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PAPER

Analysis of weight loss outcomes using VLCD in black and white overweight and obese women with and without metabolic syndrome

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OBJECTIVE: To evaluate the efficacy of very low calorie diet (VLCD) in black and white obese women. Changes in weight, metabolic profile, and body composition are assessed.
METHOD: Patients are enrolled in a self-paid, university-based, outpatient weight loss program. All are prescribed VLCD (500–800 Cal/day), an exercise regimen, and group behavioral counseling. Black and white patients are matched for age, weight, body mass index, and by metabolic syndrome (MS) status.
RESULTS: A total of 304 black and white women (152 in each group) were included the analysis. Approximately 40% of patients had MS (white women: 39.5%; black women: 41.2%). Mean baseline weights were similar. After 12 weeks, weight reduction of 9.97% was seen in white women and 9.02% drop was seen in black women (both $P<0.0001$). However, the degree of weight change was not different between the groups ($P=0.244$). Marked improvements in fasting glucose, total cholesterol, LDL, triglyceride, and blood pressures (BP) were observed (all $P<0.01$); however, no difference between cohorts were seen. Patients with MS had higher baseline weight, BP, glucose and triglyceride levels when compared to patients without MS (all $P<0.01$). Significant reductions in % body fat were seen in white and black patients, independent of MS status.
CONCLUSION: Obese patients, independent of race, were able to achieve significant weight loss when enrolled in a structured outpatient program. Weight loss significantly correlated with all aspects of MS. Our results suggest that differences seen in past studies may be influenced by socioeconomic and behavioral factors rather than differences in physiological response to dieting.
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Keywords: VLCD; metabolic syndrome; weight loss

Background

Prevalence of obesity, as defined by the body mass index (BMI) $\geq 30\,kg/m^2$, has increased in the United States by 50% over the past 10 y.[1] It is a serious public health problem among all racial groups, particularly in women of minority ethnic backgrounds.[2,3] Effect of various diet regimens on weight loss and risk factors for atherosclerosis in different racial cohorts has, to date, been incompletely assessed.

Previous trials utilizing different weight loss modalities—including energy-deficit diets,[4,5] behavioral modification,[6] and bariatric surgery[7]—have demonstrated discordance in weight loss achieved between black and white populations. While cardiovascular risks disproportionately affect black populations, it remains unclear the degree to which behavioral, physiologic, and metabolic factors contribute to the racial differences in weight loss and post-treatment recidivism. Generally, black women lose less weight than their white counterparts, even after adjustment for age and BMI. Explanations for the disparity include possible differences in resting metabolic rate (RMR),[8–10] energy expenditure following dieting,[8] level of physical activity,[11] weight-related attitudes,[12,13] and socioeconomic factors.[14,15] However, this remains controversial, as other studies have demonstrated conflicting results,[16] particularly when taking into consideration effect of dietary sodium restriction.[17]

Metabolic syndrome (MS) is defined by specific criteria as established by the Adult Treatment Panel III of the National Cholesterol Education Program (Table 1).[18] Previous studies have revealed that individuals with the MS have significantly higher cardiovascular morbidity and mortality risks,[19] with central adiposity playing a major role linking the metabolic

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Table 1 Clinical criteria of the MS

Risk factor	*Defining level*
Abdominal obesity (waist circumference)	Men >102 cm (>40 in) Women >88 cm (>35 in)
TG	>150 mg/dl
HDL	Men <40 mg/dl Women <50 mg/dl
Fasting glucose	>110 mg/dl
Blood pressure (SBP/DBP)	>130/85 mmHg

TG: triglycerides; HDL: high-density lipoprotein cholesterol. Definition requires at least three of the five risk factors.

abnormalities.[19,20] It is thus crucial to identify these high-risk individuals and provide disease-modifying therapies, most notably weight reduction treatment.

The intent of this retrospective analysis is to examine if there are systematic differences in weight loss between white and black patients, when they are subjected to self-paid, outpatient very low calorie diet (VLCD) weight loss program. Every patient was evaluated with a physician weekly, given an exercise prescription, and participated in behavior counseling. This was aimed to alleviate the single approach modality and minimized socioeconomic and behavioral factors that may influence treatment outcome. Results can be used to better understand how to design treatment interventions for culturally diverse populations.

