Effect of a Culturally Sensitive Cholesterol Lowering Diet Program on Lipid and Lipoproteins, Body Weight, Nutrient Intakes, and Quality of Life in Patients with Systemic Lupus Erythematosus

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ABSTRACT. ***Objective.*** To evaluate the effect of a culturally sensitive cholesterol lowering diet program on lipid and lipoproteins, body weight, nutrient intakes, and quality of life (QOL) in patients with systemic lupus erythematosus (SLE).

Method. Seventeen patients with SLE were randomized to a Step 2 diet intervention group or a control group for 12 weeks. The diet intervention was made up of weekly group sessions during the first 6 weeks followed by telephone counseling every 2 weeks for the last 6 weeks. Data on fasting lipid and lipoproteins, body weight, food intake (3 day food record), and QOL were collected at baseline, 6 weeks, and 12 weeks. Program acceptability was assessed in the diet group at 6 weeks.

Results. The intervention was found to be highly acceptable and culturally sensitive. The changes in nutrient intakes at 6 and 12 weeks in the diet group were –49% and –33%, respectively, for cholesterol, –44% and –32%, respectively, for percentage calories from fat, and –46% and –32%, respectively, for percentage calories from saturated fat. The corresponding figures in the control group were +22% and –8% for cholesterol, +9% and +6% for percentage calories from fat, and +5% and +7% for percentage calories from saturated fat. The treatment by time interaction was significant for all the dietary variables ($p = 0.0003$ to 0.02). QOL was reported to improve by 15–17% in the diet group and decrease by 4–6% in the control group, and the treatment by time interaction was significant ($p = 0.05$). The changes in the physiological variables at 6 and 12 weeks in the diet group were –10% and –6%, respectively, for total cholesterol, –10% and –2%, respectively, for low density lipoprotein (LDL) cholesterol, –11% and –4%, respectively, for high density lipoprotein (HDL) cholesterol, –25% and –34%, respectively, for very low density lipoprotein (VLDL) cholesterol, –8% and –24%, respectively, for triglycerides, and –2% and –5%, respectively, for body weight. The corresponding figures in the control group were –5% and –3% for total cholesterol, –6% and –5% for LDL cholesterol, 0% and +12% for HDL cholesterol, +4% and –8% for VLDL cholesterol, –6% and –15% for triglycerides, and –5% and –6% for body weight. The treatment by time interaction was significant for HDL cholesterol ($p = 0.04$). A significant reduction was seen in the diet group for total cholesterol at 6 and 12 weeks, LDL and HDL cholesterol at 6 weeks, and body weight at 12 weeks ($p = 0.0002$ to 0.01).

Conclusion. This culturally sensitive cholesterol reducing diet program was highly accepted and effective in changing the diet and QOL of patients with SLE. The effect on serum lipids, lipoproteins, and body weight, however, was modest. A larger randomized study with a longer intervention period is necessary to test the effectiveness of a cholesterol-lowering diet on lipids and lipoproteins in patients with SLE. (J Rheumatol 2002;29:2122–8)

Key Indexing Terms:
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Patients with systemic lupus erythematosus (SLE) have a high prevalence of atherosclerotic cardiovascular disease (CVD)[1-5]. The mortality rate attributed to atherosclerosis is 9 times greater among patients with SLE than among age and sex matched controls in the general population[2].

Fifty-three percent of patients with SLE have 3 or more of the CVD risk factors[6], particularly high blood pressure, obesity, and dyslipidemia[3,7-9]. Characteristics of dyslipidemia include high total cholesterol (TC), low density lipoprotein (LDL) cholesterol and triglyceride (TG), and low high density lipoprotein (HDL) cholesterol. Patients with SLE have higher TC, LDL, and TG than healthy controls[7]. Factors associated with high LDL include a diet high in fat, saturated fat, and cholesterol, low level of physical activity, and obesity[10,11].

There is some evidence that patients with SLE consume more fatty meats (higher in fat and saturated fat) than age and sex matched controls[12]. Whether a cholesterol-lowering diet in patients with SLE leads to attenuation of dyslipidemia has been examined by only one study[13]. This study, however, was not randomized, had limited counseling, did not have a behavioral maintenance program, and did not appear to be specific to the ethnic background of the patients, even though the majority of the patients were African-American. Potential confounders such as prednisone intake and physical activity were also not accounted for in the analysis.

