ALTERNATIVE THERAPIES IN WOMEN'S HEALTH

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INSIDE

CAM and Fibromyalgia

By Lynn Keegan, RN, PhD, HNC, FAAN

FIBROMYALGIA (FM), SOMETIMES TERMED FIBROMYALGIA SYNDROME or FMS, is a chronic musculoskeletal disorder that is characterized by widespread pain, tenderness at multiple anatomical sites, and other clinical manifestations such as fatigue and sleep disturbance.[1] It occurs predominantly in women and affects approximately 2-4% of people in industrialized societies.[2]

History of the Disease

For centuries, muscle pains have been known as rheumatism. Gowers coined the term fibrositis in 1904 and it was not changed to fibromyalgia until 1976. Smythe laid the foundation of modern FM in 1972 by describing widespread pain and tender points. The first controlled clinical study with validation of known symptoms and tender points was published in 1981. The important concept that FM and other similar conditions are interconnected was proposed in 1984. The first American College of Rheumatology criteria were published in 1990 and neurohormonal mechanisms with central sensitization were developed in the 1990s. Serotonergic/norepinephric drugs were first shown to be effective in 1986.[3]

The American College of Rheumatology's classification criteria for FM include diffuse soft-tissue pain of at least three months' duration and pain on palpation in at least 11 of 18 paired tender points. Symptoms often are exacerbated by exertion, stress, lack of sleep, and weather changes. FM primarily is a diagnosis of exclusion, established by clinical observation only after other causes of joint or muscle pain are ruled out. The initial workup for patients who present with widespread musculoskeletal pain generally includes a complete blood count, erythrocyte sedimentation rate, liver function tests, hepatitis C antibody, calcium, and thyrotropin. The musculoskeletal system, the neuroendocrine system, and the central nervous system, particularly the limbic system, appear to play major roles in the pathogenesis of FM.[4]

The constellation of FM symptoms is clearly recognizable as a distinct pathologic entity. Differential diagnosis must include other somatic syndromes as well as disease entities like hepatitis,

VOLUME 7 • NUMBER 6 • JUNE 2005 • PAGES 41-48

hypothyroidism, diabetes mellitus, electrolyte imbalance, multiple sclerosis, and cancer. Diagnostic criteria are given as guidelines for the diagnosis, not as absolute requirements.[5]

FM is characterized by diffuse pain and associated psychophysiological symptoms. Despite extensive research during the past three decades, the etiology and pathophysiology of FM and effective treatment approaches have yet to be delineated. Recently, it has been suggested that FM may be related to hypofunctional stress systems, particularly in the autonomic nervous system and the hypothalamic-pituitary-adrenal axis. Studies have demonstrated that FM patients exhibit lowered sympathoadrenal reactivity to stress. These findings seem to be consistent with the large volume of research indicating the inverse relationship between pain sensitivity and sympathetic reactivity.[6]

FM is associated with significant impairment on quality of life and function and substantial financial costs as well.[4] In a Canadian study investigating six-month direct and indirect costs, 180 women with primary FM completed a health resource questionnaire as well as measures of pain, psychological distress, comorbidity, and disability. Unit costs for resources were obtained from government, hospital, laboratory, and professional association sources. Regression modeling for six-month direct costs included age, disability, comorbidity, pain intensity, psychological distress, education, and work status. The average six-month direct costs were for conventional medications, complementary and alternative medicine (CAM), and diagnostic tests. The study concludes that women with FM are high consumers of both conventional and CAM services. FM also imposes important indirect costs, which were nearly 70% of the economic burden.[7]

Traditional Management

Traditional FM management involves education regarding the nature of the problem, an exercise program, and advice on stress management. However, management needs to be flexible and holistic and may involve relaxation programs, physical therapies, cognitive behavioral therapy, and analgesic medication.[2]

Clinical treatment usually includes lifestyle modifications and pharmacologic interventions meant to relieve pain, improve sleep quality, and treat mood disorders. These therapies often are ineffective or have been shown in clinical studies to have only short-term effectiveness. Pharmacologic treatments have considerable side effects. Patients may have difficulty complying with exercise-based treatments. As a result, patients seek CAM approaches, including diet therapy, acupuncture, and herbal therapy, and physicians may be asked for advice about these treatments.[1,5]

