Soy and Health

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Cleared by: Gert Meijer, VP Nutrition & Health, 21 September 2007

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Dear Health Professionals,

As part of its vitality mission, Unilever is constantly investing across the globe to improve the nutritional profile of its products while maintaining their flavour, quality and convenience and to communicate their nutritional value in a credible and responsible way. In order to bring its mission to life, Unilever has a center of excellence in Nutrition, Health and Vitality based in The Netherlands – the Unilever Food and Health Research Institute (UFHRI).

Scientists and professionals from many countries work for the UFHRI in multidisciplinary teams. They are supported by a team of professionals and specialists, including food engineers, dietitians, nutritionists, biochemists and biologists, spread across the globe. Together they support both the development of new and improvement of current Unilever products as well as their communication.

Five benefit areas and five ingredients have been selected as priorities for research and development. The ingredients have been chosen based on their recognized potential health benefits. One of these ingredients is soy. Unilever already has a strong position in soy beverages in Latin America with the AdeS brand and aims to build global leadership in soy beverages and other categories.

Aligned with these objectives, Unilever maintains constant contact with health professionals via the UFHRI - Unilever Food and Health Research Institute. As a result of this relationship, this material was created to discuss recent studies published on soy and its relationship with health.

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1 NUTRITIONAL PROFILE of soy beans

The soy bean has its roots in China. Soy beans were first grown there approximately 6000 years ago. Today soy is cultivated throughout the world, particularly in Latin America, North America and Asia.

Soy belongs to the legume family and, like other legumes, is rich in nutrients. Soy beans are a good source of protein, fibre and unsaturated fatty acids. They are low in saturated fatty acids and do not contain trans fatty acids. Furthermore, soy beans contain both omega 6 and omega 3 fatty acids, such as linoleic acid (56 % of total fat) and alpha-linolenic acid (7-8 % of total fat). The protein in soy is of good quality (Protein Digestibility Corrected Amino Acid Score [PDCAAS] of 0.9 to 1), comparable to dairy. Cooked soy beans are rich in iron and phosphor and a good source of magnesium, vitamin B2 (riboflavin) and folate.

Over the past 15 years, soy foods have become popular in non-Asian countries because of their suggested health effects. Much of the research has focused on the health of women, in particular postmenopausal women. This can be explained by the fact that soy beans are rich sources of isoflavones. Soy beans isoflavones belong to a class of plant compounds called phytoestrogens, which have estrogen-like effects. Soy beans and their products contain ~ 3.5 mg isoflavones per g protein. In Western countries, the daily intake of isoflavones via the diet is estimated to be less than 3 mg, whereas in Japan it is between 25 and 40 mg.

However, most of the heath benefits of soy, especially its cardiovascular benefit, are associated with its protein content. In 1999 the US Food and Drug Administration approved a health claim for soy products that provide at least 6.25 g soy protein per serving stating that ‘Diets low in saturated fat and cholesterol that include 25 g of soy protein a day may reduce the risk of heart disease”.

Soy beans can be eaten cooked as part of a meal, or processed to soy milk, tofu, tempeh or soy sauce. These foods are produced using different methods and each has its own nutrient profile.

2 THE CONSENSUS ON soy and health benefits

The health effects of soy have gained considerable attention from the scientific community, especially for its potential role in improving blood lipid profile, one of the important risk factors for cardiovascular disease. There are also other interesting results linking soy to potential benefits for diabetes, obesity, osteoporosis, cancer, menopause and lactose intolerance.

- ***Soy and cholesterol lowering:*** It is generally accepted that substituting animal protein with soy protein lowers the LDL cholesterol level. A lot of feeding studies in volunteers have investigated this and the average effect was captured in so-called 'meta-analyses'. A first meta-analysis showed that the LDL cholesterol-lowering efficacy of 30-50 g of soy protein was 13%. In 2006, a meta-analysis published by the American Heart Association reported that the average LDL cholesterol-lowering effect of soy protein was only 3%.

  This has led to confusion and triggered negative press. However, one should bear in mind that soy is a food, not a statin and that the 3% reduction is still relevant for prevention of cardiovascular problems. Health authorities in the USA and UK have approved claims on soy protein and cholesterol lowering, provided that there is a minimum amount of soy protein in one serving (5 g in UK; 6.5 g in USA).

