits as compared with RYGB and SG (13,16,17).

The present report describes end-of-trial changes in weight, cardiovascular disease (CVD) risk factors, medication use, diabetes remission, and behavioral status in Look AHEAD

participants who reported undergoing bariatric surgery, as compared with changes in ILI and DSE participants who did not report having surgery. Based on prior studies, we predicted greater end-of-trial improvements in all of these outcomes in surgically-treated compared with non-surgically treated participants (10–14). The present study also examined baseline demographic and clinical characteristics of participants who reported undergoing bariatric surgery, as compared with those who did not.

METHODS

Participants

A total of 5,145 men and women enrolled in Look AHEAD from 2001–2004 at 16 centers across the U.S. (1,2). Eligible individuals had type 2 diabetes, were 45–76 years, and had a BMI ≥25 kg/m^2 (or ≥27 kg/m^2 if taking insulin). Additional eligibility criteria have been reported (1,2). Participants signed a consent form approved by their center's institutional review board and were randomly assigned to ILI or DSE. The present study used the Look AHEAD trial's public access data set of 4,901 individuals that, due to consent limitations, does not include participants from American Indian sites. (Only two individuals from these sites reported undergoing bariatric surgery.)

For analyses that compared baseline characteristics and study outcomes of participants who reported undergoing bariatric surgery with those who did not, we limited the ILI and DSE comparator samples to participants with a baseline BMI ≥30 kg/m^2, the lower-limit for LAGB recommended by the FDA. This also is the eligibility criterion used in randomized trials of LAGB (15,18). Randomized and nonrandomized studies of RYGB, SG, and other surgical approaches also have included patients with BMIs <35 kg/m^2, who were operated on at their surgeons' discretion (19–21). Twenty participants in Look AHEAD who reported undergoing bariatric surgery had a baseline BMI <35 kg/m^2, of whom, 12 had this BMI value at their annual assessment visit that preceded their surgery. These 12 included two participants with BMIs <30 kg/m^2.

Interventions

The ILI and DSE interventions have been described previously (3,4,22). Participants in both groups received all usual medical care from their own primary care providers.

ILI.—In year 1, ILI participants received a comprehensive lifestyle intervention that was delivered to groups of approximately 10–20 persons. Participants were provided two to three group sessions per month and a monthly individual session with their interventionist. They were prescribed 1200–1800 kcal/day, and structured meal plans and meal replacements were used extensively during the first 4 months, with reduced use thereafter (3,22). Participants were prescribed ≥175 minutes/week of moderate intensity physical activity, to be achieved by month 6, with a further increase to ≥200 minutes/week for those who met this goal.

In year 2 and until the ILI was terminated, the intervention focused principally on maintaining the weight losses and high levels of physical activity achieved in year 1 (3,22). Each month, participants were provided an individual, in-person meeting, with a second individual contact by telephone or e-mail, approximately 2 weeks later. (This second contact

was discontinued beginning in year 5 of the ILI.) All sites also offered a monthly group meeting at which members could weigh-in and review their progress. Annual Refresher Groups and National Campaigns also were offered to help participants reverse weight gain (3,22). Attendance of group sessions was strongly encouraged but optional in year 2 and beyond.

DSE.—These participants were invited to three group sessions per year for the first four years, with one annual meeting thereafter (4). Sessions offered information but not specific behavioral strategies for adhering to diet and physical activity recommendations discussed.

Bariatric surgery.—Look AHEAD staff encouraged participants in the ILI and DSE groups who asked about bariatric surgery to remain in their assigned treatment groups. Participants who continued to express interest in surgery were instructed to consult with their own health care providers. Staff did not provide consultations or referrals on this matter and often only learned after the fact of patients' having undergone bariatric surgery. Staff did obtain information about the date and type of surgery and encouraged participants to remain in Look AHEAD to complete annual outcome assessments and to attend treatment sessions, if they desired, based on their original group assignment.

Study Assessments

At randomization and subsequent annual assessment for up to 11 years, masked assessors measured participants' weight, waist circumference, blood pressure, and medication use, as described previously (2,23) and inquired about changes in health, to determine the occurrence of cardiovascular disease (CVD) events (e.g., non-fatal myocardial infarction or stroke), the study's primary outcome. (Masked outcome assessments also were conducted by telephone every 6 months.) Fasting blood samples were collected and assayed for hemoglobin A_{1c} (HbA_{1c}), triglycerides, and other values described previously (23). Mood and quality of life were assessed by the Beck Depression Inventory (BDI-1A) (24) and the Medical Outcomes Survey, Short-Form (SF-36) (25). Physical activity was assessed by the Paffenbarger Activity Questionnaire (PAQ) (26) and alcohol intake by self-reported consumption of wine, beer, and liquor in a typical week (27). All of these latter measures (i.e., HbA_{1c}, SF-36, etc.) were obtained at randomization and at a minimum of years 1, 4, and 8, with the study's end-of-trial values coming from measures obtained at year 8 or beyond.

When participants endorsed a primary CVD outcome, staff requested and collected corroborating medical records. These materials were then reviewed by a team of central adjudicators, masked to intervention group assignment, who made a final outcome determination. Adverse event (AE) and serious adverse event (SAE) data were collected by the masked assessors at the 6-month intervals but also could be obtained by unmasked staff during participants' intervention visits. AEs and SAEs were not independently verified, if hospitalization was not required, and generally represent participants' self-reports.

Diabetes Remission

End-of-trial diabetes remission was determined using the same criteria employed in a prior analysis of Look AHEAD participants (28) in which diabetes was defined at baseline by taking diabetes medications (i.e., oral or injectable agents) or by having an HbA_{1c} ≥6.5%. Partial diabetes remission was defined by achieving an HbA_{1c} <6.5%, without the use of anti-diabetic medications. Full remission was defined by full normalization of glucose (i.e., HbA_{1c} <5.7%), with no use of medications. [As reported previously (28), participants also were eligible to enroll in Look AHEAD if they had a fasting blood glucose value ≥126 mg/dl, or presented written confirmation from their health care provider that they had type 2 diabetes, but did not have a documented HbA_{1c} >6.5% at enrollment. These participants were excluded from the present analyses of diabetes remission, as they were in the prior analysis at year 4 (28). The present analyses thus excluded 119 DSE and 125 ILI participants, respectively, and 6 participants who reported having bariatric surgery.]

