AMERICAN HEALTH CONSULTANTS® A Medical Economics Company

ALTERNATIVE THERAPIES IN WOMEN'S HEALTH

Science-based Information for Clinicians

American Health Consultants Home Page—http://www.ahcpub.com

CME for Physicians—http://www.cmeweb.com

Acupuncture and Duration of Labor

By Adriane Fugh-Berman, MD

THE EFFECT OF ACUPUNCTURE ON DURATION OF LABOR HAS BEEN examined in three rather widely spaced studies over the last two decades. Two studies were reported as positive and one reported as negative, but none of these trials was randomized and all have limitations.

The most recent trial on this subject is an Austrian case-control study published in 1998 by Zeisler that tested acupuncture during the four weeks before term.[1] In this standardized protocol, each woman received weekly treatments at the same points: Du20 (Bai Hui), He7 (Shen Men), and Pe6 (Nei Guan). The study included 116 primiparas. Participants were required to have "an uneventful pregnancy;" multiple exclusion criteria included diabetes, pregnancy-induced hypertension, breech presentation, and "poor obstetric history."

Only 57 of the original 116 women were included in the final analysis. The exclusion of such a high proportion of women from the final analysis makes interpretation of the results problematic. The authors excluded 27 women admitted to the delivery unit with more than 3 cm cervical dilation; 12 women who did not complete a minimum of four treatments; six women who underwent vacuum extraction, seven women who underwent cesarean, and six women who were induced by prostaglandins. The control group consisted of 63 primiparous women who delivered closest in time to the acupuncture-treated women.

The authors of this study reported that the median duration of the first stage of labor (defined by the authors as the time interval between 3 cm of cervical dilation and complete cervical dilation) was significantly shorter in the acupuncture-treated group (196 minutes vs. 321 minutes in the control group). Median duration of the second stage of labor was identical (57 minutes) in both groups. Significantly more women (66.7%) in the acupuncture-treated group had premature rupture of membranes (PROM) compared to the control group (33.3%). Women in the control group were treated with

Volume 1 • Number 7 • June 1999 • Pages 49-56

INSIDE

oxytocin more often during both the first (85% vs. 15%) and second stages of labor (72% vs. 28%) than those in the acupuncture-treated group.

There are a number of problems with this study. There does not appear to be a comparison reported for the two groups in terms of total duration of labor. The biggest problem is that the treatment group was so over-selected that it probably bears no resemblance to the control group. Although patients in the acupuncture group who had problems during pregnancy or labor were excluded from analysis, the control group consisted merely of "the nearest primiparous women who delivered before or after the acupuncture-treated women."

In other words, although women who were counted in the final analysis of the acupuncture group had uncomplicated pregnancies and did not undergo vacuum extraction, prostaglandin induction, or cesarean, it does not appear that any of these criteria were applied to the controls. A comparison of women with uncomplicated pregnancies who required few obstetric interventions with a cross-section of obstetrics patients may well result in differences in duration of labor even without an acupuncture intervention.

Although PROM is not considered a problem after 36 weeks, it is a serious problem prior to 36 weeks. The significantly increased frequency of PROM in the acupuncture group is a worrisome adverse effect. If this effect also occurs earlier in pregnancy, acupuncture at these points could precipitate preterm birth and should be avoided.

This study is thinly reported; there are no tables or information on individual subjects presented, only median values and ranges are reported. While the report states that the rate of vacuum extraction did not differ between the treated group and "the average vacuum extraction rate at our department," it is very odd that the comparison was made between the treated and the control group. And although it does not change the results, the fact that the authors apparently miscalculated a simple percentage of those receiving analgesia (13/57 is reported as 47% and 15/63 is reported as 54%) does not inspire confidence in the accuracy of the rest of the statistical analysis.