We addressed these issues by designing a cholesterol lowering diet intervention program that was culturally sensitive, that is, the diets recommended were ethnically-specific and were reviewed by focus groups composed of the appropriate minorities. The program was also counseling-intensive, contained a behavioral maintenance component, and controlled for potential confounders. Our initial pilot study found this program to be highly acceptable and feasible and appeared to have the capacity to alter dietary behavior[14]. A randomized study was conducted to examine the influence of the program in patients with SLE. This report presents results from the randomized study to determine the effect of a comprehensive cholesterol-lowering diet intervention program on lipid and lipoproteins, body weight, nutrient intakes, and quality of life (QOL) in patients with SLE.

MATERIALS AND METHODS

Patients. Seventeen women with SLE were recruited from Parkland Health and Hospital System outpatient arthritis clinic and randomized to a diet intervention group or a control group. To be eligible for the study, the patients had to be diagnosed with SLE for at least 6 months, have an LDL cholesterol level ≥ 100 mg/dl, and be able to read at least at the 5th grade level[15]. Patients were not eligible for the study if they were pregnant (assessed by blood test), lactating, taking ≥ 20 mg of prednisone per day, actively abusing alcohol (20 or more alcoholic drinks per week by self-report), or had inadequate cognitive ability[16]. The study was approved by the University of Texas Southwestern Medical Center Institutional Review Board.

Diet intervention. The patients in the diet intervention group were counseled to follow the National Cholesterol Education Program Step 2 diet[11]: 30% or less calories from fat (7% from saturated fat, 13% from monounsaturated fat, and 10% from polyunsaturated fat), and < 200 mg of cholesterol per day.

The diet intervention lasted 12 weeks. It was made up of weekly group counseling sessions (2 to 3 hours each) during the first 6 weeks followed by telephone counseling sessions every 2 weeks for the next 6 weeks. The patients were counseled by one of the authors (a nutritionist) and a bilingual research assistant.

All the materials used in the study and the cognitive-behavioral strategies employed to help maintain the dietary changes have been described[14]. The culturally-specific materials included menus, videos, and brochures. A set of 6 1400 kcal menus and 6 1800 kcal menus each were developed by one of the authors for African-Americans and Hispanic-Americans using ethnic-specific recipe books. Two of the 24 menus were published previously[14]. The videos, developed by the American Heart Association (AHA), pictured a Mexican and an African-American family undergoing education on food shopping and food preparation. The brochures, also developed by the AHA, were designed for Hispanic and African-American families. The menus are available from the authors and the other materials are available from the AHA.

The control group was not given any dietary advice. Patients in both the intervention and the control groups were asked to maintain their usual level of physical activity.

Data collection. Food intake (assessed by 3 day food record), lipid and lipoproteins (after overnight fast), body weight, physical activity (assessed by 7 day activity recall), QOL, and SLE disease activity were assessed at baseline and at 6 and 12 weeks. Reading ability and cognitive status were assessed at the initial eligibility screening visit.

Patient subjective response to counseling, assessed in the diet intervention group only, was collected at 6 weeks. The data were collected using a self-administered questionnaire that employed a Likert scale: 1: "no," 2: "somewhat," 3: "very or "quite a bit," and 4: "extremely"[14].

All the above measures except for QOL and SLE disease activity are described in detail in a report describing the development of the intervention program[14]. QOL was assessed using a self-administered questionnaire containing a 100 mm visual analog scale with opposite evaluative labels at each end. The questionnaire assessed general energy level and ability to perform certain tasks, quality of sleep, frequency of aches, satisfaction with food eaten, food cravings, interest in daily life, feeling of cheerfulness, satisfaction with personal life, and relations with others. The questionnaire has good internal consistency and reliability[17]. The result is presented as a sum of scores divided by the number of questions so that the final figure is in relation to a maximum score of 100. An increased score reflects improved QOL.