- ***Soy, the menopause and hot flushes:*** Some experimental research in postmenopausal women suggests that isoflavone supplementation may produce a moderate reduction in number of hot flushes, especially in women who frequently experience hot flushes.

  However, other studies have not shown any consistent evidence for that. The key question that remains is whether it is useful to start consuming soy isoflavones when entering the menopause or whether a lifelong consumption, such as in Asia, is needed.

- ***Soy and body weight:*** There is no convincing evidence from human studies that soy protein is better than other protein sources to achieve weight or fat loss. Soy protein does not provide more satiety than other types of protein. Supplementation with isoflavones may increase muscle mass in postmenopausal women, with larger effects seen in combination with physical activity, but the evidence is still very limited.

- ***Soy and cancer:*** From observational, i.e. epidemiologic studies, there is some evidence that high intake of soy foods prevents cancer of breast and possibly prostate. It is very hard to find conclusive evidence for a causal relationship between high soy intake and lower cancer risk as such experiments would take several of decades and would require large study groups.

3 POSSIBLE ADVERSE effects of soy

Several adverse effects of high (supplemental) doses of soy isoflavones have been suggested, including reduced semen quality in men, increased risk of breast cancer in women at high risk for breast cancer, and decreased thyroid function in people with iodine deficiency.

However, there is little data in humans to underpin these potential adverse effects; on the contrary, there is some data to contradict these proposed negative effects. These potential health effects are not associated with normal consumption, such as regular consumption of tofu or soy sauce.

There are so-called antinutritional substances in soy, such as trypsin inhibitors and phytate. These compounds interfere with protein digestibility and iron uptake, respectively. However cooking usually counteracts the effects of these compounds.

4 SOME RECENT developments in the area of soy and health

In the following pages, knowledgeable health professionals brought discuss some recent scientific publications on soy and its relationship with health in the areas of bone health, cognitive functioning and glycaemic control.

At menopause, the concentration of natural estrogens usually drops sharply. This may lead to increased circulating levels of lipids, increased abdominal fat mass, and acceleration of the ageing process: bones are becoming less dense, and memory and speed of information processing (i.e. parts of so-called 'cognitive functioning') may decline.

Estrogen replacement therapy is effective for maintaining bone mass, but because of its side-effects, it is no longer recommended for this purpose. Supplementation with soy isoflavones has been tested as a 'natural' way to promote **bone health**. Furthermore, isoflavone supplementation has been tested for beneficial effects on certain aspects of **cognitive functioning**. In the area of soy (protein) and cardiovascular disease, attention has shifted from lowering of lipids, towards improvement in vascular function - the ease with which blood vessels dilate -, lowering of blood pressure and healthy regulation of blood glucose (**glycaemic control**).

4.1 ISOFLAVONES AND BONE
loss in postmenopausal women

Marini H, Minutoli L, Polito F, Bitto A, Altavilla D, Atteritano M, Gaudio A, Mazzaferro S, Frisina A, Frisina N, Lubrano C, Bonaiuto M, D'Anna R, Cannata ML, Corrado F, Adamo EB, Wilson S, Squadrito F. Effects of the phytoestrogen genistein on bone metabolism in osteopenic postmenopausal women: a randomized trial. Ann Intern Med 2007;146:839-47.

Abstract:

Observational studies and small trials of short duration suggest that the isoflavone phytoestrogen genistein reduces bone loss, but the evidence is not definitive. to the objective was to assess the effects of genistein on bone metabolism in osteopenic postmenopausal women. It was a randomized, double-blind, placebo-controlled trial in 3 university medical centers in Italy.

389 postmenopausal women with a bone mineral density (BMD) less than 0.795 g/cm2 at the femoral neck and no significant comorbid conditions.

After a 4-week stabilization period during which participants received a low-soy, reduced-fat diet, participants were randomly assigned to receive placebo (n = 191) or 54 mg of genistein (n = 198) daily for 24 months. Both the genistein and placebo tablets contained calcium and vitamin D.

The primary outcome was BMD at the anteroposterior lumbar spine and femoral neck at 24 months. Secondary outcomes were serum levels of bone-specific alkaline phosphatase and insulin-like growth factor I, urinary excretion of pyridinoline and deoxypyridinoline, and endometrial thickness. Data on adverse events were also collected.