Statistical Analyses

Differences in baseline characteristics between ILI and DSE participants, as well as between those who subsequently reported having versus not having bariatric surgery, were examined with independent samples t-tests or chi-square tests. Changes in physical, laboratory, and behavioral measures, from randomization up to 11 years, were modeled with linear mixed models. End-of-trial diabetes remission was computed using observed values at year 8 and beyond, and differences among groups were analyzed using relative risk estimates. Because of the small sample size, primary and secondary outcomes did not differentiate between the type of bariatric surgery (i.e., RYGB, etc). Two-sided, p-values <0.05 were considered statistically significant. All analyses are considered exploratory and are not adjusted for multiple comparisons; the assessment of bariatric surgery was not included as an *a priori* hypothesis in the Look AHEAD protocol.

RESULTS

Participants' Randomization Characteristics

Participants in the DSE (n=2,009) and ILI (n=1,972) groups who had a baseline BMI ≥30 kg/m^2 and did not undergo surgery did not differ significantly on any randomization characteristics (see Table 1). Of the total 196 ILI and DSE participants who reported having bariatric surgery, 124 underwent RYGB, 58 had LAGB, and 11 had SG. Three additional participants had LAGB (at 3.8, 3.9, and 5.3 years, respectively) and later underwent RYGB (at 5.9, 8.0, and 9.3 years, respectively). These 196 participants differed significantly on multiple baseline characteristics from the combined 3,981 ILI and DSE participants who did not have bariatric surgery (Table 1). At randomization, those who subsequently reported having surgery, compared with those who did not, were significantly younger (54.1 vs 59.9 yr) and more likely to be female (77.6 vs 58.3%) and to have a household income >$80,000 (41.8 vs 28.9%). They also had a significantly greater baseline body weight (117.4 vs 104.0 kg), BMI (42.1 vs 37.0 kg/m^2), waist circumference (123.9 vs 116.2 cm), and HbA_{1c} (7.5 vs 7.3%), and they took a greater total number of medications (6.5 vs 5.7). However, they were less likely to have a history of a CVD event (8.2 vs 14.1%). Those who had bariatric surgery, compared with those who did not, also reported significantly more symptoms of depression

at randomization and poorer physical and mental health-related quality of life, although absolute differences were small (Table 1). Figure 1 shows the retention of participants over the course of the randomized trial.

Incident Bariatric Surgery

Over the median 9.6 years of intervention, 99 (4.7%) DSE and 97 (4.7%) ILI participants reported having bariatric surgery. Cox proportional hazard models revealed that, compared to participants in the ILI, DSE participants were no more likely to have surgery by either year 4 (HR=1.48, 95% CI=0.94, 2.34, p=0.09) or by the last study assessment (HR=1.03, 95% CI=0.78, 1.36, p=0.85; see Figure 2). DSE participants underwent surgery at a median of 5.3 years post-randomization, compared with 5.9 years for ILI participants (p=0.06).

Figure 3 shows the percentage change in body weight, as measured from randomization, for participants in DSE and ILI who elected to have surgery in a given year, as compared to the mean change for DSE and ILI participants who remained in their original treatment group at this time. For example, in year 2, the 11 DSE participants who had surgery in the ensuing year had gained 1.8% above baseline weight, compared with a loss of 1.0% for participants who remained in DSE. The 8 ILI participants who underwent surgery in the year following the year-2 annual assessment had gained 1.4% above their baseline weight, compared with a 6.6% loss for ILI participants who remained in the intervention. Across the 9 years, at the annual assessment preceding their reported surgery, surgically-treated DSE participants had an average weight change that was 4.2 percentage points less than that of DSE individuals who did not have surgery at this time (mean weight change of +2.8% vs −1.4%, respectively) (Figure 3). At their annual assessment before surgery, ILI participants had an average weight change that was 8.0 percentage points less than that of ILI individuals who did not have surgery at this time (mean weight change of +3.0% vs −5.0%, respectively). At their annual visit preceding bariatric surgery, DSE participants had a mean BMI of 43.3±6.0 kg/m^2, compared with 43.6±6.5 kg/m^2 for ILI participants who had surgery (p=0.75).

The DSE and ILI groups did not differ significantly (p=0.10) in the number of participants who had RYGB (71 vs 56), LAGB (27 vs 34), or SG (3 vs 8). Of the 12 participants with a BMI < 35 kg/m^2 at the annual assessment visit preceding their bariatric surgery, 6 reported having RYGB, 4 underwent LAGB, and 2 had SG. The two participants with the lowest BMIs -- of 27.9 and 29.8 kg/m^2 -- underwent RYGB and SG, respectively.

End-of-Trial Weight Losses

When the randomized trial was stopped, the 196 surgically-treated participants had lost a mean of 19.3% of baseline weight, compared to 5.6% and 3.3% for the ILI and DSE participants, respectively, who had not had surgery. (End-of-trial assessments of surgically-treated participants occurred a median of 4.3 years post-surgery, compared with 9.6 years post-randomization for DSE and ILI participants who did not have surgery.) Table 2 shows that weight losses of all three groups differed significantly from each other, and Figure 4 shows weight loss according to type of surgery. Participants who underwent RYGB (N=127), SG (N=11), and LAGB (N=58) lost a mean of 22.4±1.0, 16.2±3.3, and 13.0±1.5% of baseline weight, respectively. Participants who had RYGB lost significantly more weight

than those who had LAGB (p<0.001), with no significant differences between RYGB and SG (p=0.07) or SG and LAGB (p=0.37). At the trial's end, DSE participants who underwent bariatric surgery lost a mean of 18.7+1.1% of baseline weight, which did not differ significantly (p=0.40) from the 20.0±1.1% lost by ILI participants who had surgery.

End-of-Trial Changes in CVD Risk Factors and Medication Use

Surgically-treated participants (N=196) achieved significantly greater end-of-trial reductions than participants in the ILI and DSE groups in waist circumference, triglyceride levels, and HbA_{1c}, as well as significantly greater increases in HDL cholesterol. The surgically-treated group also had significantly smaller increases, as compared with the ILI and DSE groups, in the total number of medications taken, as well as a greater percentage of participants who discontinued medications for diabetes, hypertension, and lipid disorders (Table 2). Table 2 also shows that ILI, compared with DSE participants, had significantly better outcomes on several of these end-of-trial measures, including waist circumference and the number of diabetes and antihypertensive medications taken.

