Preoperative Lifestyle Intervention in Bariatric Surgery: Initial Results from a Randomized, Controlled Trial

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Objective: To document preoperative outcomes of a behavioral lifestyle intervention delivered to patients prior to bariatric surgery in comparison to treatment as usual (insurance-mandated physician supervised diet).

Design and Methods: After completing a baseline assessment, candidates for surgery were randomized to a 6-month, evidence-informed, manualized lifestyle intervention (LIFESTYLE, n = 121) or to preoperative care as usual (USUAL CARE, n = 119). At 6 months, 187 participants remained candidates for bariatric surgery and were included in the analyses.

Results: LIFESTYLE participants lost significantly more weight than those receiving USUAL CARE [8.3 ± 7.8 kg vs. 3.3 ± 5.5 kg, F(1,183) = 23.6, P < 0.0001], with an effect size of 0.72. Additionally, logistic regression modeling indicated that LIFESTYLE patients were significantly more likely to lose at least 5% of initial body weight than those in USUAL CARE [OR (95% CI) = 2.94 (1.253, 6.903)], as were participants who were heavier [OR (95% CI) = 1.07 (1.001-1.14) for each unit increase in BMI] or with larger improvements in eating behaviors [OR (95% CI) = 1.1 (1.049, 1.145) for each unit increase on the Eating Behavior Inventory].

Conclusions: A behavioral lifestyle intervention for severely overweight individuals leads to clinically significant weight loss prior to bariatric surgery. Post-surgery follow-up will allow us to examine the impact of the preoperative intervention on postoperative outcomes.

Introduction

There has been debate as to whether patients should be required to participate in a weight loss program immediately prior to bariatric surgery, with concerns raised that insurance-mandated physician supervised diets could delay or impede access to treatment (1). The American Society for Metabolic and Bariatric Surgery (ASMBS) has taken the position that the requirement for documentation of prolonged physician supervised weight loss efforts before health insurance carrier approval of bariatric surgery is inappropriate (2). However, the ASMBS notes that individual surgeons and programs should be free to recommend preoperative weight loss according to the specific needs and circumstances of the patient.

Despite the controversy surrounding insurance-mandated physician supervised diets, bariatric surgery programs often recommend preoperative weight loss and lifestyle changes. Clinical reports indicate that preoperative behavioral intervention is well received by patients, with high program satisfaction and perceived usefulness (3), and that weight loss is safe and achievable in the context of preoperative care (4,5). Available data also support the benefits of preoperative weight loss, including fewer surgical complications, shorter operative time, less blood loss, and a shorter hospital stay (6). Finally, a meta-analysis has suggested that weight loss was greater 1 year after surgery among patients who had lost weight preoperatively (7).

We are aware of just one prospective, randomized trial evaluating the impact of preoperative weight loss (8). Candidates for bariatric surgery were randomized to a preoperative weight loss requirement or routine preoperative care without this requirement. Patients with the weight loss requirement had a shorter operative time and greater weight loss 3 months after Roux-en-Y gastric bypass than the group receiving routine care, but differences in post-surgical weight loss were not sustained at 6 months (8). At follow-up 1 year after operation, there remained no difference in outcomes by randomization group, but when patients were divided according to those who did and did not lose at least 5% of initial body weight preoperatively, weight loss at 1 year was greater for those with 5% weight loss (9). Nevertheless, this was a single study of a relatively small sample instructed to lose weight by any method. Thus, many important

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questions remain regarding the optimal approaches to weight loss and behavior change prior to bariatric surgery.

We are currently conducting a randomized, controlled trial to evaluate the benefits of manualized, evidence-informed, 6-month behavioral lifestyle intervention relative to routine care prior to bariatric surgery. In this initial report, we evaluate the impact of the lifestyle intervention on body weight prior to surgery and examine factors associated with preoperative weight loss. Rigorous data on the benefits of preoperative lifestyle intervention will inform best practices for bariatric surgery preparation.

Methods and Procedures

Participants

All patients who were at least 18 years of age and seeking bariatric surgery at a Bariatric Center of Excellence at a large, urban medical center were eligible. Exclusion criteria included: (1) mental retardation or psychosis; (2) previously diagnosed genetic obesity syndrome; (3) participation in a weight management program in the 6 months prior to study enrollment; (4) uncontrolled psychiatric symptomatology sufficiently severe to require immediate treatment; (5) pregnant or lactating in the previous 6 months; (6) taking a medication known to affect body weight in the previous 6 months (e.g., second-generation antipsychotics); (7) any previous weight loss surgery; (8) medical condition requiring a specialized preoperative regimen (e.g., nonambulatory, on oxygen therapy for chronic obstructive pulmonary disease); and (10) participation in a conflicting research protocol.