At 24 months, BMD had increased in genistein recipients and decreased in placebo recipients at the anteroposterior lumbar spine (change, 0.049 g/cm2 [95% CI, 0.035 to 0.059] vs. -0.053 g/cm2 [CI, -0.058 to – 0.035]; difference, 0.10 g/cm2 [CI, 0.08 to 0.12]; P < 0.001) and the femoral neck (change, 0.035 g/cm2 [CI, 0.025 to 0.042] vs. -0.037 g/cm2 [CI, -0.044 to -0.027]; difference, 0.062 g/cm2 [CI, 0.049 to 0.073]; P < 0.001).

Genistein statistically significantly decreased urinary excretion of pyridinoline and deoxypyridinoline, increased levels of bone-specific alkaline phosphatase and insulin-like growth factor I, and did not change endometrial thickness compared with placebo. More genistein recipients than placebo recipients experienced gastrointestinal side effects (19% vs. 8%; P = 0.002) and discontinued the study. Limitations: The study did not measure fractures and had limited power to evaluate adverse effects. In conclusion, twenty-four months of treatment with genistein has positive effects on BMD in osteopenic postmenopausal women.

Study description:
These Italian researchers wanted to test if genistein, one of the most common soy isoflavones, has the potential to make the bones of post-menopausal women denser. A low bone density is generally a good predictor of bone fractures in elderly subjects.

The researchers selected 389 post-menopausal women with low bone density who were otherwise healthy. The women took either a pill with 54 mg of genistein or a placebo pill daily for 24 months. Both pills contained vitamin D and calcium, which are necessary for healthy bones. At the start of the study and after 24 months, the researchers measured bone density and performed several blood tests to get an indication of bone breakdown and formation.

After 24 months, women who had been taking the pills with soy isoflavone had an increase in bone mineral density, whereas the women who had been taking the placebo pills showed a decline in bone mineral density. The difference was 10%. In addition, the concentrations of the bone markers showed that bone formation outweighed bone loss much more in women taking genistein than in women on placebo.

Comment:
This study indicates that a combination of soy isoflavones and vitamin D and calcium is effective in increasing bone density, whereas vitamin D and calcium alone are not. However, this study does not tell us whether supplementation with isoflavones alone (i.e. without vitamin D and calcium) is beneficial for bone health, nor whether life-long soy consumption would decrease bone loss during menopause.

The amount of genistein was quite high, compared to previous studies, and one would have to consume about 110 mg of mixed soy isoflavones to have a similar dose of genistein. It is not certain that exposure to mixed soy isoflavones providing this amount of genistein would produce similar effects as isolated genistein. Especially noteworthy about this study is the fact that the subjects were osteopenic; therefore, it may be that the low bone mass of these women enhanced their response to isoflavones and that similar efficacy would not be noted in women with normal bone mass.

Including this Italian study, twenty intervention studies of at least three months duration have examined the effects of soy foods, isolated soy protein, or isolated isoflavones derived from soy beans on bone health in post-menopausal women. In 13 of these trials, statistically significant favourable effects were observed in response to the intervention in at least one bone site (e.g. hip or spine). Of the seven trials that failed to find improvements only two were appropriately-designed. Dr Mark Messina, who recently visited UFHRI in Vlaardingen concluded the following about soy (isoflavones) and bone health:

"One can characterize the findings from the clinical trials as encouraging; however, an equally valid case can be made that the data are best characterized as inconsistent."

Comment by Petra Verhoef

4.2 SOY AND glycaemic control

Azadbakht L, Kimiagar M, Mehrabi Y, Esmaillzadeh A, Padyab M, Hu FB, Willett WC. Soy inclusion in the diet improves features of the metabolic syndrome: a randomized crossover study in postmenopausal women. Am J Clin Nutr 2007;85:735-41.

Abstract:

Little evidence exists regarding the effects of soy consumption on the metabolic syndrome in humans.

We aimed to determine the effects of soy consumption on components of the metabolic syndrome, plasma lipids, lipoproteins, insulin resistance, and glycemic control in postmenopausal women with the metabolic syndrome. DESIGN: This randomized crossover clinical trial was undertaken in 42 postmenopausal women with the metabolic syndrome. Participants were randomly assigned to consume a control diet (Dietary Approaches to Stop Hypertension, DASH), a soy-protein diet, or a soy-nut diet, each for 8 wk. Red meat in the DASH period was replaced by soy-protein in the soy-protein period and by soy-nut in the soy-nut period.

