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Alternative Medicine in the Elderly: Use and Abuse

The use of alternative medical practices and herbal supplements grows each year. Many seniors welcome these adjunct treatments into their lifestyles. Our authors examine the pros and cons of some of the more common supplements and herbs.

By Piero Antuono, Jennifer Jones, and Jan Beyer

Complementary or alternative medicine (CAM) is defined as “a broad domain of healing resources that encompasses all health systems, modalities, practices, and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period.”1 In the United States, it has become an increasingly popular mode of therapy, with approximately one-third of all Americans visiting an alternative healthcare practitioner. The number of these visits, estimated to be four million, is more numerous than conventional visits to traditional physicians. Costs for these services have been estimated at more than $13 billion, most of it not reimbursed by healthcare providers.2 What is considered to be CAM in the Western World is classified as traditional medicine in other parts of the world.3 In fact, up to eighty percent of the world’s health care is considered alternative medicine in the West.

CAM has gradually expanded in some Western countries, such as Germany and Australia, where up to seventy percent of all health care interventions involve CAM.4 As a result, consumers, as well as health care professionals, are showing a growing interest in CAM. Approximately fifty percent of United States physicians have used CAM practices and perceive these modalities as having some efficacy.5 In Europe, acupuncture is widely used in pain clinics, and herbal products are among the most frequently prescribed medications. Almost a third of specialty residencies for physicians in the

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United States offer some courses in CAM, and thirty-two medical schools offer courses in CAM.6

The National Library of Medicine biographic database has recently started to collect scientific documentation on CAM. At the rate of twelve percent per year, the number of these citations is steadily increasing and is almost double the growth of traditional medical literature topics from the National Institutes of Health. The Institutes has established an Office of Alternative Medicine to promote studies in this area. Despite more than 600 worldwide journals that report CAM research, the overall quality of this research is regarded as poor, with little understanding of the mechanism of action of several of these interventions.

Despite possible risks, however, the potential benefits of some CAM practices is significant, such as access to low-cost pharmacological intervention or the use of treatments that may not rely on drugs, such as acupuncture or manipulation. Scientific studies are currently underway to study the effect of vitamins and nutritional supplements in diseases such as Alzheimer’s disease, benign prostatic hypertrophy, and heart disease; thus far, results are promising. As the body of scientifically valid knowledge on CAM broadens, these alternative modes of treatment will likely become integrated with traditional medicine. For instance, there is evidence that acupuncture,7 vitamin supplements, herbal products,4 diet,9 and medication10 may have a therapeutic benefit for arthritis sufferers.

In 1990, more than eighty percent of CAM consumers also used conventional medicine interventions.11 Most people who use alternative medicine intervention do so, not because they refuse traditional medicine, but rather as an additional intervention.12 Herbs are generally sold and recommended by the public. These consumers rely on anecdotal evidence rather than scientific proof. Frequently the lay public believes “natural” equates with “safe,” which means there are no side effects and no drug interactions. This concept is obviously erroneous. Most nutritional products can be just as dangerous as prescription drugs and possibly more dangerous, as there is not much known about their mode of action. The traditional healthcare professional has a pivotal role in counseling the consumer about valid CAM practices to be used in conjunction with traditional medicine. CAM users include patients of all ages and cultural backgrounds. With the growing number of healthy elderly, CAM is used increasingly as an intervention to maintain “healthy aging.” At times, the high cost of traditional pharmaceuticals results in the elderly being more receptive to the lure of CAM practices.

At the present time, approximately fifty percent of patients use CAM. The market for natural products is projected to be $6.5 billion in the year 2001, a growth of one hundred percent since 1994. Unlike prescription and over-the-counter medications which have been deemed safe and effective by the FDA, herbal products are labeled as “dietary supplements” according to the Dietary Supplement and Health Education Act of 1994. As dietary supplements these compounds can make “structure and function claims” but cannot make any health or therapeutic claims.13 These products may include accompanying literature if “a balanced view” is presented, but a statement about safety cannot be made without FDA evaluation. Therefore, a disclaimer stating that these compounds have not been evaluated by the FDA is required. The label must state that the product is not intended to diagnose, treat, cure, or prevent a disease, but rather is a dietary supplement intended solely for nutritional support. The manufacturing of herbal products is an unregulated process. Most preparations are not standardized. Variable manufacturing methods, herbal concentrations, and additives can determine the herbal product’s purity, the rate at which it is absorbed in the body, the maximum possible effect, and the dose needed to reach this effect.

