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Effect of soy isoflavones on blood pressure: A meta-analysis of randomized controlled trials

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Abstract *Background and aim:* The effect of soy isoflavones on blood pressure is controversial. The objective of this study was to evaluate the effect of dietary soy isoflavones on blood pressure.
Methods and Results: Trials were searched in PubMed, the Cochrane Library, Embase and references cited in related reviews and studies. A total of eleven trials were reviewed. Meta-analysis results showed a mean decrease of 2.5 mm Hg (95% CIs, − 5.35 to 0.34 mm Hg; $P = 0.08$) for systolic blood pressure and 1.5 mm Hg (95% CIs, − 3.09 to 0.17 mm Hg; $P = 0.08$) for diastolic blood pressure in the soy isoflavones-treated group compared to placebo. Meta-regression and subgroup analyses indicated that blood pressure status was a significant predictor of heterogeneity for the effect of soy isoflavones on blood pressure. Subgroup analysis of hypertensive subjects revealed that a greater blood pressure reduction was identified in the soy isoflavone-treated group compared to placebo (5 trials; SBP: − 5.94, 95% CIs [− 10.55, − 1.34] mm Hg, $P = 0.01$; DBP: − 3.35, 95% CIs [- 6.52, − 0.19] mm Hg, $P = 0.04$). In contrast, treatment with soy isoflavones did not lead to a significant reduction in blood pressure in normotensive subjects (6 trials; SBP: 0.29, 95% CIs [- 2.39, 2.97] mm Hg, $P = 0.83$; DBP: − 0.43, 95% CIs [- 1.66, 0.81] mm Hg, $P = 0.50$).
Conclusion: Soy isoflavones had an effect of lowering blood pressure in hypertensive subjects, but not in normotensive subjects. Larger trials need to be carried out to confirm the present findings.
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Introduction

Hypertension, estimated to affect approximately one billion individuals worldwide, is a major risk factor for cardiovascular disease (CVD). Starting from 115/75 mm Hg, CVD risk doubles for each increment of 20/10 mm Hg [1]. Conversely, a 4—5 mm Hg reduction in systolic blood pressure (SBP) and a 2—3 mm Hg reduction in diastolic blood pressure (DBP) can reduce CVD risk by 8—20% [2]. In addition to intensive pharmacological therapy, dietary intervention provides an important approach for preventing and treating hypertension according to the AHA (American Heart Association) and the JNC 7 (Seventh Report of the Joint National Committee) report [1,3].

Isoflavones are a group of bioactive components mainly derived from soybeans [4]. Dietary soy isoflavones have been suggested to result in arterial vasodilatation, improvement in endothelial function, and decreased blood pressure (BP), perhaps by nitric oxide (NO) dependent mechanism in animal experiments [5,6]. However, clinical trials in humans have shown inconsistent results [7—17]. In most of these clinical trials, the sample sizes were small, and the makeup of the soy isoflavones differed from trial to trial, utilizing soy-derived isoflavones, soy protein, or both. The beneficial effects of isoflavones on cardiovascular disease have been suggested to be dependent on soy protein [18—21]. Herein, we evaluated the effect of isoflavones on BP through meta-analysis of all randomized, double-blind, and placebo-controlled clinical trials with a stated amount of soy protein.

Methods

Literature search

We searched PubMed (from 1950 to October, 2009), Embase (from 1966 to October, 2009), and the Cochrane Library (Cochrane Central Register of Controlled Trials) for reports published in any language, using the query "(soy protein OR soy OR soybean OR soya) AND (isoflavones OR isoflavone) AND (blood pressure OR hypertension)". We also analyzed reference lists of original and review articles using a manual approach.

Study selection

Studies were selected for analysis if they met the following criteria: 1) published as full-length articles in English; 2) analyzed adult participants who ingested soy isoflavones for 1—12 months; 3) reported completed, published, randomized, double-blind and placebo-controlled trials with either a parallel or a crossover design; 4) examined at least 10 subjects; 5) reported means or differences between means of SBP and DBP at the start and end of the intervention, and also included standard deviations (SD), standard errors (SE), 95% confidence intervals (CIs), or probability values; and 6) provided the dose and duration of isoflavone treatment for a given soy protein intake level.

Data extraction and quality assessment

Searching, data extraction, and quality assessment were completed independently by two authors (X.X. Liu and S.H. Li) according to the inclusion criteria. Discrepancies were resolved by consensus. Extracted data included the treatment regimen (doses of soy protein and isoflavones, duration of treatment), the characteristics of the participants (number, age, sex and health status) and assessment of the mean change in SBP/DBP.

The quality of the studies was judged by concealment of treatment allocation, quality of randomization, blinding, reporting of withdrawals, and generation of random numbers. Trials scored one point for each area addressed, with a possible score between 0 and 5, where 5 represented the highest level of quality [22].

Statistical analysis

Changes in the mean SBP/DBP of soy isoflavones and control groups were entered into the meta-analysis at the start and end of the intervention. Estimates of weighted mean differences (WMDs) and 95% CIs were obtained using random-effect models [23]. Interstudy heterogeneity was formally tested using Cochrane's test ($P < 0.1$). The I^2 statistic was also examined, and a value of $I^2 > 50\%$ indicated significant heterogeneity between the trials [24]. Meta-regression analyses and previously defined subgroup analyses were performed to identify the possible source of heterogeneity. Potential publication bias was assessed with Egger regression test [25] and funnel plots. Meta-analysis and statistical analyses were performed with Stata software (version 10.0; Stata Corporation, College Station, TX) and REVMAN software (version 5.0; Cochrane Collaboration, Oxford, United Kingdom).

Results

Search results

A total of 1080 articles were identified, 1045 were excluded because they did not describe randomization and controlling or because their objectives were irrelevant to the present meta-analysis. Of the 35 potentially relevant articles screened, eleven met the selection criteria for meta-analysis [7—17] (Fig. 1). Twenty-four trials were excluded because the sources of isoflavones in 2 trials were not from soy protein; 6 trials were not randomized, double-blind, and controlled; 2 included less than 10 subjects; 4 did not measure BP; and 3 reported incomplete data for mean SBP and DBP or for SD; 6 were excluded because isolated isoflavone extracts alone were utilized. One short-term study of 7 h was excluded as well.

Study characteristics

The characteristics of the final included eleven trials are presented in Table 1. Four trials utilized a crossover design [8,9,12,17]. The sample size varied from 18 to 302 subjects. The average age of the subjects ranged from 48.5 to 66.7

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