End-of-Trial Remission of Type 2 Diabetes

Type 2 diabetes, as defined previously, was present in 3,937 participants at baseline. Figure 5 shows that at the randomized trial's end, 7.6% of bariatric surgery participants achieved full diabetes remission, compared with 1.1% of ILI and 1.1% of DSE participants, respectively. Full remission was significantly more common in surgically-treated participants than in ILI (relative risk (RR)=6.72, 95% CI=3.35, 13.48, p<0.001) or in DSE participants (RR=7.07, 95% CI=3.49, 14.30, p<0.001). Any end-of-trial remission of diabetes, including partial, was achieved by 23.1% of surgically-treated participants, 3.5% of ILI, and 2.3% of DSE participants. Any remission was significantly higher in the bariatric surgery group than in the ILI (RR=6.57, 95% CI=4.51, 9.57, p<0.001) and DSE groups (RR=10.16, 95% CI=6.65, 15.53, p<0.001).

End-of-Trial Changes in Behavioral Status

Surgically-treated participants, compared with those in ILI and DSE, reported significantly greater reductions from baseline in symptoms of depression, as well as a significantly smaller decline on the physical component score of the SF-36 (Table 2). There were no significant differences among groups, as measured from randomization, in end-of-trial changes on the SF-36 mental component score or in the weekly number of ounces of alcohol that participants reported consuming. There also were no significant differences between surgically-treated vs ILI and DSE participants, in their self-reported increases (from baseline) in weekly energy expenditure from physical activity (Table 2). ILI participants, however, reported significantly greater increases than their DSE counterparts.

Adverse Events

Table 3 shows perioperative (≤ 30 days) adverse events experienced by participants who had bariatric surgery. The most serious complications included death (one participant, LAGB), coma with life support for 18 days (one, RYGB), complications of anesthesia requiring

ventilator for 2 days (one, RYGB), and deep vein thrombosis (four, RYGB). All patients recovered fully, with the exception of the death during surgery.

DISCUSSION

This study's principal finding was that the 196 participants with type 2 diabetes and obesity who reported having bariatric surgery during the approximately 10-year Look AHEAD intervention achieved substantially greater end-of-trial reductions in body weight, CVD risk factors, and medication use, as well as greater remission of type 2 diabetes, than did the nearly 4,000 participants in the DSE and ILI groups who did not have surgery. Participants who had RYGB, SG, or LAGB collectively lost an average of 19.3% of initial weight, compared with losses of 5.8% and 3.3% in the ILI and DSE groups, respectively. They were 6 to 10 times more likely than ILI and DSE participants to achieve complete or partial remission of their diabetes and were more likely to discontinue medications for hypertension and lipid disorders.

The superior long-term weight loss and diabetes remission observed in this study with bariatric surgery plus medical therapy, as compared with ILI plus medical therapy, is consistent with findings from multiple randomized controlled trials (RCTs) of patients with overweight/obesity and type 2 diabetes. Two of these trials compared the effects of surgery to behavioral weight loss programs directly modeled on Look AHEAD's ILI (12,29). At the end of a 3-year RCT, participants assigned to RYGB, LAGB, and ILI lost a mean of 25.0%, 15.0%, and 5.7% of initial weight, respectively, with any diabetes remission (partial or complete) observed in 40%, 29%, and 0% of participants, respectively (29). This trial used the same criteria for diabetes remission as the present study. A 5-year RCT found that participants randomized to RYGB and ILI lost an average of 21.8% and 9.6% of initial weight, respectively; 55% and 14% of participants, respectively, achieved an HbA1c <7%, which was part of a triple composite end point that included achieving an LDL cholesterol <100 mg/dl and systolic blood pressure < 130 mm Hg (12). Another 5-year RCT assigned all participants to intensive medical therapy for type 2 diabetes (including weight loss) combined with RYGB, SG, or used alone (13). These three groups lost 23%, 19%, and 5% of initial weight, respectively; 29%, 23%, and 5% of participants in the three groups, respectively, achieved the diabetes remission endpoint, consisting of an HbA_{1c} <6% with or without the use of diabetes medications. In both 5-year trials, weight losses and diabetes remission rates were greatest at 1 to 2 years post-randomization.

The results of these and other RCTs (10,11), including of LAGB (15), give us confidence in the estimates of weight loss and diabetes remission observed in our self-selected sample of participants who sought bariatric surgery. Remission rates were substantially lower in the present study than in those reviewed above, potentially because our participants' older age and longer duration of diabetes. Some studies also used less stringent remission criteria (e.g., HbA_{1c} < 6%, with or without use of diabetes medications) and had shorter observation periods than employed in this trial. In addition, nearly one-third of our surgically-treated participants (N=61) reported having LAGB, which was commonly used when the Look AHEAD trial began in 2001 but started to decline in 2007 with the introduction of SG. This latter operation typically produces larger, more durable weight losses and improvements in

co-morbid conditions (including type 2 diabetes) than LAGB and is generally considered to be easier to perform than RYGB (16).

Our study's sample of only 11 SG-treated participants is too small to draw conclusions about its efficacy. Additional long-term safety and efficacy data are needed for SG, as have been provided for RYGB and LAGB by the Longitudinal Assessment of Bariatric Surgery (LABS) cohort (17). LABS (30) also provides a more reliable estimate of the risks of adverse perioperative outcomes accompanying RYGB and LAGB, as compared with our small sample (in which some reported adverse events were not independently verified). LAGB is associated with the lowest 30-day mortality rate, of approximately 0.002% vs 0.2% for laparoscopically-performed RYGB (30).

At the time they enrolled in Look AHEAD, the 196 participants who ultimately reported having bariatric surgery differed in multiple ways from those who remained in the ILI and DSE groups. They were more than 5 years younger but already had an average BMI of 42.1 kg/m^2 (compared with 37.0 kg/m^2 for other participants), which placed them in the category of class III obesity (i.e., severe), for which bariatric surgery is most commonly recommended. A large percentage of Look AHEAD participants qualified for bariatric surgery at study enrollment, by virtue of having a BMI $\geq$35 kg/m^2 and the presence of type 2 diabetes. However, the Longitudinal Assessment of Bariatric Surgery study (30) and other large cohort studies (31–33) typically enrolled patients with average BMIs of 40–50 kg/m^2, suggesting that class III obesity likely was the point at which both patients and their health care providers considered bariatric surgery to be most appropriate (at least when Look AHEAD was conducted). A total of 12 study participants, however, had a BMI <35 kg/m^2 at the annual visit preceding their surgery (10).

