Weight Loss Promotes Nonbariatric Surgery Medical Clearance

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A liquid-based weight-loss program had a high success rate among obese veterans, was cost-effective, and reduced the need for surgery.

The prevalence of overweight and obesity has continued to increase over the past several decades.[1,2] Data specific to the veteran population indicates prevalence rates are considerably higher than that of the general population, with overweight or obese veteran women and men at 68.4% and 73%, respectively.[3-6]

Traditional weight-loss programs (> 1,200 calories per day) fail to produce the degree of weight loss required to reduce surgical risk to a safe level for individuals with a body mass index (BMI) > 35. In contrast, intensive weight-loss programs using very low calorie diets (< 800 calories per day) combined with lifestyle modifications have been effective in generating considerable weight loss. These intensive weight-loss programs have also improved comorbid conditions such as insulin resistance, diabetes, hypertension, hyperlipidemia, and hypertriglyceridemia.[7-10] Additionally, these programs have reduced surgical risks by decreasing operative time and reducing hospital length of stay.[11,12] Weight loss not only improves surgical risk, but also impacts health care resource allocation.

Very low calorie diets have proven to be safe for preoperative weight loss. One prospective study evaluated the safety of a weight-reduction program with 30 patients with morbid obesity and whose elective surgery had been postponed due to patient's weight status.[13] Study participants lost ≥ 15% of their body weight. Subsequently, only 15 patients underwent surgery. Surgery was no longer indicated for 4 participants, 9 did not have surgery for reasons that were unreported, and 2 discontinued the diet. The authors suggested a very low calorie diet program is suitable for preoperative weight reduction in morbid obesity without significant complications.

Most investigations of preoperative very low calorie diets included only those patients awaiting bariatric surgery. These studies confirmed bariatric preoperative weight loss correlates with reduced postoperative complications.[11,14,15] Additionally, the National Surgery Quality Improvement Program analysis of bariatric outcomes identified superobesity (defined as > 350 pounds) as a preoperative risk factor associated with postoperative complications.[16]

Obesity-related intra- and postoperative complications during elective surgeries are concerning because of the increasing number of obese surgical patients. With a growing aging population and rising rates of obesity, the number of total knee arthroplasties (TKAs) are increasing and now surpass total hip arthoplasties.[17] The risk of intra-operative surgical complications is higher in patients with an elevated BMI than in those without, including higher blood transfusion requirements as a result of operative blood loss, difficulty in identifying anatomy leading to iatrogenic damage, or malalignment of the prosthesis.[18-20]

The risk of postoperative complications in obese patients is reported with rates as high as 32% and is primarily caused by superficial and deep surgical site infections and postoperative venous thromboembolic complications.[18,19,21,22] One retrospective study evaluated prevalence, pattern, and severity of 7,721 postoperative complications in obese and nonobese surgical patients occurring within 30 days of surgery.[23] Obese patients had significantly higher rates of postoperative myocardial infarction, wound infection, nerve injury, and urinary tract infections. The evidence

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suggests a higher risk of intra- and postoperative complications of TKA in obese patients, but there remains continued controversy in this area. Furthermore, there is a paucity of data regarding actual postponement or cancellation rate in elective procedures related to obesity. There is a lack of literature evaluating the impact of significant preoperative weight loss by nonsurgical interventions on outcomes of subsequent elective surgery

The primary aim of this study was to determine whether a medically supervised, very low calorie weight loss program (Optifast, Nestlé Health Science) could safely and effectively produce the weight loss necessary to achieve surgical clearance at the Phoenix VA Health Care System (PVAHCS). The secondary aim was to determine whether a decrease in medication utilization during the diet intervention would offset the cost of the nutrition intervention.

