

Citation:

Miller LE, Volpe JJ, Coleman-Kelly MD, Gwazdauskas FC, Nickols-Richardson SM. Anthropometric and leptin changes in women following different approaches to weight loss. *Obesity (Silver Spring)* 2009;17:199-201.

PubMed ID: [18997680](#)

Study Design:

Randomized Clinical Trial

Class:

A - [Click here](#) for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine serum leptin concentrations in women in midlife undergoing body weight (BW) reduction by one of two dietary approaches; low-carbohydrate (LC) diet compared to a low-fat (LF) diet.

It was hypothesized that women consuming a LC, high-protein (LCHP) diet for BW loss would have a significantly greater reduction in serum leptin concentration compared to women consuming a high-carbohydrate LF (HCLF) diet. Moreover, the association between change in total body fat mass (TBFM) and central abdominal fat (CAF) and change in serum leptin concentration would be stronger in the LCHP versus HCLF diet group.

Inclusion Criteria:

Women were included if:

- BMI at screening was ≥ 25 and ≤ 40 kg/m²
- Were weight stable over previous year
- Were eumenorrheic, nonpregnant and nonlactating
- Without endocrine or metabolic diseases
- Cleared by primary care physician to participate
- Informed consent was obtained prior to participation

Exclusion Criteria:

Women were excluded if:

- Did not meet BMI criteria at screening or were not weight stable over prior year
- Were pregnant or lactating
- Diagnosed with endocrine or metabolic diseases

- Were not cleared by primary care physician to participate

Description of Study Protocol:

Recruitment--Subjects were recruited by word-of-mouth and through posted announcements on the Virginia Tech campus.

Design-- Randomized clinical trial for 12 weeks

Blinding used (if applicable) implied with measurements

Intervention (if applicable)

- Women were randomized to one of two diets: 1) a low-carbohydrate, high-protein (LCHP) or 2) high-carbohydrate, low-fat (HCLF) diet for 12 weeks. Changes in anthropometric and soft-tissue mass measurements and serum leptin concentrations were assessed.
- For the LCHP diet: During the first two weeks, ≤ 20 g carbohydrate was consumed. During weeks 3-10, carbohydrate intake increased by 5 g per week until 60 g carbohydrate was reached. During weeks 11 and 12, 60 g carbohydrate was consumed. Liberal amounts of protein and fat were allowed and total energy intake was not restricted.
- For the HCLF diet: For the 12 weeks, energy intake was set at 1,500 or 1,700 kcal per day (individualized to each woman's estimated energy need) to produce a 0.5-1.0 kg BW loss per week. Macronutrient composition was 60% carbohydrate, 15% protein, and 25% fat.

Statistical Analysis

- Included descriptive statistics (mean \pm s.d.) to describe subject characteristics, independent samples *t*-tests to test for differences in baseline variables between the two diet groups, repeated ANOVA to examine group x time interactions in anthropometric body composition and biochemical variables over time.
- Pearson correlation coefficients to examine the bivariate association between change in variables of interest over the 12 week intervention within the two diet groups.
- Statistical significance was set at $P < 0.05$.

Data Collection Summary:

Timing of Measurements

- Data for both groups were collected at baseline, 6 weeks, and 12 weeks
- Laboratory samples were collected at the same time and on same weekday for each interval after an overnight fast of 12 hours.

Dependent Variables

- Changes in body weight (BW, kg) and BMI (kg/m^2)
- Changes in body composition measurements including total body (TB) fat-free tissue mass (FFSTM; kg), TB fat mass (TBFM (kg), body fat percentage (BF%), and CAF (kf) using dual-energy X-ray absorptiometry (DXA)
- Changes in serum leptin concentrations

Independent Variables

- Dietary approach to body weight reduction
- LCHP or HCLF diet

Control Variables

Description of Actual Data Sample:

Initial N: 25 women (n = 13 LCHP diet group; n = 12 HCLF diet group)

Attrition (final N): 25 women; withdrawals not discussed

Age: 39.4 ± 3.4 years

Ethnicity: not presented

Other relevant demographics:

Anthropometrics:

- There were no significant differences in any of the variables between diet groups at baseline
- Mean height = 163.6 ± 5.9 cm
- Mean weight = 81.9 ± 14.9 kg
- Mean BMI = 30.5 ± 5.1 kg/m²

Location: Virginia Tech

Summary of Results:

