

# ALTERNATIVE THERAPIES IN WOMEN'S HEALTH

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## Evening Primrose Oil for Premenstrual and Menopausal Symptoms

*By Dónal P. O'Mathúna, PhD*

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A SHIFT HAS OCCURRED IN RECENT YEARS FROM VIEWING Amenopause as “a natural life event” experienced by women to “a condition that requires medical management.”<sup>1</sup> Hormone replacement therapy (HRT) was commonly used to manage the symptoms of menopause until studies from the Women's Health Initiative in 2001-2002 reported higher risks than anticipated for some women. Many women continue to seek relief from their symptoms and commonly turn to complementary and alternative medicine (CAM). One survey found that 76% of women ages 45-65 years used CAM to treat menopausal symptoms, with 37% using herbal and natural remedies.<sup>2</sup> A 2009 survey found that 45% of women who had discontinued HRT continue to use CAM, with evening primrose oil being one of the more common interventions used.<sup>1</sup>

### Background

Evening primrose oil is obtained from the seeds of a North American wildflower (*Oenothera biennis*).<sup>3</sup> Early English settlers brought the flower back to England where it was cultivated for its nut-flavored root. An oil was extracted from the seeds and became known as the King's Cure-All. Surveys have found that it remains very commonly used in England. Two evening primrose oil products were licensed by Britain's Medicines Control Agency. The products were available by prescription to treat atopic eczema and mastalgia (breast pain). However, in 2002 the licenses were revoked after a review of studies on its effectiveness found insufficient evidence to continue its official approval.<sup>4</sup>

Evening primrose oil contains a high proportion of essential fatty acids. The two most common types present in the oil are linoleic

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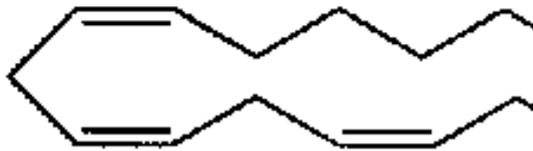
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## Gamma-linolenic acid

**G**AMMA-LINOLENIC ACID (GLA) IS AN N-6 (OMEGA-6) POLY-unsaturated fatty acid. It is composed of 18 carbon atoms and three double bonds. GLA is an all-cis n-6 polyunsaturated fatty acid also known as 18:3n-6; 6,9,12-octadecatrienoic acid; (Z,Z,Z)-6,9,12-octadecatrienoic acid; cis-6,cis-9,cis-12-octadecatrienoic acid; and gamolenic acid. The structural formula of GLA is:



**GLA (gamma-linolenic acid)**

GLA is found naturally to varying extents in the fatty acid fraction of some plant seed oils. In evening primrose seed oil, it is present in concentrations of 7-14% of total fatty

acids; in borage seed oil, 20-27%; and in black currant seed oil, 15-20%. GLA is also found in some fungal sources. GLA is produced naturally in the body as the delta 6-desaturase metabolite of the essential fatty acid linoleic acid. Under certain conditions, e.g., decreased activity of the delta-6 desaturase enzyme, GLA may become a conditionally essential fatty acid. GLA is present naturally in the form of triacylglycerols. The stereospecificity of GLA varies among different oil sources. GLA is concentrated in the sn-3 position of evening primrose seed oil and black currant seed oil and in the sn-2 position in borage seed oil. GLA is concentrated evenly in both the sn-2 and sn-3 positions of fungal oil.

GLA, supplied in the form of evening primrose oil or borage seed oil, has been studied for many years for its possible effects in arthritis and other inflammatory processes. It has been shown to suppress inflammation and reduce joint tissue injury in many animal models. ❖

**Adapted from:** Evening Primrose. Herbs & Supplements. Available at [www.pdrhealth.com/drugs/altmed/altmed-a-z.aspx?letter=E](http://www.pdrhealth.com/drugs/altmed/altmed-a-z.aspx?letter=E). Accessed May 5, 2009.

acid (about 65%) and gamma-linolenic acid (GLA, 8-10%).<sup>5</sup> Evening primrose oil is valued primarily for its GLA. It is one of the richest plant sources of GLA, with only borage oil (24%) and black currant seed oil (16%)

containing more GLA. GLA is converted into a number of anti-inflammatory prostaglandins in the body, which is why evening primrose oil is recommended to treat numerous chronic inflammatory diseases.