Two earlier studies on the same subject utilized a different set of acupuncture points than were used in the Zeisler study. The points consisted of stomach 36 (Zusanli), spleen 6 (Sanyinjiao), gallbladder 34 (Yangling-quan), and urinary bladder 62 (Shenmai). Although both studies used the same set of points, the studies found opposite results. A Swedish study by Lyrenas published in 1987 tested the effect of once-weekly acupuncture from the 36th week of pregnancy to delivery in 56 primigravidae.[3] The control group consisted of 112 primiparous women who delivered closest in time to the acupuncture-treated women.

Lyrenas analyzed only women who delivered vaginally (93% of the treated group and 96% of the controls). This study found no significant difference in first-stage, second-stage, or total delivery times between the treated and control groups. In fact, second-stage labor exceeded 2.5 hours in significantly more acupuncture-treated women than controls, and significantly fewer acupuncture-treated women delivered within one hour of the second stage.

The German trial reported in 1973 by Kubista found that an average of three acupuncture treatments in the last weeks of normal pregnancy reduced delivery time in primigravidae by 23%, compared to a control group.[4] The treatment group was apparently composed of women who were tense and worried near the end of pregnancy. The study was not randomized and the control group was matched to the treatment group exclusively with regard to the number of manual interventions during the second stage of labor.

The best of the studies reviewed above is the negative study by Lyrenas.[2] Acupuncture point stimulation has been used for various indications in obstetrics, including prenatal nausea and vomiting and analgesia during labor. There is evidence for its efficacy in nausea and vomiting

Alternative Therapies in Women's Health, ISSN 1522-3396, is published monthly by American Health Consultants, 3525 Piedmont Rd., NE, Bldg. 6, Suite 400, Atlanta, GA 30305.

PUBLISHER: Brenda Mooney.
MANAGING EDITOR: Leslie G. Coplin.
ASSOCIATE MANAGING EDITOR: Paula L. Cousins.

GST Registration Number: R128870672.

Periodical rate postage pending at Atlanta, GA.

POSTMASTER: Send address changes to ***Alternative Therapies in Women's Health***, P.O. Box 740059, Atlanta, GA 30374.

Back issues: $33. Missing issues will be fulfilled by Customer Service free of charge when contacted within one month of the missing issue's date.

Subscriber Information

Customer Service: 1-800-688-2421.

Customer Service E-Mail Address:
customerservice@ahcpub.com

Editorial E-Mail Address: leslie.coplin@medec.com

World-Wide Web: http://www.ahcpub.com

Subscription Prices

United States
$199 per year (Student/Resident rate: $105).
Outside the United States
$229 per year plus GST (Student/Resident rate: $120 plus GST).

Accreditation

American Health Consultants is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor CME for physicians. American Health Consultants designates this CME activity for 20 credit hours of Category 1 of the Physician's Recognition Award of the AMA. This CME activity was planned and produced in accordance with the ACCME Essentials. Term of approval is for one year from beginning of distribution date of May 1, 1998 with option to request yearly renewal.
For CME credit, add $50.

Questions & Comments

Please call **Leslie Coplin**, Managing Editor, at (404) 262-5534 or **Paula Cousins**, Associate Managing Editor, at (404) 262-5416, between 8:30 a.m. and 4:30 p.m. ET, Monday-Friday.

Conflict of Interest Disclosure

Dr. Coldlitz, Dr. Fugh-Berman, Dr. Hoffman, Dr. Kronenberg, Dr. McPartland, Dr. Massion, and Dr. Pan have reported no relationships with companies related to the field of study covered by this CME program. Dr. Awang has the following relationships: consultant for Leiner Health Products, Chai-Na-Ta Corp, and Health 4 All Products. Dr. Cates serves on the Women's Health Leadership Council for Advanced Care Products, Scientific Advisory Board—Contraception for Wyeth, and Prevention of Adolescent Pregnancy Advisory Board for Johnson & Johnson. Dr. Low Dog is a consultant for the Materia Medica Group. Dr. Scialli has the following relationships: consultant for TAP and Eli Lilly & Co.; speaker for TAP, Eli Lilly & Co., and Solvay; researcher for TAP, Wyeth-Ayerst, Solvay and Pfizer.