Key Findings

- Baseline serum leptin concentration for all 25 women was significantly related to BW ($r=0.69$, $P<0.001$), BMI ($t=0.59$, $P<0.01$), TB FFSTM ($r=0.42$, $P<0.05$), TB FM ($r=0.80$, $P<0.001$), BF% ($r=0.86$, $P<0.001$), and CAF ($r=0.70$, $P<0.001$).
- BW loss for all women was 6.7 ± 2.7 kg from baseline to week 12.
- In both diet groups BMI, TB FFSTM, TB FM, BF%, and CAF decreased significantly from baseline to week 12 ($P<0.001$).
- No statistically significant differences in anthropometric and body composition variables were observed between diet groups from baseline to week 12.
- Serum leptin concentrations decreased 41.8% in the LCHP group and by 44.3% in the HCLF from baseline to week 12 ($P<0.001$) with no significant difference between groups.
- In the HCLF group, the association of CAF ($r=0.73$) and FM ($r=0.83$) change with serum leptin change was strong ($P<0.001$). Leptin change did not relate to change in any variable in the LCHP group.

Variables	LCHP group	HCLF group	Statistical Significance Within Diet Groups
	Mean ± s.d	Mean ± s.d.	(baseline to week 12)

Body weight (kg)	85.6 ± 12.6	78.0 ± 16.6	
Baseline	80.5 ± 12.0	73.9 ± 15.5	<i>P</i> <0.001
Week 6	78.3 ± 11.5	71.9 ± 14.7	
Week 12			
BMI (kg/m²)	31.3 ± 4.9	29.7 ± 5.4	
Baseline	29.4 ± 4.5	28.2 ± 5.1	<i>P</i> <0.001
Week 6	28.6 ± 4.3	27.4 ± 4.8	
Week 12			
FFSTM (kg)	48.0 ± 5.4	46.2 ± 7.0	
Baseline	46.4 ± 5.0	44.9 ± 6.8	<i>P</i> <0.001
Week 6	45.8 ± 4.7	44.9 ± 6.6	
Week 12			<i>P</i> <0.001
FM (kg)	35.3 ± 8.2	29.5 ± 10.4	
Baseline	32.0 ± 8.0	26.7 ± 9.7	<i>P</i> <0.001
Week 6	30.2 ± 7.7	24.6 ± 8.8	
Week 12	40.8 ± 4.7	36.9 ± 5.9	<i>P</i> <0.001
BF% (%)	38.9 ± 5.3	35.2 ± 6.3	
Baseline	37.9 ± 5.6	33.4 ± 5.7	<i>P</i> <0.001
Week 6	10.1 ± 3.0	7.9 ± 3.3	
Week 12	9.2 ± 2.6	7.0 ± 3.0	
CAF (kg)	8.5 ± 2.4	6.3 ± 2.5	
Baseline			
Week 6	24.9 ± 9.8	18.5 ± 8.0	
Week 12	13.6 ± 4.2	11.9 ± 6.1	
Serum leptin (ng/ml)	14.5 ± 5.4	10.3 ± 3.8	
Baseline			
Week 6			
Week 12			

Author Conclusion:

Serum leptin concentrations decreased significantly in women who lost BW by either a LCHP or HCLF diet. Subjects in both diet groups lost twice as much BW in 12 weeks.

Both diets favorably lower FM, CAF, and leptin in women in midlife, suggesting that beneficial changes in leptin can be similarly achieved through different dietary approaches for BW loss. The association between CAF loss and serum leptin reduction was greater in women in the HCLF than the LCHP group.

Reviewer Comments:

Limitations included:

- *Small sample size*
- *Inclusion of only women in midlife*
- *The HCLF diet was limited to 25% of total energy from dietary fat. Dietary fat restriction may have been beneficial to other body composition and energy balance regulatory hormones which were not measured.*

Strengths included:

- *Standardized measurements*
- *Randomized trial design*
- *Adequate statistical power*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

- | | | |
|----|---|-----|
| 1. | Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies) | Yes |
| 2. | Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about? | Yes |
| 3. | Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice? | Yes |
| 4. | Is the intervention or procedure feasible? (NA for some epidemiological studies) | Yes |

Validity Questions

- | | | |
|------|---|-----|
| 1. | Was the research question clearly stated? | Yes |
| 1.1. | Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified? | Yes |

1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	Was the selection of study subjects/patients free from bias?	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	No
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	Were study groups comparable?	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method of handling withdrawals described?	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes

4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	Was blinding used to prevent introduction of bias?	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	???
6.6.	Were extra or unplanned treatments described?	No
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outcomes clearly defined and the measurements valid and reliable?	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes

7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	???
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	Was the statistical analysis appropriate for the study design and type of outcome indicators?	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	???
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	Yes
9.	Are conclusions supported by results with biases and limitations taken into consideration?	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	Is bias due to study's funding or sponsorship unlikely?	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes

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