CAM Use by Fibromyalgia Patients

CAM use for all chronic conditions has increased in recent years. One stratified random selection study in university-based primary care clinics assessed the frequency and types of CAM therapy used by 612 women and men aged 18-84 years who have osteoarthritis, rheumatoid arthritis, or FM. Subjects with FM used an average of 3.9 CAM therapies vs. 2.4 for subjects with rheumatoid arthritis and 2.1 for subjects with osteoarthritis. Health care providers should be aware of the high use of CAM and incorporate questions about its use into routine assessments and treatment planning.[8]

A U.S. study evaluating the frequency and pattern of CAM use in patients referred to a FM treatment program at a tertiary care center discovered that CAM use is prevalent. Patients referred to the Mayo Fibromyalgia Treatment Program between February 2003 and July 2003 were invited on their initial visit to participate in a survey regarding CAM use during the previous six months. Of the 304 patients invited to participate, 289

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

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GST Registration Number: R128870672.

Application to mail at periodical postage rates is pending at Atlanta, GA 30304.

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

Back issues: $45. Missing issues will be fulfilled by Customer Service free of charge when contacted within one month of the missing issue's date.

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$319 per year (Student/Resident rate: $150).

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Outside the United States

$349 per year plus GST (Student/Resident rate: $165 plus GST).

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Statement of Financial Disclosure

In order to reveal any potential bias in this publication, and in accordance with Accreditation Council for Continuing Education guidelines, physicians have reported the following relationships with companies related to the field of study covered by this CME program. Dr. Hardy is on the scientific advisory board for Pharmavite and Herbalife. Dr. Berga is a consultant for Pfizer, Organon, and Women First, Inc., and is involved in research for Berlex and Health Decisions, Inc. Ms. Ball is a consultant for STERIS Corp. and AORN; stockholder for STERIS Corp. and Encision; and speaker's bureau for AORN. Dr. Balk, Ms. Coons, Ms. Coplin, Dr. Keegan, Dr. Milan, and Dr. O'Mathúna have no relationships with companies related to the field of study covered by this continuing education program. This publication does not receive commercial support.

(95%) completed the survey (263 women and 26 men). Ninety-eight percent of the patients had used some type of CAM therapy during the previous six months. The 10 most frequently used CAM treatments were exercise for a specific medical problem (48%), spiritual healing (prayers) (45%), massage therapy (44%), chiropractic treatments (37%), vitamin C (35%), vitamin E (31%), magnesium (29%), vitamin B complex (25%), green tea (24%), and weight-loss programs (20%).[9]

A Canadian study documented health service utilization and examined whether psychological vulnerability was associated with visits to physicians and CAM providers. Women with a diagnosis of primary FM (n = 178) completed a psychosocial test measuring pain, perceived stress, global psychological distress, sexual abuse history, comorbidity, and disability due to FM. Subjects also completed a health services questionnaire documenting visits to physicians and CAM providers during the previous six months. The researchers found subjects made an average of 7.2 visits to physicians and 11.3 visits to CAM providers. The number of physician visits was significantly associated with more comorbidity. Psychologically vulnerable subjects were more likely to use CAM services than those not so classified.[10]

Systematic Reviews

A Cochrane database study reviewed 505 articles to provide up-to-date, evidence-based guidelines for the optimal treatment of FM. Data synthesis found major limitations to the FM literature, with many treatment trials compromised by short duration and lack of masking. FDA has not approved any medical therapies specifically for FM management. Current evidence suggests efficacy of low-dose tricyclic antidepressants, cardiovascular exercise, cognitive behavioral therapy, and patient education. A number of other commonly used FM therapies, such as trigger point injections, have not been evaluated adequately. Based on current evidence, the authors recommended a stepwise program emphasizing education, certain medications, exercise, cognitive therapy, or all four.[11]

