# Soy and Heart Health



**2011 EDITION**

In 2006, the most recent year for which data are available, an estimated 17.6 million Americans were affected by coronary heart disease (CHD), which includes myocardial infarction and angina pectoris. It is estimated that in 2010, about 785,000 Americans had a new coronary attack; 470,000 suffered a recurrent attack; and an additional 195,000 had a silent first heart attack.[1]

The number of coronary deaths divides approximately evenly between men and women, although the average age of a person having a first heart attack is 64.5 for men and 70.3 for women. Approximately 425,425 Americans died of CHD in 2006, representing about 17 percent of all deaths in the United States and making CHD the number one killer of Americans.[2]

Despite these grim statistics, CHD death rates decreased by a remarkable 59 percent between 1950 and 1999, and by 33 percent between 1994 and 2004. While much of this decrease is due to improved medical treatment, improvements in lifestyle also greatly impact CHD morbidity and mortality. In most people, the etiology of CHD primarily involves risk factors that can easily be modified through lifestyle changes.

An analysis of three large prospective cohort studies that included approximately 400,000 participants found that about 90 percent of CHD patients have at least one of the following risk factors:[3]

- *High total blood cholesterol levels (≥240 mg/dl or 6.22 mmol/l) or current medication with cholesterol-lowering drugs*
- *Hypertension (systolic blood pressure ≥140 mm Hg or diastolic blood pressure ≥90 mm Hg) or current medication with blood pressure-lowering drugs*
- *Current cigarette use*
- *Clinical report of diabetes*

Dietary choices can significantly impact the risk of developing CHD. While markedly reducing CHD risk via dietary modification requires a comprehensive approach, there is no doubt that soyfoods can play an important role in heart-healthy diets.

## Effects of Soyfoods on Circulating Lipid Levels

Soyfoods have been recognized by nutritionists for decades as rich sources of high-quality protein. Over the past 15 years, the effect of soy protein on blood cholesterol levels has attracted attention from the nutrition and medical communities. Research in this area was first conducted decades ago. The first rodent studies[4, 5] showing that soy protein lowered cholesterol levels were published more than 60 years ago, and the first clinical trial demonstrating this effect was published in 1967.[6] Throughout the 1970s and 1980s, Italian researchers were instrumental in showing that soy protein directly lowered blood cholesterol levels in very hypercholesterolemic patients.[7-9] Nevertheless, it was not until 1995 that the cholesterol-lowering effects of soy protein received widespread recognition.

In that year, a meta-analysis of the clinical data, which included 38 different comparisons, found that soy protein reduced low-density lipoprotein (LDL) cholesterol by approximately 13 percent.[10] This reduction was independent of the fatty acid content of soyfoods and was larger than that reported for any other single non-pharmacological treatment. Because statins were not yet widely used in clinical practice, the effect of soy protein was essentially equal to that of the available cholesterol-lowering medications.

The results of the 1995 meta-analysis prompted much investigation into the cholesterol-lowering effects of soy protein. Some of this research has been directed at identifying the specific soybean components and mechanisms responsible for cholesterol reduction, whereas other research explored the responses to soy protein in different subpopulations such as hypercholesterolemic subjects or pre- and postmenopausal women. In regard to mechanism, some data suggest that cholesterol reduction is a result of the upregulation of hepatic LDL receptors by the peptides formed upon digestion of soy protein.[11, 12] Researchers also continue to explore whether isoflavones in soybeans impact the cholesterol-lowering effects of soy protein.[13] Soybeans are essentially the only nutritionally-relevant source of these diphenolic compounds.[14]

**FDA-Approved Health Claim for Soy:**
*25 grams of soy protein per day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease*

In 1999, the U.S. Food and Drug Administration (FDA) approved a health claim for soy protein and CHD based on its cholesterol-lowering effects.[15] Despite the large amount of research upon which the health claim was based, the cholesterol-lowering ability of soy protein has come under challenge in recent years. The FDA announced in December 2007 their intention to re-evaluate the evidence in support of the claim, although they have stated publically that the reason for doing so is not because the evidence is no longer supportive, but rather, because of the large number of relevant clinical trials published since the claim was first approved.

