One hundred–pound weight losses with an intensive behavioral program: changes in risk factors in 118 patients with long-term follow-up[1,2]

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ABSTRACT

Background: Treatment of severe obesity is difficult; in the past, lifestyle measures did not prove effective. Recently, however, intensive behavioral interventions using meal replacements and low-energy diets have enabled some severely obese persons to achieve nonobese weights.

Objective: We assessed rates of weight loss, changes in risk factors and medication requirements, and long-term weight maintenance in patients who lost ≥100 pounds (45.5 kg).

Design: Over a 9-y period, we prospectively identified patients who lost ≥100 pounds (45.5 kg) and actively recorded follow-up weights. Charts were systematically reviewed to assess outcome measures and side effects. The intervention included meal replacements (shakes and entrées), low-energy diets, weekly classes, and training in record keeping and physical activity. Assessments included weekly weights, laboratory studies, medication use, lifestyle behaviors, side effects, and follow-up weights.

Results: Sixty-three men and 55 women lost ≥100 pounds. At baseline, the subjects' average weight was 160 kg, 97% had ≥1 obesity-related comorbidity, and 74% were taking medications for comorbidities. Weight losses averaged 61 kg in 44 wk. Medications were discontinued in 66% of patients with a cost savings of $100/mo. Despite medication discontinuation, significant decreases in LDL cholesterol (20%), triacylglycerol (36%), glucose (17%), and systolic (13%) and diastolic (15%) blood pressure values were seen. Side effects were mild, and only 2 patients had severe or serious adverse events. At an average of 5 y of follow-up, patients were maintaining an average weight loss of 30 kg.

Conclusion: Intensive behavioral intervention can be very effective with minimal risk for certain severely obese persons. *Am J Clin Nutr* 2007;86:301–7.

KEY WORDS Severe obesity, intensive behavioral treatment, meal replacements, long-term weight maintenance, hypertension, diabetes, low-energy diets

INTRODUCTION

Approximately 5% of US adults have severe obesity (1), and the prevalence is increasing twice as fast as that of less severe obesity (2). Severe obesity—defined by a body mass index (BMI; in kg/m^2) of ≥40—is also termed morbid, extreme, or class 3 obesity (3). This extreme degree of obesity is accompanied by a significantly higher prevalence of common comorbid conditions (3) and rates of premature mortality twice those seen with less severe degrees of overweight (4). Furthermore, self-esteem and physical function are assessed to be significantly lower in severely obese than in less obese persons (5).

Lifestyle or pharmacologic interventions are usually not successful for severe obesity (6, 7). Whereas very-low-energy diets (VLEDs) have been used successfully to treat some persons with severe obesity (8, 9), only limited information is available about long-term follow-up. Bariatric surgery approaches, used for >40 y (10), were recommended as the treatment of choice by a National Institutes of Health Consensus Panel (11). Minimally invasive techniques have reduced the mortality and morbidity associated with bariatric procedures (7), but the gastric bypass procedure is expensive (12, 13) and has an operative mortality rate of 0.2–2.0% (7, 10, 12, 14, 15) and a complication rate of ≥20% (10, 12, 16).

Intensive behavioral interventions enable some severely obese persons to achieve nonobese weights (17, 18). The present study was an observational study with the objectives of determining the benefits and risks of a weight loss of 100 pounds achieved by following an intensive behavioral program and of assessing long-term maintenance of weight loss. Over a 9-y period, we prospectively identified patients who lost ≥100 pounds (45.5 kg) in our program; here, we report the outcomes of weight loss, risk factor changes, medication use, side effects, and long-term maintenance of weight loss.