In addition to having a higher baseline BMI and taking more medications than participants who did not have surgery, those who reported having bariatric surgery were more likely to be female and white, and to have a household income of more than $80,000 (the latter which may have given them more health care options). Their baseline mood and physical- and mental-health- related quality of life also were slightly less favorable than that of participants who did not have surgery. Once the intervention began, participants in the ILI who reported having surgery may have done so, in part, because of feelings of disappointment or discouragement about their weight change, which was approximately 8 percentage points less than that of ILI participants who did not have surgery. Weight change of DSE participants who had surgery also trailed (by approximately 4 percentage points) that of other DSE participants.

This observational study, conducted within a randomized trial, had many strengths, including a very large, well characterized sample of individuals with overweight/obesity and type 2 diabetes who participated for a median of 9.6 years in a state-of-the-art lifestyle intervention or in a DSE intervention. Both interventions were associated with excellent study retention. Limitations include the relatively small number of surgically-treated participants and their self-selection for surgery. We relied upon their reports of their surgical experience and were unable to determine their precise weight at the time of surgery (or their perioperative complications). Moreover, some patients may have undergone bariatric surgery

and not informed study staff, potentially resulting in underreporting of this event. In addition, the shorter duration of follow-up evaluation in surgically vs non-surgically treated participants may have prevented us from detecting potential longer-term deteriorations in weight or diabetes control that have been observed in bariatric-surgery patients (13,31).