Methods

Subjects

This is a retrospective chart review of the subjects who participated in the weight loss program at the University Obesity Center between 1999 and 2001. The study was approved by the Institutional Review Board of University of California, Los Angeles. During the study period, over 732 subjects participated in the program. A total of 304 were selected who met the following inclusion and exclusion criteria. Inclusion criteria were an age of at least 18 y and less than 65 y, BMI of at least 25, and enrollment of at least 12 weeks. Exclusion criteria were participation in a dietary program or use of anorexic medication within 6 months prior to enrollment, prior history of bariatric surgery, or active use of weight loss medications. Stratified categorization, with blocking within strata, was used to ensure that both ethnic groups would contain subjects with matching age and BMI, with approximately equal numbers of severely obese subjects (BMI 40 kg/m^2 or higher) and subjects fulfilling criteria for the MS.

Study design and data collection

During the study, all study subjects were prescribed a VLCD and an exercise regimen, and participated in classes on behavioral modification. The 1-h group-teaching sessions were held each week for 12 weeks and were led by experts in nutritional counseling. Participants were given instructions on 30 min of aerobic exercise, combined with 15 min of light weight training three to five times per week. Dietitians and psychologists were available for consultation at each visit. The program also offered a series of weekly lectures and interactive meetings on diet, exercise, and behavioral modification. All participants were encouraged to attend these seminars held during clinic hours.

For the VLCD diet plan, a commercially prepared meal replacement powder was used to provide between 500 and 800 calories a day. Each formula packet provided 100 calories and 15 g of high biological value protein when mixed with water. Subjects were placed on either five packets per day, providing a total daily intake of 500 calories, or five packets combined with a defined meal of about 300 calories for a total of about 800 calories per day. Every participant was seen on a weekly basis by a physician to assess his/her success with the diet program, where his/her weight and vital signs were measured. The weight was measured using a single calibrated scale. Complete blood count, electrolytes, and liver function tests were also recorded at baseline and at 2-week intervals. Body composition using bioimpedance analysis (Biodynamics Corporation, Model BC300, v3.0) was assessed at baseline and repeated at week 12.

Statistical analysis

In this study, weight, BMI, blood pressure, serum lipid profile, and fasting glucose level were measured at baseline and after 12-week diet intervention. The changes from baseline (defined as week 12's value−baseline value) and % change (defined as 100 × (week 12's value−baseline value)/baseline value %) were also obtained.

Within each racial group, paired *t*-test was used to compare the changes of the study variables from baseline. For comparing the two racial groups, either the Mann–Whitney U test was used if data were not normally distributed or Student's *t*-test was used for continuous variables. χ^2 test was employed for categorical variables. McNemar's test was used to compare the MS status before and after the diet intervention.

Linear regression model was developed for investigating the relationship between the change in BMI and the change in the component of MS. The model is

$$Y_j = \alpha + \beta 1 Y_{0j} + \beta 2 X_j + \varepsilon_j, \quad j = 1, 2, \ldots, n$$

where Y_j is the change in factor Y for subject j, Y_{0j} is the baseline value of factor Y for subject j, X_j is the change in BMI for subject j, and $\beta 1$ and $\beta 2$ are the regression coefficients for Y_0 and X, respectively. ε_j is the error term $\varepsilon_j \sim N(0, \sigma^2)$.

All analyses were performed using SAS version 8.1 software (SAS Institute, Cary, NC, USA). All tests are two-sided and the significance level is 0.05.

Results

Study population

Patient population profile demonstrates no difference in baseline characteristics between black and white subjects

(152 in each group). Mean baseline weights for black and white subjects are 105.3 and 104.9 kg, respectively (Table 2). Baseline systolic and diastolic blood pressures, lipid profile, and fasting glucose level were also similar between the two cohorts (all $P>0.05$). Within each group, however, there were significant differences in baseline clinical and laboratory characteristics comparing subjects with or without MS, with the exception of triglyceride level in black women and LDL level in both black and white women. A total of 62 of the 152 black women (40.8%) met the criteria for having the MS, and 60 of white women had MS (39.5%).

Weight response in bi-ethnic cohorts following VLCD

Following treatment, total weight loss achieved in black and white subjects was similar at week 12 (Table 3). Mean weight loss in black women was 20.9 kg (9.1%) and 23.0 kg in white women (9.9%), with both statistically significant. While significant reductions in blood pressure, fasting glucose, and serum lipid levels were seen for both groups following intervention (all $P<0.05$), between-group analysis (using Whitney–Mann test) revealed a similar degree of change for all weight-related variables.