SUBJECTS AND METHODS

The Health Management Resources Weight Management Program at the University of Kentucky (UK) is a partnership between UK and Health Management Resources (HMR; Boston, MA). Since 1985, at the UK-HMR Program, weight losses of ≥100 pounds (45.5 kg) have been acknowledged, weekly weights have been recorded, and follow-up weights have been recorded by one of us (JWA). Since 1995, data from all treated patients have been maintained in a database by HMR, and JWA

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has systematically recorded outcome data for these patients. Our objective was to obtain data on >100 patients so that selected subgroup analyses would be statistically valid. In addition to data recorded by JWA, the HMR databases were searched for patients who met selection criteria between 1 January 1995 and 31 December 2003. This end-date allowed for a minimum follow-up of 2 y.

The 2 treatment options for patients with severe obesity included the Medically Supervised option and the Healthy Solutions option as described previously (18). Briefly, the Medically Supervised option provided only meal replacements (shakes or entrées) during the weight loss phase. Patients used 5 shakes/d or 3 shakes plus 2 entrées/d. Patients in the Medically Supervised group were seen weekly by program physicians for ≥4 wk and then biweekly; laboratory studies (chemistry, lipid, and hematology panels) were obtained biweekly or monthly. The Healthy Solutions option did not require medical supervision or laboratory studies. Patients in that group used 3 shakes, 2 entrées, and ≥5 servings of fruit and vegetables daily. All patients attended core classes for ≈12 wk and then ongoing classes until they reached their weight goal or entered maintenance. These weekly 90-min classes reiterated these treatment components: weekly attendance and midweek phone calls; daily record keeping; ≥8.4 mJ (2000 kcal) physical activity/wk; ≥35 servings of meal replacements/wk; and, in the Healthy Solutions option, ≥35 servings of fruit and vegetables/wk (19). Weekly weights were measured by clinic staff.

When patients achieved their goal weight, or when their weight loss slowed, they entered the maintenance program (20). These weekly 60-min classes reiterated these components: daily record keeping; ≥14 meal replacements/wk; ≥35 servings of fruit and vegetables/wk; and ≥8.4 mJ physical activity/wk. Patients were encouraged to participate in the maintenance program for ≥6 mo, but many continued in that program for longer periods (21, 22).

Patient selection and chart reviews

Patients achieving weight losses of ≥100 pounds (45.5 kg) over 9 y were evaluated. Clinic charts included a detailed history, physical examination, medical progress notes, medication records, laboratory studies, and behavioral data. Most chart reviews were made immediately after patients had completed active treatment, so that questions about diagnoses, medications, behavioral data, laboratory studies, and side effects could reviewed with nurses, physicians, or educators. All patients were assigned a code number, and all data were recorded and analyzed without knowledge of patient identification. Baseline values represent those obtained at the initial evaluation before initiating weight loss.

Diagnoses were based on information from referring physician, our history and physical examination, and laboratory studies. Self-reported diagnoses of hypertension, diabetes, degenerative joint disease, sleep apnea, and gastroesophageal reflux disease (GERD) were accepted. Fasting blood work was obtained at baseline, and the following diagnostic criteria were used: diabetes, glucose values ≥7.0 mmol/L; impaired fasting glucose (IFG), 5.6–6.9 mmol/L (23); and dyslipidemia along with any of the following values: LDL cholesterol ≥ 2.6 mmol/L, triacylglycerols ≥ 1.7 mmol/L, and HDL cholesterol < 1.3 mmol/L (women) and < 1.1 mmol/L (men) (24). Hypertension was diagnosed with 2 values >139 or >89 mm Hg for systolic or diastolic blood pressure, respectively (25).

This study was approved by the Institutional Review Board at the University of Kentucky. Because the follow-up reported here was considered part of medical care, separate written informed consent to the follow-up was not considered necessary.

Laboratory measurements and medication records

Laboratory studies were performed by LabCorp (Louisville, KY). Laboratory measurements were obtained at baseline; at 2, 4, 6, 8, 10, and 12 wk; and then monthly. Liver function tests (LFTs) included serum aspartate aminotransferase (AST), alanine aminotransferase (ALT), bilirubin, alkaline phosphotase, and γ-glutamyltransferase (GGT). Information on the use of medication for dyslipidemia, hypertension, diabetes, degenerative joint disease, and GERD was extracted. Medication and dosage at baseline and at completion of weight loss were analyzed. The costs of medications were estimated by using *Red Book* (26). Before 2000, pilot studies with antiobesity medications were being conducted; doses and duration of phentermine or fenfluramine use were recorded.