In conclusion, this secondary, observational study provided a unique opportunity to examine the health benefits of bariatric surgery in patients who had first failed a comprehensive lifestyle intervention, as recommended by stepped-care algorithms for obesity management (7–9). Bariatric surgery, compared with continued participation in the ILI (or DSE), was highly effective in improving weight, diabetes remission, and other CVD risk factors. Other reports from Look AHEAD, in turn, have demonstrated that ILI, compared with DSE, produced greater long-term improvements in cardio-metabolic risk factors, kidney function, sleep apnea, health-related quality of life, and mood, while reducing medication and hospitalization costs over the decade-long intervention (2,34–38).

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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For participants who provided informed consent, their de-identified data from the Look AHEAD trial are available through the NIDDK Central Repository (https://repository.niddk.nih.gov/pages/archive/). This site includes the study protocol, the analysis plan, study forms, and detailed descriptions of the data.

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What is already known about this subject?

- The Look AHEAD study showed, in patients with obesity and type 2 diabetes, that an approximately 10-year intensive lifestyle intervention (ILI) improved weight loss, diabetes remission, other cardiovascular disease (CVD) risk factors, and quality of life significantly more than a usual care control group, known as Diabetes Support and Education (DSE).

What does this study add?

- This report examines the total of 196 participants in the ILI and DSE who elected to have bariatric surgery over the 10 years. Consistent with findings from randomized controlled trials, surgically-treated participants had substantially greater improvements on all of the above outcomes than did participants in the ILI and DSE groups at the end of the randomized trial.

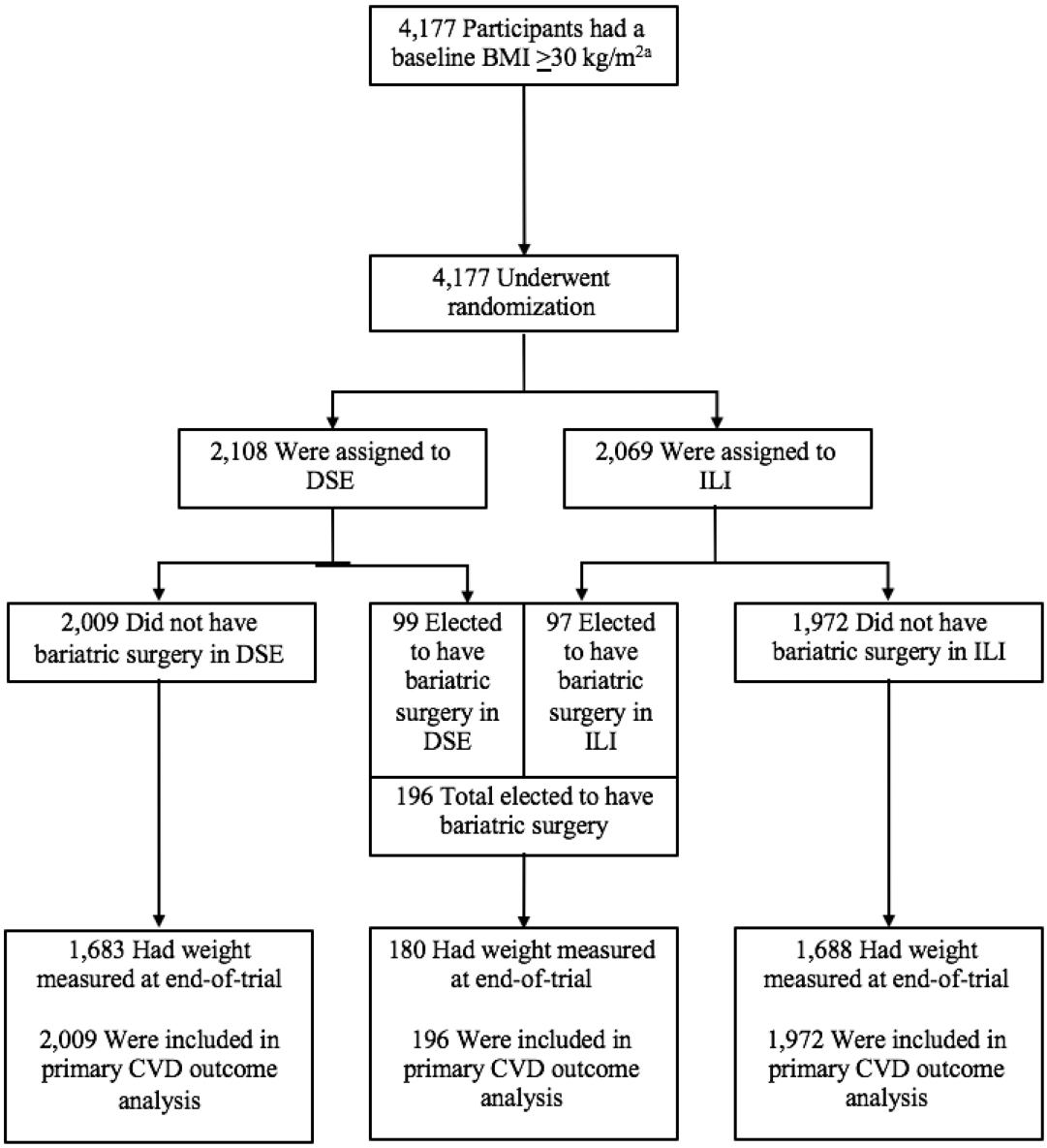
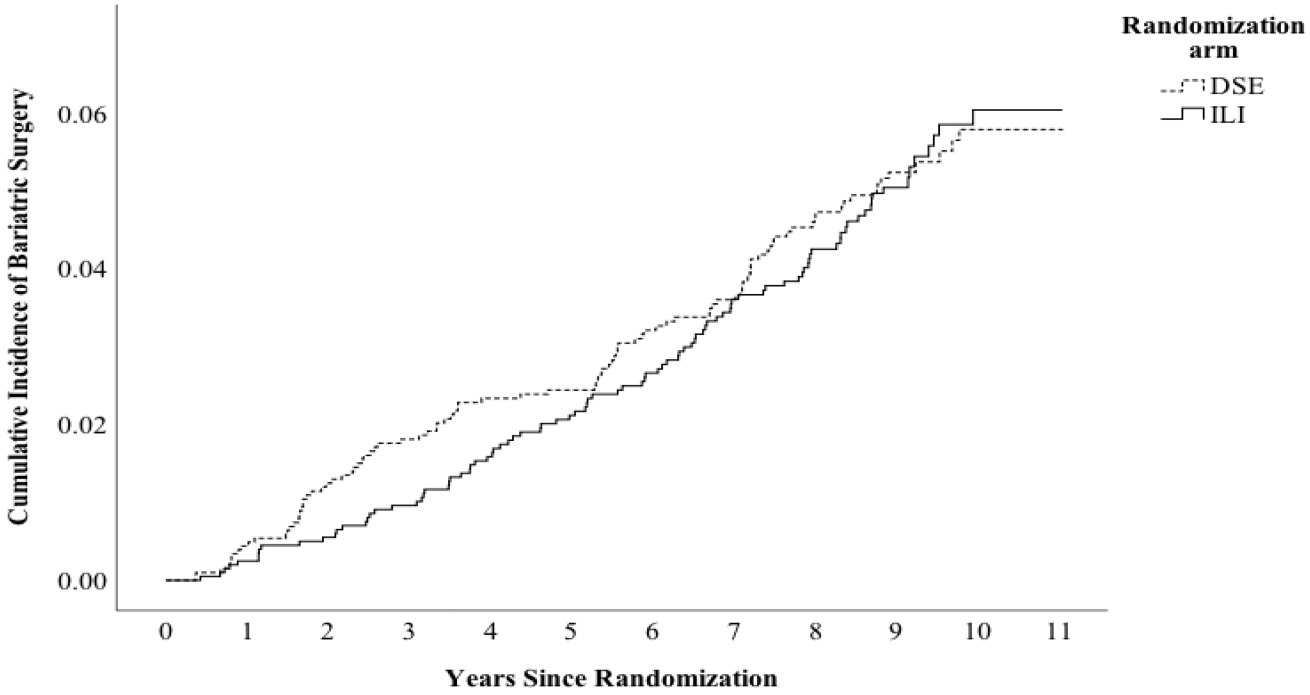