Most of the research and professional literature on these compounds comes from Europe and Asia. In Germany, a special commission (Commission E) was set up in 1978 to review and approve herbal treatments; recommendations are based on safety, historical data, and efficacy studies. There are several herbal drugs that are potentially dangerous. For instance, efedra (Ma Haung) contains ephedrine and is frequently used in combination with caffeine, which can have a strong stimulatory effect on the heart. Efedra caused several deaths in the United States before the FDA intervened and withdrew its use. Another, pennyroyal is used to induce abortion or delay menses, but it is toxic to the liver and the central nervous system. Comfrey, used topically on wounds, and internally for gastric ulcers, contains hepatotoxic pyrrolizidine alkaloids. Another questionable product is 5-HTP (hydroxytryptophan) used for depression, weight
loss, and insomnia; it may cause gastric distress and possible heart valve problems.

**Vascular Disease**

Gingko biloba is one herbal product that has frequently been discussed in the literature, specifically for conditions affecting the elderly. This herb, an extract from a leaf of the gingko tree, is one of the most widely prescribed drugs in Europe. It is primarily used to treat decreased peripheral vascular circulation, dementia, and impotence based on vascular disease. It is also widely used as an antioxidant, antiallergy medication, and anticlotting agent. However, it is not an innocuous drug since it may interfere with other drugs that affect clotting, such as Coumadin and Heparin. Individuals using aspirin and ibuprofen should also use it with caution. Gingko may reduce blood pressure and therefore should not be used with nutritional supplements that have a similar effect, such as St. John's Wort (SJW).

Many double-blind studies on gingko, most reported in the German literature, have been carried out. A meta-analysis of forty studies found gingko to be useful in improving symptoms such as difficulty in concentration, memory, confusion, dizziness, headaches, and depression. Four double-blind randomized clinical trials with gingko for intermittent claudication demonstrated that it could increase pain-free walking by seventy-five to one hundred ten percent. Gingko was shown to be helpful for claudication in a study in which patients were evaluated on a treadmill. After twenty-four weeks of treatment, the treated group could walk twice as fast as the placebo group. A small study of gingko in Alzheimer's disease and multi-infarct dementia in 216 patients demonstrated a significant positive response in twenty-eight percent of patients taking gingko versus ten percent of placebo patients. A more recent study reported in JAMA of 309 patients with many types of dementia demonstrated a positive response for one year. The study was, however, fraught with a high dropout rate, and only a moderate response on memory and activities of daily-living scales, which was approximately half of what conventional memory drugs, such as donepezil and rivastigmine, demonstrated. Gingko has been tested in Alzheimer's disease in Europe with overall mixed results. Two large United States-based multicenter, placebo-controlled studies are underway and results should be available in several years.

Gingko has also shown efficacy in treating sexual dysfunction in patients receiving antidepressants. In one study, eighty-four percent of subjects reported positive effects related to libido, erection, orgasm, and resolution.

Vitamin E, also known as Tocopherol, has been used for angina, arteriosclerosis, high cholesterol, dementia, and Alzheimer's disease. Vitamin E is an antioxidant and thus inhibits platelet aggregation, which can prolong bleeding. Recently, it has been shown that vitamin E may limit the amounts of LDL cholesterol and therefore reduce the risk of heart disease. All of these findings are not completely substantiated, and currently vitamin E is used as a preventative agent rather than a therapeutic one. It is known that Tocopherol, a form of vitamin E, is easily absorbed by the body. Another form, Tocopheryl acetate is more difficult to absorb and has a longer shelf life. Therefore, smaller doses of Tocopheryl acetate may be indicated due to its longer mode of action. Furthermore, the D form of vitamin E is thought to be more effective than the "D,L" form, which is a synthetic form of vitamin E. Vitamin E has been tested in Alzheimer's disease in the United States. It appeared to be as effective as the prescription drug, Selegiline, in postponing time of admission to a nursing home, time of death, and significant loss of activities of daily living. Vitamin E is generally well tolerated but can prolong bleeding time. It is currently being tested with the prescription drug, Donepezil, in a multicenter trial for the prevention of Alzheimer's disease.

The root of ginseng has long been used in Asia for the treatment of memory loss associated with aging, as well as to fight infection and to increase mental alertness. Most of these claims remain unsubstantiated, and, in fact, studies have shown no difference from placebos. The most commonly recognized effect of ginseng is a caffeine-like response, which may explain its common side effects of insomnia and agitation. Because of these effects, it should be avoided in people with high blood pressure.