Recruitment and randomization

All attendees at a group information session for patients seeking bariatric surgery were asked if they would be willing to be contacted about participation in research. Patients were assured that a decision to hear about research would not obligate them to participate, their medical care would be the same whether or not they agreed to participate, and information provided for research would have no bearing on their candidacy for surgery. The research study was approved by the University of Pittsburgh Institutional Review Board, and all participants provided informed consent.

Of 1,678 patients who were at least 18 years old, had not reported a previous weight loss surgery, were not flagged as having a high-risk medical condition requiring a specialized preoperative regimen, and were not being recruited into a conflicting research protocol, 934 were screened and contacted to verify eligibility/interest in the present study. After completing the baseline assessment, participants were block randomized to behavioral lifestyle intervention (LIFESTYLE, \( n = 121 \)) or usual preoperative care (USUAL CARE, \( n = 119 \)), with stratification by BMI.

After randomization, any participant who stopped seeking bariatric surgery was inactivated from study participation and was no longer followed. Please see Figure 1 for details on participant screening and flow.

All patients were required to complete a physician supervised diet and activity program, including documentation of weight loss or maintenance, to obtain insurance approval for bariatric surgery. For LIFESTYLE patients, documentation of participation in the study intervention fulfilled this requirement. USUAL CARE patients arranged their physician supervised diet independently.

Measures

An investigator-designed questionnaire was used to collect demographic data including sex, age, race/ethnicity, education, employment status, income, and marital status. Weight was measured at baseline using a digital scale at the study office. At 6 months, weight was collected from the electronic medical record for participants who were unable to complete the assessment at the study office. Height was measured once at baseline using a mounted stadiometer. Participants were weighed and height measured in street clothes, without shoes. BMI was calculated as weight in kilograms divided by the square of height in meters.

Patients completed a battery of questionnaires and interviews at each assessment. Measures of depression and eating behavior were included because they may be related to weight loss among bariatric surgery patients (10,11). The widely used, psychometrically sound Beck Depression Inventory (BDI) (12), a 21-item self-report questionnaire, was used to assess severity of depressive symptoms. Items are rated on a 0-3 scale, with total scores ranging from 0 to 63. A semi-structured clinical interview, the overeating section of the Eating Disorder Examination (EDE) (13), was used to document binge eating, defined as at least one episode with loss of control per week over the last 3 months, regardless of whether the amount of food consumed was objectively or subjectively large (>12 total objective and subjective bulimic episodes). The EDE has shown good validity for the assessment of binge eating among patients prior to undergoing bariatric surgery (14). Participants also completed the Eating Behavior Inventory (EBI) (15), a reliable and valid tool used to assess eating behaviors conducive to weight loss. The EBI consists of 26 items, each rated on a 5-point scale from “never or hardly ever” to “always or almost always”, with total scores ranging from 26 to 130. EBI scores have consistently been shown to be sensitive to weight management interventions, and the magnitude of change tends to parallel the amount of weight loss (15).

Behavioral lifestyle intervention

Patients randomized to LIFESTYLE participated in an evidence-based behavioral weight management program developed by the University of Pittsburgh Obesity and Nutrition Research Center (ONRC). Adaptations based on clinical expertise included providing information about how surgery facilitates weight loss, emphasizing the role of self-management, and addressing factors that have been related to postoperative weight control, such as eating behaviors and mood. Following other investigators (16), we describe the intervention as evidence informed because it is based on behavioral weight control, which is supported by a substantial body of evidence, but also incorporates adaptations for bariatric surgery, which are not yet based on evidence.

Details about the study intervention have been reported previously (17). The study intervention emphasizes the potential health benefits of lifestyle change pre- and post-surgery and is designed to instill realistic expectations regarding preoperative weight loss (5% of initial body weight or 1-2 pounds per week). The objective is to decrease calorie intake through diet and increase energy expenditure through physical activity. Participants are given a goal of 1200-1400 calories per day and instructed to stay within the range while maintaining a balanced diet consistent with nutritional guidelines for bariatric surgery. Surgery candidates are directed to take a daily...
multivitamin and educated about the importance of adequate protein intake and compliance with nutritional supplements after operation. Participants are given a goal of 30 min of physical activity at least 5 days a week. Since sustained physical activity is often difficult for severely overweight individuals, interventionists work with participants to introduce 10-min bouts of activity into their day (18), with walking or swimming recommended. Participants are assisted in self-monitoring and setting small, incremental goals for behavior change. The skills required to make the recommended changes in diet and physical activity are discussed, practiced, and reinforced throughout the intervention.