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### Mechanism of Action

How evening primrose oil might treat premenstrual or menopausal symptoms is not clear. Some studies have shown that women with premenstrual syndrome tend to have lower than normal levels of GLA.<sup>5</sup> Epidemiological studies have shown a connection between low dietary levels of GLA and a number of illnesses. However, a precise mechanism of action for evening primrose oil is not known.

### Clinical Studies

Very few high-quality studies have been conducted using evening primrose oil for specific conditions in humans. A 1994 study remains the only controlled study of evening primrose oil and menopausal symptoms.<sup>6</sup> The impact of evening primrose oil on hot flashes and night sweats was examined in 56 menopausal women randomized to either evening primrose oil (4 g/d plus 80 mg/d vitamin E) or placebo.<sup>7</sup> Only 35 women finished the six-month study. Although all women showed some improvements, no significant differences were found between the two groups.

## Summary Points

- Evening primrose oil is a popular complementary treatment for the symptoms of premenstrual and menopausal symptoms.
- Controlled clinical trials consistently demonstrate that evening primrose oil is no better than placebo in treating such symptoms.
- The oil is a rich source of gamma-linolenic acid (GLA), which is useful for general health.

Evening primrose oil has been one of the more popular natural therapies for premenstrual syndrome (PMS). However, no new studies were identified since a 2001 systematic review identified four randomized controlled trials on the topic.<sup>8</sup> This review concluded that evening primrose oil was no better than placebo in treating PMS. This conclusion was in agreement with an earlier systematic review that found most earlier studies had been of poor quality.<sup>9</sup> A Cochrane systematic review is being conducted on the topic, but only the protocol for the review is currently available.<sup>10</sup>

Evening primrose oil's reputation for relieving PMS is based primarily on anecdotal evidence and older, uncontrolled studies. More recent randomized controlled trials have found no significant differences between the groups. Controlled trials are particularly important when studying PMS because it has been found to be highly responsive to placebos, with up to 80% of subjects improving after receiving a placebo.<sup>11</sup>

Evening primrose oil also has been used to treat mastalgia, including that associated with PMS. One of the largest studies ever conducted on mastalgia investigated this claim.<sup>4</sup> A total of 555 women were randomized to one of four groups. Each woman took 4 g/d of capsules containing either evening primrose oil alone, evening primrose oil plus multivitamins, multivitamins alone, or placebo. After four months of blinded treatment, all groups showed an average 35% reduction in breast pain. No statistically significant differences were found between any of the four groups. The study continued as an open trial for another six months with all subjects receiving evening primrose oil, either with or without multivitamins. Breast pain was reduced by another 50%, but with no differences between the two groups. The researchers concluded that evening primrose oil was not superior to placebo in treating mastalgia. A meta-analysis of randomized controlled trials for mastalgia was published in 2007.<sup>12</sup> While bromocryptine, danazol,

and tamoxifen showed significant pain relief, evening primrose oil did not. This conclusion was based on results from four controlled trials.

### Adverse Effects

The most commonly reported adverse effects of evening primrose oil in clinical trials are gastrointestinal. These are usually mild to moderate, with nausea being the most common. The effects of long-term use have not been examined. The withdrawal of evening primrose oil's medical license in Britain was not based on concerns about safety, but for lack of evidence of effectiveness. Evening primrose oil has been popularly recommended to shorten the duration of labor, but a retrospective study found that women taking the oil during their pregnancies were in labor for an average of 3 hours longer.<sup>13</sup> Although causation could not be established, women who are pregnant or breast feeding should, in general, avoid herbs and dietary supplements until they have been demonstrated to be safe.

### Formulation

Most studies have used four 500 mg capsules taken twice daily (a total of 4 g/d evening primrose oil). Recommendations range from 2-6 g/d.

### Conclusion

A relatively small number of studies have examined the effectiveness of evening primrose oil in treating PMS and menopausal symptoms. The controlled studies consistently show that evening primrose oil is no more effective than placebo. Such symptoms are known to respond well to the placebo effect, which may explain why use of evening primrose oil is popular.