Side effect assessment

Nurse and physician notes were reviewed to assess side effects. Side effects (adverse events) were classified, with the use of common terminology, as mild, moderate, severe, or serious (27). Hospitalization was considered as a serious adverse event. Side effect information was not available for patients using the Healthy Solutions option.

Follow-up weights

More than 95% of follow-up weights were measured in the clinic by clinic staff during patient visits, and only 22 weights at ≥2 y were self-reported. Weights were available for 81% of patients at ≥ 24 mo of follow-up.

Statistical analyses

All statistical analyses were done with the analyst blinded to patient identification. Changes from baseline values were evaluated by using Student's *t* test for paired samples, and differences between sexes were compared by using the *t* test for 2 samples. Reported *P* values were 2-sided, and $P < 0.05$ was considered to indicate significance. Mean responses between subgroups were compared among the 3 groups by using an analysis of variance (ANOVA) with post hoc comparisons of means based on the Tukey-Kramer multiple comparison procedure, which controls the type 1 error rate per endpoint at the 0.05 level of significance (SAS-PC software, version 8.2; SAS Institute Inc, Cary, NC).

RESULTS

Baseline characteristics

Over 9 y, 656 patients with severe obesity enrolled in the UK-HMR Program, and 118 patients (18%) lost ≥100 pounds (45.5 kg); each year of the study, from 9 to 27 patients (median: 14 patients) achieved this weight loss. Baseline characteristics are presented in **Table 1**; ages for men and women were not significantly different. Men had significantly ($P < 0.001$) higher initial weights than did women, but baseline BMI values did not differ significantly.

TABLE 1
Baseline characteristics of the subjects and their weight loss[1]

	Men (n = 63)	Women (n = 55)	All (n = 118)
Age (y)	43.9 ± 1.3	42.4 ± 1.6	43.3 ± 1.0
Initial weight (kg)	173.8 ± 4.3	143.9 ± 4.4[2]	159.9 ± 3.4
Initial BMI (kg/m^2)	53.9 ± 1.5	51.5 ± 1.7	52.7 ± 1.5
Weight loss (kg)	66.1 ± 2.8	55.2 ± 1.9[2]	61.0 ± 1.6
Weight loss (% of initial weight)	38.0 ± 0.9	38.4 ± 1.1	38.2 ± 0.7
Treatment to lowest weight (wk)	42.7 ± 1.8	45.6 ± 1.8	43.9 ± 1.3
Treatment to 45.5-kg loss (wk)	23.6 ± 1.0	31.2 ± 1.5[2]	26.7 ± 1.0

[1] All values are $\bar{x}$ ± SEM.
[2] Significantly different from men, $P < 0.01$.

Dyslipidemia, affecting 74.5% patients, was the most common comorbidity (**Table 2**), but hypertension was noted in 72.9%. Eighteen percent of patients had diabetes, and 28.0% had impaired fasting glucose values. Diagnoses of degenerative joint disease, obstructive sleep apnea, and GERD were found in 39.8%, 22.0%, and 19.5% of patients, respectively. Ninety-seven percent of patients had at least one of these diagnoses.

Weight losses

Men lost significantly ($P = 0.0033$) more weight and lost weight at a more rapid rate than did women (Table 1), but weight loss as a percentage of baseline weight did not differ significantly between the sexes (**Figure 1**). Men lost an average of 45.5 kg in 24 wk and an average total of 66 kg in 43 wk. Women lost an average of 45.5 kg in 31 wk ($P < 0.001$ for weeks versus men) and a total of 55 kg in 44 wk. Overall, 42% of patients achieved their maximum weight loss in the weight-loss phase and 58% achieved this weight in the maintenance phase.