In 2008, the American Heart Association (AHA) formally expressed their opposition to the health claim being affirmed. In their

*Recent research indicates that soy protein lowers LDL cholesterol by 3 to 5 percent. On a population level, each 1 percent decrease in LDL reduces CHD risk and/or mortality by 2 to 5 percent. Therefore, even a 3 percent reduction in LDL could lower risk for heart disease by as much as 15 percent.*

2006 position paper, the AHA acknowledged the important role soyfoods can have in heart-healthy diets because they are low in saturated fat and high in polyunsaturated fats.[16] However, the decrease in LDL in response to soy protein, which they estimated based on the results of 22 studies to be approximately 3 percent, was insufficient in their view to warrant a health claim.[16] The AHA endorsed the health claim in 2000 shortly after it was first issued.[17]

Importantly, however, the AHA did not conduct a formal statistical analysis of the 22 studies upon which they based their estimate of the potency of soy protein. When such an analysis was conducted, Jenkins et al.[18] found that the AHA had considerably underestimated the hypocholesterolemic effects of soy protein. Further, when the analysis was limited to the 11 studies that provided evidence that the control and soy diets were matched, soy protein was found to lower LDL by 5.2 percent. This estimate is in line with the results of other recently published meta-analyses[19-21] and is similar to the effects of soluble fiber, which also boasts a health claim.[22] Furthermore, recent research suggests that soy protein decreases postprandial triglyceride levels, which is increasingly viewed as important for reducing CHD risk.[23]

In addition to the direct effect of soy protein, Jenkins et al.,[18] using National Health and Nutrition Examination Survey III population survey data, estimated as a result of differences in fatty acid intake that, when soyfoods replace more traditional sources of protein in the Western diet, LDL is reduced by 3-6 percent. There was a 4 percent reduction in LDL when 24 g soy protein – an amount similar to the 25 g/day established by FDA as the threshold intake for cholesterol reduction – replaced a comparable amount of the more commonly consumed protein sources. Thus, as a result of the combination of soyfoods displacing traditional source of protein in Western diets (which tend to be high in saturated fat) and the direct effects of soy protein, soyfoods can be expected to decrease LDL by approximately 8 percent. Although the current estimates of the cholesterol-lowering effects of soy protein are lower than initially reported, since each 1 percent decrease in LDL lowers CHD risk 1-3 percent, incorporating soyfoods into the diet can substantially reduce CHD morbidity and mortality.[24, 25]

*Substituting soyfoods for protein-rich foods higher in saturated fat may lead to a decrease in blood cholesterol.*

It is important to note that 25 g/day soy protein was established as the threshold intake because most trials used at least this much protein and not because less than this amount is inefficacious. In fact, there is evidence suggesting that lower amounts are indeed efficacious.[20, 26] Not surprisingly, comprehensive dietary approaches that have resulted in reductions in LDL ranging from 20-30 percent have relied heavily on soyfoods; the high quality of soy protein and its hypocholesterolemic effects combined with the favorable fatty

acid profile of soyfoods make these foods especially attractive in such diets.[27] Recent analyses indicate that, to lower CHD, saturated fat should be replaced with polyunsaturated fat and not the refined carbohydrate that is often the case.[28, 29] As discussed below, soyfoods are high in polyunsaturated fat.