### Recommendation

In spite of its popularity, evening primrose oil is no more beneficial than placebo in treating menopausal or PMS symptoms. Some women may have very low levels of GLA in their diet, or may not produce adequate amounts within their bodies. They may receive some general health benefits from supplementing their diet with evening primrose oil. However, its usefulness in treating any particular condition associated with premenstrual syndrome or menopause is not supported by clinical research. ❖

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## Effect of Maternal Alcohol Consumption on Fetal Growth and Preterm Birth

ABSTRACT & COMMENTARY

By **John C. Hobbins, MD**

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*no financial relationship to this field of study. This article originally appeared in the April issue of OB/GYN Clinical Alert; for that publication it was reviewed by Catherine LeClair, MD. Dr. LeClair reports no financial relationship to this field of study.*

**Synopsis:** *Low levels of alcohol consumption during pregnancy is not associated with small-for-gestational age or preterm birth. Conversely, higher levels of alcohol intake during pregnancy is associated with an increased risk of preterm birth, even after ceasing alcohol intake before the second trimester.*

**Source:** O'Leary CM, et al. The effect of maternal alcohol consumption on fetal growth and preterm birth. *BJOG* 2009; 116:390-400.

IT HAS BEEN VERY DIFFICULT TO STUDY THE EFFECTS OF alcohol consumption on the fetus and on pregnancy, in general, because one depends so heavily on a patient's candor regarding true alcohol consumption and the effect of confounding variables, such as smoking. In Australia, drinking some alcoholic beverages in pregnancy is quite common, and, as opposed to the United States where drinking even the smallest amount of alcohol is strongly discouraged, the Australian National Health and Medical Research Council in 2001 recommended that "if women choose to drink during pregnancy, they should have less than seven standard drinks per week and, on any one day, no more than two standard drinks."<sup>1</sup>

With this backdrop in mind, a group of Australian investigators studied a random sample of 4,719 women who delivered in Western Australia between 1995 and 1997. The sample represented 10% of births in the region, and information regarding alcohol consumption was obtained via questionnaires sent out after birth. The authors were interested in two outcomes: the number of preterm births — defined as those delivering before 37 weeks — and the incidence of small-for-gestational age (SGA) births. To quantify the latter outcome, an optimal birth weight was calculated using the sex of the infant, maternal height, parity, and gestational age. Then the actual birth weight was matched up to this and, if it was below the 10th percentile, the infant was considered to be SGA.

As to alcohol consumption, the authors coded "low" as less than three drinks per week, "moderate" as 2-5 drinks per week, "heavy" as more than seven drinks per week, and "binging" as more than two drinks at a time (although this was difficult to sort out from the paper).

In this random sampling, about 50% of the study participants did consume some alcohol during pregnancy. Those women in the low level category who continued to drink showed little change in their drinking patterns. However, in all the other categories, there was a general decrease in the average consumption of alcohol. Interestingly, the percentage of heavy and binge drinkers decreased by two-thirds during pregnancy.

The punch line is that in each category there was no statistically significant difference in the rate of preterm birth in any category (compared with abstainers). However, if data from the low level group, representing the largest study group, were excluded from the analysis, then there was a 78% percent increase in preterm births (over abstainers). The incidence of SGA was higher among heavy and binge drinkers (13%) compared with the rate reported in the overall population (8.9%). However, since the heavy and binge group was heavily spiked with smokers, there was no difference in the incidence of SGA when the authors accounted for this confounding variable. The strangest result was that heavy drinkers who stopped drinking before the second trimester had the highest rate of preterm birth.

#### ■ COMMENTARY

In a matter of 40 years, the pendulum has swung from clinicians infusing huge amounts of IV alcohol to stop preterm labor to, now, telling patients that any amount of alcohol consumed by a mother may be dangerous to the health of her fetus. In Europe, and now I realize in Australia, there is a more relaxed approach to alcohol and pregnancy. The above study does not address the effects of alcohol in small doses on the fetal brain, but it does address two issues — its affect on fetal growth and preterm birth. The bottom line is that, with one exception, there is no major effect on these two outcomes, if the confounding variable of maternal smoking is taken into account.

