

Citation:

Paniagua JA, de la Sacristana AG, Sánchez E, Romero I, Vidal-Puig A, Berral FJ, Escribano A, Moyano MJ, Pérez-Martínez P, López-Miranda J, Pérez-Jiménez F. A MUFA-rich diet improves postprandial glucose, lipid and GLP-1 responses in insulin-resistant subjects. *J Am Coll Nutr.* 2007 Oct; 26 (5): 434-444.

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Study Design:

Prospective Cohort Study

Class:

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

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To determine the metabolic effects on three weight maintenance diets:

- A diet rich in saturated fat (SAT)
- A diet rich in monounsaturated fat (MUFA) and
- A carbohydrate-rich diet (CHO) on the following:
 - Body weight
 - Fasting and postprandial glucose
 - Lipid metabolism and acute postprandial responses of insulin
 - GLP-1 and P/I in a selected population of insulin-resistant patients without previous anti-diabetic treatment.

Inclusion Criteria:

- Ages 35-75 years
- History of fasting glycemia <125mg/dL with HbA1C <6.5% without any drug or previous insulin treatment
- BMI >25kg/m²
- Waist circumference ≥102cm in men and ≥88cm in women
- Menopause was confirmed in women by FSH concentrations >40IU per liter and the absence of menses for at least one year
- Having an insulin sensitive index ISI (composite) less than 4.0.

Exclusion Criteria:

- Signs of diabetic retinopathy, nephropathy or macrovascular complications
- Cigarette smoking

- Alcohol consumption
- Use of diuretics, steroids, β -blockers or use of medications that might affect glucose metabolism
- Abnormal results from screening blood tests of hepatic, renal, thyroid and adrenal function.

Description of Study Protocol:

Recruitment

Participants were recruited from the diabetic patients records at primary care centers in Cordoba in 2003-2004.

Design

- A randomized Williams Latin Square crossover study design was used in this study
- Subjects were randomly allocated to three groups and underwent three dietary periods of 28 days each in a crossover design.

Dietary Intake/Dietary Assessment Methodology

- Each subject completed a three-day food record prior to the start of the study to ascertain usual energy intake
- Subjects also completed weighed food records throughout the study to assess compliance with prescribed intervention diets.

Blinding Used

Not applicable.

Intervention

- Low-fat, high-CHO diet: 65% CHO and 20% fat (6% SAT, 8% MUFA, 6% PUFA)
- A Mediterranean Diet: 47% CHO, 38% fat (9% SAT, 23% MUFA, 75% of which was provided in the form of extra virgin olive oil and 6% PUFA)
- A saturated fat-rich diet: 47% CHO, 15% protein and 38% fat (23% SAT, 9% MUFA and 6% PUFA)
- Subjects were instructed to maintain their usual exercise regime during the study.

Statistical Analysis

- Changes in anthropometry, calorimetry and biochemical determinations were analyzed using repeated-measures design, with one repeated-measures factors: Diet
- Individual P-values were reported when statistically significant using the post hoc Tukey's test
- In designing the study, preliminary data were used to obtain power calculations (80% power and an α of 5%) for detecting a difference of 15% in fasting serum glucose and HOMA-IR
- The data presented were all tested for normality of distribution
- The Friedman test was used for variables that did not log transform
- Plasma glucose, triacylglycerol, HDL, GLP-1 and insulin were analyzed by calculating the incremental area under the curve (AUC) with a formula based on the trapezoid rule with adjustment for baseline concentrations
- $P < 0.05$ was considered significant.

Data Collection Summary:

Timing of Measurements

- Adherence to the dietary protocols was determined by measuring fatty acid concentrations at the end of each dietary period
- Before the start of the study, energy expenditure was measured in the fasting state by indirect calorimetry to estimate daily energy needs
- Each subject completed a three-day food record prior to starting the study to assist in estimating daily energy needs
- During the protocol, subjects attended the research clinic twice a week to discuss their energy and macronutrient intakes with the program dietitian
- Body weight was measured twice weekly and was not permitted to vary by more than 1kg
- Total dietary intake was estimated weekly and three-day weighed food record was collected on six occasions during the study
- A standardized breakfast was consumed on the last day of each diet period as a test breakfast and venous blood samples were taken to assess glucose, triacylglycerol, HDL, insulin and GLP-1 levels.