of pregnancy (see *Alternative Therapies in Women's Health*, January 1999, pp. 9-11), but there are no convincing data that acupuncture (at least at these sets of acupuncture points) has a positive effect on duration of labor in term pregnancies. ❖

References

1. Zeisler H, et al. Influence of acupuncture on duration of labor. *Gynecol Obstet Invest* 1998;46:22-25.
2. *Taber's Cyclopedic Medical Dictionary*, 18th ed. Philadelphia, PA: FA Davis Co.; 1997.
3. Lyrenas S, et al. Acupuncture before delivery: Effect on labor. *Gynecol Obstet Invest* 1987;24:217-224.
4. Kubista E, Kucera H. Uber die anwaendung der akupunktur zur geburtsvorbereitung. *Z Geburtshilfe Perinatol* 1974;178:224-229.

Estriol: A Kinder, Gentler Estrogen?

By Adriane Fugh-Berman, MD

IN DISCUSSIONS ABOUT HORMONE REPLACEMENT THERAPY (HRT), patients may ask about estriol or tri-estrogen formulations. Both of these are being promoted by some alternative medicine practitioners as safer forms of estrogen therapy than conjugated estrogens. Estriol has been touted as a "good" estrogen that does not increase the risk of breast cancer; claims are also made that it may reduce the risk of developing breast cancer. These claims are unsubstantiated.

Estriol is a weak, short-acting estrogen sometimes used to treat menopausal symptoms including hot flashes or urogenital atrophy;[1] it has also been found beneficial in bone mineral density.[2,3] It is not commonly used by conventional medical practitioners in the United States, but a number of alternative practitioners prescribe it.

Tri-estrogen is described in a publication distributed by Women's International Pharmacy (a compounding pharmacy in Madison, WI) as "a natural estrogen formula that attempts to minimize the risks of estrogen and maximizes its benefits. Tri-estrogen utilizes the benefits of all three naturally occurring estrogens: estrone (E1), estradiol (E2) and estriol (E3) in a safe and effective way." No evidence is presented for this claim; a MEDLINE search failed to turn up any clinical trials on tri-estrogen preparations.

Tri-estrogen preparations (also called "Tri-Est") are mixtures of estrone, estradiol, and estriol (typically in a 1:1:8 ratio). It is usually administered orally in doses of 2.5-5 mg/d (either continuously or 25 days a month). Although the hormones in Tri-Est are the same as endogenously produced hormones, this is no assurance of long-term safety. High levels of endogenous hormones are associated with increased breast cancer risk.[4,5]

Natural progesterone is often prescribed with this regimen. Topical forms of progesterone, however, may not achieve serum levels high enough to ensure endometrial protection. (See *Alternative Therapies in Women's Health*, April 1999, pp. 33-36.) Oral progestins are a better choice.

Claims that estriol does not cause endometrial stimulation are based on a 1978 study which found that estriol in a dose of 2-8 mg/d improved hot flashes and other symptoms in 52 symptomatic menopausal women (higher doses were more effective).[6] Endometrial biopsy showed no evidence of endometrial hyperplasia after six months. However, six months is not enough time for hyperplasia production in women on any estrogen.

Two recent studies show that estriol does cause endometrial stimulation. Twenty-nine postmenopausal women scheduled for hysterectomies were treated with vaginal estriol (0.5 mg/d) or 17β-estradiol (0.05 mg/d).[7] Biochemical and histological signs of estrogenic stimulation were found in the endometrium, myometrium, and vagina. Similar signs of estrogenic stimulation were found with both estradiol and estriol therapy. And a Swedish study of 1,110 women with postmenopausal bleeding found that endometrial hyperplasia (5-8 mm by transvaginal sonography) was significantly more common in women taking estriol than in women taking sequential estrogen and progestin therapy or with women not receiving HRT.[8]

Proponents also claim that estriol has anticancer effects. This claim is based on a handful of studies (almost all by the same researcher) done in the 1960s and 1970s. These old studies are often referenced as evidence of estriol's benefits and are therefore worth discussing.