The surprise finding in this study was that when heavy or binge drinkers stopped drinking after the first trimester, they had the highest rate of preterm birth (13%). The authors postulate that sudden abstinence “may trigger an inflammatory or other metabolic response resulting in an elevation of cytokines” responsible for preterm labor. My guess is that this result could have been due to the small numbers of patients in this category (type 1 error). However, the authors justifiably make the case that if heavy or binge drinkers were to stop or modify this activity in early pregnancy — before the second trimester this article would suggest — we would not have to worry about this unexpected finding.

Speaking of things to worry about, a few years back we were interested in correlating measurements of certain areas of the fetal brain with maternal alcohol consumption and, then, later, with sophisticated testing of reaction times in the same children. To make a long story short, we found that indirect measurements of the size of the fetal frontal lobe correlated inversely with the amount of alcohol consumed. This, in turn, correlated with how poorly the children performed during the above testing process. However, there was no discernible effect unless the average alcohol consumption exceeded 2.9 drinks per day at the time of entry into the study.<sup>2,3</sup>

Smoking and alcohol certainly seem to go together, even in pregnant women. For example, the two of us doing the fetal ultrasound measurements in the above study were supposedly blind to which patients were imbibers and which ones were controls, but it became immediately clear who was who, because, often, soon after the “exposed” patients walked in, the ultrasound room smelled like the smoking lounge at Denver International Airport.

At least one-third of those in the “exposed” group in our study were in the restaurant business where it is common to have “a pop or two” before going home. Although most of these individuals stopped after finding out (sometimes late) that they were pregnant, many of them seemed to exude guilt, fueled by all the warnings out there against any exposure to alcohol. Fortunately, most available data suggest that their guilt is likely unfounded, since it appears at this time that to create full-blown fetal alcohol syndrome, or, it seems, to cause even less severe effects on the fetal brain, larger amounts of alcohol would need to be consumed regularly. The Australian study indicates that the same could be said for preterm birth and IUGR. Although smaller amounts of consumed alcohol cannot be completely excluded as having subtle effects on the fetal brain, there is much more evidence out there to indicate that smoking is more detrimental to the fetus than an occasional glass of wine. ❖

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# A Diet by Any Other Name Is Still a Diet

ABSTRACT & COMMENTARY

**Malcolm Robinson, MD, FACP, FACG, AGAF**

*Dr. Robinson is Emeritus Clinical Professor of Medicine, University of Oklahoma College of Medicine, Oklahoma City; he reports no financial relationship to this field of study. This article originally appeared in the April 15, 2009 issue of Internal Medicine Alert; for that publication it was reviewed by Gerald Roberts, MD. Dr. Roberts reports no financial relationship to this field of study.*

**Synopsis:** *Regardless of levels of fat, protein, and carbohydrate proportions, all diets with lowered caloric intake modestly reduced weight.*

**Source:** Sacks FM, et al. Comparison of weight-loss diets with different compositions of fat, protein, and carbohydrates. *N Engl J Med* 2009;360:859-873.

THERE HAS BEEN BURNING CONTROVERSY REGARDING the “best” diet(s) for the treatment of overweight individuals, and previous studies have revealed wildly contradictory results. Most past studies were relatively small and adherence was often poor or impossible to ascertain, and few investigations lasted as long as 1 year. Even the longer and thus more realistic studies contradicted each other in terms of detecting the ideal weight-loss diet. The present authors believed that a large study was indicated to select the best weight-loss diet, and they felt that weight change over two years would be more revealing than results from shorter trials. A total of 811 particularly well-educated and motivated patients with body mass index levels between 25 kg/m<sup>2</sup> and 40 kg/m<sup>2</sup> were randomly assigned to one of four diets with varied targeted percentages of energy from fat, protein, and carbohydrates. Age range was from 30 to 70 years, and diabetes and unstable cardiovascular disease were exclusions, as were any medications that might affect body weight. Diets contained similar foods to the extent possible and all diets met guidelines for cardiovascular health (low cholesterol, saturated fat, and high fiber). Food was prepared at home. The diets contained dietary fat content of 20% or 40%. Carbohydrate levels were 65%, 55%, 45%, or 35%. Protein made up either 15% or 25% of calories. Primary outcomes were changes in body weight after two years in 2 × 2 factorial comparisons of high fat vs.

low fat, average protein vs. high protein, and highest carbohydrate vs. lowest carbohydrate content. Patients lost an average of 6 kg after six months (7% of initial weight), but average weight began to rise after 12 months. There were no differences between any of the assigned diets and degree of weight loss, rate of ultimate weight increases later in the study, or any similar clinical parameter. Overall average weight loss across study groups was 4 kg, and almost 15% of the participants reduced body weight by at least 10%.