Changes in MS status

Prevalence of MS in black and white subjects is shown in Table 4, before and at week 12. In the black group, 121 patients had no change in their MS status, six changed from negative to positive, and 25 changed from positive to negative (McNemar's test $P=0.001$). In the white group, 119 patients had no change in their MS status, 10 changed from negative to positive, and 23 changed from positive to negative (McNemar's test $P=0.024$). However, the change in MS status between the two ethnic groups was not significantly different (χ^2 test $P=0.776$).

Weight response based on BMI stratification

We next evaluated whether initial BMI impacts magnitude of weight loss in the two groups by a similar degree. Between-group weight comparison following intervention as stratified

Table 2 Baseline characteristics for black and white patients

	Black			*White*			*Total*		
	MS(−)	*MS(+)*	P-*value*	*MS(−)*	*MS(+)*	P-*value*	*Black*	*White*	P-*value*
Age (y)	43.5±11	46.9±11	0.0735	43.1±11	47.8±10	**0.011**	44.9±11	44.9±11	0.988
No. of patients	90	62	—	92	60	—	152	152	—
Weight (kg)	96.1±24	118.4±33	<**0.0001**	95.0±22	120.2±29	<**0.0001**	105.3±21	104.9±28	0.907
BMI (kg/m^2)	35.3±8	44.5±11	<**0.0001**	34.9±7	44.6±10	<**0.0001**	39.1±10	38.7±10	0.742
GLC (mg/dl)	90 ±10	123±48	<**0.0001**	90.4±10	122.6±65	**0.0003**	103±35	103±44	0.857
SBP (mmHg)	120±16	135±14	<**0.0001**	119±14	135±15	<**0.0001**	126±19	125±16	0.652
DBP (mmHg)	77±9	84±10	<**0.0001**	77±8.0	86.5±9	<**0.0001**	80±10	81±9	0.431
TCHOL (mg/dl)	213±41	220±42	0.339	215±41	233±52	**0.026**	216±42.2	222±47	0.251
TRIG (mg/dl)	117±75	180±83	**0.004**	114±60	217±96	<**0.0001**	143±114	152±91	0.418
HDL (mg/dl)	60±13	50±15	<**0.0001**	62±13	51±11	<**0.0001**	56±15	58±13	0.513
LDL (mg/dl)	129±43	133±35	0.526	130±36	138±49	0.248	131±40	133±42	0.593

No difference in mean age, weight, BMI, or components of MS was noted. Within each racial group, however, significant disparity is associated with the presence of MS. MS(−): without MS; MS(+): with MS; BMI: body mass index; GLC: fasting glucose; SBP: systolic blood pressure; DBP: diastolic blood pressure; TCHOL: total cholesterol; TRIG: triglyceride; HDL: high-density lipoprotein cholesterol; LDL: low-density lipoprotein cholesterol. Bold values represent *P* values <0.05.

Table 3 Comparison of changes in weight and metabolic variables before and after VLCD

	Black women				*White women*				*Between-group difference: weeks 0–12*	
Parameters	*Baseline (mean+s.d.)*	*12 weeks (mean+s.d.)*	*% change*	P-*value*	*Baseline (mean+s.d.)*	*12 weeks (mean+s.d.)*	*% change*	P-*value*	*Mean*	*P-value*
Weight (kg)	105±21	95±28	−9.1	<**0.0001**	104±28	94±25	−9.9	<**0.0001**	2.06	0.1594
BMI (kg/m^2)	39.1±10.1	35.6±9.4	−9.1	<**0.0001**	38.7±10.0	34.9±9.2	−9.9	<**0.0001**	0.31	0.2934
GLC (mg/dl)	104±35	100±28	−5.5	<**0.0001**	103±44	98±30	−4.4	**0.0459**	1.42	0.8234
SBP (mmHg)	126±19	119±16	−5.9	<**0.0001**	126±16	118±16	−5.9	<**0.0001**	−0.11	0.9081
DBP (mmHg)	80±10	77±9	−5.2	<**0.0001**	81±9	77±8	−5.6	<**0.0001**	0.36	0.7744
TCHOL (mg/dl)	216±42	200±41	−7.3	<**0.0001**	222±47	203±47	−8.7	<**0.0001**	3.54	0.7266
TRIG (mg/dl)	143±137	127±125	−11.3	**0.0054**	154±91	131±81	−15.1	<**0.0001**	7.16	0.1904
HDL (mg/dl)	56±15	52±15	−7.1	<**0.0001**	58±13	53±13	−8.7	<**0.0001**	1.05	0.4518
LDL (mg/dl)	131±40	122±40	−6.6	**0.0006**	134±42	124±39	−7.3	**0.0003**	1.08	0.9065

Significant improvements in weight and BMI are seen for both black and white subjects. Improvement in SBP, DBP, and total cholesterol is noted in black subjects, while improvements in SBP, DBP, total cholesterol, triglycerides, and low-density lipoprotein are seen in white subjects. Bold values represent *P* values <0.05.