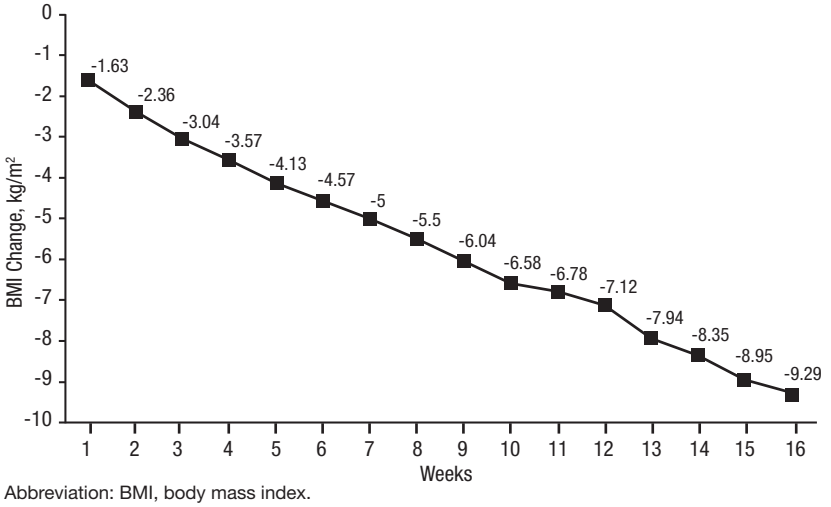
METHODS

This was a prospective, theory-based pilot study exploring weight status in response to a very low calorie diet, utilizing a quasi-experimental design. The PVAHCS Institutional Review Board approved the study.

Subjects participated in a medically supervised weight-loss program, including a liquid-meal replacement and weekly education administered by a registered dietitian. Twenty male and female veterans with obesity who had been denied medically indicated nonbariatric elective surgery due to obesity/morbid obesity and who met the study's inclusion criteria were recruited.

Inclusion criteria included veterans aged 18 to 70 years, BMI > 30, and a nutritional consult for weight loss prior to elective (nonbariatric) surgery. The exclusion criteria included active medical conditions for which weight loss would be contraindicated, active alcohol or substance abuse, and psychological issues that could prevent compliance.

Figure 1. Average Change in BMI in all Particpants[a]



Abbreviation: BMI, body mass index.
[a]Values are ± standard error of the mean.

Screening Measures

A complete metabolic panel and prealbumin levels were assessed at baseline and used as indicators of overall electrolyte, hydration, and nutritional status. A complete blood count and thyroid stimulating test were used to rule out anemia, infections, and thyroid disorders. Because rapid weight loss may precipitate serious ventricular arrhythmias, an electrocardiogram was performed at baseline and after each 50 pounds of weight loss.

Intervention

Subjects consumed 5 Optifast packets per day (each mixed with 6-10 ounces of water), providing 800 calories per day (34% protein, 49% carbohydrate, and 17% fat; with 100% of the Dietary Reference Intake for vitamins and minerals). Participants were enrolled in the program for a minimum of 6 weeks and a maximum of 16 weeks.

The research dietitian provided participants with weekly modules focused on lifestyle and education plans developed by Nestlé (eTable 1, available at www.fedprac.com). Concentrating initially on behavior modification techniques and later introducing concepts dealing with food minimized distracting stimuli for participants. Subjects were required to consume an additional 2 quarts of noncaloric liquid to maintain hydration and were educated not to consume any liquids or solids containing calories. Subjects were required to maintain a diary on timing of Optifast and fluid consumption. Caffeine intake was limited (< 200 mg per day) because of its effects on fluid loss, cardiac stimulation, and irritation to the gastric mucosa. Participants served as their own controls.

Three weeks prior to completing the liquid diet, patients were instructed on a 3-week dietary transition plan, incorporating solid foods into their meal plan. Transition guidelines used the plate method, based on recommendations from the Dietary Guidelines for Americans to assist individuals in making healthy food choices, as patients were transitioned

Table 1. Baseline Demographics and Clinical Characteristics

	All	Completers	Withdrawals
Mean, y ± SD (range)	55.1 ± 7.9 (43-68)	56.1 ± 8.1 (43-68)	52.8 ±7.3 (45-59)
Gender, no.			
Male	18	14	4
Female	2	2	0
Race/ethnicity, no.			
Non-Hispanic white	18	15	3
African American	2	1	1
Comorbid conditions, no.			
Diabetes/prediabetes	12	8	4
Hypertension	16	12	4
Hyperlipidemia	12	9	3
Mental health diagnoses, no.			
Depression			
Obsessive compulsive disorder	11	7	4
Posttraumatic stress disorder	1	0	1
Panic disorder	2	2	0
	1	1	0
Elective surgery referrals, no.			
Hip	1	1	0
Hernia	2	1	1
Knee	17	14	3

from the liquid to solid food.[24] During transition week 1, subjects consumed 4 shakes per day and 1 meal (885 kcal per day); the second transition week consisted of 3 shakes and 2 meals (1,030 kcal per day); and the final transition week included 1 shake and 3 meals (1,080 kcal per day).