Figure 1:

The figure shows the flow of participants through the approximately 10-year Look AHEAD randomized trial. The 4,177 participants are from a total of 4,901 represented in the Look AHEAD public access data set. All 4,177 participants were selected to have a baseline body mass index (BMI) ≥ 30 kg/m^2, with the exception of two patients with BMIs of 27.9 and 29.9 kg/m^2 who had bariatric surgery (and were included in the analyses). End of trial was assessed at year 8 or beyond, depending on when participants entered the study.



No. of participants who had bariatric surgery in each year												Total
DSE	0	9	16	11	10	2	14	7	18	8	4	99
ILI	0	5	6	8	12	10	10	17	11	11	7	97

Figure 2:
Cumulative incidence of bariatric surgery in the diabetes support and education (DSE) and intensive lifestyle interventions (ILI) groups.

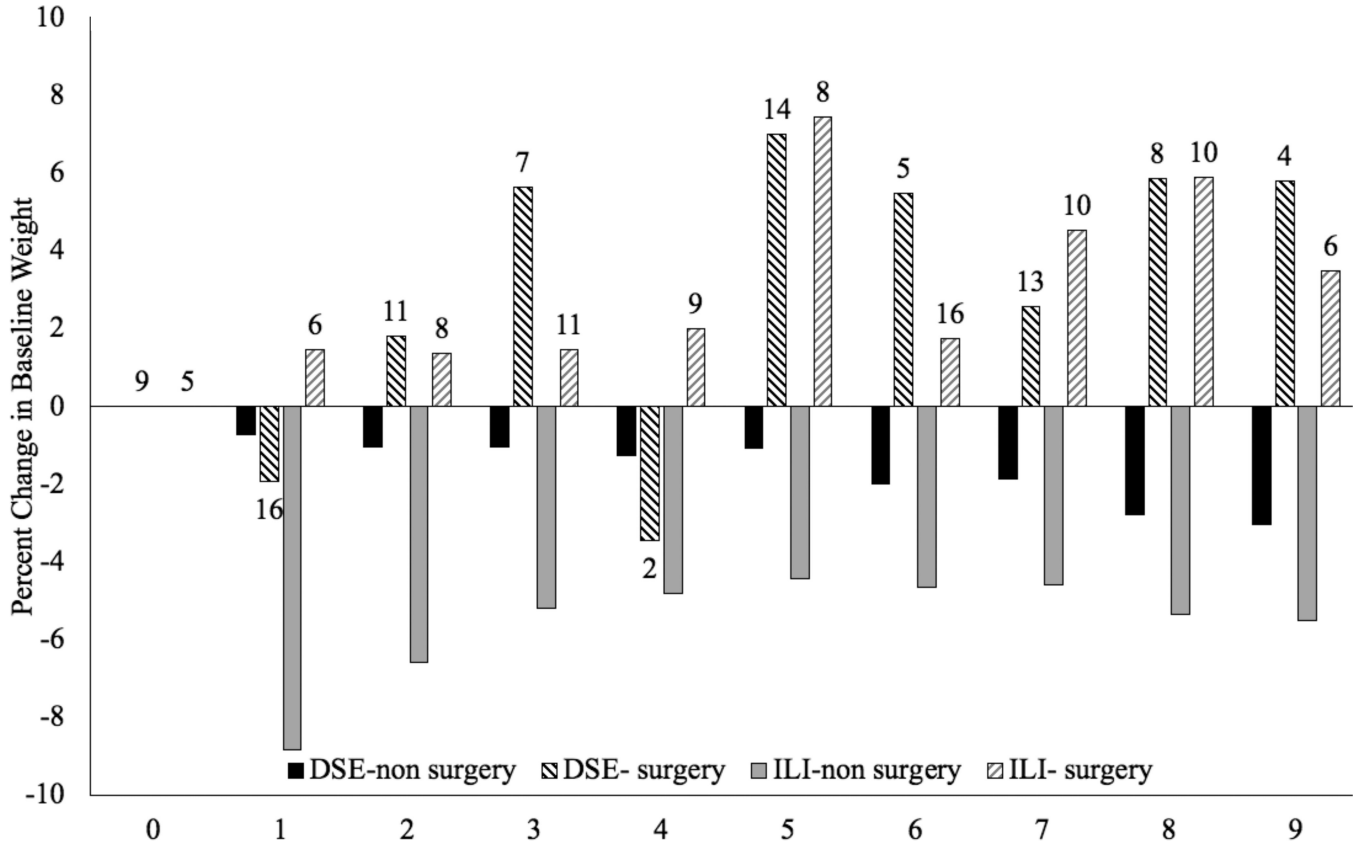


Figure 3:

The figure shows the mean percentage change in baseline weight from years 1 to 9 for participants assigned to the diabetes support and education (DSE) and intensive lifestyle intervention (ILI) groups. For DSE and ILI participants who elected to have bariatric surgery, the figure shows the number who did so each year and their weight change (as assessed from baseline) at the last annual assessment before surgery, as compared to the mean weight change at the same time for DSE and ILI participants who did not have surgery. Year 0 shows that 9 DSE and 5 ILI participants who had surgery in the first year of the trial. A total of 18 surgery participants did not provide a measured weight at the annual assessment that preceded their having surgery. Three participants had LAGB and later went on to have RYGB. Their weights are only included for their first surgery, LAGB.

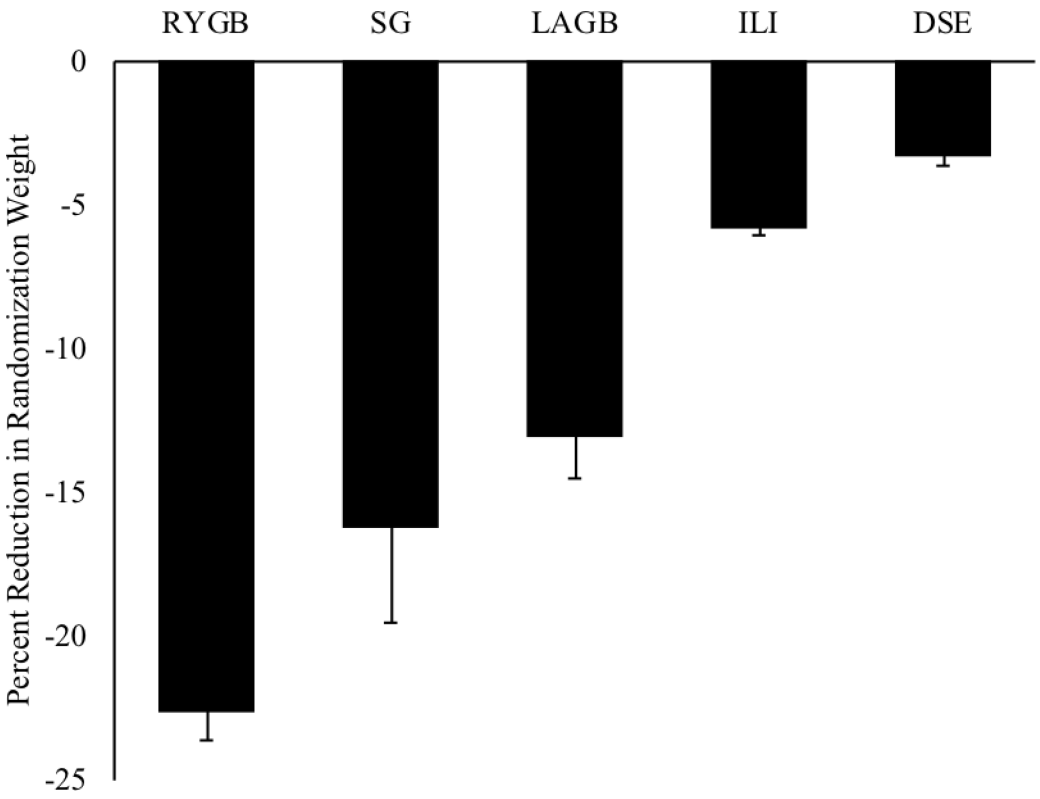


Figure 4:

Percent reduction in initial weight at the end of trial for participants assigned to the intensive lifestyle intervention (ILI) and diabetes support and education (DSE) groups, as well as those who underwent Roux-en-Y gastric bypass (RYGB, N=127), sleeve gastrectomy (SG, N=11) or laparoscopic adjustable banding (LAGB, N=58). Three participants had LAGB and later went on to have RYGB. Their end-of-trial weights are counted in the RYGB category.