Approximately 84 percent of the lipids in soybeans are unsaturated. The predominant fatty acid in soybeans is the essential omega-6 fatty acid linoleic acid, which reduces blood cholesterol levels.[30] Over the years, some concerns have arisen that too much of this fatty acid could increase CHD risk by increasing inflammation. Recently, the AHA rejected concerns about the pro-inflammatory properties of omega-6 fats and concluded that that these fatty acids play a critically important role in heart-healthy diets.[31] However, recent analysis indicates that the most efficacious substitution is when saturated fat is replaced with a combination of omega-6 and omega-3 polyunsaturated fat.[32] In addition to providing omega-6 fats, soybeans provide alpha-linolenic acid (ALA), an essential omega-3 fatty acid.[33] Although ALA does not possess the same properties as the long-chain omega-3 fatty acids found in cold-water fish, evidence suggests that ALA has direct coronary benefits; the degree is a matter of some debate.[34-37]

Finally, in response to the ingestion of soy protein, meta-analyses have found very modest increases (1-3 percent) in high-density lipoprotein (HDL) cholesterol and modest decreases (5-10 percent) in triglyceride levels. Each 1 percent or 1 mg increase in HDL lowers CHD risk by 2-3 percent.[33-35] Although there is debate about whether an elevated triglyceride level is an independent predictor of CHD risk,[36] recent evidence suggests that the role of fasting triglyceride levels in the etiology of CHD has been underestimated.[37, 38] Furthermore, new research suggests that soy protein decreases postprandial triglyceride levels, elevated levels of which are increasingly viewed an important CHD risk.[23]

## Beyond Effects on Lipid Levels

There is epidemiologic evidence that soyfoods exert coronary benefits independent of their effect on blood cholesterol levels. For example, after controlling for a wide variety of CHD risk factors, a prospective study involving nearly 65,000 postmenopausal women from Shanghai found that soy protein intake was associated with an 86 percent reduction in the risk of non-fatal myocardial infarction.[39] In agreement, a cross-sectional study involving 406 Chinese adults

ages 40-65 years old (134 males, 272 females) without confirmed relevant diseases found that soyfood intake was inversely related to bifurcation intima-media thickness, although the association was more apparent in men than women.[40] Also, a prospective study involving 40,462 Japanese participants (40-59 years old, without cardiovascular disease or cancer at baseline) found that, when comparing women with frequent (≥5x/week) versus infrequent (≤2x/week) soy consumption, the multivariable hazard ratios were 0.64, 0.55 and 0.31 for risk of the incidence of cerebral infarction, myocardial infarction and CHD mortality, respectively.[41]

For two reasons, it is highly unlikely that the cholesterol-lowering effects of soyfoods were primarily responsible for the effects observed in these three epidemiologic studies. First, soy protein consumption in the upper intake categories was between 8 and 16 g/day, which, based on the results from the clinical studies, is likely too little to lower cholesterol. Second, the protective effects were far greater than could be expected from the cholesterol reduction typically associated with soy protein. Perhaps it is possible the observed protection could simply be the result of soyfood intake being associated with a healthier overall lifestyle (i.e., healthy user effect). This explanation is also unlikely because most of the studies controlled for a wide range of potentially confounding variables, and soy consumption in Asia is much less reflective of an overall lifestyle than it is in countries where soyfoods have not been part of the traditional diet.

In support of the epidemiologic studies are various clinical studies that show soyfoods, soy protein or soybean isoflavones favorably affect a number of biological measures that impact heart disease risk. The proposed hypotensive effects of soyfoods are particularly intriguing. A recent meta-analysis found that soyfoods reduced systolic and diastolic blood pressure by about 6 mm Hg and 4 mm Hg, respectively, although these data were based on only five studies.[42] Other biological processes and measures related to heart disease that may be favorably affected by various soy components include endothelial function, systematic arterial compliance, LDL-oxidation and LDL particle size.[43] However, because of the inconsistent and/or limited data, no conclusions can be made about the effects of soy on these CHD markers except for endothelial function.