SLE disease activity was assessed using the Systemic Lupus Activity Measure (SLAM), a valid and reliable tool[18]. The tool was administered by a senior Fellow trained by one of the authors, a rheumatologist. The tool assesses both disease activity and disease severity and both dimensions are incorporated in the scales. The result was expressed as a composite score. The composite score was calculated by adding all the graded responses for each question. An increased composite score reflects increased disease activity.

Statistical analyses. Data analyses were conducted on 8 diet patients and 8 control patients including a control patient who missed the week 12 data collection visit. One of the 17 patients recruited was excluded from the analyses because she missed both the followup visits. This decision was based on the exception to the general rule of "include withdrawals when possible": a patient should only truly be considered as "in" the clinical trial itself when the first step of therapy is initiated[19,20]. Analyses were conducted using the SAS statistical package, version 8.0.

Group differences at baseline were assessed by t test (continuous variables) or chi-square (categorical variables). Repeated measures analysis of variance was used to examine the treatment by time interaction effect on TC, LDL, HDL, VLDL, TC:HDL ratio, TG, body weight, nutrient intakes [percentage total calories from fat, saturated fat (SFA), monounsaturated fat (MUFA) and polyunsaturated (PUFA), and cholesterol], and QOL. Physical activity and prednisone and cholesterol drug doses were not included as covariates because they did not change over time in either group. Repeated measures analysis of variance was also used to assess the change in lipid and lipoprotein profile over time within each treatment group.

RESULTS

Baseline characteristics. The baseline characteristics (Table 1) were similar in the 2 groups. Average age was mid-forties in both groups. African-Americans made up about 60% of the sample in both groups and the rest were mostly Hispanics. Most women had only a high school or lower level of education. The average SLE duration was 13.7 years in the diet group and 9.2 years in the control group. Disease activity was similar in the 2 groups. Prednisone intake was slightly higher in the control group. Four patients in the diet group and 5 patients in the control group were taking cholesterol-lowering drugs. No patient took any weight loss drugs, either by prescription or over-the-counter.

Lipid, lipoproteins, and body weight. The lipid, lipoprotein, and body weight values did not differ significantly at baseline in the 2 groups (Table 2). The diet group showed a greater reduction than the control group in TC, VLDL, and TG at both 6 and 12 weeks and HDL and LDL at 6 weeks (Table 2). At 12 weeks, HDL decreased in the diet group and increased in the control group, and LDL decreased more in the control group than in the diet group compared to the respective baseline values. The TC:HDL ratio increased at 6 weeks and decreased at 12 weeks in the diet group and decreased at both 6 and 12 weeks in the control group compared to the respective baseline values. The treatment by time interaction effect (Table 2), however, was significant only for HDL ($p = 0.04$).

Repeated measures analysis of variance within the diet group (Table 3), however, showed a significant reduction in TC at 6 and 12 weeks, LDL at 6 weeks, and body weight at 12 weeks compared to the respective baseline value ($p = 0.01$ to 0.0002). These significant changes were also reflected in the confidence intervals. A similar analysis in the control group (Table 4) showed no significant change in any of the variables.

Nutrient intakes. At baseline (Table 5), there was no significant difference in any of the dietary variables except percentage calories from PUFA, which was significantly higher ($p = 0.04$) in the diet group than in the control group. At both 6 and 12 weeks, the diet group reported a greater change than the control group in percentage calories from total fat, SFA, MUFA, and PUFA, and dietary cholesterol (Table 5). The treatment by time interaction effect was significant for all the dietary variables ($p = 0.0003$ to 0.03).

QOL. QOL was not significantly different at baseline between the 2 groups. At followup, the diet group reported an increase of 15–17% in QOL (mean ± SD, baseline: 59.4 ± 7.8; 6 weeks: 69.5 ± 5.1; 12 weeks: 68.4 ± 7.8), whereas the control group reported a decrease of 4–6% in this measure (baseline: 56.3 ± 15.1; 6 weeks: 53.2 ± 14.1; 12 weeks: 53.8 ± 18.2). The treatment by time interaction effect was significant ($p = 0.05$). Repeated measures analysis of variance within the diet group showed a significant increase in QOL at both 6 and 12 weeks compared to the baseline value ($p = 0.03$ to 0.01). A similar analysis in the control group showed no significant reduction in QOL at either timepoint.

