

Hypertension and Soy: A Best Evidence Review

Introduction

Best Evidence Reference

Effect of Soy Nuts on Blood Pressure and Lipid Levels in Hypertensive, Prehypertensive, and Normotensive Postmenopausal Women

Welty FK, Lee KS, Lew NS, Zhou JR
Arch Intern Med. 2007;167:1060-1067

Abstract

This study was selected from [Medscape Best Evidence](#), which uses the McMaster Online Rating of Evidence System. Of a possible top score of 7, this study was ranked as 6 for newsworthiness and 6 for relevance by clinicians who used this system.

Commentary

According to the 2003 guidelines from the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, the risk for cardiovascular disease, beginning at blood pressure of 115/75 mm Hg, doubles with each increment of 20/10 mm Hg. Furthermore, individuals who are normotensive at 55 years of age have a 90% lifetime risk of developing hypertension. Finally, individuals with a systolic BP of 120-139 mm Hg or a diastolic BP of 80-89 mm Hg should be considered as prehypertensive and require health-promoting lifestyle modifications to prevent cardiovascular disease.^[1]

The goal of the trial under discussion in this review was to evaluate whether use of soy protein instead of other protein sources, as part of the Therapeutic Lifestyle Changes (TLC) diet, provides added benefit for postmenopausal hypertensive and normotensive women compared with the usual TLC diet. The TLC diet is recommended by the National Cholesterol Education Program (NCEP) in subgroups of people with specific medical conditions and risk factors, such as high LDL cholesterol or other lipid disorders, cardiovascular disease, diabetes mellitus, insulin resistance, or metabolic syndrome.

The source of soy protein provided in the study was a half cup of unsalted, dry-roasted soy nuts containing 25 g of soy protein and 101 mg of aglycone isoflavones (genistein, daidzein, and glycitein).

A total of 60 postmenopausal women (48 with normal blood pressure and 12 with hypertension) participated in this randomized, crossover trial testing a TLC diet alone vs TLC diet of similar energy with 25 g of soy protein substituted for 25 g of non-soy protein. Exclusion criteria included:

- Current cigarette smoking or smoking in the previous year;
- Coronary artery disease;
- Diabetes or fasting blood sugar > 126 mg/dL;
- History of breast cancer;
- Systolic blood pressure (SBP) of 165 mm Hg or diastolic blood pressure (DBP) of 100 mm Hg;
- Systemic or endocrine disorder affecting bone, mineral, or lipid metabolism;
- More than 21 drinks per week; and
- Use of lipid-lowering drugs, hormone therapy, or osteoporosis medication.

Use of soy products was discontinued for 2 months prior to the start of the study. Participants were taught to follow the TLC diet, which consisted of the following breakdown, supplied by registered dietitians:

- 30% of total calories from fat (\leq 7% saturated, 12% monounsaturated, 11% polyunsaturated);
- 15% of calories from protein;
- 55% carbohydrates;
- $<$ 200 mg of cholesterol each day;
- 1200 mg of calcium;
- 2 fatty fish meals per week; and
- Sodium limited to 2 g per day for those who were hypertensive.

During the first 8 weeks, participants were randomized to either the soy or the non-soy TLC diet followed by a 4-week TLC-diet-alone washout period and then a crossover to the other arm for the last 8 weeks. Participants were instructed to maintain their current level of exercise. Those not exercising at the start of the experiment were instructed to walk 30 minutes each day and to maintain the same level of physical activity throughout the trial to avoid confounding of weight loss and exercise. Those with an exercise routine were instructed to continue and maintain the same level throughout the study period. Participants recorded the minutes of physical activity each day throughout the trial.

Data collected included:

- Lipid profiles at the end of each 8-week period;
- 24-hour urine sample for isoflavone and creatinine levels, to test for compliance with the soy protein and determine whether there were between-group differences; and
- 2 blood pressure readings at the end of each diet period taken at least 30 seconds apart at the follow-up visits; if the discrepancy between readings was $>$ 5 mm Hg, a third measurement was taken.

Results were as follows:

- Soy nuts significantly reduced SBP and DBP in all of the hypertensive women and 83% of the normotensive women.
- Mean decrease of SBP was 9.9% (15 mm Hg) in hypertensive women and 5.2% (roughly 6 mm Hg) in normotensive women.
- Mean decrease of DBP was 6.8% (nearly 6 mm Hg) in hypertensive women and 2.9% (2 mm Hg) in normotensive women.
- Body mass index and daily exercise remained steady for participants in the study.
- Low-density lipoprotein cholesterol and apolipoprotein B were lowered by 11% and 8%, respectively, in the hypertensive women on the soy diet; no change in lipid profile was seen in normotensive women.

Rates of coronary heart disease are lower in Asian than in Western countries.^[2,3] Soy in the diet may partially explain this difference. The study by Welty and colleagues showed that the simple dietary change of substituting soy protein for non-soy protein can lower blood pressure by approximately the same magnitude of antihypertensive medications. The trial also suggests that dietary soy can reduce cholesterol in those with high blood pressure.

As is known from preceding studies, small differences in blood pressure can make big differences in cardiovascular risk:

- Increase of SBP by 20 mm Hg and DBP by 10 mm Hg doubles cardiovascular risk.^[4]

- Reductions of 12 mm Hg in SBP for 10 years prevents 1 death for every 11 patients with stage 1 hypertension.^[5]
- Reducing DBP by 2 mm Hg can lower risk for coronary heart disease by 6% and stroke by 15%.^[6]

Although this is not the first study to affirm an association between soy and reduction of blood pressure,^[7,8] it does open up another possibility of what form of soy to eat; a handful of dry-roasted, unsalted soy nuts is an especially convenient and satiating option for patients.

Another intriguing question addressed by this trial is: What constitutes the active ingredient(s) in soy? In the hypertensive group of the current study, the control and soy diets contained the same amount of protein, polyunsaturated fat, and carbohydrate; only the isoflavone content was higher in those on the soy diet. Is this the factor, therefore, responsible for the benefit seen in both blood pressure and lipids in the hypertensive group? Dietary isoflavones are thought to be cardioprotective because of their structural similarity to estrogen.^[9,10] Some studies suggest that the nature of the proteins may increase the anti-inflammatory response and contribute to the atherosclerosis-preventive activities of a soy-rich diet.^[11,12] Such questions, however, cannot be answered from this study design, which involved only 12 hypertensive women. (The soy vs non-soy diets of the 48 normotensive women differed not only in isoflavone content but also in protein, polyunsaturated fat, and carbohydrate content.) In addition, phytoestrogen supplements in the form of isolated isoflavone tablets have had no effect on blood pressure in earlier trials.^[13,14] As with other dietary vs supplement issues (eg, antioxidants from foods vs from vitamins),^[15] the answer may be whole foods; whole sources are best for supplementing and balancing the nutrients needed for maintenance of normal blood pressure, cardiovascular health, and health in general.

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