



## Women's Health Update

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### Research News in Women's Health

#### Thyroid Function and Soy

Concerns about the possible goitrogenic effects of soybean isoflavones abound. These concerns are based primarily on *in vitro* research,<sup>1</sup> animal studies,<sup>2</sup> and older reports of goiter occurring in infants who were fed soy formulas that did not contain added iodine. This problem was addressed by adding iodine to formulas and there have been no cases reported since then.<sup>3</sup> In a 2003 randomized, double-blinded, placebo-controlled study, researchers investigated the effect of a daily soy supplement on thyroid function in 38 postmenopausal women who were not on hormone replacement therapy. One group of women took a soy product containing 90 mg/day of isoflavones and the other group took a placebo.<sup>3</sup>

Customary thyroid tests, thyroid stimulating hormone, thyroxine, and tri-iodothyronine were measured at baseline and after 3 and 6 months. All three measures, in both groups, were statistically almost identical at 6 months, and levels were similar between the isoflavone-treated group and the placebo groups for each of the measurements. The conclusion was that, in healthy individuals, who do not have iodine deficiency, soy isoflavones do not affect thyroid function adversely.

*Commentary:* The potential adverse effects of soy have been aggressively publicized by a number of people who are vehemently against soy use. I do not know or understand the source of this opposition and I believe it has created unnecessary confusion among consumers and patients who use natural medicine. I prefer a studious, academic approach to evaluating and understanding the benefits and risks of soy, based on reliable research, rather than perspectives dominated by personal opinions and heated emotions.

*In vitro* studies have shown that genistein and daidzein, the two main isoflavones in soy, interfere with thyroid enzymatic reactions that are critical to the production of thyroid hormone.<sup>1</sup> Animal studies have demonstrated that soy isoflavones, in a dose-dependent manner, have an inhibitory effect on thyroid peroxidase and goiter development is more common in rats fed a soy diet, especially if they are deficient in iodine.<sup>2</sup> Other aspects of thyroid function including thyroid-hormone levels and thyroid gland weight, were not affected adversely in the animal studies.

Concerns regarding soy and thyroid function in humans began when there were some case reports of goiter development in infants who were *exclusively* fed soy formulas.<sup>3</sup> Since iodine was added to the formulas, no cases of goiter have been reported. A study on women with elevated cholesterol levels revived concerns about thyroid hormone suppression.<sup>4</sup> These women were fed 40 g of soy daily with either 90 mg or 56 mg of soy isoflavones per day for 6 months. Cholesterol figures, steroid hormone levels, and thyroid hormones were measured at 90 and 180 days. Small effects on thyroid hormone were measured but there were no clinical changes detected.

Concerns about the effect of soy isoflavones on thyroid function in adult women. The potential antithyroid effects of soy appear to be directly related to iodine. If there is an iodine deficiency, then soy may be able to interfere with optimal thyroid function. However, iodine deficiency can be addressed easily with simple dietary changes or supplementation. It is my opinion, from reading the research on soy and thyroid hormone, whether in men or women, that women should feel reassured that there is no clinically significant effect of soy on thyroid function or hormones as long as these patients have normal iodine levels. A daily serving of wholesome soy foods is probably safe for most women.

**Isoflavones and No Estrogenic Effects on the Endometrium**  
Nikander E, Rutanen E, Nieminen P, et al. Lack of effect of isoflavones on the vagina and endometrium in postmenopausal women. *Fertil Steril* 2005;83:137-142

#### Isoflavones and No Estrogenic Effects on the Endometrium

According to this randomized, double-blind, placebo-controlled, crossover trial, isoflavone use in postmenopausal women does not affect the endometrium, and does not improve vaginal dryness: 64 postmenopausal women aged 35 to 69 years were given either 114 mg/day of isoflavones or placebo for 3 months. They were then crossed over to the other arm after a washout period of 2 months. All women were breast cancer survivors and had menopause symptoms including moderate to severe hot flashes, when the study began. The results of isoflavone therapy demonstrated no effect on any of the endpoints measured. These included a vaginal maturation index, endometrial thickness, endometrial histology, estrogen and progesterone receptor expression, and the endometrial proliferation marker Ki-67. Placebo therapy had no effect on any end point as well except for a decreased maturation index, although not statistically different between the isoflavone group. Vaginal dryness did not improve in either group as well.

*Commentary:* The isoflavone intake of 114 mg/day used in this study is higher than the typical Asian diet intake of up to 80 mg/day. This study is quite short to see a thickening of the endometrium or change in histology, however the marker Ki-67 used to indicate endometrial proliferation, can detect these effects with shorter term use, and all of the treated women expressed this antigen while on the isoflavone treatment.