Outcome Measurements

Subjects were weighed weekly. To assess dietary compliance, participants were given a log to record daily intake of the liquid diet, additional liquids consumed, and physical activity. Bioelectrical impedance analysis was used pre- and postintervention to determine body composition, including body fat percentile.

Biochemical outcome measures affected by very low calorie diets (lipids, hemoglobin A_{1c}, fasting glucose) were measured at baseline and every 4 weeks, and clinical outcomes were measured weekly. A BodyGem handheld indirect calorimeter measured resting energy expenditure (REE) to monitor caloric needs during weight loss and to guide the transition to solid food. Medication use related to obesity was recorded weekly, and the total medication costs were calculated pre- and postintervention.

Medication Management

Blood pressure was monitored weekly. If a patient was prescribed warfarin, the primary care provider and pharmacist were alerted, because it was anticipated that dosages would change with weight loss. Patients on insulin had a 50% reduction on week 1, and subsequent adjustments were made at the discretion of the provider based on glucose monitoring. Oral hypoglycemic agent adjustments were also made based on glucose monitoring.

All patients were prescribed ursodeoxycholic acid 300 mg twice a day to reduce the risk of gallstone formation.[25] Psyllium was provided to prevent constipation, a commonly reported adverse event (AE) of Optifast. Over-the-counter lactase additives were recommended for patients with known lactose intolerance. As recommended by the Optifast program, patients were instructed to avoid nonsteroidal anti-inflammatory drugs, aspirin and laxatives, amphetamines/stimulants, pseudoephedrine, and sugar-containing medications. Medications were adjusted according to clinical practices.

Statistical Analysis

Distributions of continuous measurements at the beginning (baseline) and end (follow-up) of the study and changes in these measurements (follow-up minus baseline) were tested for normality using the Shapiro-Wilk test. Where both baseline and follow-up values of a given measurement were distributed normally, both baseline and follow-up values are shown as mean ± SD (Table 1). If ≥ 1 baseline and follow-up measurements were not normally distributed, both baseline and follow-up measurements are shown as median with interquartile range. Changes in measurements are either shown as mean ± SD or median and interquartile range as appropriate. Significance of the former changes was evaluated with a paired *t* test; whereas the latter changes were evaluated with a Wilcoxon signed rank test.

RESULTS

A total of 65 veterans were referred to the program. Eighteen male and 2 female veterans ranging from ages 43 to

Table 2. Clinical Measures Before and After Intervention

Measure[a]	N (Baseline/ Follow-up)	Baseline	Follow-up	Change, %	*P* Value
Weight, lbs.	20/20	320 ± 50	269 ± 45	-16 ± 8	< .0001
Body fat, lbs.	20/16	124 ± 25	92 ± 19	-26 ± 9	< .0001
Fat-free mass, lbs.	20/16	194 (172, 225)	168 (141, 192)	-14 ± 5	< .0001
Body fat, %	20/16	38.0 (36.1, 39.6)	34.6 (33.4, 35.1)	9 ± 4	< .0001
BMI, kg/m^2	20/20	44.9 ± 6.3	37.7 ± 5.7	-16 ± 8	< .0001
Systolic BP, mm Hg	20/16	126 (118, 138)	112 (108, 116)	-14 ± 11	< .0001
Diastolic BP, mm Hg	20/16	79 (78, 86)	74 (69, 78)	-8 ± 13	.029
Plasma cholesterol, mg/dL	20/16	169 (154, 198)	140 (124, 170)	-21 (-28, 4)	.0042
LDL-C, mg/dL	20/16	93 (77, 122)	81 (62, 108)	-19 (-37, 3)	.065
HDL-C, mg/dL	19/16	39 ± 8	38 ± 7	-4 (-22, 10)	.52
Plasma triglyceride, mg/dL	20/16	194 (105, 266)	94 (78, 140)	-37 (-49, -21)	.0052
Fasting plasma glucose, mg/dL	20/16	106 (98, 137)	96 (88, 102)	-13 ± 15	.0047
A_{1c}, %	20/16	6.2 (5.9, 6.7)	5.4 (5.2, 5.8)	-10 ± 7	< .0001
Prealbumin	20/16	28.5 (24.0, 31.5)	23.0 (20.0, 31.0)	-11 ± 18	.029
Resting energy expenditure, calories/d	20/15	2,595 (1,980, 2,825)	1,920 (1,530, 2,150)	-24 ± 11	< .0001
Resting energy expenditure per kg fat-free mass, calories/kg/d	20/15	12.6 ± 1.4	11.3 ± 1.6	-11 ± 10	.0005

