

Citation:

Zhan, Siyan and Suzanne C Ho Meta-analysis of the effects of soy protein containing isoflavones on the lipid profile Am J Clin Nutr 2005;81:397-408

PubMed ID: [15699227](#)

Study Design:

Meta-analysis

Class:

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

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To identify and quantify the effects of soy protein containing isoflavones on the lipid profile.

Inclusion Criteria:

- Published trials in English
- Randomized crossover or parallel design
- amount of soy isoflavones was available
- initial lipid profile was reported
- lipid profile at conclusion of study was available

Exclusion Criteria:

- no control group
- use of whole soybean (vs soy protein)
- failure to meet inclusion criteria

Description of Study Protocol:**Recruitment**

RCT's selected from PUBMED data base and by examination of cited reference sources.

Design : Meta analysis

Blinding used (if applicable) N/A

Intervention (if applicable) N/A

Statistical Analysis:

- **Principal effect was defined as the mean difference between change in lipid concentrations among subjects (final value-initial: for both soy and control groups) Variance was determined in order to assign weight and evaluate pooled effect. Raw data was used when available. In the absence of raw data, variance was determined from SD.**
- Estimates of the average effect of soy protein containing isoflavones on lipid values and 95% CIs were calculated using both fixed effect and random effect models.

Data Collection Summary:

Search terms: not specified

Data abstracted from articles included: Dose, duration, initial and final lipid profile (LDL, triacylglycerol, HDL, and total cholesterol)

Dependent Variables:

- changes in serum lipid concentrations

Independent Variables:

- intake of soy protein containing isoflavones

Description of Actual Data Sample:

Number of studies identified: not specified

Final N: 23 studies were included in the meta analysis. N =1381 subjects *

* Note: this number does not match the N's listed in Table 1 or figures 1,2, 3, or 4

Ethnicity: not reported

Other relevant demographics:: none reported

Anthropometrics not reported

Summary of Results:

Key Findings:

- Soy protein decreased total cholesterol 0.22 mmol/L (95% CI:-0.29, -0.16), LDL cholesterol 0.21 mmol/L (95% CI: -0.3, -0.13) and Triacylglycerol 0.109 mmol/L (95% CI -0.16, -0.05). HDL cholesterol increased in the soy protein group 0.04 mmol/L (95% CI: 0.00, 0.07)
- Subjects with hypercholesterolemia had greater reductions of total cholesterol (0.25 mmol/L, 95%CI: -0.33 to -0.17) than normal subjects (0.17 mmol/L, 95%CI: -0.25 to -0.08).
- Subjects consuming low-fat and low-cholesterol diets had greater reductions in total cholesterol than did subjects following a usual diet [-0.26 mmol/L, 95% CI: -0.33 to -0.18)

and -0.16, 95%CI: -0.24 to -0.07, respectively)

- Total cholesterol decreased to a larger extent in subjects with daily consumption of ≥ 80 mg of isoflavones contained in soy protein than in those ingesting lesser amounts.. There was a negative dose-response relation between the duration of intervention and the reduction of serum cholesterol.
- In linear regression analysis that considered the effect of initial lipid concentrations and the interaction of intervention amount and duration, only the amount of soy protein containing isoflavones was independently associated with the change in total cholesterol.
- Pooled estimates of treatment effects in the subgroup analyses:
 - the reduction of LDL cholesterol was more significant in men than in women
 - initial lipid concentrations did not appear to influence changes in LDL-C or triacylglycerol
 - soy protein containing isoflavones had a significant effect on HDL-C among subjects with hypercholesterolemia
 - a negative dose-response relation between the length of intervention and the decline in LDL-C or triacylglycerol was observed, but longer interventions were associated with a greater improvement in HDL-C.
- compared with casein, the intake of soy protein containing isoflavones was beneficial for improving lipid profiles. Compared with isoflavone-depleted soy protein, intake of soy protein containing isoflavones markedly decreased the LDL-C concentration, with a net change of -0.15 mmol/L (95%CI: -0.27, -0.03), but had no significant effect on HDL-C or triacylglycerol.

Other Findings:

- Results were more marked in women, and subjects with baseline hypercholesterolemia.
- There was a greater reduction of total cholesterol in pre-and perimenopausal women than in postmenopausal women.

Author Conclusion:

Soy protein containing isoflavones significantly reduced serum total cholesterol, LDL cholesterol, and triacylglycerol. HDL cholesterol was significantly increased. Changes were related to dose of isoflavones, duration of exposure, sex, and initial serum lipid concentrations of the subjects.

Reviewer Comments:

Meta-analysis can magnify the quality of available evidence in either a positive or negative direction. Pooling data from diverse or poor quality studies has the potential of magnifying errors and limitations of the available body of evidence.

Research Design and Implementation Criteria Checklist: Review Articles

Relevance Questions

- | | | |
|----|---|-----|
| 1. | Will the answer if true, have a direct bearing on the health of patients? | Yes |
| 2. | Is the outcome or topic something that patients/clients/population groups would care about? | Yes |

- | | | |
|----|---|-----|
| 3. | Is the problem addressed in the review one that is relevant to nutrition or dietetics practice? | Yes |
| 4. | Will the information, if true, require a change in practice? | Yes |

Validity Questions

- | | | |
|-----|--|-----|
| 1. | Was the question for the review clearly focused and appropriate? | Yes |
| 2. | Was the search strategy used to locate relevant studies comprehensive? Were the databases searched and the search terms used described? | Yes |
| 3. | Were explicit methods used to select studies to include in the review? Were inclusion/exclusion criteria specified and appropriate? Were selection methods unbiased? | Yes |
| 4. | Was there an appraisal of the quality and validity of studies included in the review? Were appraisal methods specified, appropriate, and reproducible? | Yes |
| 5. | Were specific treatments/interventions/exposures described? Were treatments similar enough to be combined? | Yes |
| 6. | Was the outcome of interest clearly indicated? Were other potential harms and benefits considered? | Yes |
| 7. | Were processes for data abstraction, synthesis, and analysis described? Were they applied consistently across studies and groups? Was there appropriate use of qualitative and/or quantitative synthesis? Was variation in findings among studies analyzed? Were heterogeneity issues considered? If data from studies were aggregated for meta-analysis, was the procedure described? | Yes |
| 8. | Are the results clearly presented in narrative and/or quantitative terms? If summary statistics are used, are levels of significance and/or confidence intervals included? | Yes |
| 9. | Are conclusions supported by results with biases and limitations taken into consideration? Are limitations of the review identified and discussed? | Yes |
| 10. | Was bias due to the review's funding or sponsorship unlikely? | Yes |

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