CAM is gaining increasing popularity among individuals with FM and for whom traditional medicine generally has been ineffective. A systematic review of randomized controlled trials (RCTs) and non-RCTs on CAM studies for FM was conducted to evaluate the empirical evidence for their effectiveness. Few RCTs achieved high scores on the CONSORT, a standardized evaluation of the quality of methodology reporting. The review found that acupuncture, certain herbal and nutritional supplements (magnesium, SAMe), and massage therapy have the best evidence for effectiveness with FM. Other CAM therapies either have been evaluated in only one RCT with positive results (Chlorella, biofeedback, relaxation), in multiple RCTs with mixed results (magnet therapies), or have positive results from studies with methodological flaws (homeopathy, botanical oils, balneotherapy, anthocyanidins, dietary modifications). Lastly, other CAM therapies have neither well-designed studies nor positive results and currently are not recommended for FM treatment (chiropractic care).[12] Although SAMe and magnesium both have been discussed as possibly having therapeutic benefit, no recent clinical trials were found that document either therapy as particularly beneficial.

UK researchers carried out a systematic review from 1980-2000 of RCTs of nonpharmacological interventions for FM. The review yielded 25 RCTs, and the main categories of interventions tested in the studies were exercise therapy, educational intervention, relaxation therapy, cognitive-behavioral therapy, acupuncture, and forms of hydrotherapy. Strong evidence did not emerge with respect to any single intervention, though preliminary support of moderate strength existed for aerobic exercise.[13]

Clinical Trials

Exercise. A Canadian study that measured mood and physical function of individuals with FM who participated in 23 weeks of supervised aerobic exercise found that exercise can improve physical function, mood, symptom severity, and aspects of self-efficacy for at least one year. Outcomes included a six-minute walk test, Beck Depression Inventory (BDI), State-Trait Anxiety Inventory, Arthritis Self-Efficacy Scale (ASES), Fibromyalgia Impact Questionnaire (FIQ), tender point count, patient global assessment score, and exercise compliance. Outcomes were measured at the start and end of the exercise classes as well as six and 12 months later. Analyses were conducted on 29 intent-to-treat (or 18 efficacy) subjects. Six-minute walk distances and BDI total scores were improved at follow-up in all analyses. BDI cognitive/affective scores were improved at the end of 23 weeks of exercise (both analyses) and at the 12-month follow-up (efficacy analysis only). BDI somatic scores were improved at six-month (both analyses) and 12-month follow-up (intent-to-treat only). FIQ and ASES function were improved at all follow-up points. ASES pain was improved in efficacy analyses only (all follow-up points). Tender points were unchanged after 23 weeks of exercise and at follow-up. Exercise duration at follow-up (total minutes of aerobic plus anaerobic exercise in the preceding week) was related to gains in physical function (six- and 12-month follow-up) and mood (six-

month follow-up).[14]

In order to assess the effect of exercise in FM, a Cochrane Controlled Trials Register was reviewed in a Norwegian study; 17 studies of exercise interventions on cardiorespiratory endurance, muscle strength, and/or flexibility were selected. The results from the studies are inconsistent, but low-intensity aerobic exercise regimens were found to be one of the few effective treatments. In these studies, subjective pain levels fail to show significant improvement, although improvements are seen on other parameters such as in the number of tender points, total myalgic scores and reduced tender point tenderness, aerobic capacity, physical function, subjective well-being, and self-efficacy.[15]

Therapeutic Touch. A pilot study tested the effectiveness of six therapeutic touch treatments on the experience of pain and quality of life for persons with FM. Its findings support that subjects who received therapeutic touch had a statistically significant decrease in pain for each pre-therapeutic to post-therapeutic touch treatment, as well as significant improvement in quality of life from pre-first to pre-sixth treatment.[16] Therapeutic touch, a controversial CAM modality, may be an effective treatment for relieving pain and improving quality of life in this specific population.

Acupuncture. Acupuncture has become a widely used treatment modality for musculoskeletal pain conditions. Acupuncture is shown to enhance blood flow and recovery in surgical flaps. The mechanisms behind the effect on blood flow were suggested to rely on vasoactive substances, such as calcitonin gene-related peptide, released from nociceptors by the needle stimulation.