*Heart disease is the leading cause of death for both men and women in the United States.*

Endothelial cells line the blood vessels and their functioning can impact CHD risk. A recent meta-analysis found that soybean isoflavones favorably improved endothelial function in postmenopausal women. When the data from this meta-analysis were subanalyzed, the improvement was only found in those women who had impaired endothelial function at baseline. Of course, these women are at greater risk of having or developing CHD. This finding provides an explanation for the inconsistent literature in that some studies included women with both impaired and normal endothelial function. It may also be that the observed anti-inflammatory effects of isoflavones occur only in subjects at risk of CHD who have elevated levels of inflammatory markers.[44]

### Heart Healthy Sources of Soy Protein

| Soyfood | Serving size | Grams of soy protein |
|---|---|---|
| Fortified soymilk | 1 cup | 6-7 |
| Soy cereal | 1 ¼ cup | 7 |
| Soy yogurt, vanilla | 1 cup | 6 |
| Soy breakfast patty | 2 patties | 11 |
| Soy bar | 1 bar | 14 |
| Soy chips | 1 bag | 7 |
| Soynut butter | 2 Tbsp | 7 |
| Soynuts, roasted, unsalted | ¼ cup | 11 |
| Tofu | ½ cup | 10 |
| Edamame | ½ cup | 11 |
| Soy burger | 1 patty | 13-14 |
| Soy pasta | ½ cup (cooked) | 13 |
| Soy pudding | ½ cup | 6 |

## How Much Soy Protein do Asians and Americans Consume?

There exists considerable confusion in some circles about the role soy plays in the diets of Asian populations and precisely how much soy Americans consume. Soy protein is widely used by the food industry and is found in small amounts in an extensive array of foods in the U.S. However, soy protein is added to foods primarily for its functional properties, i.e., to improve shelf stability and texture. Consequently, U.S. daily per capita soy protein intake is only 1-2 g/day. That represents about 2 percent of total protein intake.[45] Obviously, because soy protein intake is so low, U.S. isoflavone intake is also very low (<2 mg/day). Furthermore, although each gram of protein in minimally processed or traditional soyfoods is associated with about 3.5 mg isoflavones, the protein used by the food industry is often quite low in isoflavones.

In Japan, the daily intake of soy protein among those consuming a traditional diet is approximately 10 g, which represents more than 10 percent of their total protein intake.[46] Large studies from Shanghai, China, show men consume about 12-13 g of soy protein per day,[47] which represents about 15 percent of total protein intake,[48] and that women consume about 9 g/day.[49] Individuals in the upper one-quarter of intake consume about 15-20 g soy protein daily. Ten grams soy protein translates to about 1.5 servings since 1 serving of a traditional soyfood provides about 7 g protein, although some soyfoods can provide considerably more than this.

In Japan, about half of soy intake comes via unfermented foods, and four foods – tofu, miso, natto and fried tofu – account for about 90 percent of all soy consumption.[50, 51] In Shanghai, most of the soy consumed is unfermented, and soymilk, tofu and processed soy products other than tofu account for about 80 percent of total soy consumption.[39]

In conclusion, these intake data indicate that most Americans need to substantially increase their soy intake to match the levels common to the traditional cuisines of many Asian populations. This can easily be done through a variety of fermented and unfermented soyfoods.

## Summary and Conclusions

In summary, soyfoods may make important contributions to heart-healthy diets through several different mechanisms. They provide high-quality protein but minimal amounts of saturated fat. They provide ample amounts of omega-6 and omega-3 essential fatty acids. Importantly, soy protein directly lowers blood cholesterol levels, modestly elevates HDL and decreases triglyceride levels. Finally, soyfoods appear to favorably affect CHD risk factors independent of lipid levels such as endothelial function, systematic arterial compliance, LDL oxidation, LDL particle size and blood pressure.

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The United Soybean Board (USB) is a farmer-led organization comprised of 69 farmer-directors. Working with independent academic researchers affiliated with the National Institutes of Health (NIH) and academic institutions, USB has invested millions of dollars into health and nutrition research related to soy. Soybean farmers take pride in producing one of the healthiest food crops in the world. To access healthy soy recipes and more nutrition information, please visit SoyConnection.com.



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