Attendance at offered group and individual instructional/counseling sessions was associated with weight loss at the rate of 0.2 kg/session attended. All diets improved lipid-related risk factors and fasting insulin levels. Patients were given daily meal plans, and they were instructed to record daily meal plans in a food diary and using a web-based tool. Each participant had a goal of 90 minutes of moderate physical activity per week. Laboratory data collection was extensive as were questionnaires regarding food craving, satiety, and diet satisfaction.

At two years, both low-fat diet arms and the highest-carbohydrate diet decreased low-density lipoprotein cholesterol more than the high-fat diets or the lowest-carbohydrate diet. All diets decreased triglycerides by between 12% and 17%. High-density lipoprotein levels were highest with the lowest-carbohydrate diet vs. the highest. Food craving and similar measures didn’t differ between the diet arms. There were no differences in adverse events between groups. There was a high rate of patient retention, but biochemical studies indicated that none of the groups were very successful in strict adherence to their assigned diets. Patient motivation, probably best mirrored in attendance at counseling sessions, seemed most important as a marker for weight-loss success.

## ■ COMMENTARY

This important study makes it clear that no miracle diet has emerged as a panacea for the current epidemic of obesity. In fact, it would appear that any diet that successfully lowers caloric intake will lead to weight reduction. As many of us have long suspected, calories seem to be calories, regardless of their format. It is unlikely that any other study will be as well-designed or executed, and the length of the study and excellent patient retention are commendable.

As pointed out in an accompanying editorial,<sup>1</sup> the protein intake in the study was supposed to differ by 10% — but the measurement of urinary nitrogen excretion showed that the “real” intake varied by only 1% or 2%. Similar data showed that these patients, despite

### Dietary Supplements Linked to Liver Injuries

THE FDA IS WARNING CONSUMERS TO IMMEDIATELY STOP using Hydroxycut products by Iovate Health Sciences, of Oakville, Ontario, and distributed by Iovate Health Sciences USA of Blasdell, NY. Iovate has agreed to recall Hydroxycut products from the market.

The FDA has received 23 reports of serious health problems ranging from jaundice and elevated liver enzymes, to liver damage requiring liver transplant. One death due to liver failure has been reported to the FDA. Other health problems reported include seizures, cardiovascular disorders, and rhabdomyolysis.

Liver injury, although rare, was reported by patients at the doses of Hydroxycut recommended on the bottle. Symptoms of liver injury include jaundice and brown

their excellent motivation, didn't stay on their diets. They obviously ate things that weren't on their diets, and they ate more than the diets allowed. Human nature being what it is, this shouldn't be all that surprising.

The editorial did provide readers a little hope. It described an experiment in Europe that used the combined resources of entire "villages" to get their resident children to eat more wisely and get more exercise. Amazingly, the prevalence of overweight children fell from the 17.8% in nearby communities to only 8.8%. If this approach is further documented as widely effective, we should participate (if only we can muster the self-discipline and control a wildly advertising food industry). ❖

#### Reference

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#### CME Objectives

After reading *Alternative Therapies in Women's Health*, the health care professional will be able to:

1. evaluate alternative medicine and complementary therapies for women's health concerns;
2. identify risks and interactions associated with alternative therapies;
3. discuss alternative medicine options with patients;
4. offer guidance to patients based on latest science and clinical studies regarding alternative and complementary therapies.

#### CME Instructions

Physicians participate in this continuing medical education program by reading the article, using the provided references for further research, and studying the questions at the end of the article. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity, you must complete the evaluation form provided and return it in the reply envelope provided at the end of the semester to receive a certificate of completion. Upon receipt of your evaluation, a certificate will be mailed.