A Swedish study examined the effect of needle stimulation on local blood flow in the anterior tibial muscle and overlying skin in 15 FM patients suffering from a widespread chronic pain condition. Two modes of needling (deep muscle stimulation and subcutaneous needle insertion) were performed at the upper anterior aspect of the tibia, i.e., in an area without focal pathology or ongoing pain in these patients. Blood flow changes were assessed non-invasively by photoplethysmography. The results showed that deep muscle stimulation resulted in a larger increase in skin blood flow (mean standard error [SE]): 62.4% [13.0] and muscle blood flow: 93.1% [18.6], compared to baseline, than did subcutaneous insertion (mean [SE] skin blood flow increase: 26.4% [6.2]; muscle blood flow increase: 46.1% [10.2]). However, in FM patients, subcutaneous needle insertion was followed by a significant increase in both skin and muscle blood flow, in contrast to findings in healthy subjects where no significant blood flow increase was found following the subcutaneous needling. The different results of subcutaneous needling between the groups (skin blood flow: $P = 0.008$; muscle blood flow: $P = 0.027$) may be related to a greater sensitivity to pain and other somatosensory input in FM patients.[17]

Chiropractic. Some clinicians report that chiropractic is not useful in FM patients because of poorly designed studies and questionable results in published work.[12]

A recent example is a study advocating chiropractic care done by a private practitioner of chiropractic in Canada. The objective of this investigation was to determine whether a chiropractic treatment regimen that combines ischemic compression and spinal manipulation effectively reduces the intensity of pain, sleep disturbance, and fatigue associated with FM. In addition, the objective was to study the dose-response relation and identify the baseline characteristics that may serve as predictors of outcome. Subjects were assessed in a private practice setting with self-administered questionnaires taken at baseline, after 15 and 30 treatments, and one month after the end of the treatment trial. Subjects were adult members of a regional Fibromyalgia Association and had been diagnosed with FM for more than three months. Fifteen women (mean age 51.1 years) completed the trial. Nine (60%) were classified as respondents. A statistically significant lessening of pain intensity and corresponding improvement in quality of sleep and fatigue level were observed after 15 and 30 treatments. After 30 treatments, the respondents showed an average lessening of 77.2 (standard deviation [SD] = 12.3) in pain intensity and an improvement of 63.5 (SD = 31.6) in sleep quality and 74.8 (SD = 23.1) in fatigue level. The improvement in the three outcome measures was maintained after one month without treatment. A trend, determined as not statistically significant, suggests that older subjects with severe and more chronic pain and a greater number of tender points respond more poorly to treatment. The author concludes that this study points to a potential role for chiropractic care in the management of FM, but suggests that RCTs should be conducted to test this hypothesis.[18]

Adverse Effects

Because of widespread and growing CAM use, especially by persons with chronic illnesses, it is essential to review efficacy and adverse effects of CAM therapies.[1] None of the treatments in question is totally devoid of risks. By and large the data are not compelling, not least due to their paucity and methodological limitations. It is, therefore, concluded that research efforts must be directed toward defining which form of CAM generates more good than harm for which condition.[19]

Conclusion

Nontraditional treatment alternatives range from use of nutritional and herbal supplements to acupuncture and mind-body therapy. Little is known about efficacy and tolerance of CAM therapies in FM and other chronic musculoskeletal pain syndromes. Most studies on these treatments have been performed for osteoarthritis, rheumatoid arthritis, or focal musculoskeletal conditions. Clinical trials are scarce, and the quality of these trials often is criticized because of small study population size, lack of appropriate control interventions, poor compliance, or short duration of follow-up. CAM is immensely popular for musculoskeletal conditions. It is, therefore, essential to define CAM's value for such indications. Collectively the evidence demonstrates that some CAM modalities show significant promise, e.g., acupuncture, exercise, and stress management. There is a lot of evidence that FM patients use CAM, but unfortunately few trials of these therapies exist and more are certainly warranted.