Endometrial biopsies were obtained in only 29 of 46 women who had not undergone hysterectomy which leaves 17 women where no sample was obtained. This leaves us short of a good understanding of whether or not soy isoflavones have a stimulatory effect on the endometrium. Also of interest, is that here is another study showing no effect on vasomotor symptoms which we can add to the pool of previous studies with mixed results.

In the April issue of the *Townsend Letter*, I wrote about a study that did show an increase in hyperplasia after 5 years of use, in some women who were using 150 mg/day of isoflavones.<sup>5</sup> This was in contrast to another study I reported on in that issue, demonstrating that an average dietary intake of 42.5 mg/day of soy isoflavones was associated with a decreased risk of endometrial cancer.<sup>6</sup> It could be that long term (5 years or more) exposure to quite high intakes (150 mg/day) is associated with a proliferative effect on the endometrium, but the lower doses in the dietary intake range, do not.

#### Acupuncture Reduces Osteoarthritis of the Knee

Berman B, Lao L, Langenberg P, Lee W, et al. Effectiveness of acupuncture as adjunctive therapy in osteoarthritis of the knee: A randomized, controlled trial. *Ann Intern Med* 2004;141:901-910.

A recent randomized, controlled trial demonstrated that acupuncture as an adjunct to anti-inflammatory and analgesic therapy reduced pain and improved physical function in men and women who had osteoarthritis of the knees. Five hundred and seventy (570) men and women, (63% of the subjects were women), with a mean age of 65.5, who had moderate or worse osteoarthritis of the knee were enrolled in a 6 month trial. Individuals were randomized to receive acupuncture, sham acupuncture, or education. Acupuncture was given 23 times during a 26-week period. An accepted osteoarthritis index was used to evaluate pain and function.

After 8 weeks, function improved in the pure acupuncture group but not in the sham group. Pain was unaffected. After 26 weeks, the acupuncture-treated group had significantly greater improvements than the sham acupuncture group in function and in pain scores ( $P < 0.01$  and  $P < 0.003$ , respectively). Subjects who received acupuncture had approximately a 40% improvement in both pain-reduction and function. Pain relief required at least 8 weeks to take effect and increased in effect as the study progressed. Because of the high dropout rate in the education group, results were not analyzed for this group.

*Commentary:* Previous studies and reviews have suggested that acupuncture is both safe and effective for treating pain and loss of function from osteoarthritis of the knee. This current study is the largest study of acupuncture for osteoarthritis ever conducted. While the study shows that acupuncture was effective as an adjunctive therapy, the study does not inform us about the use of acupuncture as a sole therapy or as an adjunct to other natural therapies, such as dietary changes or use of supplements, including glucosamine sulfate, chondroitin sulfate, or S-Adenosylmethionine (SAME). The cost of weekly acupuncture as an adjunctive treatment may be prohibitive to many patients. However, an intervention that provides significant symptomatic improvement and is free of adverse events should be considered as an important therapeutic option.

#### Oral Contraceptives and Overweight Women

Holt VL, Scholes D, Wicklund KG, Cushing-Haugen KL, Daling JR. Body mass index, weight, and oral contraceptive failure risk. *Obstet Gynecol* 2005;105:46-52

In women who take oral contraceptives appropriately, more than 400,000 pregnancies occur annually. Despite this, we know very little about the risk factors for oral hormonal contraceptive failure. This case-controlled study evaluated the potential role of body mass index (BMI) in oral contraceptive (OC) users. Two hundred and forty-eight (248) women with a mean BMI of 26.3 ( $\text{kg}/\text{m}^2$ ) became pregnant while using OCs and 533 age-matched controls with a mean BMI of 24.9 did not. The odds of becoming pregnant were 58% higher for overweight women who had a BMI of  $> 27.3$  versus women with a BMI less than or equal to 27.3. The odds of pregnancy were the highest for women with a BMI of  $> 32.2$ .

*Commentary:* The results suggest that overweight women are more likely than leaner women to become pregnant while using OCs. If these results are accurate, we could expect 2-4 more pregnancies per 100 woman-years in women who are on OCs and are overweight. Alternative contraception, or additional contraception methods should be discussed for overweight women who have been using OCs and do not want to become pregnant. These would include condoms, diaphragms and cervical caps.

#### References

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## INSTITUTE OF WOMEN'S HEALTH & INTEGRATIVE MEDICINE

Program Director: Tori Hudson, N.D.

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For more information call Karen Hudson, M.P., H.C. Executive Director  
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