#### CME Questions

18. Evening primrose oil is one of the best plant sources of the fatty acid:
  - a. EPA.
  - b. FDA.
  - c. GLA.
  - d. LLA.
19. The evidence from randomized controlled trials shows that evening primrose oil is effective for treating:
  - a. menopausal symptoms.
  - b. premenstrual syndrome.
  - c. breast pain.
  - d. None of the above
20. Which of the four diets was most effective in producing sustained weight loss?
  - a. Fat, protein, carbohydrate: 20%, 15%, and 65%
  - b. Fat, protein, carbohydrate: 20%, 25%, and 55%
  - c. Fat, protein, carbohydrate: 40%, 15%, and 45%
  - d. Fat, protein, carbohydrate: 40%, 25%, and 35%
  - e. Weight loss didn't vary among these diets
21. The highest rate of preterm birth occurred in the heavy and binge drinkers who decreased their intake or quit drinking after the first trimester.
  - a. True
  - b. False

Answers: 18. c, 19. d, 20. e, 21. a.

urine. Other symptoms include nausea, vomiting, light-colored stools, excessive fatigue, weakness, stomach or abdominal pain, itching, and loss of appetite.

Hydroxycut products are dietary supplements that are marketed for weight loss, as fat burners, as energy-enhancers, as low-carb diet aids, and for water loss under the Iovate and MuscleTech brand names. Although the FDA has not received reports of serious liver-related adverse reactions for all Hydroxycut products, Iovate has agreed to recall the following products: Hydroxycut Regular Rapid Release Caplets, Hydroxycut Caffeine-Free Rapid Release Caplets, Hydroxycut Hardcore Liquid Caplets, Hydroxycut Max Liquid Caplets, Hydroxycut Regular Drink Packets, Hydroxycut Caffeine-Free Drink Packets, Hydroxycut Hardcore Drink Packets (Ignition Stix), Hydroxycut Max Drink Packets, Hydroxycut Liquid Shots, Hydroxycut Hardcore RTDs (Ready-to-Drink), Hydroxycut Max Aqua Shed, Hydroxycut 24, Hydroxycut Carb Control, and Hydroxycut Natural.

Hydroxycut Cleanse and Hoodia products are not affected by the recall. Consumers who have any of the products involved in the recall are advised to stop using them and to return them to the place of purchase. The agency has not yet determined which ingredients, dosages, or other health-related factors may be associated with risks related to these Hydroxycut products. The products contain a variety of ingredients and herbal extracts. ❖

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## Patients on Warfarin Therapy Report Potentially Interacting CAM Exposure

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**T**HIRTY-FOUR PERCENT OF PATIENTS ON WARFARIN THERAPY reported using potentially interacting complementary and alternative medicine (CAM), according to a recent study published on-line April 28 on the web site of *The Annals of Pharmacotherapy*.

Researchers at the Faculty of Pharmaceutical Sciences, University of British Columbia, Vancouver, Canada, wanted to estimate the prevalence of CAM use, including orally administered herbals, botanicals, vitamins, and supplements, that may pose a risk to patients on warfarin therapy. The researchers administered a survey to hospital inpatients and clinic outpatients, asking them about drug exposure (including CAM) over the previous month, self-reported bleeding events, use of alcohol and vitamin K-rich foods, and medical conditions.

The researchers verified prescription medication use, and checked laboratory records for out-of-range international normalized ratios (INRs), which were defined as greater than 4 or less than 2. They then compared use of CAM, including products with reported or theoretical interactions with warfarin, between patients with and without self-reported bleeding or out-of-range INR.

The results showed that among the 314 patients who completed the survey, 44.3% reported using CAM at least weekly. Potentially interacting CAM was used by 34.1% of all patients, or 18.2% if vitamin E was excluded as an interacting CAM. Vitamin E was used by 24.2% of all patients and 71.0% of those who used potentially interacting CAM. There was no significant difference in CAM use or consumption of vitamin K-rich foods between patients with and without INRs greater than 4 or for patients with and without INRs less than 2.

In conclusion, the use of potentially interacting CAM in this cohort was higher than the use previously reported among patients on warfarin therapy, the researchers say. However, they did not associate exposure to CAM with an increase in the risk of self-reported bleeding or out-of-range INR. ❖

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# ALTERNATIVE THERAPIES IN WOMEN'S HEALTH

Science-based Information for Clinicians

ATWH060109TM

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If so, how? _____						
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