A combination of individual, face-to-face counseling sessions and telephone coaching was utilized to minimize participant burden and maximize the intensity of intervention during 6 months. The first 2 months consisted of 8 weekly individual, face-to-face sessions. Weekly contacts continued for the next 4 months, consisting of one individual, face-to-face session and three telephone coaching sessions per month. Thus, the intervention consisted of a total of 12 individual, face-to-face sessions and 12 telephone contacts. Face-to-face sessions lasted 1 h, consisting of a weigh-in, review of self-monitoring records, a didactic presentation, and homework. Telephone coaching was shorter in duration (15-20 min) and

| Figure 1 | Patient recruitment and flow. | 929 Patients Screened | 634 Excluded |
|-----------------|-----------------------------|----------------------|--------------|
|                 |                             | 194 Did not meet inclusion criteria |
|                 |                             | 99 Diet in past 6 mo. |
|                 |                             | 86 Weight-related medication past 6 mo. |
|                 |                             | 8 Pregnant/lactating past 6 mo. |
|                 |                             | 1 Severe psychiatric symptomatology |
|                 |                             | 435 Declined to participate |
|                 |                             | 132 Time commitment |
|                 |                             | 87 Distance |
|                 |                             | 82 Surgeries uncertain |
|                 |                             | 134 Other/unknown reasons |
| 300 Consented   |                             | 60 Withdrew (Did not complete baseline assessment) |
| 240 Randomized  |                             | 121 Assigned to Preoperative Lifestyle Intervention |
|                 |                             | 18 Inactivated after randomization (7 provided specific reasons for not pursuing surgery, 11 unknown reasons) |
|                 |                             | 103 Remained candidates for surgery |
|                 |                             | 119 Assigned to Preoperative Usual Care |
|                 |                             | 35 Inactivated after randomization (25 provided specific reasons for not pursuing surgery, 10 unknown reasons) |
|                 |                             | 1 Died |
|                 |                             | 84 Remained candidates for surgery |
| 103 Bariatric Surgery Candidates Followed | 98 Completed lifestyle intervention |
|                 | 5 Did not complete lifestyle intervention |
| 84 Bariatric Surgery Candidates Followed | 58 Completed usual care diet with bariatric surgery group program |
|                 | 26 Completed usual care diet individually |
| 6 Month Assessment | 99 Participated in assessment visit |
|                 | 4 Weights obtained from medical record |
| 6 Month Assessment | 72 Participated in assessment visit |
|                 | 9 Weights obtained from medical record |
|                 | 3 Declined to participate |
included a review of progress, problem solving, and goal setting. Interventionists received training in behavioral and surgical management of obesity and regular supervision.

**USUAL CARE**

After randomization, USUAL CARE patients received a synopsis of the information provided to participants in the lifestyle intervention but did not have any additional contact with the study staff until the 6-month assessment. To meet health insurance requirements, patients completed a non-standardized, physician supervised diet and activity program in the context of routine presurgical care. Most patients were seen once a month for 6 months, either in group sessions provided under the auspices of the bariatric surgery program or as arranged individually.

**Analytic plan**

Descriptive statistics were used to summarize demographic characteristics of study participants. Two-sample $t$-tests, Wilcoxon tests, and chi-square analyses (or Fisher’s exact tests) were performed for continuous and categorical variables, respectively, to test for differences between participants who were and were not randomized, between the two study randomization groups, and between those who were and were not inactivated on baseline and demographic variables.

Participants who failed to complete the baseline assessment and withdrew prior to randomization ($n = 60$) and participants who were randomized ($n = 240$) did not differ significantly in BMI or demographic characteristics. Additionally, participants who were inactivated after randomization ($n = 53$) and those who remained candidates for surgery and were not inactivated ($n = 187$) did not differ significantly on baseline BMI or demographics.

To test the hypothesis that the intervention would have a positive impact on weight loss relative to routine care at 6 months, we fit a longitudinal model using SAS mixed models. We included fixed terms for time (0, 6 months), group (LIFESTYLE, USUAL CARE), and the group by time interaction, as well as initial BMI. Time was treated as a categorical variable, and a random term was included to account for individual variability. Similar mixed models were applied to secondary outcomes of eating behaviors and depressive symptoms collected at baseline and 6 months. Planned contrasts were set to compare conditions in changes from baseline to the 6 months for weight. Effect size was calculated based on the $t$-statistic. We computed weight loss and percent weight loss for all participants for whom we collected weight at 6 months (184/187). We then compared computed weight loss and percent weight loss for all participants for whom we collected weight at 6 months (184/187). We then compared conditions in percent weight loss using a linear regression model.

