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FILE: ▪Evening Primrose Oil (*Oenothera biennis*)
▪Fish Oil
▪Mastalgia

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RE: Evening Primrose Oil and Fish Oil Used for Mastalgia

Blommers J, de Lange-de Klerk ESM, Kuik DJ, Bezemer PD, Meijer S. Evening primrose oil and fish oil for severe chronic mastalgia: A randomized, double-blind, controlled trial. *American Journal of Obstetrics and Gynecology* 2002;187:1389-1394.

Breast pain, or mastalgia, is the most commonly reported breast problem in general medical practice. Approximately 15% of women who report breast pain require treatment, for which medications such as bromocriptine and danazol are used. While these medications have frequent and major adverse side effects, evening primrose oil is relatively innocuous, and its use has become widespread in spite of a lack of evidence of its effectiveness. Evening primrose oil's mechanism of action may involve changes in prostaglandin metabolism. In this article, the researchers discuss their study on evening primrose oil and fish oil, which also induces changes in prostaglandin metabolism, in a double-blind, controlled clinical trial to assess the oils' usefulness in treating severe mastalgia.

Between 1993 and 1996, 120 premenopausal women in Amsterdam who met the selection criteria were separated by cyclic vs. noncyclic pain, then randomly assigned to one of four groups: FC, fish oil and control oil; EC, evening primrose oil and control oil; EF, fish oil and evening primrose oil; and CC, two control oils. Corn oil was used as the control for fish oil, and a combination of corn oil and wheat germ oil was the control for evening primrose oil. The researchers surmised that since corn and wheat germ oils are commonly used by Dutch women, these dosages would not cause any major effects.

Three grams of each oil were taken daily. Vitamin E, often recommended for treatment of fibrocystic and painful breasts, was added to all oils for all groups to reach a total of 33 mg per day to prevent oxidation of the oils; this amount is much less than the usual recommended amount for treating breast pain. The treatment continued for 6 months.

The primary outcome measure was the change in percentage of days with breast pain, measured by the difference between the last 3 months of the trial period and the 3 month run-in period before the trial began. Changes in breast complaints were assessed by a patient opinion questionnaire upon randomization and at 3 and 6 months. Secondary outcome measures included change in the severity of pain and patients' opinions, derived from diary cards using a scale from 0 to 3, and taking the difference of severity in the final 3 months compared to the 3-month run-in period.

The non-cyclic subjects had experienced significantly more hysterectomies ($P < .001$) and a higher percentage of pain days ($P = .02$) than cyclic subjects. Side effects, primarily stomach and abdominal complaints, were reported as minor, but were experienced by 45 women (38%) throughout the study.

The total study population showed a significant decrease in percentage of days with pain (-13.0%, 95% CI), but the decrease in severity of pain was not significant. While fish oil showed more decrease in percentage of pain days than control oils, and evening primrose oil showed less decrease than control oils, none of the effects were significant. Overall, the effects of the study oils on the change in severity of pain were almost identical to control oils. Patients' opinions about the effects of the oils was comparable for all oils used.

The authors found no difference in the effects of evening primrose oil, fish oil, or control oils in this population of women with mastalgia. This is in contrast to other studies mentioned by the authors, but they defend the design and follow-up of this study compared to previous works on evening primrose oil. They offer three interpretations of their finding of no significant differences between the oils: (1) there may have been no intrinsic effect of any oil; (2) perhaps all the oils and the vitamin E had an intrinsic effect; or (3) the reduction in pain reported by the subjects was a result of time and care; attention can reduce stress, and keeping a diary can improve coping, leaving little room for further pain reduction by the study oils.

Although this study refuted earlier claims for the use of evening primrose oil to treat breast pain, it may be interesting in the future to compare it to flax oil, also believed to influence prostaglandin metabolism. Study design should correct for the possibilities of all the oils having an effect as well as the psychological component. The finding that attention and care can reduce the subjective experience of pain for mastalgia sufferers also points toward pursuing research into this type of therapy.

— *Diane S. Graves, MPH, RD*

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