Table 4 Change in MS status following intervention

Black women				*White women*			
(−)MS at baseline		*(+)MS at baseline*		*(−)MS at baseline*		*(+)MS at baseline*	
89 (total)		63 (total)		92 (total)		60 (total)	
(−)MS at week 12	(+)MS at week 12	(−)MS at week 12	(+)MS at week 12	(−)MS at week 12	(+)MS at week 12	(−)MS at week 12	(+)MS at week 12
83	6	25	38	82	10	23	37
McNemar's test (Δ in MS status) $P=0.001$				McNemar's test (Δ in MS status) $P=0.024$			

A significant number of women in both groups who has initial diagnosis of MS no longer meet the criteria for the syndrome after intervention (McNemar's test). However, the change in MS status between the two ethnic groups was not significantly different.

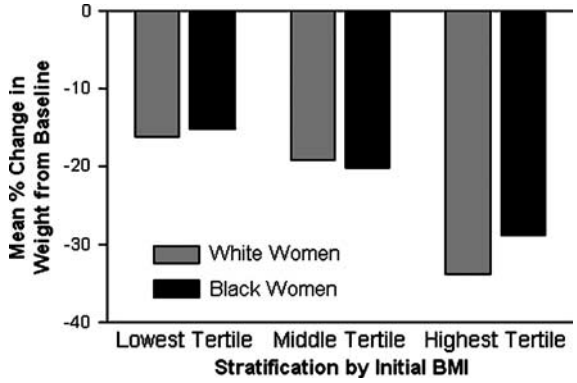

Figure 1 Stratification of patients based on initial BMI. Success with weight loss was similar when comparison was made between black and white women across all tiered subgroups.

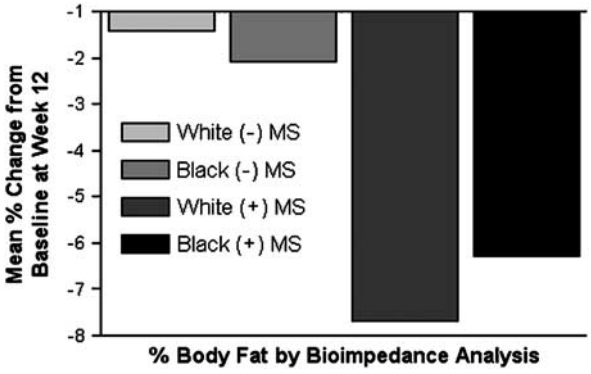

Figure 2 Changes in body fat (% fat) in black and white women before and following weight loss. Comparison between the two ethnic cohorts demonstrated no difference in reduction of % fat within subgroups defined by MS status. Significant difference was noted between (−)MS and (+)MS patients for both black and white women.

by initial BMI is shown in Figure 1. As expected, patients in the lowest BMI tertile lost less weight than patients in the highest tertile. However, comparison of the two groups demonstrated that race does not significantly impact degree of weight loss achieved through VLCD, independent of the initial BMI.

Change in body composition following weight loss

Baseline % body fat values for black and white women are 44.2 ± 4.8 and $47.3+5.5\%$, respectively ($P>0.05$). No significant difference in reduction of % body fat following weight loss was seen between black and white women (Figure 2). However, within each cohort, when subjects with MS are compared to those without, the drop in % body fat is significantly more marked in the (+MS) subgroup, likely a reflection of greater weight loss achieved in this subgroup.

Correlation between weight and MS

Linear regression model was developed to study the correlation of change in BMI with the changes in the components of the MS. There was no significant correlation between race and the changes in BMI with components of the MS; therefore, race was not included in the model. However, the changes in the components of the MS were significantly correlated with their baseline values; thus, the baseline measurement was included in the model. Relationship between baseline BMI and baseline metabolic parameters is shown in Table 5.

Following weight loss, significant relationship was seen between change in BMI and lowering of glucose, systolic and diastolic blood pressure, total cholesterol, LDL, and triglyceride levels (all $P<0.05$; Table 6). Positive correlation was also seen for change in HDL with weight loss in white women ($P<0.0001$) but failed to reach statistical significance in black women ($P=0.0785$). The estimated regression coefficients of change in BMI for each component of the MS are listed in Table 7.