A series of linear regression models was conducted to explore factors that potentially related to weight loss, including demographic characteristics (age, sex, education, employment status, income, race/ethnicity, and marital status) eating behaviors (EDE and EBI baseline values, as well as baseline to 6 month change values), and depressive symptoms (BDI baseline and change values). First, we ran univariate analyses for each factor controlling for group and initial BMI (the effects of group and BMI were calculated without any other covariates). Next, a multivariate model was selected considering all significant factors from univariate analyses and using a stepwise method with group and initial BMI forced into the model. Finally, following the same modeling strategy, we examined the effects of these factors on the probability that a participant lost at least 5% of initial body weight using logistic regression analysis.

Statistical significance was set at $P \leq 0.05$, and all tests were two-tailed. All analyses were performed using SAS, version 9.2 (SAS Institute, Cary, NC).

**Results**

**Participant characteristics**

Participants ($n = 240$) were 86.7% female, 82.9% white, 0.8% Hispanic or Latino, 52.3% married, and 85.8% had education beyond high school. Mean BMI was 47.9 ± 6.7 kg/m$^2$, and age was 45.2 ± 11 years. Patients randomized to LIFESTYLE and USUAL CARE did not differ significantly in baseline BMI or demographic variables.

At 6 months, USUAL CARE participants were significantly more likely than LIFESTYLE to have been inactivated ($35/119$ (29.4%) vs. $18/121$ (14.9%), $X^2=7.37$, $P=0.007$). Among the 103 LIFESTYLE patients who remained candidates for surgery at 6 months, 97 completed the intervention and used it to fulfill their insurance requirement for a 6-month physician supervised diet (mean contacts 19.4/24, 80.8%); three discontinued the study intervention and arranged their physician supervised diet independently; and two never began the study intervention due to time constraints and also arranged their physician supervised diet independently; and two never began the study intervention due to time constraints and also arranged their physician supervised diet independently. Six-month weights were collected for all. All 84 surgery candidates retained in USUAL CARE documented participation in an insurance-mandated preoperative diet (58 by completing six group sessions offered by the bariatric surgery program and 26 by completing an individual diet program); three participants were lost to follow-up.

**Intervention outcomes**

Baseline and 6-month values for body weight and other outcomes are shown in Table 1. With respect to changes in body weight, there was a significant effect for time, indicating that participants lost weight over 6 months [$F(1,183) = 147$, $P < 0.0001$]. Additionally, there was a significant group by time interaction: LIFESTYLE participants lost an average of 4.98 kg more weight than USUAL CARE, respectively, in a linear regression model for percent weight loss ($6.3 \% \pm 5.8 \%$ vs. $2.5 \% \pm 4.0 \%$; $t(1,182) = 5.01$, $P < 0.0001$). Additionally, 53.4% of LIFESTYLE patients vs. 21.0% of USUAL CARE patients ($X^2=20$, $P < 0.0001$) lost at least 5% of initial body weight. At least 10% weight loss was achieved by 24.3% of LIFESTYLE patients vs. 3.7% of USUAL CARE patients (Fisher exact test, $P < 0.0001$).

For EBI, there was a significant group effect [$F(1,177) = 7.4$, $P = 0.007$], a time effect [$F(1,152) = 287$, $P < 0.0001$], as well as a significant group by time interaction [$F(1,152) = 13.3$, $P = 0.0004$], indicating that LIFESTYLE participants had larger improvements in eating behaviors than USUAL CARE participants. However, there was a significant effect for time only for EDE subjective bulimic
Factors associated with preoperative weight loss

Results of univariate and multivariate linear regression modeling for body weight are presented in Table 2. Group, initial BMI, sex, age, baseline EBI score, as well as the change in EBI and change in BDI from baseline to 6 months, were significantly associated with weight loss in univariate models; the other variables of interest were not associated with weight loss. Baseline BMI, sex, age, and the change in EBI were retained in the final multivariate model. Consistent with the results from mixed models, there was a significant intervention effect ($\beta = -3.22, t = 3.03, P = 0.003$). Male participants lost an average of 3.98 kg more than females ($t = 2.54, P = 0.01$). Furthermore, those with larger BMIs lost more weight ($\beta = 0.29, t = 3.56, P = 0.0005$), as did older subjects ($\beta = 0.14, t = 2.94, P = 0.004$) and those with larger improvement in EBI scores ($\beta = 0.25, t = 5.49, P < 0.0001$). Results of linear regression modeling for percent weight loss yielded a similar pattern of results with the exception that sex was no longer a significant predictor (data not shown).