A study published in 1966 included 57 pre- and postmenopausal subjects with breast cancer and 41 without breast cancer. This study reports that women with breast cancer excreted 30-60% less estriol per 24 hours than did controls.[9] However, these results were not statistically significant. The text states, "The differences between the group means for estriol excretion alone, or for the mean or median Eq values between the two groups did not attain the 5% confidence level by various parametrical and nonparametrical tests."

"Eq" stands for "estriol excretion quotient," a ratio of

estriol to estrone and estradiol (an unusual test that apparently was invented by the authors). The authors' entire basis for their conclusion is a higher number of "subnormal" Eq among breast cancer patients compared with controls in a subanalysis. "Subnormal" is not defined, and such results on an unvalidated test count for nothing.

Additionally, there is reason to suspect that a number of women in the control group may have had abnormal ovarian function that could have affected results: nine of 24 premenopausal women in the control group were infertile, two of 10 postmenopausal controls had "other cancers," and three had "polycystic ovaries or cortical fibrosis."

In a later article,[10] the same author cites three studies (including the above study) as evidence for reduced estriol excretion in breast cancer and cites seven studies that found no difference. Although he notes that "initial reports of reduced estriol excretion in breast carcinoma have not been substantiated by others,"[10] he continues to argue that estriol may be useful in breast cancer prevention.[10,11] This is particularly notable given that by his own report six of 24 breast cancer patients treated with estriol (5-15 mg/d) experienced "increased growth of metastases," and two developed endometrial hyperplasia. Five others also experienced vaginal bleeding.[10]

Another oft-quoted citation contends that estriol arrests metastasis or causes remission of breast cancer in 37% of patients. This is based on a commentary by Follingstad that contains a reference to an unpublished study (by Lemon), in which an unspecified number of postmenopausal breast cancer patients received 2.5-15 mg of estriol for an unspecified amount of time.[12] It is explicitly stated that the study was designed as a safety study and not designed to test efficacy.

In summary, there is evidence that estriol is estrogenic and when administered on a continuous basis can serve as hormone replacement therapy. However, there are few trials on this therapy. There is no reasonable scientific evidence that estriol has anticancer effects or that it is safer than estradiol or conjugated estrogens. ❖

References

1. Cardozo L, et al. Meta-analysis of estrogen therapy in the management of urogenital atrophy in postmenopausal women: Second report of the Hormones and Urogenital Therapy Committee. *Obstet Gynecol* 1998;92:722-727.
2. Minaguchi H, et al. Effect of estriol on bone loss in postmenopausal Japanese women: A multicenter prospective open study. *J Obstet Gynaecol Res* 1996;22:259-265.
3. Itoi H, et al. Comparison of the long-term effects of oral estriol with the effects of conjugated estrogen, 1-alpha-hydroxyvitamin D3 and calcium lactate on vertebral bone loss in early menopausal women. *Maturitas* 1997;28:11-17.
4. Hankinson SE, et al. Plasma sex steroid hormone levels and risk of breast cancer in postmenopausal women. *J Natl Cancer Inst* 1998;90:1292-1299.
5. Colditz GA. Relationship between estrogen levels, use of hormone replacement therapy, and breast cancer. *J Natl Cancer Inst* 1998;90:814-823.
6. Tzingounis VA, et al. Estriol in the management of the menopause. *JAMA* 1978;239:1638-1641.
7. van Haaften M, et al. Biochemical and histological effects of vaginal estriol and estradiol applications on the endometrium, myometrium and vagina of postmenopausal women. *Gynecol Endocrinol* 1997;11: 175-185.
8. Granberg S, et al. Endometrial sonographic and histologic findings in women with and without hormonal replacement therapy suffering from postmenopausal bleeding. *Maturitas* 1997;27:35-40.
9. Lemon HM, et al. Reduced estriol excretion in patients with breast cancer prior to endocrine therapy. *JAMA* 1966;196:1128-1136.
10. Lemon HM. Pathophysiologic considerations in the treatment of menopausal patients with oestrogens; the role of oestriol in the prevention of mammary carcinoma. *Acta Endocrinol Suppl* (Copenh) 1980;233:17-27.
11. Lemon HM, et al. Inhibition of radiogenic mammary carcinoma in rats by estriol or tamoxifen. *Cancer* 1989;63:1685-1692.
12. Follingstad AH. Estriol, the forgotten estrogen? *JAMA* 1978;239:29-30.