Abbreviations: BMI, body mass index; BP, blood pressure; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol.
[a]Values are mean ± SD or median (25th percentile, 75th percentile). *P* values are by paired *t* test for changes distributed normally, shown as mean ± SD and by Wilcoxon signed rank test for changes not normally distributed shown as median (25th percentile, 75th percentile).

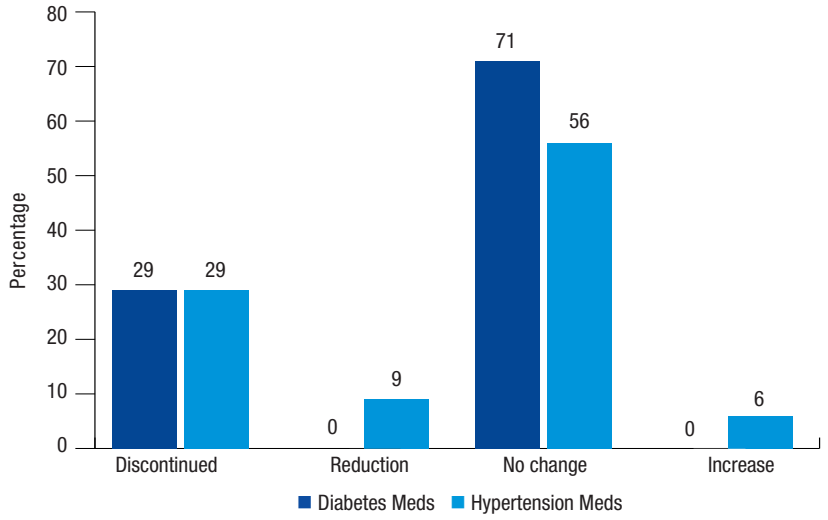
68 years, with a mean age of 55 years (SD ± 7.9) consented to participate; 16 (80%) completed the study. Four subjects dropped out; 1 due to lactose intolerance uncontrolled by lactase, 1 due to exacerbation of obsessive compulsive disorder, 1 moved out of state, and 1 opted out before beginning the dietary intervention. Comorbidities included psychiatric diagnoses (80%), hypertension (80%), diabetes (60%), and hyperlipidemia (60%). Baseline characteristics were not different between those who withdrew and those who completed the study (Table 1). Study outcomes based on intent-to-treat analysis are presented in Table 2.

BMI decreased linearly during the intervention (Figure 1). In 10 subjects, the change in BMI postintervention was both statistically (-16 ± 8%, $P < .0001$) and clinically significant and sufficient for surgical clearance. Eight (40%) had surgery and 2 (10%) no longer needed surgery due to self-reported improved quality of life and decreased pain. Despite the clinically and statistically significant weight loss, 14.5% of the weight lost was fat-free mass; decrease in body fat was 9% ± 4% ($P < .0001$).

All study subjects consumed 5 Optifast packets per day for at least 10 weeks and no longer than 16 weeks. Of the participants who completed the intervention, the majority elected to continue the intervention time to 16 weeks; however 1 participant went to week 10 and 2 participants completed through week 13. Nonadherence in this protocol was defined as > 2 weeks of weight gain. Two participants gained weight for 6 and 7 weeks, respectively.

Mean systolic blood pressure, plasma triglyceride and fasting glucose levels, A_{1c}, and REE levels decreased significantly postintervention. Additionally, patients experienced either dose reduction or discontinuation of diabetes or hypertension medication use postintervention (Figure 2). Discontinued diabetes

Figure 2. Effect of Weight Loss on Medication Utilization



medications included rosiglitazone (n = 1), glyburide (n = 1), and metformin (n = 2). Discontinued or reduced antihypertensives included furosemide (n = 1), thiazides (n = 3), beta blockers (n = 1), angiotensin-converting enzyme inhibitors (n = 4), calcium channel blockers (n = 2), and angiotensin II receptor antagonists (n = 2).