Logistic models were used to explore factors associated with ≥5% weight loss. The final multivariate model included group, baseline BMI, and the change in EBI. Participants in LIFESTYLE were more likely to lose at least 5% initial weight than those in USUAL CARE [OR (95% CI) = 2.94 (1.253, 6.903)]. Additionally, those who were heavier [OR (95% CI) = 1.07 (1.001, 1.14)] for each unit increase in BMI, or had a larger improvement in EBI scores [OR (95% CI) = 1.1 (1.049, 1.145) for each unit increase in EBI], were more likely to lose at least 5% of their initial weight. Age was of borderline significance [OR (95% CI) = 1.04 (0.998, 1.084) for every year increase in age]. Too few participants in USUAL CARE achieved ≥10% weight loss to run models based on this outcome.

Discussion

Initial results of this randomized, controlled trial indicate that bariatric surgery candidates who participated in a 6-month, evidence-informed behavioral lifestyle intervention experienced significantly greater weight loss, had a greater probability of achieving a ≥5% and ≥10% weight loss, reported greater improvements in eating behaviors, and were more likely to remain candidates for surgery at post-intervention than patients receiving usual preoperative care. Moreover, although the impact of the study intervention on postoperative outcomes is not yet known, 53% of patients achieved at least 5% weight loss, a magnitude of preoperative weight loss that has been associated with shorter operating room times (19) and greater postoperative weight loss 1 year after Roux-en-Y gastric bypass (9).

The present investigation adds to a growing body of evidence that behavioral intervention leads to significant short-term weight loss even among extremely obese individuals. Average loss of 6.3%
of initial body weight among surgery candidates completing the 6-month lifestyle intervention may be compared to results from a trial in which patients required to lose weight prior to Roux-en-Y gastric bypass lost 8.2% of body weight (8). Findings may also be compared to results from nonsurgical samples of severely overweight individuals participating in university-based clinical trials of behavioral weight control. For example, in a study of diet and physical activity interventions among adults with class II or III obesity (20), 60-80% of study completers lost >5% of their baseline body weight at 6 months. Among adults with class III obesity and type 2 diabetes receiving the intensive lifestyle intervention in the Action for Health in Diabetes (Look AHEAD) trial, 67% achieved at least 5% weight loss at 1 year (21). Although more modest than findings from previous studies, the percentage of patients achieving >5% weight loss in the present study was substantial.

In our sample of surgery candidates (with an average BMI of 48 kg/m² and age of 45 years), those who were heavier and had greater improvements in eating behaviors were more likely to achieve a 5% weight loss, with a trend toward better outcomes among older patients. Although findings require replication, they are consistent with the broader literature on behavioral weight control. It has been well established that heavier patients tend to lose more weight. In the study by Goodpaster and colleagues (20), the heavier participants with class III obesity had a significantly greater percent weight loss than class II obese participants at 1 year. In secondary analyses from the Look AHEAD trial, participants in the intensive lifestyle intervention group with class III obesity had a significantly greater percent weight loss than overweight participants at 1 year (21). Additionally, among a less obese sample of adults at risk for developing type 2 diabetes in the Diabetes Prevention Program (DPP), older participants were particularly successful at meeting their weight loss and physical activity goals, while psychosocial and depression measures were unrelated to goal achievement (22). Although results indicated that depressive symptoms and binge eating were not associated with weight loss in multivariate models, postoperative follow-up is essential because these factors have been associated with poorer weight outcomes after bariatric surgery (10,11).

Strengths of the present study include its randomized, controlled design, and evidence-informed, manualized behavioral lifestyle intervention. Nonetheless, it also has limitations. Most notably, only one out of four patients screened for participation were randomized, and thus generalizability of results may be limited. In future reports, we will examine whether preoperative behavioral lifestyle intervention has an impact on postoperative outcomes, including fewer complications and greater longer term weight loss. More studies are needed on when to initiate and how to integrate surgical and behavioral interventions in the management of severe obesity. This is particularly true given mounting evidence that a significant minority of bariatric surgery patients experience poor long-term weight loss (23,24). Self-regulation of eating and activity are critical for management of severe obesity, and both pre- and postoperative lifestyle interventions (25) will be necessary to optimize long-term outcomes following bariatric surgery.

In summary, the major finding of the present investigation is that a 6-month, evidence-informed behavioral lifestyle intervention was associated with significantly greater weight loss than a comparison condition in which patients were routinely required to complete an insurance-mandated diet and exercise program for surgery approval.

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