Chronic venous insufficiency, a common ailment in the elderly, has been studied with horse chestnut seed extract (HCSE). The active ingredient of HCSE is escin, an anti-inflammatory drug that inhibits proteolytic enzymes thus promoting collagen and elastin formation. Of thirteen studies reported in the German literature, eight of which were placebo controlled, and five of which were an
active comparator, involving a total of 1083 patients, HCSE was found superior to placebo in eliminating signs of venous insufficiency. Commission E recommended that HCSE "represents a treatment option worth considering." In a second study comparing HCSE and compression stockings in 240 patients, HCSE was as effective as compression stockings and five times more effective than placebo.

Arthritis
Glucosamine and chondroitin are components of the cartilage matrix and stimulate cartilage formation. Their main indication is degenerative joint disease. When chondroitin was compared to diclofenac, a potent anti-inflammatory drug, diclofenac worked faster but chondroitin worked better and lasted longer after cessation of treatment. When glucosamine was compared to ibuprofen, in a double-blind study with forty patients, the effect of glucosamine was better than ibuprofen at eight weeks of treatment, with less than half of the side effects of ibuprofen. In a three-year study of osteoarthritis of the knee in 212 patients, glucosamine improved x-ray findings at one and three years, and increased joint space from baseline.

Prostatic Disease
Urinary frequency in aging men is a common complaint often related to prostatic hypertrophy. Saw palmetto (serenoa repens), a plant native to the southeastern United States, has antiandrogenic, antiestrogenic, and anti-inflammatory properties. It can decrease prostate size, help urinary symptoms within one month, and has no effect on PSA levels. A three-month open label trial using saw palmetto 150 mg twice daily in 505 patients demonstrated significant responses on urodynamic measures of mean flow, residual volume, and prostatic volume. A double-blind placebo-controlled study in 110 patients with the same dose demonstrated significant reduction in nocturia, dysuria flow rate, and post-void residual. A comparative study between 160 mg twice daily of saw palmetto and 5 mg of finasteride in 1098 men with moderate benign prostatic hypertrophy (BPH) demonstrated that saw palmetto and finasteride were clinically equivalent in the treatment of men with 'mild to moderate symptoms of BPH. There were no significant differences in adverse events. Two meta-analyses of eighteen trials (2139 patients) using saw palmetto and twenty-five trials (6840 patients) using alpha-1 blockers demonstrated that both compounds were equally effective in reducing symptoms of prostatic hypertrophy when compared to the placebo-treated patients. Dropouts and adverse events were fewer in the saw palmetto group.

Depression
St. John's Wort (SJW) is among the most commonly used aids for depression, a frequent condition in the elderly. Its active ingredient, hypericin, appears to inhibit monoamine oxidase and prevent serotonin uptake mechanisms targeted by conventional antidepressants. Because of the potential side effects on blood pressure due to its mechanism of action, it should not be taken with tyramine-containing foods such as cheeses, red wine, yeast, or pickled herring. In Germany it is licensed for depression, anxiety, and sleep disorders. It has proven to be as effective as standard antidepressants, with fewer and milder side effects, and represents fifty percent of all prescriptions for depression, totaling three million yearly.

Recent review and meta-analyses of randomized trials with SJW, involving 1757 outpatients with mild to moderate depression, have been published. Findings demonstrated that SJW was superior to placebo and as effective as amitriptyline and imipramine. Of the twenty-three randomized control studies identified between 1983 and 1994 in this report, none were published in English. Recently, in the Evidence Based Medicine publication, twenty-seven studies were reported on this compound; these included seventeen placebo-controlled, and five with active comparators. These studies involved 2291 patients, who were followed up to twelve weeks. SJW showed response in fifty-six percent of patients versus twenty-five percent of placebo patients. In comparator studies, fifty-one percent of patients responded to SJW versus fifty-two percent of patients treated with a tricyclic antidepressant. Inherent limitations in these studies were the small number of patients enrolled in single trials, low dose of comparator drugs, and inconsistency among products tested. In a drug-monitoring study conducted on 3250 patients who were followed by 663 different practitioners, primarily internists, over a period of two to four weeks, trials using 300 mg of SJW demonstrated that sixty-five percent of patients were improved.
and fifteen percent were symptom free. A very recent comparative study between SJW and fluoxetine (Prozac®) in a double-blind, randomized multicenter study of 149 patients, most of whom were women between ages sixty and eighty, with a new diagnosis of depression, demonstrated that after a six-week treatment period of 400 mg SJW versus 10 mg of fluoxetine, seventy-one percent of patients responded to SJW, and seventy-two percent to fluoxetine. The most common side effect of this drug is gastrointestinal sensitivity and possibly photosensitivity.