Lifestyle behaviors

Since 1995, most patients in our program have been treated with LEDs (3.3–5 mJ/d), and patients have only occasionally been treated with selected VLEDs (<3.3 mJ/d) (8, 9). The Healthy Solutions option has been available since 2000, and some patients chose daily consumption of 3 shakes, 2 entrées, and 5 servings of fruit and vegetables. Whereas 18 patients initially selected VLEDs, only 2 continued this low-energy intake for 10 wk, and none continued it for 20 wk. Most patients (80%) elected to use "shakes only" to initiate the diet (**Table 3**). Shakes and entrées were selected by 17% and < 4% selected the Healthy Solutions option to initiate weight loss. As recommended by our strategy that "more is better," which encourages the consumption of additional shakes, entrées, or nutrition bars to curb hunger and avoid other foods, 32% of subjects used additional meal replacements during the first week. The use of shakes alone declined slowly over time, but, at 40 wk, more than one-half of these patients were using shakes as their predominant meal replacement. Overall, 64% of patients lost more than half their weight by using shakes only for meal replacement. Only 7% of patients lost half of their weight by using the Healthy Solutions option.

Estimated energy intake during the first week of diet averaged only 3.6 mJ/d. This intake increased slowly and steadily, reaching a peak of 5.9 mJ/d at 40 wk. We do not have estimates of energy intakes from food eaten other than that provided by the meal replacements, so the energy intake values underestimated total energy intake. Physical activity self-reported during the first week was 7.2 mJ/wk (representing walking ≈7 miles/wk), and it increased steadily to 13.2 mJ/wk (walking ≈21 miles/wk) by 40 wk. Patients estimated food intake and energy expenditure by using the HMR calorie system (19, 28).

Lipoprotein changes

Baseline and end-of-treatment lipoprotein values in all patients and in subgroups are presented in **Table 4**. Eighty-four patients (75%) had LDL-cholesterol values ≥ 2.6 mmol/L without pharmacotherapy (Table 4). Average serum lipoprotein changes for the entire group of patients were significant for cholesterol (−19.5%; $P < 0.001$), LDL cholesterol (−20.2%;

TABLE 2
Diagnoses, medication use, and medication cost[1]

Condition	Subjects	Subjects taking medication[2]	Medicine discontinued	Medication cost[3]	
				Initial	Final
	n	n	n	$/mo	
All patients	118	87	57	157	57
Dyslipidemia	88	11	11	105	0
Hypertension	86	62	42	80	44
Diabetes mellitus	21	15	11	213	44
Degenerative joint disease	47	47	40	60	13
GERD	23	18	10	107	56

[1] GERD, gastroesophageal reflux disease.
[2] Medication for dyslipidemia, hypertension, diabetes, degenerative joint disease, or GERD.
[3] Medication cost for patients initially taking medications.

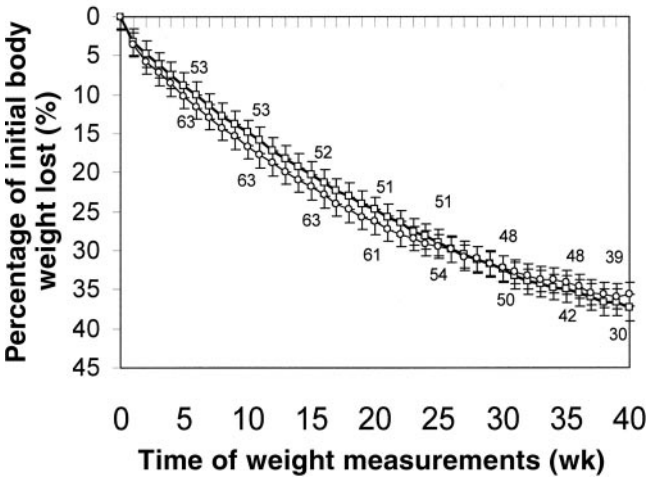

FIGURE 1. Mean (±SEM) weight loss as a percentage of initial body weight. The numbers of men (○) are indicated below the lines, and the numbers of women (□) are indicated above the lines. Weekly weight measurements were not available for 2 women.