Recommendation

CAM therapies have been documented and proven useful in many chronic conditions. In lieu of these findings and ongoing clinical investigations, using CAM in FM is a useful adjunct and sometimes complete intervention for these distressing symptoms. FM patients may want to consider the validated use of exercise and stress management while continuing to explore new therapies that are personally beneficial to them. ❖

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Long-Term Effects of Vitamin E on Cardiovascular Disease and Cancer

Source: Lonn E, et al.; HOPE and HOPE-TOO Trial Investigators. Effects of long-term vitamin E supplementation on cardiovascular events and cancer. *JAMA* 2005;293:1338-1347.

Abstract: Experimental and epidemiological data suggest that vitamin E supplementation may prevent cancer and cardiovascular events. Clinical trials have generally failed to confirm benefits, possibly due to their relatively short duration. These researchers sought to evaluate whether long-term supplementation with vitamin E decreases the risk of cancer, cancer

death, and major cardiovascular events. A randomized, double-blind, placebo-controlled international trial (the initial Heart Outcomes Prevention Evaluation [HOPE] trial conducted between December 21, 1993, and April 15, 1999) of patients at least 55 years old with vascular disease or diabetes mellitus was extended (HOPE-The Ongoing Outcomes [HOPE-TOO]) between April 16, 1999, and May 26, 2003. Of the initial 267 HOPE centers that had enrolled 9,541 patients, 174 centers participated in the HOPE-TOO trial. Of 7,030 patients enrolled at these centers, 916 were deceased at the beginning of the extension, 1,382 refused participation, 3,994 continued to take the study intervention, and 738 agreed to passive follow-up. Median duration of follow-up was 7.0 years. Participants were given a daily dose of natural source vitamin E (400 IU) or matching placebo. Primary outcomes included cancer incidence, cancer deaths, and major cardiovascular events (myocardial infarction, stroke, and cardiovascular death). Secondary outcomes included heart failure, unstable angina, and revascularizations. Among all HOPE patients, there were no significant differences in the primary analysis: for cancer incidence, there were 552 patients (11.6%) in the vitamin E group vs. 586 (12.3%) in the placebo group (relative risk [RR], 0.94; 95% confidence interval [CI], 0.84-1.06; P = 0.30); for cancer deaths, 156 (3.3%) vs. 178 (3.7%), respectively (RR, 0.88; 95% CI, 0.71-1.09; P = 0.24); and for major cardiovascular events, 1,022 (21.5%) vs. 985 (20.6%), respectively (RR, 1.04; 95% CI, 0.96-1.14; P = 0.34). Patients in the vitamin E group had a higher risk of heart failure (RR, 1.13; 95% CI, 1.01-1.26; P = 0.03) and hospitalization for heart failure (RR, 1.21; 95% CI, 1.00-1.47; P = 0.045). Similarly, among patients enrolled at the centers participating in the HOPE-TOO trial, there were no differences in cancer incidence, cancer deaths, and major cardiovascular events, but higher rates of heart failure and hospitalizations for heart failure. The authors concluded that in patients with vascular disease or diabetes mellitus, long-term vitamin E supplementation does not prevent cancer or major cardiovascular events and may increase the risk for heart failure.

■ COMMENT BY SARAH L. BERGA, MD

THE RATIONALE FOR THIS STUDY IS INTERESTING. AS THE trial investigators point out, oxidative injury has been implicated as a key mechanism, leading to atherosclerotic cardiovascular disease and cancer. For instance, LDL cholesterol is more atherogenic when it is oxidized. Also, oxidative cellular metabolism generates oxygen-free radicals that are thought to damage DNA and other cellular structures, thereby initiating and promoting tumorigenesis. The most active form of vitamin E is α-tocopherol, and it has been shown to possess antioxidant activity in many in vitro model systems. Further, epidemiological studies indicated an inverse link between vitamin E intake from dietary sources and cardiovascular disease and cancer. Thus, it seemed only a small leap of logic to think that exogenously administered vitamin E might be good for those with established cardiovascular disease. Indeed, it has been common practice for cardiologists to recommend its use. Further, observational studies indicated that diets high in fresh fruits and vegetables (that provide a ready source of vitamin E) were associated with a reduced incidence of cancer. The present study was undertaken to see if long-term exogenous administration of vitamin E use would confer reduced cardiovascular disease and cancer in those at high risk for these outcomes. When the initial results yielded null results, the investigators decided to continue the study to see if additional time would yield different results. The final results are presented in the current article.