The soy-nut regimen decreased the homeostasis model of assessment-insulin resistance score significantly compared with the soy-protein (difference in percentage change: -7.4 +/- 0.8; P < 0.01) or control (-12.9 +/- 0.9; P < 0.01) diets. Consumption of soy-nut also reduced fasting plasma glucose more significantly than did the soy-protein (-5.3 +/- 0.5%; P < 0.01) or control (-5.1 +/- 0.6%; P < 0.01) diet. The soy-nut regimen decreased LDL cholesterol more than did the soy-protein period (-5.0 +/- 0.6%; P < 0.01) and the control (-9.5 +/- 0.6%; P < 0.01) diet. Soy-nut consumption significantly reduced serum C-peptide concentrations compared with control diet (-8.0 +/- 2.1; P < 0.01), but consumption of soy-protein did not.

Short-term soy-nut consumption improved glycemic control and lipid profiles in postmenopausal women with the metabolic syndrome

Study description:
The metabolic syndrome often occurs in overweight people. It is a clustering of metabolic abnormalities that occurs in individuals with insulin resistance (i.e. individuals whose body cells produce too little insulin to take up circulating glucose). The metabolic abnormalities include low serum concentrations of HDL-cholesterol, high serum concentrations of triglycerides, and high blood pressure. More and more subjects suffer from the metabolic syndrome.

This was a crossover clinical trial of the effects of soy consumption on markers of the metabolic syndrome in 42 postmenopausal women with the metabolic syndrome.

The women were randomized to consume a control diet (red meat-DASH diet) without soy products, a DASH diet where red meat was substituted with texturized soy protein and a DASH diet where red meat was substituted with soy-nut. DASH stands for Dietary Approaches to Stop Hypertension, which is basically a diet of low fat dairy, whole grains, and fruits and vegetables. Each diet period lasted for 8 weeks with 2 washout periods of 4 weeks (i.e. a period during which subjects consumed a usual diet). It was found that the soy diets significantly reduced insulin resistance, fasting plasma insulin and LDL-cholesterol compared to the control diet.

The reductions were stronger in the soy-nut diet, during which significant improvements in fasting blood glucose and C-peptides (i.e. peptides which are formed when proinsulin is split into insulin and C-peptide) were also observed.

Comment:
The effects of soy on blood glucose and insulin levels, although not completely new, are very relevant to health given that high blood glucose is a risk factor for type 2 diabetes and cardiovascular disease in otherwise healthy populations.

It is established that saturated fatty acids (SAFA) increase insulin resistance. In this study, one serving of red meat was substituted with 30 g of soy nut or protein on a daily basis, effects were observed in response to the intervention in at least one bone site (e.g. hip or spine). Of the seven trials that failed to find improvements only two were appropriately-designed. Dr Mark Messina, who recently visited UFHRI in Vlaardingen concluded the following about soy (isoflavones) and bone health:

resulting in a SAFA intake of 7% energy for the control diet and 5% energy for the soy diets (not statistically significant). This 28% lower SAFA in the soy diet would be expected to result in approximately 3% reduction in insulin resistance; however, 8% and 15% reductions were observed for soy protein and soy-nut diets respectively, compared to the control diet.

The soy-nut diet showed more favourable effects on insulin metabolism than texturized soy protein, possibly through better glucose handling. It is possible that a whole food such as the soy-nut, unlike soy protein, could have slowed the rate of glucose delivery into the circulation. Another advantage of the soy-nut is its higher (27%) content of polyunsaturared fats (PUFAs) compared to the soy protein.

At present, insufficient evidence exist for a PUFA effect on blood glucose and insulin levels. Also, this would not explain why the soy protein diet with the same PUFA content as the control diet resulted in lower insulin resistance. Hence, the data suggest that other mechanisms beyond fatty acids explain the effects on glucose and insulin metabolism of soy, possibly linked to fibre (which was not discussed by the authors) and/or a possible anti-oxidant and anti-inflammatory effects of soy isoflavones.