$P < 0.001$), and triacylglycerols (−36.2%; $P < 0.001$) but not for HDL cholesterol (1.5%). Comparisons between subgroups for each outcome measure are provided in Table 4. Patients with abnormally high LDL-cholesterol values had significantly greater reductions in LDL than did other groups.

The response patterns for individual lipoproteins over time are described, but data are not shown. Average LDL-cholesterol values dropped promptly with weight loss to 23% below baseline at 4 wk and then increased to stable values ≈18% below baseline by 24 wk. Average HDL-cholesterol values rapidly decreased to 15% below baseline by ≈6 wk and then returned to baseline values by 40 wk. Women and men had similar HDL-cholesterol response patterns. Triacylglycerol values decreased progressively over time, reaching a nadir at ≈48 wk.

Fasting plasma glucose changes

Reductions in mean fasting plasma glucose values to below baseline were significant in all groups ($P < 0.001$) and were as follows: all patients, 17%; patients with normal baseline values, 9%; patients with IFG, 20%; patients with diabetes not on pharmacotherapy ($n = 8$, data not shown), 34%; and diabetes, 37% (Table 4). Statistical comparisons of changes between subgroups are indicated. Patients with IFG had a 14% decrease in glucose values at 2 wk and a further decrease to values 20% below baseline at 16 wk (data not shown).

Blood pressure changes

Systolic and diastolic blood pressures decreased significantly in all groups ($P < 0.001$, Table 4). Average decreases to 13% and 15% below baseline in systolic and diastolic blood pressures, respectively, were seen. Patients receiving pharmacotherapy had reductions to 12–14% below baseline in systolic and diastolic blood pressures, despite a reduction in dosage in all patients and the discontinuation of all antihypertensive therapy in 73% of patients initially treated. The largest blood pressure reductions were seen in patients with hypertension who received no pharmacotherapy.

Medication changes

At baseline, 87 patients (74%) were on pharmacotherapy for ≥1 comorbid condition (Table 2). Medication doses were reduced in all patients. Medications were discontinued for 66% of all patients, 100% of patients with dyslipidemia, 67% of patients with hypertension, 73% of patients with diabetes, 83% of patients with degenerative joint disease, and 56% of patients with GERD. The initial monthly cost of medications averaged $157 per patient; after weight loss, their monthly savings averaged $100.

Antiobesity medications are prescribed only occasionally (<5% of patients) at this clinic. Phentermine (18.75 mg/d) was prescribed for 4 patients at ≈13 wk because of excessive hunger and difficulty in following the diet. In addition, in 1996, 8 patients participated in a prospective clinical trial and received phentermine (18.75 mg/d) and fenfluramine (20 mg/d) after diet initiation for an average duration of 26 wk.

Side effects

Thirteen patients reported no side effects over 43 wk. Constipation was noted in 31% of patients, and it was managed with fiber supplements. Dizziness was seen in 32%, and it appeared to be related to medications, inadequate fluid intake, or long intervals between meal replacements. Dizziness was managed effectively without altering the intervention. Other side effects seen in ≥5% of patients were hair loss in 18%, nausea in 12%, abdominal pain in 9%, diarrhea in 9%, and headaches in 5%. One person experienced a severe side effect related to abdominal pain; this was managed symptomatically. One patient had a serious adverse event related to the treatment program and was hospitalized after 28 wk of weight loss for an elective cholecystectomy. Five other patients were hospitalized for the following reasons: cellulites, 1; ventral hernia repair, 2; ovarian cyst removal, 1; and parathyroidectomy for preexisting disease, 1.