Reader Questions

Colloidal silver has been called a natural antibiotic. Is there any truth to this, and are there any risks to consuming silver?

Response: The promotion and use of silver products is a revival of a 19th century fad in which silver compounds were touted as panaceas. Although the most popular claim for currently marketed silver products is that they are "natural" antibiotics capable of preventing and treating infections, manufacturers of these supplements have

claimed that silver is an "essential" mineral and that silver compounds are helpful in more than 650 different diseases.[1]

Silver compounds do have antibiotic effects and have been used for this purpose for centuries. Prior to World War II, silver compounds were quite popular to treat infections ranging from colds to gonorrhea. Now available in oral solutions, aerosols, vaginal douches, and injectables, silver compounds have been advertised as efficacious for preventing cancer, AIDS, and diabetes, and for treating systemic fungal infections, tuberculosis, and malaria.[1]

Although small, harmless amounts of silver are found naturally in mushrooms, milk, and bran, silver is not an essential mineral and can accumulate in the body.[1] Argyria refers to the bluish skin discoloration caused by silver deposits in the dermis. Although this discoloration is harmless, it is permanent, and treatment with chelating agents is usually ineffective.[2] Long-term use has resulted in silver deposits in visceral organs;[1] in rare cases neurological deficits have been observed.[3] The minimal oral dosage necessary to cause systemic argyria is 25-30 g over six months.[2]

Silver acetate is used in some smoking deterrent lozenges and chewing gums, and several cases of argyria have been reported in heavy users of these preparations. Decorated desserts may also contain silver; the metallic sugar balls used to decorate cakes are coated with real silver, and bits of silver foil are sometimes used to decorate desserts, especially in India. About 10 cases of argyria were reported in Japan due to breath fresheners (Jintan brand) that contained silver.[2] A recent case of argyria was reported in a 79-year-old man who, in order to stop smoking, consumed silver sugar cake decorations for 15 years.[2] Over three years, he developed blue lunulae and a gray-brown discoloration over his skin, particularly prominent in the sun-exposed parts of his face, neck, and hands. In one case, a schizophrenic patient who had consumed silver anti-smoking pills for 40 years developed seizures; an extremely high serum concentration of silver was detected.[4]

The marketing of silver as a "natural antibiotic" is misleading. Short-term use for a cold would probably cause no harm (although there is no evidence that it is effective). The possibility that patients may think that silver is an adequate treatment for bacterial or systemic fungal infections could have serious adverse consequences. And if consumers ingest silver preparations regularly in the hopes of averting infections, more cases of argyria can be expected in the future. Although the most common manifestation of argyria, discoloration of the skin, is harmless, the gray coloration is permanent and cosmetically unappealing.

Adriane Fugh-Berman, MD

References

1. Fung MC, et al. Colloidal silver proteins marketed as health supplements. *JAMA* 1995;274:1196-1197.
2. Hanada K, et al. Silver in sugar particles and systemic argyria. *Lancet* 1998;351:960.
3. Westhoven M, Schafer H. Generalized argyrosis in man: Neurological, ultrastructural and x-ray microanalytical findings. *Arch Otorhinolaryngol* 1986; 243:260-264.
4. Ohbo Y, et al. Argyria and convulsive seizures caused by ingestion of silver in a patient with schizophrenia. *Psych Clin Neurosci* 1996;50:89-90.

