Meta-analysis of the effects of soy protein intake on serum lipids
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Authors' objectives
To examine the relationship between soy protein consumption and serum lipid concentrations in humans.

Searching
The medical literature was searched for studies evaluating the effects of soy protein on serum cholesterol concentrations in humans.

Study selection
Study designs of evaluations included in the review
Controlled studies of either a crossover or a parallel design, with baseline values of serum cholesterol concentrations, were included.

Specific interventions included in the review
Studies were included if they had used isolated or textured soy protein. The average prescribed dose of soy protein was 47 g (range: 17 - 124). Studies were excluded if they had used several sources of vegetable protein, or if whole soybeans rather than soy protein were used.

Participants included in the review
No inclusion criteria were given, but it is noted that both community- and hospital-based participants were recruited. Adults and children of both sexes were included, as were participants with normal cholesterol concentrations and hypercholesterolaemia, vegetarians, omnivores and lacto-ovo-vegetarians.

Outcomes assessed in the review
Net change in serum lipid concentrations (defined as change during the soy diet minus change during the control diet), weight change, dietary fat intake and cholesterol intake.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the authors performed the selection.

Assessment of study quality
The authors do not report the method used to assess quality, or how the quality assessment was performed.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the authors performed the data extraction.

Methods of synthesis
How were the studies combined?
A random-effects model was used to quantify the average effects of soy protein on serum lipid values, according to the method of DerSimonian and Laird (see Other Publications of Related Interest).

How were differences between studies investigated?
Preliminary tests for homogeneity indicated substantial variability. Subgroup analyses were applied to examine the effects of the following variables in relation to changes in serum lipid concentrations: baseline serum lipid values, type...
of soy protein used, amount of soy protein ingested, type of diet, age group of participants, and similarity of the control and soy treatment diets.

**Results of the review**

There were 38 studies (published in 29 articles; n=743), of which 22 were of a randomised crossover design, 12 were fixed-sequence crossover studies and 4 were randomised parallel studies.

Changes in serum lipid concentrations: compared to control regimes, the ingestion of diets containing soy protein was accompanied by a significant reduction in serum concentrations of total cholesterol, low-density lipoprotein (LDL) cholesterol and triglycerides. The net change in serum cholesterol concentrations (38 studies with 743 participants) was a decrease of 23.2 mg per decilitre (mg/dl) (95% confidence intervals, CI: 13.5, 32.9), or 9.3%; the net change in serum LDL cholesterol concentrations (31 studies with 564 participants) was a decrease of 21.7 mg/dl (95% CI: 11.2, 31.7), or 12.9%. The consumption of soy protein (30 studies with 628 participants) significantly decreased serum triglyceride concentrations by 13.3 mg/dl (95% CI: 0.3, 25.7), or 10.5%.

Soy protein intake did not significantly affect serum high-density lipoprotein (HDL) cholesterol concentrations (net change was an increase of 2.4%) or very low-density lipoprotein cholesterol concentrations.

Predictors of treatment effect: the initial serum cholesterol concentration was the only significant predictor of changes in serum cholesterol concentrations (p<0.001).

**Authors’ conclusions**

The consumption of soy protein is associated with significant decreases in serum cholesterol, LDL cholesterol and triglyceride concentrations, and with a non significant increase in serum HDL cholesterol concentrations. The decreases in serum cholesterol and LDL cholesterol concentrations were strongly related to the participants initial serum cholesterol concentrations, accounting for approximately 77% of the variance among studies.

**CRD commentary**

Information relating to the literature search is very limited, and the authors’ search strategy could not be reproduced from this paper. There is no mention of an attempt to locate unpublished literature. No details are presented about how the studies were selected, quality assessed or data extracted. The precise total number of participants is unclear since there are discrepancies between figures in tables 1 and 2.

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