Decades of Research Show Soy Protein Lowers LDL-Cholesterol

Author : Dr. Mark Messina

Date : July 25, 2019

Two newly published analyses support the efficacy of soy protein for lowering blood cholesterol levels.[1,2] Published in top tier peer-reviewed nutrition and medical journals, the combined research directly addresses recent challenges to the cholesterol-lowering effect of soy. Adding to the significance of this work is that the analyses were based on the 46 studies that the U.S. Food and Drug Administration included in its recent evaluation of the evidence related to the existing soy protein and coronary heart disease health claim.[3]

The FDA approved a health claim for soy protein in 1999.[4] Since that time, 11 other countries have approved similar claims,[5] the most recent to do so was Canada, which approved its claim in 2015.[6]

In the first analysis, which was published in the *Journal of Nutrition*, David Jenkins, MD, PhD and colleagues from the University of Toronto, found that soy protein significantly lowers LDL-cholesterol, the type of cholesterol known to raise risk of heart disease.[1] This finding concurs with several previously published meta-analyses.[7-9]

A meta-analysis is a statistical procedure for combining data from multiple studies. Decisions about the effectiveness of an intervention cannot be based on the results of a single study, because results typically vary from one study to the next. Meta-analyses overcome this problem by synthesizing data across studies. However, in its evaluation of the evidence supporting the health claim, the FDA chose not to meta-analyze the data.[3]

Of the studies identified by the FDA, 41 involving 3,228 participants were determined to be suitable for inclusion in the meta-analysis by Dr. Jenkins and colleagues for the evaluation of LDL-cholesterol.[1] The analysis found that soy protein lowered LDL-cholesterol 3.2%. Although modest, over time, each 1% reduction in LDL-cholesterol is thought to reduce the risk of heart disease by 1 to 2%. Jenkins also found the results of the studies to be consistent in that three out of every four studies in the analysis showed a reduction in LDL-cholesterol, although not all of these were statistically significant.

The second analysis by Dr. Jenkins and colleagues, which was published in the *Journal of the American Heart Association*, consists of a cumulative meta-analysis of the FDA-identified studies.[2] The analysis aimed to determine whether at any point -- before or after the FDA authorized soy protein health claim was approved -- the data showed soy protein did not statistically significantly lower cholesterol. Statistical significance is the means by which scientists determine whether a

finding is likely to have occurred by chance. If a finding is statistically significant, there is high likelihood that the observed finding is reliable.

For the cumulative analysis, a meta-analysis was conducted chronologically each time another study was published. The studies in the cumulative analysis were published over the past three decades, between 1981 and 2013. So, for example, in 1999, when the health claim was approved, the cumulative meta-analysis included 11 data points whereas by 2003, the analysis included 27 data points and by 2013, it included 50 data points. Importantly, at every stage of the cumulative meta-analysis the LDL-cholesterol-lowering effect of soy protein was shown to be statistically significant.

The combined research by Dr. Jenkins and colleagues provides important understanding of the cholesterol-lowering effect of soy protein. It shows that despite the recent challenges to its efficacy, soy protein significantly lowers LDL-cholesterol levels and further, that the effect of soy protein has remained consistent over the past three decades. Clearly, this research supports the value of soy protein for lowering cholesterol and the role that foods containing soy can play in heart-healthy diets.

1. Blanco Mejia S, Messina M, Li SS, et al. A meta-analysis of 46 studies identified by the FDA demonstrates that soy protein decreases circulating LDL and total cholesterol concentrations in adults. *J Nutr*. 2019;149(6):968-81.
2. Jenkins DJA, Blanco Mejia S, Chiavaroli L, et al. Cumulative meta-analysis of the soy effect over time. *Journal of the American Heart Association*. 2019;8(13):e012458.
3. Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease. A Proposed Rule by the Food and Drug Administration on 10/31/2017. https://www.federalregister.gov/documents/2017/10/31/2017-23629/food-labeling-health-claims-soy-protein-and-coronary-heart-disease.
4. Food labeling: health claims; soy protein and coronary heart disease. Food and Drug Administration, HHS. Final rule. *Fed Regist*. 1999;64(206):57700-33.
5. Xiao CW. Health effects of soy protein and isoflavones in humans. *J Nutr*. 2008;138(6):1244S-9S.
6. Summary of Health Canada's Assessment of a Health Claim about Soy Protein and Cholesterol Lowering. Bureau of Nutritional Sciences Food Directorate Health Products and Food Branch. https://www.canada.ca/en/health-canada/services/food-nutrition/food-labelling/health-claims/assessments/summary-assessment-health-claim-about-protein-cholesterol-lowering.html.
7. Anderson JW, Bush HM. Soy protein effects on serum lipoproteins: A quality assessment and meta-analysis of randomized, controlled studies. *J Am Coll Nutr*. 2011;30(2):79-91.
8. Jenkins DJ, Mirrahimi A, Srichaikul K, et al. Soy protein reduces serum cholesterol by both intrinsic and food displacement mechanisms. *J Nutr*. 2010;140(12):2302S-11S.
9. Zhan S, Ho SC. Meta-analysis of the effects of soy protein containing isoflavones on the lipid profile. *Am J Clin Nutr*. 2005;81(2):397-408.