CME Questions

26. Acupuncture point stimulation has been shown to be effective in:

a. decreasing duration of labor.
b. decreasing the incidence of premature rupture of membranes.
c. decreasing cesareans.
d. None of the above.

27. Which of the following statements is true about estriol?

a. There is reasonable evidence that estriol prevents breast cancer.
b. There is reasonable evidence that estriol is effective in treating hot flashes and urogenital atrophy.
c. Estriol has all of the benefits of conjugated estrogens and none of the risks.
d. All of the above.

28. Excess silver consumption can cause:

a. gray discoloration of the skin.
b. blue lunulae.
c. neurological deficits.
d. All of the above.

29. Treatment of argyria by chelation is generally:

a. ineffective.
b. effective.

30. Elevated homocysteine levels have been linked to an increased risk of which of the following?

a. Cardiovascular disease
b. Neural tube defects
c. Recurrent pregnancy loss
d. All of the above.

With Comments from Adriane Fugh-Berman, MD

Homocysteine Defense Formula™

Label Information

"Promotes healthy heart and circulatory function"

"Important facts you should know:

Sundown's Homocysteine Defense Formula contains a select combination of vitamins which help nutritionally to fortify the body, promoting healthy heart and circulatory function.

Research confirms the importance of healthy homocysteine levels for optimum cardiovascular and circulatory function.

The body requires vitamins B_6, B_{12} and folic acid to break down homocysteine into non-harmful nutrients.

These three essential B vitamins, plus vitamin B_2 and choline, when taken regularly, help maintain healthy levels of homocysteine in the blood."

"For additional cardiovascular protection, take this product with any one of Sundown's quality vitamin E, CoQ10 or garlic products."

Suggested Use

As a dietary supplement, take one tablet daily, preferably with a meal or as directed by a health care professional.

Supplement Facts

Serving size: one tablet

	Amount per serving	*% daily value*
Vitamin B_2	25 mg	1470
Vitamin B_6	25 mg	1250
Vitamin B_{12}	500 mcg	8335
Folic acid	800 mcg	200
Choline	25 mg	*

*Recognized as essential, but no U.S. RDA set

Produced under USP good manufacturing processes

Homocysteine Defense Formula™ is a trademark of Sundown Vitamins®, Boca Raton, FL 33487 (the retail and mass merchandising division of Rexall Sundown, Inc.).

Price: $7.25, 60 tablets

Comments

Elevated homocysteine levels have been linked to an increased risk of, among other things, cardiovascular disease,[1] neural tube defects, and recurrent pregnancy loss.[2] Although folate or pyridoxine alone will lower homocysteine levels, the combination of folate, pyridoxine, and vitamin B_{12} is more effective. The FDA has required enriched grains to be fortified with folic acid since January 1998. However, this will only supply about 100 mcg/d.[3]

The levels of these vitamins in this formula are reasonable and along the lines of doses used in trials of these nutrients to lower homocysteine. A standard vitamin B-complex would contain more B_2 and B_6 (typically 50 or 100 mg) but would contain less folic acid (typically 100 mcg) and vitamin B_{12} (typically 100 mcg). Vitamin B_2 is not involved in homocysteine metabolism.

To my knowledge, choline has not been tested in a clinical trial for this purpose, so its inclusion in this formula demonstrates some knowledge of nutrition: Choline is an important methyl donor and its metabolism is closely interrelated with methionine. Affecting one of these nutrients causes compensatory changes in the others. For example, rats fed a diet deficient in choline will show diminished total folate concentrations.[4] Choline is not considered an essential nutrient because it can be synthesized endogenously; however, dietary intake may still be important, as choline-deficiency syndromes have been identified in humans.

By its label, this product has adequate doses of nutrients known to lower homocysteine levels and should be effective for that purpose. Although it may cost less to buy a B-complex vitamin and add some extra folic acid, this product is not unreasonably priced, especially when compared to other combination dietary supplements.