The study design was an international, multicenter, double-blind, randomized, 2 × 2 factorial trial that evaluated the antihypertensive ramipril vs. placebo and vitamin E vs. placebo alone in 9,541 patients at high risk for cardiovascular events. All patients were at least 55 years old at the start of the trial. The initial observation period was 3-5 years and included almost 5,000 patients in the vitamin E and placebo arms. The continuation phase included more than 3,500 patients in each arm, with a mean follow-up of 7.0 years. Natural vitamin E was given at a dose of 400 IU daily. Mean plasma vitamin E increased from 30 to 49 mmoL/L in the vitamin E group. Compliance was high, and the data were analyzed by intention-to-treat.

The results showed no decrease in fatal or nonfatal cancer. Specifically, there was no reduction in prostate, colorectal, or breast cancer. Vitamin E use also did not reduce myocardial infarction, stroke, cardiovascular death, unstable angina, revascularization, or total mortality. There was an increase in hospitalization for heart failure in the vitamin E group.

Vitamin E long has been touted as a mainstay in the armamentarium for chemoprevention of aging. Even before the results of the Women's Health Initiative (WHI) cast a shadow on the use of standard hormone therapy regimens, the use of vitamin E had been advocated as a "natural intervention" for the control of menopausal hot flashes. Given the increased patient and physician trepidation concerning HRT that followed the publication of the WHI results, many menopausal women have looked for alternative therapies for the amelioration of hot flashes and found vitamin E. Physicians generally endorse the exogenous intake of vitamin E, thinking that it is certainly safe, even if less effective than HRT for the control of hot flashes. As is typically the case, the less we know about a substance, the safer it appears. Conversely, the more a substance is studied, the less the promise and the more the risk. This caveat appears to hold also for vitamin E supplementation. Mul-

tivitamins typically contain about 30 IU, but there are many mega-vitamin preparations that contain doses as high as 800 IU. Interestingly, there are no clinical trial data to suggest that vitamin E is effective in the amelioration of hot flashes, although there is wide-spread belief that its use is helpful in this context.

Taking the aggregate results at face value, how might we reconcile the observational and cellular data with the results of this and similar studies showing no benefit when vitamin E is administered in randomized clinical trials to at-risk populations? One worries about dose. The use of 400 IU led to a modest increase, but we have no way to know if the increase was "too large" or "too small." Perhaps vitamin E only works as prophylaxis, and this study included older individuals with a high risk for CVD. If the observational studies are right, one would suspect that vitamin E would work when overall health and health behaviors are good, but that it would not help once there was established disease. This might suggest that there are synergistic or additive effects when vitamin E levels are in the right range, but that vitamin E alone cannot reverse health misbehaviors or established disease even when levels are raised.

Observational studies showed that individuals with good diets that led to high circulating vitamin E levels had better cardiovascular health and less cancer. In this context, vitamin E might be a marker for dietary rigor but not the active ingredient in a diet that confers health. Vitamins in food are delivered as part of a "matrix" that contains many other substances in addition to the vitamins that we recognize. Indeed, it is more than a bit presumptuous to think that we can do a better job of conferring nutritional adequacy than exercising dietary discretion.

By now it is clear that randomized, clinical trials evaluating agents intended for chemoprevention of aging raise epistemological concerns and challenge the validity of modern scientific methodologies. In the past, we used the scientific method of altering one variable at a time to identify those key substances whose levels were so critical that their manipulation yielded clear and robust changes in an organism's physiological or health status. A prime example might be cortisol, a hormone whose range must be "just right" for health. Using binary scientific method, we were able to isolate the effective range of this incredibly critical hormone. But the science of health promotion is less simplistic and does not involve adjusting the level of a single substance. Health is a state and there are many important determinants to maintaining it. Of course, in a health care system that rewards transactions, especially simple transactions like writing a prescription for an easy-to-take product, health promotion continues to be suspect and poorly rewarded. One can only conclude that we will continue to be stymied in our efforts to promote good health unless we can provide reliable information on how to do this while avoiding the hucksterism of mercantile promotions. ❖

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CE 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.