Dependent Variables

- Body weight was measured twice weekly
- Energy expenditure was measured in the fasting state by indirect calorimetry
- Postprandial glucose, triacylglycerol, HDL, insulin, and GLP-1 levels were assessed using venous blood samples drawn after a standardized breakfast was consumed on the last day of each diet period
- Serum levels of glucose, insulin, HbA1C, cholesterol, triacylglycerols, HDL, LDL, Apo A1, Apo B, GLP-1, fatty acids and insulin resistance were assessed at the end of each diet period.

Independent Variables

Dietary intake was assessed using three-day food records and confirmed using serum fatty acids measurements taken at the end of each diet period.

Control Variables

None.

Description of Actual Data Sample:

- *Initial N*: N=59 potential subjects who were screened
- *Attrition (final N)*: N=11
 - Seven females
 - Four males
 - 18 subjects did not meet inclusion criteria
 - Nine subjects refused to participate
 - The remainder were excluded due an insulin sensitivity index that did not meet study criteria
- *Age*: 62±9 years
- *Ethnicity*: Not reported
- *Other relevant demographics*: None reported
- *Anthropometrics*:

- BMI=32.6±7.8kg/m²
- Waist circumference: 106.2cm for men and 112.8cm for women
- HbA1C: 6.0±0.5%
- Insulin Sensitivity Index: 2.9±0.9 ISIm²
- Location: Spain.

Summary of Results:

Energy Expenditure, Dietary Intake and Body Weight

Resting energy expenditure and body weight did not change during the three dietary periods.

	SAT	MUFA	CHO	P-Value
Energy intake, kJ per day	9,565±769	9,586±743	9,526±716	0.7
Total fat, % per g per kg per day	38%/1.64g	38%/1.64g	20%/0.86g	0.00
Saturated fat, % per g per day	23%/82g	9%/32.4g	6%/21.3g	0.00
Monounsaturated fat, % per g per day	9%/32.2g	23%/81.5g	8%/28.5g	0.00
Polyunsaturated fat, % per g per day	6%/21.4g	6%/21.0g	6%/21.0g	0.00
Carbohydrate, p% per g per kg per day	47%/4.55g	47%/4.52g	65%/6.25g	0.00
Protein, % per g per kg per day	15%/1.45g	15%/1.44g	15%/1.45g	0.7

Fatty Acid Composition

- The proportion of myristic acid (P<0.05), palmitic acid (P<0.01), stearic acid (P<0.05) and total saturated fatty acids (P<0.01) were significantly increased after the SAT diet compared to the MUFA and CHO dietary periods
- The proportion of oleic acid was significantly increased after eating the MUFA diet compared to the CHO and SAT diets (P<0.01).

Biochemical Results

- Fasting glucose was decreased during the MUFA and CHO periods compared with the SAT period (5.02±0.1, 5.03±0.1, 5.5±0.2mmol/L, P<0.05)
- The mean HOMA-IR decreased during the MUFA period compared to the SAT and CHO periods (2.32±0.35, 2.72±0.37, 2.52±0.37mmol/L X μU/ml, P<0.01)
- HDL, ApoA1 and ApoB concentrations fell during the CHO diet (P<0.05 in all cases)
- Postprandial integrated AUCs of glucose and insulin were significantly higher in response to the standard CHO breakfast than to the MUFA and SAT breakfasts (P<0.05 and P<0.01 respectively)
- Postprandial AUC of total triacylglycerols fell during the CHO diet compared with the other two diets (P<0.05)
- Fasting plasma GLP-1 concentrations were similar during the three diet periods, but the postprandial AUC of plasma GLP-1 in response to the CHO-rich meal was significantly lower than following the MUFA and SAT breakfasts (P<0.05)

- Fasting serum proinsulin decreased after the MUFA diet compared to the CHO and SAT diets (P<0.05)
- Fasting insulin levels, total cholesterol, triacylglycerol and LDL levels did not change during the three diet periods.

Author Conclusion:

- Weight-maintenance with a MUFA-rich diet improved insulin resistance and fasting proinsulin levels in insulin-resistant subjects
- Ingestion of a virgin-olive-oil-based breakfast decreased postprandial glucose and insulin concentrations, and increased HDL and GLP-1 concentrations as compared with a carbohydrate-rich diet.

Reviewer Comments:

None.

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?	No
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?	No
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?	???
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?	Yes
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?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
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?	No
7.6.	Were other factors accounted for (measured) that could affect outcomes?	No

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)?	No
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	No
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?	No
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?	No
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