Discussion

Our study demonstrated that comprehensive outpatient program utilizing VLCD could effectively induce weight loss in black and white women with similar success. The two ethnic cohorts in the study were matched for age, BMI, and status of the MS prior to intervention. Following strict VLCD using liquid meal replacements for 12 weeks, black and white women achieved significant weight loss of 9.1 and 9.9%, respectively. When subjects were stratified based on their initial BMI, success with weight loss was also similar between

races in all tiered subgroups. Moreover, the number of patients with MS in each group were also reduced by the end of intervention (Table 4, +MS white women: 60→37, +MS black women: 63→38). When specific weight-related risk factors were analyzed, similar improvements in systolic and diastolic blood pressures, total cholesterol, and triglycerides were also seen in both white and black subjects. Although some previous weight loss studies have demonstrated conflicting results,[4–6,17,21–23] we have shown here that similar efficacy can be achieved through an outpatient regimen combining aggressive dietary intervention with exercise and behavioral counseling.

When patients were tiered based on initial BMI, no difference in the prevalence of MS between black and white women was seen. A significant gradation in severity of all components of the MS, however, was observed with increasing weight (Table 2). After intervention, patients with highest initial BMI lost most weight, with concomitant greatest improvements of MS components. Significant relationship was seen between drop in BMI with lowering of glucose, systolic and diastolic blood pressure, total cholesterol, LDL, and triglyceride levels for both ethnic groups (Table 6). The degree of correlation is particularly impressive in patients with the MS, as evident by number of women who no longer met the defined criteria for the syndrome after treatment. It strongly suggests an association between clustering of the MS components with adiposity and the importance of weight loss in management of abnormalities associated with the MS. This is consistent with previous findings.[18,24] We also demonstrate in the study that this metabolic response is independent of one's ethnic make-up.

Behavioral differences between black and white women have been well documented in previous studies.[12,13,25–27] Difficulty with weight loss in black communities may stem from divergence in behavioral patterns that highlight cultural differences. It is well established that patients who sustain a long-term exercise regimen are more likely to achieve success with weight maintenance, regardless of race. Past studies showed that black subjects are less likely to achieve physical activity goals as compared to their white counterparts,[6,28] particularly when encouragement to exercise is not strictly enforced. In our study, we attempt to minimize this disparity by prescribing an exercise regimen to all patients that incorporated both cardiovascular and weight resistance training. The patients' ability to achieve exercise goals was monitored weekly. Overall, both patient groups report good compliance as well as improvement in the level of physical activity following weight loss.

Another important factor that has been shown to influence treatment outcome is socioeconomic status (SES). Comparison of patients from different SES may confound results because of its effect on behavioral pattern, self-perception, and access to care. The risk for obesity is highest in black women of low SES.[25,29] This pattern was also seen in white women, but to a much lesser degree. Possible

Table 5 Relationships (Spearman's correlation coefficient) of BMI with components of the MS in black and white women; correlation is based on initial values

	Black (BMI)		*White (BMI)*	
	Spearman r	P-*value*	*Spearman* r	P-*value*
Glucose	0.338	<**0.0001**	0.346	<**0.0001**
SBP	0.487	<**0.0001**	0.502	<**0.0001**
DBP	0.375	<**0.0001**	0.522	<**0.0001**
Cholesterol	−0.077	0.3457	0.069	0.3961
Triglyceride	0.158	**0.0409**	0.406	<**0.0001**
HDL	−0.215	**0.0078**	−0.206	**0.011**
LDL	−0.009	0.9127	0.002	0.977

Bold values represent *P* values <0.05.

Table 7 Estimated regression coefficients of change in BMI for each component of the MS

Components of MS	*Regression coefficient for change in BMI (estimate±s.e.)*	P-*value*
Δ Glucose	1.67±0.46	<**0.001**
Δ SBP	0.91±0.31	**0.003**
Δ DBP	0.14±0.18	0.446
Δ Total cholesterol	4.54±0.71	<**0.0001**
Δ Triglyceride	5.32±1.35	**0.0001**
Δ HDL	1.20±0.23	<**0.0001**
Δ LDL	2.36±0.62	<**0.001**

Bold values represent *P* values <0.05.