Diet counseling. The patients reported the counselors to be supportive (3.9 ± 0.4), the materials to be helpful in enhancing their understanding of their diet goals (3.7 ± 0.4), the menus and recipe books to be culturally sensitive (3.4 ± 0.5), the menus, recipe books and the food provided during the counseling sessions to be useful in planning their diet (3.0 ± 0.4), and the behavior maintenance sessions to be helpful in maintaining their diet (3.4 ± 0.3).

Table 1. Baseline characteristics of the diet group and the control group.

Variable	Diet Group, n = 8	Control Group, n = 8
Age, yrs	44.1 ± 9.3*	45.3 ± 11.7
Sex	8 women	8 women
Ethnicity, n		
African-American	5	5
Hispanic	3	2
Caucasian	0	1
Education, n		
High school or less	5	6
Some college	3	2
SLE duration, yrs	13.7 ± 9.2	9.2 ± 9.3
Median	12.2	6.2
SLE disease activity**	8.9 ± 2.2	10.5 ± 4.9
Median	8.0	10.5
Prednisone, mg	3.8 ± 4.4	6.6 ± 7.9
Median	2.5	3.8
Cholesterol-lowering drugs, n	4	5

* Mean ± SD. ** Disease activity was assessed in 7 patients in the control group and 7 patients in the diet group.

DISCUSSION

This study was conducted to assess the efficacy of a cholesterol-lowering diet in patients with SLE. The intervention was counseling-intensive, included a behavioral maintenance component, and was culturally sensitive. Whether a culturally sensitive intervention is more effective than a "regular" intervention has not been studied, but we decided to recommend culturally-specific diets in our study since SLE occurs at higher frequency in minorities[21-24] and since the majority of patients with SLE at Parkland Health and Hospital System, where we recruited our subjects, belong to racial minorities.

All aspects of the diet intervention were found to be highly acceptable by the diet group and were reflected in their dietary modifications. According to the food records at 6 weeks, the patients in the diet group surpassed the diet goals for cholesterol intake (119 vs 200 mg/day), and percentage calories from fat (21.4 vs 30%) and SFA (6.3 vs 7%). At 12 weeks, the reported dietary modifications had regressed somewhat, but cholesterol intake and percentage

Table 2. Lipid and lipoproteins and body weight at baseline, 6 weeks, and 12 weeks. Values are mean ± SD.

Variable	Diet Group, n = 8	Control Group* n = 8	p**
TC, mg/dl (mmol/l)			
Baseline	222.4 ± 24.3 (5.8 ± 0.6)	199.3 ± 49.4 (5.2 ± 1.3)	0.40
6 wks	200.6 ± 20.7 (5.2 ± 0.5)	190.0 ± 28.3 (4.9 ± 0.7)	
12 wks	210.1 ± 25.4 (5.4 ± 0.7)	194.3 ± 24.1 (5.0 ± 0.6)	
LDL, mg/dl (mmol/l)			
Baseline	136.4 ± 23.7 (3.5 ± 0.6)	125.3 ± 36.9 (3.2 ± 1.0)	0.80
6 wks	123.5 ± 20.9 (3.2 ± 0.5)	117.8 ± 24.7 (3.0 ± 0.6)	
12 wks	134.4 ± 20.6 (3.5 ± 0.5)	119.1 ± 26.8 (3.1 ± 0.7	
HDL, mg/dl (mmol/l)			
Baseline	55.6 ± 17.4 (1.4 ± 0.4)	44.0 ± 10.8 (1.1 ± 0.3)	0.04
6 wks	49.4 ± 16.5 (1.3 ± 0.4)	43.9 ± 8.0 (1.1 ± 0.2)	
12 wks	53.3 ± 15.9 (1.4 ± 0.4)	49.4 ± 11.6 (1.3 ± 0.3)	
VLDL, mg/dl (mmol/l)			
Baseline	22.3 ± 16.5 (0.6 ± 0.4)	17.5 ± 7.1 (0.5 ± 0.2)	0.50
6 wks	16.8 ± 14.1 (0.4 ± 0.4)	18.2 ± 11.6 (0.5 ± 0.3)	
12 wks	14.8 ± 7.1 (0.4 ± 0.2)	16.1 ± 9.7 (0.4 ± 0.3)	
TG, mg/dl (mmol/l)			
Baseline	151.6 ± 85.2 (1.7 ± 0.9)	150.8 ± 62.2 (1.7 ± 0.7)	0.80
6 wks	139.0 ± 72.5 (1.6 ± 0.8)	141.5 ± 66.5 (1.6 ± 0.8)	
12 wks	114.6 ± 30.2 (1.3 ± 0.3)	128.0 ± 43.8 (1.5 ± 0.5)	
TC:HDL ratio			
Baseline	4.3 ± 1.2	4.7 ± 1.6	0.40
6 wks	4.4 ± 1.2	4.5 ± 1.1	
12 wks	4.2 ± 0.9	4.2 ± 1.4	
Body weight, lb (kg)			
Baseline	174.7 ± 18.5 (79.4 ± 8.4)	189.7 ± 53.9 (86.2 ± 24.5)	0.50
6 wks	170.6 ± 16.2 (77.6 ± 7.4)	180.3 ± 43.6 (81.9 ± 19.8)	
12 wks	166.6 ± 16.3 (75.7 ± 7.4)	179.2 ± 44.6 (81.5 ± 20.3)	