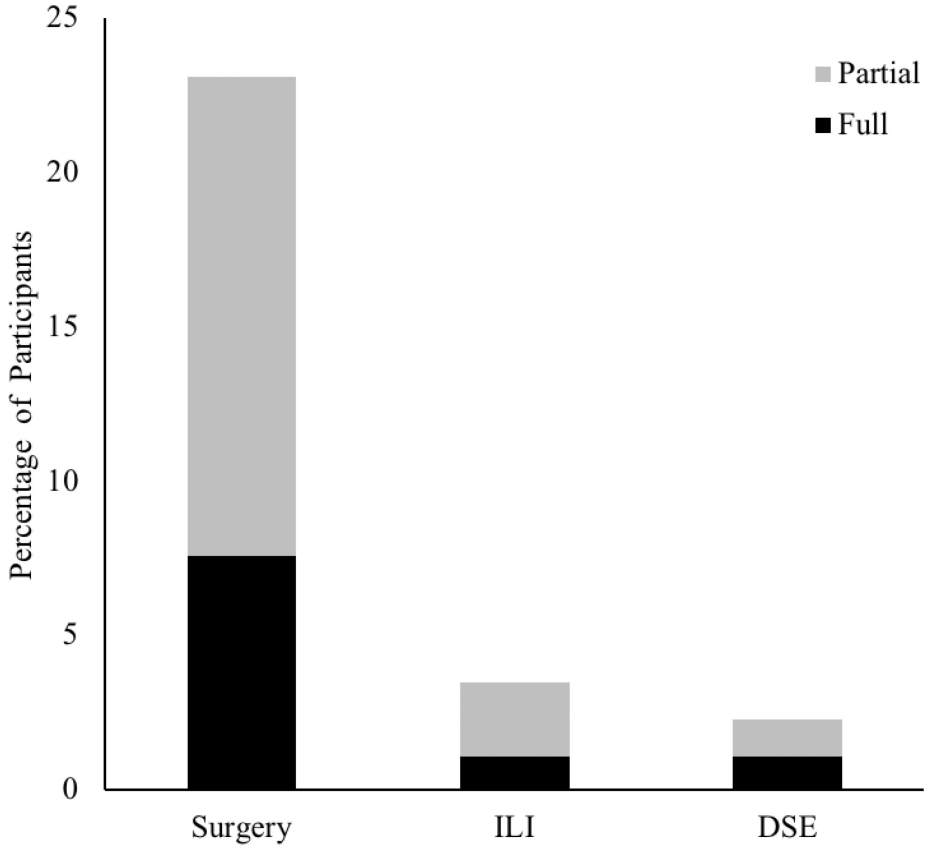


Figure 5:

Percentage of participants who achieved end-of-trial remission of type 2 diabetes (partial or full), according to assignment to the intensive lifestyle intervention (ILI) or diabetes support and education (DSE) groups, as well as participants who had bariatric surgery.

Table 1.

Baseline characteristics of participants randomly assigned to DSE and ILI, as well as those who reported having bariatric surgery.

		Non-Surgery		Surgery	P-Value, Total Non-Surgery vs. Surgery
Characteristic	**DSE**	**ILI**	**Total**		
	N = 2009	**N = 1972**	**N = 3981**	**N = 196**	
Age, y	59.1±6.7	58.6±6.6	58.9±6.7	54.1±5.3	<0.001
Female	1184 (58.9)	1138 (57.7)	2322 (58.3)	152 (77.6)	<0.001
Race/Ethnicity					0.06
Non-Hispanic White	1319 (65.7)	1315 (66.7)	2634 (66.2)	147 (75.0)	
Non-Hispanic Black	350 (17.4)	326 (16.5)	676 (17.0)	26 (13.3)	
Hispanic	278 (13.8)	269 (13.6)	547 (13.7)	17 (8.7)	
Other/Mixed	62 (3.1)	62 (3.1)	124 (3.1)	6 (3.1)	
Household Income					<0.001
<$40K	2596 (32.9)	588 (33.2)	1184 (33.0)	41(22.3)	
$40K-$80K	688 (38.0)	676 (38.1)	1364 (38.0)	66 (35.9)	
>$80K	528 (29.1)	509 (25.7)	1037 (28.9)	77 (41.8)	
Education					0.21
<13 yrs	379 (18.9)	390 (19.8)	769 (19.3)	26 (13.3)	
13–16 yrs	762 (37.9)	728 (36.9)	1490 (37.4)	79 (40.3)	
>16 yrs	816 (40.6)	820 (41.6)	1636 (41.1)	87 (44.4)	
History of CVD event	269 (13.4)	293 (14.9)	562 (14.1)	16 (8.2)	0.02
Weight (kg)	103.8±17.7	104.2±18.4	104.0±18.0	117.4±18.3	<0.001
BMI (kg/m^2)	37.0±5.1	37.1±5.3	37.0±5.2	42.1±5.8	<0.001
Waist circumference (cm)	116.1±12.7	116.3±13.3	116.2±13.0	123.9±12.4	<0.001
SBP (mmHg)	131.0±17.5	129.8±17.5	130.4±17.5	130.5±19.3	0.96
DBP (mmHg)	70.7±10.1	70.4±10.1	70.6±10.1	70.1±10.5	0.54
HbA_{1c} (%)	7.3±1.2	7.2±1.1	7.3±1.2	7.5±1.3	0.01
Triglycerides (mg/dL)	179.5±116.7	184.6±119.1	182.0±117.9	190.3±111.1	0.34
Total Cholesterol (mg/dL)	190.6±36.9	191.1±38.0	190.9±37.5	194.0±34.8	0.25
LDL (mg/dL)	112.4±32.1	112.2±32.3	112.3±32.2	113.4±30.2	0.64
HDL (mg/dL)	43.4±11.9	43.0±11.3	43.2±11.6	44.1±10.9	0.29

Characteristic	DSE	Non-Surgery		Surgery	P-Value, Total Non-Surgery vs. Surgery
		ILI	Total		
	N = 2009	N = 1972	N = 3981	N = 196	
No. of Medications					
Total	5.6±3.1	5.6±3.0	5.6±3.0	6.4±3.2	<0.001
Diabetes	1.5±1.0	1.6±1.0	1.5±1.0	1.8±1.0	0.001
Antihypertensive	1.3±1.1	1.3±1.1	1.3±1.1	1.4±1.1	0.42
Lipid Lowering	0.6±0.6	0.6±0.6	0.6±0.6	0.6±0.6	0.45
Smoking Status					0.79
Current	87 (4.3)	95 (4.8)	182 (4.6)	5 (2.6)	
Former	933 (46.4)	920 (46.7)	1853 (46.5)	87 (44.4)	
Never	984 (49.0)	954 (48.4)	1938 (48.7)	103 (52.6)	
BDI Score	5.5±4.6	5.8±5.2	5.6±4.9	6.8±5.8	0.01
SF-36, PCS	47.6±8.0	47.7±8.0	47.7±8.0	45.8±7.7	0.002
SF-36, MCS	52.6±7.7	53.9±8.3	54.2±8.0	52.8±8.5	0.02
Alcoholic drinks (oz/week)	8.18±20.9	8.01±21.6	8.1±21.3	6.2±17.2	0.22
Paffenbarger (kcal/week)	824.9±1175.3	833.8±1067.9	829.3±1123.3	774.2±1103.3	0.63

Note: Values shown are mean+standard deviation or N ((%); alcoholic drinks = sum in ounces of beer, wine, and liquor.

Table 2.

End-of-trial changes in CVD risk factors, medication use and discontinuation, and behavioral outcomes in participants randomly assigned to DSE and ILI, as well as those who reported having bariatric surgery [Mean+SE) or N(%)].