TABLE 3
Self-reported values for product use, estimated energy intake, and physical activity[1]

Product use	Week 1	Week 10	Week 20	Week 30	Week 40
Shakes only (%)	79.5	70.9	63.7	56.4	53.3
Shakes + entrées (%)	17.1	25.6	29.2	32.1	33.3
Shakes, entrées, and fruit and vegetables (%)	3.4	3.5	7.1	11.5	13.4
Additional nutrition bars or soup (%)	31.6	57.3	69.9	71.8	76.7
Energy intake (mJ/d)[2]	3.6 ± 0.08[3]	4.5 ± 0.14	4.5 ± 0.15	5.1 ± 0.21	5.9 ± 0.45
Physical activity (mJ/wk)	7.2 ± 0.54	12.5 ± 0.56	13.8 ± 0.68	13.2 ± 0.61	13.2 ± 1.1

[1] $n = 117$.
[2] Intakes from shakes, entrées, nutrition bars, soup, fruit, and vegetables; does not include additional food consumed from outside those categories.
[3] $\bar{x}$ ± SEM (all such values).

TABLE 4
Serum lipid, plasma glucose, and blood pressure values at baseline and changes seen at completion of weight loss[1]

	All patients		Normal initial values			Abnormal values (no pharmacologic treatment)			Disease diagnosis (pharmacologic treatment)			
	Baseline	Change	Subjects	Baseline	Change	Subjects	Baseline	Change	Subjects	Baseline	Change	P^2
		%	*n*		%	*n*		%	*n*		%	
Total cholesterol (mmol/L)	5.38 ± 0.08[3]	−19.5 ± 1.3[4]	45	4.64 ± 0.06	−18.7 ± 2.2[a,4]	55	5.89 ± 0.08	−21.7 ± 1.5[a,4]	11	4.71 ± 0.30	−4.7 ± 6.6[b]	< 0.001
LDL cholesterol (mmol/L)	3.28 ± 0.07	−20.2 ± 1.9[4]	16	2.25 ± 0.07	−6.1 ± 4.8[a]	84	3.53 ± 0.07	−23.3 ± 1.8[b,4]	11	2.71 ± 0.22	−6.5 ± 8.7[a]	< 0.001
HDL cholesterol (mmol/L)	1.17 ± 0.03	1.5 ± 2.0	52	1.34 ± 0.04	−5.2 ± 3.2[a]	48	0.95 ± 0.03	8.1 ± 0.6[b,4]	11	1.05 ± 0.05	7.8 ± 4.0[b,c]	< 0.001
Triacylglycerols (mmol/L)	1.84 ± 0.08	−36.2 ± 2.6[4]	52	1.25 ± 0.04	−26.5 ± 3.4[a,4]	48	2.43 ± 0.11	−49.8 ± 9.4[b,4]	11	2.15 ± 0.36	−15.3 ± 13.6[a,b]	0.019
Glucose (mmol/L)	6.22 ± 0.23	−17.4 ± 1.7[4]	57	4.99 ± 0.05	−9.0 ± 1.5[a,4]	30	5.94 ± 0.05	−19.5 ± 1.4[b,4]	14	10.67 ± 1.01	−37.0 ± 7.8[b,c,4]	< 0.001
Systolic BP (mm Hg)	132.9 ± 1.5	−13.2 ± 1.1[4]	38	122.5 ± 1.3	−11.5 ± 1.5[a,4]	17	144.7 ± 2.8	−18.8 ± 2.5[a,4]	54	136.9 ± 2.3	−12.2 ±1.7[a,4]	0.061
Diastolic BP (mm Hg)	86.2 ± 1.0	−15.2 ± 1.3[4]	35	81.4 ± 0.8	−12.4 ± 1.9[a,4]	20	96.1 ± 1.5	−23.4 ± 2.5[b,4]	54	85.7 ± 1.5	−14.0 ± 1.9[a,4]	0.006

[1] BP, blood pressure. Disease diagnoses (dyslipidemia, diabetes, and hypertension) were made if values were outside the normal range: <5.2 mmol/L for total cholesterol; <2.6 mmol/L for LDL cholesterol; ≥1.1 and ≥1.3 mmol/L for HDL cholesterol in men and women, respectively; <1.7 mmol/L for triacylglycerols; <5.6 mmol/L for glucose (30 abnormal values represents impaired fasting glucose, 5.6–6.9 mmol/L); and <140 and <90 mm Hg for systolic and diastolic BP, respectively. Values in a row with different superscript letters differ significantly.
[2] ANOVA *F* test.
[3] $\bar{x}$ ± SEM (all such values).
[4] Significantly different from baseline, $P < 0.01$.