* One subject in the control group is missing all the lipid and lipoprotein values at week 12 and body weight value at weeks 6 and 12. ** p value reflects overall treatment by time interaction effect assessed by repeated measures analysis of variance.

total calories from fat were still well below the goal (155 vs 200 mg/day and 26.1 vs 30%, respectively) and percentage calories from SFA was only slightly above the diet goal (7.9 vs 7%). These results correspond to those of another study[25], in which 178 hypercholesterolemic women placed on the Step 2 diet for 6 months reported 25% calories from fat and 7.5% from SFA at the end of the intervention period. In our study the reported intakes for the control group were above the diet goals throughout the study.

Dietary modification in the diet group was accompanied by a significant and sustained improvement in QOL in this group (15–17%), whereas the control group reported deterioration in this measure throughout the study (4–6%). The improvement seen in the diet group was more than twice that observed by Shah and colleagues, who measured QOL, using the same measure, in 47 obese women placed on a low fat *ad-libitum* diet for 6 months[17]. The greater improvement seen in this study cannot be explained by dietary fat intake, which was similar in the 2 studies, or by calorie intake, which was actually lower in our study (1145–1214 vs 1580 kcal). The difference may be due to the intensive group counseling that the patients received in this study.

The 6 week decrease in TC and LDL (21.8 and 12.9 mg/dl, respectively) in the diet group was maintained at the level of only 16–56% at 12 weeks (12.3 and 2.0 mg/dl, respectively). VLDL and TG, however, continued to decrease, albeit nonsignificantly, throughout the study (5.5–7.5 and 12.6–37.0 mg/dl, respectively). In comparison, Hearth-Holmes and colleagues[13], who placed 28 patients with SLE on a Step 1 diet for 3 months and 26 of the same patients on a Step 2 diet for another 3 months, reported a significant reduction in TC (15 mg/dl) but not LDL (9.6 mg/dl) or TG (4.8 mg/dl). The patients in that study had higher baseline TC and LDL values than patients in our study (18.5 and 21.2 mg/dl, respectively). A study by Denke[26], in which 41 hypercholesterolemic non-SLE subjects were placed on a high saturated fat diet for 1 month and a Step 1 diet for 4 months, reported a decrease of 14.4 mg/dl in TC, 11 mg/dl in LDL, 1 mg/dl in VLDL, and 2 mg/dl in TG following the Step 1 diet.

In this study, HDL did not change in the control group at 6 weeks, but increased by 5.4 mg/dl at 12 weeks compared to the baseline value. In comparison, HDL decreased in the diet group at both 6 and 12 weeks compared to the baseline

Table 3. Least square mean differences and confidence intervals in the diet group (n = 8).