Several, but not all, studies also suggest a beneficial role of soy protein in glucose and insulin metabolism in either subjects with the metabolic syndrome or healthy individuals. More studies are required to distentangle effects of soy protein, other soy nutrients, and isoflavones. It is, however, promising to find that soy - next to the already confirmed lipid-lowering effect - may influence yet another risk factor for cardiovascular disease.

Comment by Livia Augustin

4.3 ISOFLAVONES
and cognitive function

Fournier LR, Ryan Borchers TA, Robison LM, Wiediger M, Park JS, Chew BP, McGuire MK, Sclar DA, Skaer TL, Beerman KA. The effects of soy milk and isoflavone supplements on cognitive performance in healthy, postmenopausal women. J Nutr Health Aging 2007;11:155-64.

Abstract:
The decline in oestrogen concentrations in women after menopause can contribute to health related changes including impairments in cognition, especially memory.

Because of the health concerns related to hormone replacement therapy (HRT), alternative approaches to treat menopausal symptoms, such as nutritional supplements and/or diet containing isoflavones, are of interest.

This study investigated whether soy isoflavones (soy milk and supplement) could improve cognitive functioning in healthy, postmenopausal women. A total of 79 postmenopausal women, 48-65 years of age, completed a double-blind, placebo-controlled trial in which they were randomly assigned to one of three experimental groups: cow's milk and a placebo supplement (control); soy milk and placebo supplement (soy milk, 72mg isoflavones/day); or cow's milk and isoflavone supplement (isoflavone supplement, 70mg isoflavones/day).

Cognitive functioning was assessed using various cognitive tasks before the intervention (baseline) and after the intervention (test). RESULTS: In contrast to predictions, soy isoflavones did not improve selective attention (Stroop task), visual long-term memory (pattern recognition), short-term visuospatial memory (Benton Visual Retention Test), or visuo-spatial working memory (color match task). Also, the soy milk group showed a decline in verbal working memory (Digit Ordering Task) compared to the soy supplement and control groups. In conclusion, soy isoflavones consumed as a food or supplement over a 16-week period did not improve or appreciably affect cognitive functioning in healthy, postmenopausal women.

Study description:
Decreased estrogen levels may play a role in cognitive decline in postmenopausal women. Isoflavones, due to their estrogenic effects, have hence been proposed to improve cognitive function in post-menopausal women.

In this study 79 postmenopausal women were randomly assigned to one of three experimental groups: cow's milk and a placebo supplement (control); soy milk and placebo supplement (soy milk, 72 mg isoflavones/day); or cow's milk and isoflavone supplement (isoflavone supplement, 70 mg isoflavones/day).

The study lasted 16 weeks. Before and after intervention, cognitive function was tested via a battery of several tests. The scores on the various tests were used to create scores on aspects of, e.g. memory and concentration. The soy isoflavones, either derived from soy milk or from a supplement mixed with cow's milk, did not affect cognitive function.

Comment:
This study was generally well-designed, but has two major drawbacks: the study size was small and the study duration short. Thus it may have lacked the power to show a positive effects of isoflavones, if this was indeed present.

For comparison, a 3-year study among ~800 subjects aged 50-70 years was needed to find that folic acid supplementation improved memory and cognitive speed.

Including this study, 9 human intervention studies have tested effects of soy isoflavones on cognitive function. Most of these studies included post-menopausal women. The doses of isoflavones ranged from 60-110 mg/d, and the duration ranged from 1-52 weeks.

Three of these studies showed no beneficial effect of isoflavones of cognitive function, whereas the other six showed beneficial effects on one or more cognitive tests. Two of the negative studies were the largest (both ~200 subjects) and the longest (24 and 52 weeks), which makes them more credible. Currently, there is too little evidence to conclude that isoflavones improve cognitive function in post-menopausal women.

Comment by Petra Verhoef

5 CONCLUDING remarks

As with so many other nutrient-health relationships, the soy field finds itself confronted with inconsistencies in findings from both epidemiologic studies and trials. The trials are often poorly designed; small numbers of subjects, and short study durations. In addition, study populations are very heterogeneous: e.g. pre- versus post-menopausal women; healthy versus diseased subjects; subjects with normal bone density and osteopenia, etc.

On top of that, soy products that have been tested differ a lot, which may affect the concentration of protein and other bioactive compounds such as isoflavones. The general inconsistency in reports on health effects of soy could confuse the general public and makes it difficult to build claims around soy and health.

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