Variable	DSE (N=2009)	ILI (N=1972)	Bariatric Surgery (N=196)	P-Value		
				DSE vs. ILI	DSE vs. surgery	ILI vs. surgery
Weight loss (%)	−3.3±0.3%	−5.8±0.3%	−19.3±0.8%	<0.001	<0.001	<0.001
Weight (kg)	−3.4±0.5	−5.9±0.5	−22.1±1.5	<0.001	<0.001	<0.001
BMI (kg/m^2)	−0.8±0.2	−1.7±0.2	−7.5±0.8	<0.001	<0.001	<0.001
Waist circumference (cm)	+0.4±0.4	−1.0±0.4	−13.0±1.1	0.009	<0.001	<0.001
SBP (mmHg)	−3.0±0.5	−3.5±0.5	−4.4±1.6	0.59	0.42	0.57
DBP (mmHg)	−5.3±0.3	−4.7±0.3	−3.9±0.8	0.08	0.11	0.39
HbA1c (%)	+0.1±0.1	+0.1±0.0	−0.8±0.1	0.38	<0.001	<0.001
Triglycerides (mg/dL)	−40.2±3.8	−41.8±3.8	−68.0±11.3	0.76	0.02	0.03
LDL (mg/dL)	−24.1±1.0	−24.6±1.0	−19.7±3.1	0.76	0.18	0.14
HDL (mg/dL)	+4.6±0.5	+5.0±0.5	+12.1±1.4	0.54	<0.001	<0.001
No. of Medications						
Total medications	+2.5±0.1	+2.2±0.1	+0.2±0.3	0.01	<0.001	<0.001
% (95% CI) Discontinuing	0.8 (0.5, 1.4)	1.1 (0.7, 1.7)	6.7 (3.8, 11.5)	0.64	<0.001	<0.001
Diabetes	+0.5±0.0	+0.4±0.0	−0.7±0.1	0.002	<0.001	<0.001
% (95% CI) Discontinuing	4.0 (3.1, 5.1)	5.5 (4.5, 6.8)	31.5 (24.8, 39.0)	0.05	<0.001	<0.001
Antihypertensive	+0.6±0.0	+0.5±0.0	−0.0±0.1	0.001	<0.001	<0.001
% (95% CI) Discontinuing	3.1 (2.3, 4.2)	3.2 (2.3, 4.3)	19.1 (13.3, 26.7)	0.91	<0.001	<0.001
Lipid Lowering	+0.5±0.0	+0.4±0.0	+0.2±0.1	0.09	<0.001	0.001
% (95% CI) Discontinuing	7.9 (6.2, 9.9)	8.1 (6.4, 10.0)	18.6 (12.1, 27.4)	0.87	<0.001	<0.001
BDI Score	−0.1±0.2	−0.4±0.2	−1.9±0.6	0.21	0.003	0.02
SF-36, PCS	−5.7±0.3	−4.8±0.3	−1.3±0.9	0.02	<0.001	<0.001
SF-36, MCS	−0.5±0.3	−0.0±0.3	+0.7±0.8	0.18	0.15	0.40
Alcoholic drinks (oz/week)	+0.1±0.1	+0.2±0.1	+0.7±0.4	0.64	0.14	0.21
Paffenbarger (kcal/week)	+10.8±46.2	+156.5±46.3	+138.4±145.1	0.03	0.40	0.91

Note: Values shown are mean±standard error or N (%). Physical and laboratory measurements and number of medications used from baseline through 10 years were modeled and unadjusted with the exception of the Beck Depression Inventory (BDI), which was modeled through the last administration at year 8. SF-36 = Short-Form 36; PCS = physical component summary; MCS = mental component summary

Table 3.

Perioperative (≤30 days) adverse events experienced by Look AHEAD participants who had bariatric surgery (N = 196).

Complication, N(%)	LAGB N = 58	RYGB N = 127	SG N = 11	Total N = 196
Total Complications	**7 (12.1%)**	**33 (26.0%)**	**2 (18.2%)**	**42 (21.4%)**
Nausea, vomiting, food intolerance	1 (1.7%)	4 (3.1%)	0 (0.0%)	5 (2.6%)
Deep vein thrombosis/blood clot	0 (0.0%)	4 (3.1%)	0 (0.0%)	4 (2.0%)
Bleeding (gastrointestinal, intraperitoneal)	0 (0.0%)	2 (1.6%)	1 (9.1%)	3 (1.5%)
Pulmonary complications (e.g., airway obstruction, atelectasis, pneumonia, pneumothorax, respiratory failure, asthma)	0 (0.0%)	3 (2.4%)	0 (0.0%)	3 (1.5%)
Cardiac arrhythmia	0 (0.0%)	2 (1.6%)	0 (0.0%)	2 (1.0%)
Intestinal obstruction/Blockage	0 (0.0%)	2 (1.6%)	0 (0.0%)	2 (1.0%)
Dehydration	1 (1.7%)	1 (0.8%)	0 (0.0%)	2 (1.0%)
Dyspnea	1 (1.7%)	1 (0.8%)	0 (0.0%)	2 (1.0%)
Transfusion	1 (1.7%)	1 (0.8%)	0 (0.0%)	2 (1.0%)
Abdominal hematoma	1 (1.7%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Coma (life support for 18 days)	0 (0.0%)	1 (0.8%)	0 (0.0%)	1 (0.5%)
Death	1 (1.7%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Diarrhea	0 (0.0%)	1 (0.8%)	0 (0.0%)	1 (0.5%)
Esophageal stent	0 (0.0%)	0 (0.0%)	1 (9.1%)	1 (0.5%)
Development of esophageal pouch, requiring fluid to be removed from lap band	1 (1.7%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
Feeding tube inserted	0 (0.0%)	1 (0.8%)	0 (0.0%)	1 (0.5%)
Ketosis	0 (0.0%)	1 (0.8%)	0 (0.0%)	1 (0.5%)
Pyloric sphincter dilation	0 (0.0%)	1 (0.8%)	0 (0.0%)	1 (0.5%)
Post-operative complication with anesthesia, on ventilator for 2 days	0 (0.0%)	1 (0.8%)	0 (0.0%)	1 (0.5%)
Surgery for blockage	0 (0.0%)	1 (0.8%)	0 (0.0%)	1 (0.5%)

Note: Adverse events were reported by participants at annual assessment visits (or 6-month telephone calls), as well as at intervention visits, and were not independently verified if hospitalization was not required.