Variable	LSM Difference	p*	Lower CI	Upper CI
TC†, mg/dl				
Baseline–6 wks	–21.8	0.0002	–31.0	–12.5
Baseline–12 wks	–12.3	0.010	–21.5	–3.0
LDL†, mg/dl				
Baseline–6 wks	–12.9	0.003	–20.8	–5.0
Baseline–12 wks	–2.1	0.600	–10.0	5.8
HDL†, mg/dl				
Baseline–6 wks	–6.3	0.0003	–9.1	–3.4
Baseline–12 wks	–2.4	0.090	–5.2	0.5
VLDL†, mg/dl				
Baseline–6 wks	–5.5	0.300	–16.8	5.8
Baseline–12 wks	–7.5	0.200	–18.8	3.8
TG††, mg/dl				
Baseline–6 wks	–12.6	0.600	–67.9	42.7
Baseline–12 wks	–36.9	0.200	–92.2	18.4
TC:HDL ratio				
Baseline–6 wks	0.1	0.600	–0.3	0.4
Baseline–12 wks	–0.1	0.400	–0.5	0.2
Weight‡, lb				
Baseline–6 wks	–4.1	0.120	–9.4	1.2
Baseline–12 wks	–8.1	0.006	–13.4	–2.8

* Changes over time are compared by repeated measures analysis of variance within the diet group.
† To express TC, LDL, HDL, VLDL in mmol/l, multiply by 0.02586
†† To express TG in mmol/l, multiply by 0.01129.
‡ To express weight in kg, divide by 2.2.

Table 4. Least square mean differences and confidence intervals in control group (n = 8).

Variable	LSM Difference	p*	Lower CI	Upper CI
TC†, mg/dl				
Baseline–6 wks	–9.3	0.4	–31.6	13.0
Baseline–12 wks	2.1	0.8	–21.3	25.5
LDL†, mg/dl				
Baseline–6 wks	–7.5	0.4	–24.8	9.8
Baseline–12 wks	–2.0	0.8	–20.1	16.1
HDL†, mg/dl				
Baseline–6 wks	–0.1	1.0	–7.4	7.3
Baseline–12 wks	+7.0	0.1	–0.7	14.7
VLDL†, mg/dl				
Baseline–6 wks	0.7	0.8	–5.1	6.5
Baseline–12 wks	–0.7	0.8	–6.8	5.4
TG††, mg/dl				
Baseline–6 wks	–9.3	0.6	–45.6	27.0
Baseline–12 wks	–16.0	0.4	–54.1	22.0
TC:HDL ratio				
Baseline–6 wks	–0.3	0.4	–0.9	0.4
Baseline–12 wks	–0.6	0.1	–1.3	0.1
Weight‡ lb				
Baseline–6 wks	–1.2	0.8	–11.6	9.3
Baseline–12 wks	–2.2	0.7	–12.7	8.2

* Changes over time are compared by repeated measures analysis of variance within the control group. † To express TC, LDL, HDL, VLDL in mmol/l, multiply by 0.02586. †† To express TG in mmol/l, multiply by 0.01129. ‡ To express weight in kg, divide by 2.2.

Table 5. Percentage total calories from fat, saturated fat (SFA), monounsaturated fat (MUFA), and polyunsaturated fat (PUFA), and dietary cholesterol at baseline, 6 weeks, 12 weeks. Values are mean ± SD.

Variable	Diet Group*, n = 8	Control Group*, n = 8	p†
Percentage fat calories			
Baseline	38.4 ± 6.1	30.9 ± 6.5	0.0003
6 wks	21.4 ± 7.7	33.8 ± 8.3	
12 wks	26.1 ± 11.4	32.7 ± 10.3	
Percentage SFA calories			
Baseline	11.7 ± 3.1	11.2 ± 4.0	0.01
6 wks	6.3 ± 2.3	11.8 ± 2.9	
12 wks	7.9 ± 4.5	12.0 ± 6.3	
Percentage MUFA calories			
Baseline	15.1 ± 5.4	11.7 ± 2.0	0.03
6 wks	7.9 ± 3.6	11.6 ± 3.8	
12 wks	9.0 ± 5.1	12.0 ± 3.9	
Percentage PUFA calories			
Baseline	7.9 ± 2.1	5.3 ± 1.5	0.01
6 wks	4.7 ± 1.5	6.5 ± 3.5	
12 wks	6.0 ± 2.4	5.5 ± 1.5	
Dietary cholesterol, mg			
Baseline	232 ± 68	229 ± 89	0.02
6 wks	119 ± 52	279 ± 146	
12 wks	155 ± 91	210 ± 134	