Table 6 Relationship (Spearman's correlation coefficient) of change in BMI with the change in components of the MS in black and white women

	Black (Δ BMI)		*White (Δ BMI)*		*Total (Δ BMI)*	
Components of MS	*Spearman* r	P-*value*	*Spearman* r	P-*value*	*Spearman* r	P-*value*
Δ Glucose	0.188	**0.0203**	0.219	**0.0068**	0.20	**0.0004**
Δ SBP	0.335	<**0.0001**	0.261	**0.0012**	0.29	<**0.0001**
Δ DBP	0.345	<**0.0001**	0.131	0.1091	0.23	<**0.0001**
Δ Cholesterol	0.387	<**0.0001**	0.402	<**0.0001**	0.39	<**0.0001**
Δ Triglyceride	0.326	<**0.0001**	0.331	<**0.0001**	0.32	<**0.0001**
Δ HDL	0.143	0.0785	0.362	<**0.0001**	0.27	<**0.0001**
Δ LDL	0.289	**0.0003**	0.189	**0.0201**	0.23	<**0.0001**

Bold values represent *P* values <0.05.

mechanisms by which SES may influence weight loss may be due to disparity in education and knowledge regarding nutrition as well as a diminished focus on the influence of diet on general health among people of low SES. Epidemiological studies have also shown that low-SES communities are often surrounded by more fast food restaurants and liquor stores than communities of moderate or high SES,[30] often making attainment of a healthy diet more difficult. In our study, we attempt to minimize the impact of this potential confounder. Patients were screened based on initial questionnaires. In addition, patients from both ethnic cohorts were selected from women who were self-motivated to start the program voluntarily and had the financial means to participate in this private fee-for-service weight loss regimen for at least 12 weeks.

Ethnic differences in physiological response to weight loss must be considered. In our study, effects of weight loss on glucose metabolism and lipid profile are similar in black and white women. While significant reductions in blood pressure and serum lipid were observed following weight loss, the beneficial effects did not differ with race. Gower *et al*[22] reported similar findings in a study involving 37 premenopausal women undergoing weight loss. As in our study, black and white patients did not differ significantly with respect to age or baseline BMI. While Gower *et al* reported a lower baseline triglyceride level for black women, a trend toward a lower level was seen for black women in our study but failed to reach statistical significance.

Ethnic differences in treatment success reported in previous studies may also be related to characteristics of the weight loss program involved. While biological and cultural factors are important, type of treatment employed—including diet used, type of exercise regimen, content of follow-up regimen, as well as availability of patient services—may all contribute to a program's success. In our study, VLCD using meal replacements was used to eliminate confounding cultural differences in dietary pattern. Success with VLCD using meal replacement has been observed for more than 20 y, often resulting in weight loss of 1.5–2.5 kg/week.[31,32] Our high rate of compliance observed is likely attributed to limited contact with ordinary food and ease of preparations through use of meal replacements.[33] Our study only included female patients since some studies have reported gender disparity in response to VLCD.[32,34] We also incorporated a strict exercise regimen for all patients to ensure that minimal physical activity level is achieved.

Our study has several strengths and limitations. The analysis was intentionally based on examination of patients who formed the two ethnic cohorts with similar starting weight and cultural habits and predispositions. Intervention using meal replacement helped to minimize risk of dietary incompliance, while strict exercise prescription aimed to ameliorate ethnic difference in the level of physical activity. Counseling as well as implementation of support groups allowed for behavioral education and crosscultural exchange of ideas and social perceptions. Since the program is based on fee-for-service enrollment, majority of patients have strong health motivations and are from similar socioeconomic backgrounds. Patients were highly compliant, which is likely related to weekly follow-up assessments. This allowed for the unique opportunity to counsel and implement changes based on each patient's individualized needs. While lack of SES diversity in our study helped to attenuate its confounding effect, it is as a potential drawback. Our study participants, particularly black women, may not be representative of the black population in the general community. This study did not address the issue of weight maintenance using our comprehensive treatment paradigm. Long-term treatment success and resolution of metabolic derangements comparing the bi-ethnic cohorts need to be further assessed.

Conclusion

The increasing prevalence of obesity and associated MS presents serious implications for provision of health care in the United States. With cardiovascular risks disproportionately affecting black populations, it is important to develop a program that will effectively treat obesity in this community. The study showed that black and white women do respond in the same way physiologically to weight loss intervention using VLCD. Significant and similar weight loss was observed despite potential cultural, behavioral, and socioeconomic differences. With the increasing prevalence of MS in both white and black communities, we emphasize the importance of a comprehensive program utilizing aggressive dietary intervention, close patient follow-up, exercise prescription, and behavioral counseling.

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