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Editor's Correspondence | Dec 12 2011

Soy Isoflavone Supplementation in Menopausal Women

Larry E. Miller, PhD; Morgan E. Stewart, PhD

Arch Intern Med. 2011;171(22):2067-2068. doi:10.1001/archinternmed.2011.582.

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Article References Correspondence (1) Comments

We would like to congratulate Levis and colleagues¹ for a well-designed study and thoughtful analysis on the effect of soy isoflavone supplementation on bone loss and menopausal symptoms. However, there are some issues with this trial that warrant further analysis and explanation.

Through 2 years, subject attrition rates were 18.8% with soy isoflavone and 34.1% for placebo ($P = .008$). While the authors state that the baseline characteristics of the subjects who completed the trial were similar to those who withdrew, this explanation is inadequate. Were the reasons for study discontinuation available for comparison? It is unlikely that a discrepancy of this magnitude would occur by chance alone.

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Soy Isoflavone Supplementation in Menopausal Women—Reply
Arch Intern Med. 2011;171(22):2067-2068. doi:10.1001/archinternmed.2011.583.

Soy Isoflavones in the Prevention of Menopausal Bone Loss and Menopausal Symptoms: A Randomized, Double-blind Trial

Author Affiliations: Department of Medicine, Nephrology Associates of South Miami, Miami, Florida.

Correspondence: Dr Busse, Department of Medicine, Nephrology Associates of South Miami, 9193 72nd St SW, Ste 200, Miami, FL 33173 (jorgebusse@aol.com).

Financial Disclosure: None reported.

1. Winkelmayer WC, Liu J, Chertow GM, Tamura MK. Predialysis nephrology care of older patients approaching end-stage renal disease. *Arch Intern Med*. 2011;171(15):1371-1378.

In reply

We appreciate the comments of the letter writers, all of whom pointed toward an important, perhaps the most important, goal of earlier nephrology care, which is to slow the progression of chronic kidney disease. Our study¹ was not designed to investigate this question. Furthermore, these data should not deter any clinician from timely referral to a nephrologist. Our study merely pointed toward certain trends in practice patterns that are unproven and even potentially harmful, including earlier initiation of dialysis and injudicious use of erythropoiesis-stimulating agents. These trends may actually have obscured true advances on other care domains that would otherwise have led to measurably improved outcomes. Our article should serve as a wake-up call toward more rigorous testing of any nephrology-driven interventions and focus on practices that are shown to be both safe and effective.

Wolfgang C. Winkelmayer, MD, ScD
Glenn M. Chertow, MD, MPH
Manjula Kurella Tamura, MD, MPH

Author Affiliations: Division of Nephrology, Stanford University School of Medicine, Palo Alto, California.

Correspondence: Dr Winkelmayer, Division of Nephrology, Stanford University School of Medicine, 780 Welch Rd, Ste 106, Palo Alto, CA 94304 (wcv1@stanford.edu).

Financial Disclosure: None reported.

1. Winkelmayer WC, Liu J, Chertow GM, Tamura MK. Predialysis nephrology care of older patients approaching end-stage renal disease. *Arch Intern Med*. 2011;171(15):1371-1378.

Soy Isoflavone Supplementation in Menopausal Women

We would like to congratulate Levis and colleagues¹ for a well-designed study and thoughtful analysis on the effect of soy isoflavone supplementation on bone loss and menopausal symptoms. However, there are some issues with this trial that warrant further analysis and explanation.

Through 2 years, subject attrition rates were 18.8% with soy isoflavone and 34.1% for placebo (P=.008). While the authors state that the baseline characteristics of the subjects who completed the trial were similar to those who withdrew, this explanation is inadequate. Were the reasons for study discontinuation available for comparison? It is unlikely that a discrepancy of this magnitude would occur by chance alone.

In regard to hot flashes, the assessment tool was the Women's Health Questionnaire (WHQ), consisting of 36 items that evaluate the physical and emotional health of middle-aged women.² Each question in the WHQ is graded as "yes definitely," "yes sometimes," "no not much," or "no not at all" and then simply dichotomized to "yes" or "no" responses. Next, the responses are scored and reported using 9 different domain scores including somatic symptoms, depressed mood, cognitive difficulties, anxiety/fear, sexual functioning, vasomotor symptoms, sleep problems, menstrual problems, and attraction. Why the domain scores are not presented, but the dichotomized results from an individual question of "I have hot flushes" are reported, is unclear.

This article would be strengthened by addressing some of the aforementioned issues. Assessment of the reasons for discontinuation and a sensitivity analyses may help to address the impact of disproportionate subject attrition on subject outcomes, particularly since intent-to-treat analyses were not used. Also, an analysis of the WHQ domain scores, not of the responses to individual questions, is encouraged.

Larry E. Miller, PhD
Morgan E. Stewart, PhD

Author Affiliations: Sprim USA, San Francisco, California.

Correspondence: Dr Miller, Sprim USA, 235 Pine St, Ste 1175, San Francisco, CA 94104 (larry.miller@sprim.com).

Financial Disclosure: None reported.

1. Levis S, Strickman-Stein N, Ganjei-Azar P, Xu P, Doerge DR, Krischer J. Soy isoflavones in the prevention of menopausal bone loss and menopausal symptoms: a randomized, double-blind trial. *Arch Intern Med*. 2011;171(15):1363-1369.
2. Wiklund I, Holst J, Karlberg J, et al. A new methodological approach to the evaluation of quality of life in postmenopausal women. *Maturitas*. 1992;14(3):211-224.

In reply

A total of 66 randomized participants did not complete the study (23 in the soy isoflavone group and 43 in the placebo group).¹ A comparable number of women in each group reported moving out of state, having a sick family member, a new job, or a desire to eat soy products as the reason to discontinue their participation. Although there was a marked difference in the proportion of participants who were no longer interested in participating in the study or were lost to follow-up (16 [19%] in the soy isoflavone group and 30 [34%] in the placebo group), we did not find any objective measures that could explain this difference.

At baseline, responses to all 9 different subscales in the Women's Health Questionnaire were similar between participants in both treatment arms.² At 12 months, scores in all domains were comparable between groups, except in the vasomotor symptoms domain where women in the soy isoflavone group had statistically significantly higher scores than women in the placebo group (P=.04). At 24 months, scores in all domains were comparable in both groups.

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