* One subject in both the diet group and control group is missing baseline diet analysis. † p value reflects overall treatment by time interaction effect assessed by repeated measures analysis of variance.

value (6.2 and 2.3 mg/dl, respectively). Similar decreases in HDL (3–4.5 mg/dl) were also observed in the diet groups of the diet intervention studies reviewed above[13,26]. In our study, the TC:HDL ratio increased by 2% at 6 weeks and decreased by 2% at 12 weeks in the diet group, and decreased by 4% at 6 weeks and 11% at 12 weeks in the control group. This change, however, was not significant over time in either group or between groups. Nevertheless, the fact that HDL decreased in the cholesterol-lowering diet group in this study and others[13,26], and that it is negatively associated with cardiovascular risk, suggest a need to include treatment modalities that will at least maintain if not improve HDL levels. Increasing physical activity is a well known way of increasing HDL levels. This study did not attempt to increase physical activity and the authors propose that an increase in physical activity be recommended in future dietary intervention studies to maintain or increase HDL levels.

In the control group, the reductions in the means for TC, LDL, VLDL, and TG at 12 weeks appeared higher than they were because one of the control subjects missed the 12 week measurement, and her lipid and lipoprotein values at baseline were much higher than the average values for the control group. The changes in the means in the control group at 12 weeks with and without this subject were –5.0 and +5.0 mg/dl, respectively, for TC, –6.2 and +0.3 mg/dl, respectively, for LDL, –1.4 and –0.2 mg/dl, respectively, for VLDL, and –22.8 and –10.3 mg/dl, respectively, for TG. Table 2 describes the raw data, while Tables 3 and 4 model the response.

In this study, body weight in the diet group continued to decrease beyond 6 weeks and the reduction was 4.1 lb at 6 weeks and 8.1 lb at 12 weeks compared to the baseline value. In comparison, Denke[26] reported a weight loss of 0.6 lb at 4 months in patients who were placed on a Step 1 diet for 4 months following a high fat diet for 1 month. Body weight also apparently decreased in the control group in our study. Most of this decrease (81–90%), however, can be explained by the control subject discussed earlier who missed both the 6 and 12 week visits for weight and whose baseline weight was 60 lb heavier than the average weight in the control group, making the mean change in body weight in the control group appear much bigger than it was. The mean baseline weight of the control group with and without this patient was 189.7 lb (Table 2) and 181.2 lb, respectively.

The discrepancy between the small attenuation in the reported dietary changes and the larger attenuation in the TC and LDL changes at 12 weeks in the diet group suggests that adherence to diet therapy was greater on the day the food records were kept, an observation noted by other investigators[27]. The attenuation of the changes in TC and LDL at 12 weeks suggests a need to determine whether a longer group intervention would help maintain the 6 week changes, and what happens to these changes beyond the intervention period. Intensive interventions are expensive and labor intensive and so the length of the intervention would have to be carefully considered in order to provide valuable data, yet be economically feasible.

In summary, the diet intervention was found to be highly acceptable and culturally sensitive. The patients in the diet group reported significant improvements in their diet and QOL. The decreases in TC and LDL at 6 weeks were not well maintained at 12 weeks, implying a need to study whether a longer group intervention would result in better maintenance of the lipid values. A larger randomized study with a longer group intervention period is necessary to test the effectiveness of a cholesterol-lowering diet on lipids and lipoproteins in patients with SLE. HDL levels modestly, but insignificantly, decreased in the diet group, implying that a treatment modality such as increasing physical activity that will help maintain or improve HDL during diet intervention is needed.

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