References

1. Mayer EL, et al. Homocysteine and coronary atherosclerosis. *J Am Coll Cardiol* 1996;27:517-527.
2. Eskes TK. Open or closed? A world of difference: A history of homocysteine research. *Nutr Rev* 1998; 56:236-244.
3. Oakley, GP. Eat right and take a multivitamin. *N Engl J Med* 1998;338:1060-1061.
4. Zeisel SH. Choline and phosphatidylcholine. In: Shils ME, et al., eds. *Modern Nutrition in Health and Disease.* 9th ed. Baltimore, MD: Lippincott, Williams & Wilkins; 1998:516-517.

With Comments from Adriane Fugh-Berman, MD

Low-calorie Entrees Decrease Total Calorie Intake

Source: Rolls BJ, et al. Energy density but not fat content of foods affected energy intake in lean and obese women. *Am J Clin Nutr* 1999;69: 863-871.

Design and Setting: A within-subjects study of women who consumed meals in the laboratory for four test periods of four days each.

Subjects: 34 women (17 lean, 17 obese), aged 18-45.

Treatment: Food representing half of each subject's usual energy intake was manipulated either for energy density or fat density. Besides the "compulsory entrees," volunteers could eat whatever else they wanted. The amount of this self-selected food was monitored.

Outcome Measures: Intake of self-selected foods.

Results: In both lean and obese subjects, consumption of low-energy density foods reduced intake of self-selected foods at meals by 16%. Fat content did not significantly affect energy intake. Palatability of diets was comparable and ratings of hunger did not differ between diets.

Funding: NIH grants DK-39177 and DK-08926 and the International Life Sciences Institute Foundation. General Mills, Inc. conducted fiber analyses of foods and Quidel donated OvuQuick kits used in the study.

Comments: Energy density means calories. Essentially, this study manipulated entrees for both fat and calories, and found that eating foods high in fiber and moisture but low in calories reduced subjects' appetites. Calories were lowered by utilizing foods containing more water and fiber. So, the low-fat, low-calorie entree utilized more fruit and vegetables; the low-fat, high-calorie entree utilized more pasta, rice, and bread, and the high-fat, high-calorie entree utilized more butter, oil, and full-fat products. Fat promotes satiety, but eating a high-fat entree clearly did not reduce subjects' appetite for side dishes.

It is very interesting that only manipulating half of the usual caloric intake resulted in significantly decreased total intake. This could have implications for dieters. Eating low-calorie entrees (without limiting side dishes) may seem less daunting to dieters than trying to eat low-calorie everything all the time. Entrees based on fruits or vegetables appear to be filling, reduce the intake of other foods and have other health benefits as well. ❖

Incorporating Exercise into Daily Life May Be as Good as Going to the Gym

Source: Andersen RE, et al. Effects of lifestyle activity vs. structured aerobic exercise in obese women: A randomized trial. *JAMA* 1999;281:335-340.

Design and Setting: 16-week randomized controlled trial with one-year follow-up. Study was conducted in a university-based weight management program.

Subjects: 40 obese women, aged 21-60.

Treatment: Low-fat diet (1,200 kcal/d) and either a structured aerobic exercise program (three step aerobics classes weekly) or moderate lifestyle activity (increasing physical activity for 30 minutes a day on most days by walking short distances, taking stairs instead of elevators, etc.).

Outcome Measures: Changes in body weight, body composition, cardiovascular risk factors, and physical fitness.

Results: Both groups lost weight (8.3 kg in the aerobic group and 7.9 kg in the lifestyle group), with no significant difference between the groups. Serum triglyceride levels and total cholesterol levels decreased significantly in both groups with no significant differences between groups. The aerobic group lost less fat free mass. At one-year follow-up, the aerobic group regained 1.6 kg while the lifestyle group regained 0.08 kg.