Alterations of LFTs were the most common laboratory abnormalities. At baseline, 15% had elevated AST or ALT values; 29% developed abnormalities during weight loss. For patients with normal LFTs throughout treatment, ALT values increased to 40% above baseline at 2 wk and returned to baseline by 24 wk. For patients with LFT abnormalities, ALT values increased to 89% above baseline at 6 wk and returned to baseline by 24 wk. Abnormalities in GGT, LDH, creatine kinase, and alkaline phosphatase were seen at baseline in <5% of patients; values improved with weight loss. Serum uric acid values were elevated in 7%; these values increased by 25% at 2 wk and then returned to 25% below baseline; no attacks of gout were observed. Persons with normal uric acid values had a transient increase of 10% at 2 wk, and values returned to <75% of baseline values. Chronic renal insufficiency was seen in 5%; serum creatinine values increased from 1.6 mg/dL at baseline to 1.7 mg/dL at 2 wk and then decreased to 1.2 mg/dL by 40 wk.

Follow-up weights

Patients regained almost half of the weight (25 kg) they lost over the first 30 mo, and then average weight gains stabilized and increased insignificantly (7 kg) over the next 30 mo (**Table 5**). Absolute weight losses were 61.0 kg (initial), 46.5 kg at 12 mo, 38.0 kg at 24 mo, 35.8 kg at 36 mo, 26.8 kg at 48 mo, and 29.4 kg at 60 mo. Thus, for the 31 available patients who had weights at the 5-y follow-up, the data indicated a maintained weight loss of 29.4 kg, which represented 46.5% of their initial weight loss and a weight-loss maintenance of 17.9% of initial body weight. Weights for 50 patients (73% of eligible patients) were available between 48 and 72 mo. With the use of these additional values to impute weight changes at 60 mo, the estimated amount of the weight loss from initial body weight that was maintained was 30.0 kg (18.6%), or 49.3% of the initial weight loss. Sixty patients (≈65% of those eligible) visited the clinic for retreatment or maintenance between 2.5 and 5 y after completing the weight-loss program.

DISCUSSION

Severe obesity is accompanied by many cardiovascular risk factors, including dyslipidemia (in 75% of our patients), hypertension (in 73%), type 2 diabetes mellitus (in 18%), impaired fasting glucose (in 28%), degenerative joint disease (in 40%), and sleep apnea (in 22%). Impressive improvements in all risk factors were seen. Despite discontinuation of all medications in 66% of patients, substantial improvements in lipoprotein, glucose, and blood pressure values occurred. Although it is difficult to estimate, maintenance of a high percentage of these risk factor

TABLE 5
Follow-up weights at 6–60 mo after initial weight loss (0 mo)[1]

		Weight loss		
Follow-up time	Eligible subjects[2]	No.[3]	Percentage IBW	Loss
	n		%	*kg*
0 mo	118	118	38.2 ± 0.7[4]	61.2 ± 1.6
6 mo	118	92	33.8 ± 1.0	53.8 ± 2.1
12 mo	118	77	29.6 ± 1.1	46.5 ± 2.2
18 mo	118	50	28.3 ± 1.6	43.9 ± 2.9
24 mo	118	53	24.0 ± 1.6	38.0 ± 3.0
30 mo	108	41	23.5 ± 1.6	36.2 ± 2.8
36 mo	104	42	22.5 ± 2.1	35.8 ± 4.0
42 mo	95	28	22.4 ± 2.6	34.9 ± 4.8
48 mo	79	29	18.5 ± 2.3	26.8 ± 3.4
54 mo	75	17	19.0 ± 3.5	32.9 ± 8.3
60 mo	68	31	17.9 ± 2.9	29.4 ± 5.7
60 mo[5]	68	50	18.6 ± 2.0	30.0 ± 3.9