DISCUSSION

To the authors' knowledge, this was the first study using a low calorie liquid diet to achieve weight loss to qualify for nonbariatric elective surgery. This diet provides an alternative intervention for individuals who would otherwise be denied elective surgery due to extreme obesity. Eighty percent of participants completed 10 to 16 weeks of the 800 calorie liquid diet plan with significant weight loss of 16 BMI ± 8%. The intervention was well tolerated without significant AEs.

It is difficult to compare these results to prior studies, as the target populations differ. Previous studies utilizing calorie levels < 800 calories per day included mostly women and consequently, their preintervention weights were lower than in the current study population.[10] This study population was predominately older males with a high prevalence of comorbid medical and psychiatric conditions. Despite these demographic and clinical differences, improvements in biochemistries were similar to those demonstrated previously.[8-10] The observations for beneficial changes in cardiovascular and glycemic risk factors and reduced medication use related to weight loss and calorie control are consistent with previous results.[8-10]

To the authors' knowledge, REE has not been reported in earlier investigations of very low calorie diet interventions. This study found significant decreases in REE, which was measured pre- and postintervention. Participants were given postintervention REE value and individualized meal plans were developed from this number. An interesting and unexpected finding was that this number seemed to provide useful reinforcement for patients as they transitioned to solid food. This may have helped improve adherence to meal plans. Despite concerns regarding possible weight gain, the weight loss continued at a similar rate during the transition, demonstrating that continued weight loss can occur with a combination of food and liquid diet.

The need for elective surgery may have increased motivation to adhere to this weight-loss program. The dropout rate was 20%; lower than previous studies using very low calorie diets and substantially better than traditional weight-loss programs.[8,9]

An unexpected finding was that 10% of participants who qualified for knee replacement surgery chose to postpone surgery due to decreased pain and improved quality of life. Over the past 20 years, the estimated cost of 1 TKA was $15,000 with an estimated $9 billion spent annually for this procedure in the U.S.[26] Importantly, obesity increases the risk of TKA revision surgeries, which are both expensive (average cost of Medicare-covered TKA revision surgeries is $73,696) and projected to increase 66% over the next 25 years.[27] Weight loss prior to surgery not only may decrease risk for revisions of TKA, but in some cases also may delay or eliminate the need for surgery.

Although there are significant costs associated with certain weight loss programs, the savings associated with reducing the need for surgery would be substantially greater than that associated with the dietary intervention. The estimated private sector cost of an 18-week weight-loss program (12-week liquid with 6-week transition) is $3,500 per participant. This study program was estimated to cost $2,400 per participant for the 16-week (13-week liquid diet and 3-week transition) program. Patients with obesity awaiting orthopedic, gastrointestinal, or neurosurgery were often referred for bariatric surgery to obtain weight loss. Bariatric surgery averages $17,000 to $26,000, which is more expensive than this diet program.[28]

The majority of AEs observed in this intervention were expected and similar to other studies.[10] Among the 20 participants, 18 experienced a total of 60 AEs, of which 38 (63%) were considered to be study-related. Although constipation was a known AE, 25% of participants subjectively complained of decrease in frequency of bowel movements. The 2 most frequent and unanticipated AEs were increased blood urea nitrogen/creatinine (n = 9) and reduced sodium (n = 7).

Nonadherence was often related but not limited to the following: inappropriate social cues for eating, lack of social support, sabotage by family or peers, filling an emotional void with food, and/or psychological eating related to depression and posttraumatic stress disorder. Prior to starting a similar intervention, a complete mental health assessment for individuals with known or suspected mental health diagnoses seems warranted.

CONCLUSION

The study limitations are its small and predominantly male sample size and lack of a randomized control. Nonetheless, this study demonstrated the feasibility of the medically supervised weight loss program to obtain the necessary weight loss in 50% of the veterans (with higher comorbidities and more advanced age). Because of the results of this investigation, the authors have initiated a randomized controlled trial utilizing this intervention. The Optifast program had a high success rate, was cost-effective, and may obviate the need for surgery. ●

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Author disclosures

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