Funding: National Research service award NF32DK09241-01 and NIH Research Scientist Development Award K02-MH00702-08.

Comments: Making time to go to the gym can be difficult for many people, and may be particularly daunting for those who are obese. It is heartening to learn that merely walking more and using stairs more may result in positive changes in terms of weight loss, body composition, and lipids. It bears noting that this level of weight loss—and weight loss maintenance—is far superior to that attained with weight loss drugs as well. However, it is impossible to separate out the effects of exercise on these variables in this study because everyone consumed a low-calorie diet. It would have been preferable to include a third

arm in this study looking at the effects of low-fat diet alone without changes in exercise. ❖

Type and Amount of Fat Associated with Breast Cancer Risk

Source: Holmes MD, et al. Association of dietary intake of fat and fatty acids with risk of breast cancer. *JAMA* 1999;281:914-920.

Objective: To determine whether total intake of fat or intake of fatty acids are associated with breast cancer.

Setting/Methods/Subjects: The Nurses Health Study, a cohort study of 88,795 U.S. women who are sent detailed health and diet questionnaires every two years. The study began in 1976; this report is a 14-year follow-up of those women who answered the 1980 diet questionnaire and who did not have diagnosed cancer (other than non-melanoma skin cancer) prior to 1980.

Results: 2,956 women were diagnosed with breast cancer during this period. Compared to women eating 30-35% fat, women who consumed less than 20% of their calories from fat did not have a lower incidence of breast cancer than those who ate higher amounts. The incidence of breast cancer was slightly higher in women who consumed less than 30% of calories from fat. No increased risk was found for increased intake of animal fat, polyunsaturated fat, saturated fat, or trans-unsaturated fats (in models in which fat intake replaced carbohydrate intake). In general, increased intake of vegetable oils or monounsaturated fat also didn't make a difference. Women who consumed the most omega-3 fats from fish had a slightly increased risk of breast cancer.

Funding: NIH grant CA40356. Additional funding for individual authors from Harvard Center for Cancer Prevention and the 50th Anniversary Program for Scholars in Medicine.

Comments: This study found no increased risk of breast cancer with increased intake of any fat or fatty acid (with the surprising exception of omega-3 fatty acids from fish). Even women who consumed more than 50% of their calories from fat were not at increased risk. These data were analyzed in a number of different ways, quite thoroughly. For example, breast cancer risk factors were examined in order to ensure that a low-fat diet was not a marker for elevated risk. (In other words, if women who knew that they were at elevated risk of breast cancer deliberately altered their diets, then more high-risk women would show up in the low-fat group. This was not the case).

This study is particularly interesting given that epidemiologically, populations that consume very low-fat diets have a lower rate of breast cancer incidence; additionally, animal experiments show a lower rate of mammary tumors with diets that contain under 20% fat.

The number of women eating a diet under 20% fat was relatively small (20 cases of breast cancer/6,539 person-years) but probably accurately reflects the percentage of the general U.S. population consuming this type of diet, which is quite stringent.

The Nurses Health Study is a large observational study that has provided many interesting findings over the years. However, observational trials can provide only evidence, not proof. That will have to await the results of the Women's Health Initiative, a large-scale, randomized controlled trial. While the main purpose of the trial is to examine the effect of hormone replacement therapy vs. placebo on a variety of health outcomes, there is also a low-fat diet arm to this trial. Results, however, will not be available until about 2007. ❖

Note to Readers

The editors invite you to submit product labels for review or submit questions about articles in or relevant to *Alternative Therapies in Women's Health*. Please send your questions or product labels (and any available promotional material) to: *Alternative Therapies in Women's Health*, c/o American Health Consultants, P.O. Box 740056, Atlanta, GA 30374. Or you may contact the staff via e-mail at leslie.coplin@medec.com or paula.cousins@medec.com

In Future Issues:

Folic Acid and Pregnancy

Blue-Green Algae: Panacea or Poison

Feverfew and Migraine

St. John's Wort and Depression