**Insomnia**

Valerian (Valeriana officinalis) is primarily used for insomnia and anxiety. It is widely used in Europe with more than fifty tons sold every year in France. It enhances the activity of GABA neurotransmitters and can antagonize the hypnotic effects of alcohol but not alcohol's effects on impaired judgment and reaction time. In double-blind studies including respectively, 128 subjects and twenty-seven insomniacs, valerian extract produced a significant decrease in subjectively evaluated sleep latency scores and a significant improvement in sleep quality in approximately eighty-nine percent of patients. This intervention when effective, appears to be superior to traditional hypnosedatives such as benzodiazepines, which have the disadvantage of sedation, decreased REM sleep and dependence, and anticholinergic effects.

Melatonin has been promoted as a sleep aid, antioxidant, anti-aging agent, and antidepressant. Up to fifty percent of people over age sixty-five complain of sleep disturbances, and forty percent of all prescriptions for sedatives are written for people over age sixty-five. The cause of these sleep disturbances may be related to decreased melatonin with normal aging, chronic disease, and drugs. Recent studies have demonstrated the role of melatonin in sleep and its use as a substitute for benzodiazepines to induce sleep. In twelve elderly insomniacs with various illnesses, a double-blind, placebo-controlled, crossover study of six weeks duration with two mg melatonin demonstrated sleep efficiency was greater with melatonin. Melatonin has also been promoted as an anti-aging medication. The hypothesis is that it helps reduce the accumulation of free radicals, which may have a damaging effect on neurons. This mechanism may be enhanced by activity on enzymatic metabolism. It appears to protect proteins and lipids in membranes, stimulate glutathione-peroxidase, and to be more effective as an antioxidant than vitamin E or glutathione in vitro. Extensive studies in humans, however, have not been done. The long-term effects of high doses of melatonin are unknown.

**Conclusions**

Since there are no current regulations for nutritional supplements, elderly who utilize CAM preparations should be cautioned to use a reliable source. The older adult must be assertive in asking his or her doctor or pharmacist about drug interactions, dosing, and the correct formulation to use. With the increased use of herbal compounds, healthcare professionals must be aware of potential drug interactions. The healthcare professional has a responsibility to guide the elderly consumer in the interpretation of extravagant claims in light of scientific evidence so that informed decisions concerning CAM may be made. The elderly may not respond to dosages tested and recommended in the young; currently very little is known about the response of the elderly to these products. Consequently, older adults should not take herbal products without first consulting a doctor or pharmacist. Since many older adults are taking a number of prescription drugs, negative interactions are more likely to occur. A blend of CAM with traditional medical interventions can hopefully result in maximum patient benefit.

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**Endnotes**


5. See Daniel L. Blumberg et al., The Physician and Unconventional Medicine, 1 ALTERNATIVE THERAPIES HEALTH & MED. 31 (1995).


11. See Eisenberg, supra note 2.


15. See S. Kanowskwi et al., Proof of Efficacy of the Ginkgo Biloba Special Extract EGB 761 in Outpatients Suffering from Mild to Moderate Primary Degenerative Dementia of the Alzheimer Type or Multi-Infarct Dementia, 29 PHARMACOPSYCHIATRY 47 (1996).


19. See C. Diehm et al., Comparison of Leg Compression Stocking and Oral Horse-Chestnut Seed Extract Therapy in Patients with Chronic Venous Insufficiency, 347 LANCET 292 (1996).


23. See Jean-Christophe Carraro et al., Comparison of Phytotherapy (Permixon) with Finasteride in the Treatment of Benign Prostate Hyperplasia: A Randomized International Study of 1,098 Patients, 29 PROSTATE 231 (1996).

24. See Timothy J. Wilt et al., Saw Palmetto Extracts for Treatment of Benign Prostatic Hyperplasia: A

29. See G. Harrer et al., Comparison of Equivalence between the St. John's Wort Extract LoHyp-57 and Fluoxetine, 49 ARZNEIMITTELFORSCHUNG 189 (1999).

30. See Peter D. Leathwood et al., Aqueous Extract of Valerian Root (Valeriana Officinalis L.) Improves Sleep Quality in Man, 17 PHARMACOLOGY BIOCHEMICAL BEHAV. 65 (1982); Olav Llindahl & Lars Lindwall, Double-Blind Study of a Valerian Preparation, 32 PHARMACOLOGY BIOCHEMICAL BEHAV. 1065 (1989).