[1] IBW, initial body weight.
[2] The subjects for whom at least the indicated number of months had passed after they completed their initial weight loss.
[3] The number of patients who had measurements at this time point.
[4] $\bar{x}$ ± SEM (all such values).
[5] Values were imputed by using the weights available between 48 and 72 mo.

reductions probably would reduce coronary heart disease risk by >50% (29).

Mild-to-moderate side effects were seen in 88% of patients over the treatment period, which averaged 44 wk. A loss of >20% of initial body weight during the first 20 wk would be expected to produce nonspecific symptoms of headache and fatigue; a reduction in fiber consumption usually produces gastrointestinal side effects. Only one person had a severe side effect (abdominal pain), which resolved. One serious adverse event, an elective cholecystectomy, was related to the diet, and 5 patients were hospitalized for unrelated problems. The frequency and severity of side effects were considerably lower than those reported earlier for VLEDs (9). The safety of these diets has allowed us to treat patients with severe problems—ie, elderly subjects with severe congestive heart failure, patients on hemodialysis or peritoneal dialysis, and candidates for heart, liver, or kidney transplant.

Long-term maintenance of weight loss has improved considerably over the past 15 y. In our first reports (8, 9), at 2 y, patients were maintaining ≈50% of their initial 17-kg weight loss. The patients in the current study were maintaining 62% of their initial 38-kg weight loss at 2 y. Our previous meta-analysis of long-term maintenance of weight loss indicated that all obese patients from 4 large VLED study groups were maintaining ≈29% of the weight loss (or 7 kg) at 5 y (30). The data from the current study suggest that, at 5 y, these severely obese patients are maintaining weight losses of ≈49% of the initial weight loss (≈30 kg).

A limitation of this study was the availability of long-term follow-up weights. We obtained clinic weights for >80% of patients at ≥ 2 y, but, at the 5-y follow-up, only 36% of patients weights that were measured between 2.5 and 5 y. Whereas 74% of patients had weights measured between 4 and 6 y, precise estimates of weights at 5 y were difficult, even when linear mixed models or orthogonal polynomial equations were used (22). For these reasons, we reported weights obtained at 6-mo anniversaries.

Long-term maintenance of weight loss remains a major challenge (30, 31). Greater initial weight losses are associated with greater maintenance of weight loss than are smaller initial weight losses (30–33). Procedures that enhance maintenance of weight loss are regular physical activity (30, 31, 34, 35), low fat intake (31, 34, 35), generous consumption of vegetables and fruit (31), regular use of meal replacements (34, 36, 37), self-monitoring (31, 34), and ongoing treatment or coaching (21, 33). Most of the patients reported here participated in active treatment and weekly behavioral education sessions for >18 mo during weight loss and initial maintenance activities. During this period, they were encouraged to obtain ≥8.4 mJ physical activity/wk, to consume >35 servings of vegetables and fruit/wk, and to consume 2 meal replacements/d. Most patients also returned for retreatment during the 5-y follow-up. Moreover, many continued to use shakes and entrées for indefinite periods of time. These lifestyle behaviors undoubtedly contributed to their success in weight maintenance.

In conclusion, an intensive, medically supervised, behavioral weight-management intervention using meal replacements effectively enabled certain severely obese persons to lose ≥45.5 kg and to maintain approximately one-half of that weight loss for 5 y. Follow-up weights were available for 81% of our patients at ≥2 y. At 2, 3, 4, and 5 y, patients were maintaining weight losses of 38, 36, 27, and 30 kg, respectively.

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