

Citation:

Pan A, Franco OH, Ye J, Demark-Wahnefried W, Ye X, Yu Z, Li H, Lin X. Soy protein intake has sex-specific effects on the risk of metabolic syndrome in middle-aged and elderly Chinese. J Nutr. 2008 Dec;138(12):2413-21.

PubMed ID: [19022966](#)

Study Design:

cross sectional study

Class:

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

Research Design and Implementation Rating:

 NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To investigate the relationship between soy protein intake and the risk of Metabolic Syndrome (MetS) and its components among middle-aged and elderly Chinese.

Inclusion Criteria:

This study was part of the Nutrition and Health of Aging Population in China project which included:

- noninstitutionalized Chinese people,
- aged 50-70 years, and
- stable residents for at least 20 years in Beijing or Shanghai, China.

In particular for this study:

- participants were reviewed March to June 2005,
- 1 rural site and 2 urban sites in each of the two locations were used, and
- participation of only 1 member per household.

Exclusion Criteria:

Subjects were excluded if they had any of the following conditions: self care disability, severe psychological disorders, tuberculosis or other communicable disease, AIDS; cancer, coronary heart disease, stroke, Alzheimer's disease, or dementia.

Participants were additionally excluded if there was incomplete data or they provided implausible responses for dietary data or self reported coronary heart disease, stroke or cancer.

Description of Study Protocol:

Recruitment

From the subjects already participating in the Nutrition and Health of Aging Population in China, participants in this study were randomly selected from selected streets of the residency registration.

Design

cross sectional study of dietary impact on metabolic syndrome within a large cohort study

Blinding used (not specified)

Intervention (not applicable)

Statistical Analysis (Stata 9.2, StataCorp)

- Quartile distribution analysis of soy protein intake: lowest quartile was reference group
- multivariate logistical regression to evaluate the association between total soy protein intake and MetS, adjusting for relevant and important demographic and biological confounders and covariates
- all models included age, geographic location, residential region, current drinking and smoking status, marital status, educational level, employment status, BMI, physical activity level, and presence of comorbidity.
- Dietary factors included in final models were total energy intake, dietary fat, cholesterol, nonsoy protein, and fiber intake
- tests of linear trend conducted using median value of each quartile as a continuous variable.

Data Collection Summary:

Timing of Measurements

Initial interview and personal questionnaire including a Food Frequency Questionnaire covering the past year, in participant's home.

Physical assessment (including fasting blood draw) in medical clinic within 4 months (March - June 2005) of in home interview

Dependent Variables

- MetS components (updated National Cholesterol Education Program Adult Treatment Panel III criteria for Asian Americans):
 - hyperglycemia: fasting plasma glu \geq 5.6 mmol/L or previously diagnosed type 2 diabetes or oral antidiabetic agents or insulin,
 - hypertriglyceridemia: triglycerides \geq 1.7 mol/L
 - high blood pressure: \geq 13/85 mmHg or current use of antihypertensive medications
 - central obesity: waist circumference \geq 90 cm in men or \geq 80 cm in women
 - low HDL Cholesterol: $<$ 1.03 mmol/L in men or $<$ 1.30 mmol/L in women

Independent Variables

- Soy intake: Results of soy intake estimated from FFQ were segmented into quartiles where information on subjects with intake in the lowest quartile were used as the reference population.

Control Variables

Age, Sex, Location, Marital status, Education level, Smoking, Activity, Alcohol, and Dietary Intake (total energy, total fat, non-soy protein, carbohydrate, fiber, and cholesterol)

Description of Actual Data Sample:

Initial N: 3533 potential participants; of which, 3379 agreed to participate; of which, 3289 had complete data; of which 124 were excluded for implausible data and 354 were excluded for self-reported comorbidities.

Attrition (final N): 2811 (1173 male, 1638 female)

Age: 50-70 years (median age 58.4 ± 6.0)

Ethnicity: Chinese

Other relevant demographics:

- 77.1% had ≤ 9 years education;
- 87.2% married; 54.1% retired;
- 27.1% currently smoking; and
- 27.1% currently drinking alcohol

Anthropometrics (medians):

- BMI, 24.4 ± 3.6 kg/m²
- Waist circumference, 83.3 ± 10.6 cm
- Blood pressure, Systolic 139.0 ± 22.1 , Diastolic 79.7 ± 10.7 mm Hg
- Plasma HDL cholesterol, 1.28 ± 0.33 mmol/L
- Plasma triglycerides, 1.36 ± 1.05 mmol/L
- Fasting plasma glucose, 5.82 ± 1.75 mmol/L

Location: Beijing (north, 46.4 % participants) and Shanghai (south, 53.6% participants) China

Summary of Results:

Key Findings

- Participants with Metabolic Syndrome (MetS) were older ($p=0.015$) and were more likely to be female, from Beijing, living in urban communities, overweight or obese, and/or to have a comorbidity.
- There was no significant association between soy protein intake and the risk of MetS after adjustment for potential confounding factors. However; there was a marked difference in association between soy protein and the risk of MetS between men and women (p -trend = 0.008).
- Adjusted OR between highest and lowest quartiles of soy protein intake: men=1.64, 95% CI: 0.95-2.81; women=0.66, 95% CI: 0.42-1.03
- Soy protein intake was associated with increased risk of hyperglycemia (p -trend = 0.007 total, 0.005 in men) and marginally reduced risk of elevated blood pressure (p -trend = 0.056 total, 0.049 in men).

- There were significant interactions between soy protein intake and six in the association with hypertriglyceridemia (P=0.005), low HDL cholesterol level (P=0.060), and hyperglycemia (P=0.081).
 - The positive association between soy protein intake and hyperglycemia was primarily in males (P-trend=0.005); men in the top quartile of soy protein intake had an 89% increased risk compared with the lowest quartile (OR=1.89, 95% CI=1.22-2.92)
 - Soy protein intake and elevated blood pressure were inversely associated in men (P-trend=0.049).
 - Soy protein intake was not significantly associated with any component of MetS in women.

Other Findings

- The median level of soy protein intake was 7.82 g/d (IQR = 4.65-12.60 g/d, 7.64g/d in men and 8.02 g/d in women).

Author Conclusion:

A higher intake of soy protein tended to be associated with a reduced risk of Metabolic Syndrome (MetS) in women but an elevated risk in men. One of the potential mechanisms for the sex-dependent effects of soy may be linked to its estrogen-like activity. Habitual soy protein intake conferred sex-specific effects on risk of MetS, with moderately reduced risk in middle-aged and elderly women but elevated risk in men. It significantly increased risk for hyperglycemia but reduced risk for hypertension in middle-aged and elderly men.

Reviewer Comments:

Strengths: large population based study of individuals who consumed significant amounts of soy proteins in their long term diet

Weakness: Authors note that the Food Frequency Questionnaire was not validated and sex hormone concentrations were not measured. The Chinese population presented here was also relatively low educated (less than 9 years of school) and not employed (n=1521 retired and n=599 unemployed or on welfare); therefore, these results may not be generalizable to other populations.

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?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
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)	N/A
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?	Yes
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.)	Yes

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?	No
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?	N/A
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
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.)	N/A
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?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
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?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
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)?	Yes
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?	N/A
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

Copyright American Dietetic Association (ADA).