CE/CME Instructions: Physicians and nurses participate in this continuing medical education/continuing 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. When your evaluation is received, a certificate will be mailed to you.

CE / CME Questions

23. In a study of patients in the Mayo Fibromyalgia program, 95% percent of survey respondents reported CAM use during the prior six months.
- a. True
- b. False

24. Several clinical trials have found which CAM therapy may be effective in management of fibromyalgia?
- a. Exercise
- b. Massage therapy
- c. Chiropractic
- d. Herbal supplements

25. The use of vitamin E at a daily dose of 400 IU has been shown to:
- a. reduce the risk of cardiovascular disease.
- b. reduce the risk of breast cancer.
- c. reduce the risk of stroke.
- d. increase the risk of dementia.
- e. increase the risk of hospitalization for heart failure.

Answers: 23. a, 24. a, 25. e.

Judge Removes Ban on Sale of Ephedra

A federal judge has struck down the FDA ban on dietary supplements containing ephedra. FDA had pulled the weight-loss aid from the market more than a year ago after it was linked to dozens of deaths.

The judge ruled in favor of Nutraceutical Corp., a Utah supplement company that challenged the FDA's ban. Nutraceutical claimed that ephedra "has been safely consumed" for hundreds of years, and that FDA was wrongly regulating ephedra as a drug and not as a food, according to the Associated Press.

Judge Tena Campbell agreed, saying federal law places more restrictive rules on FDA in determining whether to ban foods as opposed to drugs. The judge said the law requires FDA to prove that a dietary supplement is harmful, rather than having the manufacturer prove it is safe, as is required with drugs.

Nutraceutical President Bruce Hough says the lawsuit had little to do with ephedra and more to do with forcing FDA to follow the rules Congress set down for it. He said Nutraceutical interprets the ruling to mean that the company is allowed to start selling ephedra supplements again, but added that it is too soon to say whether it will put the products back on the market.

FDA spokeswoman Kimberly Rawlings says the agency is "evaluating the decision." Campbell's ruling sends the matter back to FDA "for further rulemaking consistent with the court's opinion" and keeps the agency from enforcement action against the companies.

Majority of Older Adults Use CAM

Nearly three out of every four adults older than age 50 use some kind of complementary and alternative medicine (CAM), such as acupuncture and herbal medicine, according to a new study. The study found that 71% of older adults used some form of alternative medicine in 2000. A study conducted in 2002 found a lower rate—about 62%—among all adults.

"Many types of alternative medicine have not been tested for safety and effectiveness, and yet a large majority of older adults are using them," says Gong-Soog Hong, MS, PhD, co-author of the study and professor of consumer sciences at the Ohio State University in Columbus. "This tells us there is a serious need for more consumer education."

Hong and her colleagues presented their research at the annual meeting of the American Council on Consumer Interests in Columbus on April 9. The researchers used data from the 2000 Health and Retirement Survey, conducted by the University of Michigan and funded primarily by the National Institute on Aging. The survey included 848 respondents aged 50 and over.

The survey asked about the use of six types of alternative medicine: chiropractic, acupuncture, massage therapy, breathing exercises, herbal medicine, and meditation. The most commonly used form of alternative medicine was chiropractic, which about 43% of respondents had used. Acupuncture was the least used.

Some of the results will need more research to explain, Hong says. For example, the findings showed African Americans, widows, and more religious people all tended to use alternative medicine more often than did other older adults.

The researchers could more readily understand other results. Respondents, for instance, were more likely to use alternative medicine if they said they were in poor health and if they reported more problems with daily activities, such as carrying groceries, eating, or bathing.

Of those who described their health as poor, 65% said they used some form of alternative medicine they considered preventive or curative—a higher percentage than among any other group. In addition, about 63% of respondents who said they were not satisfied with their health care also tried alternative therapies classified as preventive or curative.

Hong and her colleagues are now working on a study that will take a more comprehensive look at what alternative medicines people are using and how often they are using them.

"Alternative medicine provides an important option in response to the need for health care in the United States," Hong says. "We need to know more about who is using alternative medicine and ensuring that they are educated about the medicines and therapies they are using." ❖

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