Hypocholesterolaemic effects of soya proteins: results of recent studies are predictable from the Anderson meta-analysis data

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CRD summary
This review evaluated the hypocholesterolaemic effects of soy protein. The data suggested the beneficial effects of soya proteins were probably not consequent on gross dietary changes and most likely depended on some components that elicit a pharmacological effect on the low-density lipoprotein receptor system. Methodological and reporting weaknesses suggested that these conclusions should be viewed with caution.

Authors' objectives
The authors' objective seemed to be to evaluate the hypocholesterolaemic effects of soy protein using a nomogram prepared on the basis of the quartiles of initial cholesterol concentrations reported in a previous meta-analysis.

Searching
MEDLINE and other unspecified published material were searched (from 1995). Language restrictions were not reported.

Study selection
Studies that reported a clear definition of total and low-density lipoprotein cholesterol levels and had a duration of at least three weeks were eligible for inclusion. The included studies were crossover or parallel controlled trials of four to 24 weeks duration. The included participants were males and females with a mean age of 25 to 67 years. Participants were menopausal, postmenopausal, hypercholesterolaemic, low cholesterol, diabetic and dialysis patients. The included studies were of isolated soya proteins or soya drink with isoflavones compared with control diet of casein, milk proteins, milk, wheat, egg, dairy or animal proteins (various doses). The outcomes assessed in the included studies were net changes in total cholesterol and low-density lipoprotein cholesterol (LDL-C).

The authors stated neither how the papers were selected for review nor how many reviewers performed the selection.

Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
Net changes in total cholesterol and low-density lipoprotein cholesterol were reported as absolute change mg/dL. The studies were divided into quartiles and 95% confidence intervals (CIs) calculated. The authors stated neither how the data were extracted for the review nor how many reviewers performed the data extraction.

Methods of synthesis
The studies were combined in a nomogram based on the quartiles of initial cholesterol concentrations in the Anderson meta-analysis and corresponding 95% CIs for net change in cholesterol.

Results of the review
Thirty-three controlled trials were included (n=1,030): 15 parallel double-blinded trials (n=413); nine crossover double-blinded trials (n=354); and nine crossover trials (n=263).

The authors reported that a diet that included soy protein was associated with a reduction in total cholesterol (mean was -11.7mg/dL) and low-density lipoprotein cholesterol (mean was -8.6mg/dL). Participants in the first quartile (with normal cholesterol levels) showed mean reductions of 3.6mg/dL. Participants in the second quartile (with mild hypercholesterolaemia) showed mean reductions of 5.0mg/dL. Participants in the third quartile (with moderate hypercholesterolaemia) showed mean reductions of 18.5mg/dL.
These results fell within the 95% CIs reported in the Anderson meta-analysis.

**Authors’ conclusions**
The data suggested the beneficial effects of soya proteins were probably not consequent on gross dietary changes, but most likely depended on components that elicited a pharmacological effect on the low-density lipoprotein receptor system.

**CRD commentary**
The review question was not supported by clear inclusion criteria for participants, study design or intervention, which may have led to subjective decisions during study selection. Language restrictions were not reported and the authors did not report any attempt to search for unpublished studies, which could have introduced language and publication biases into the review. Study selection and data extraction were not described, so it was unknown whether the authors attempted to minimise the possibility of bias and error in the review process. The quality of the primary studies and statistical heterogeneity was not assessed, so the synthesis of these may not have been reliable. The results were poorly reported and the narrative description of results did not appear to correlate with those shown in tables. In light of these limitations the authors’ conclusions should be viewed with caution.

**Implications of the review for practice and research**
The authors did not state any implications for practice or further research.

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