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Herbal Remedies: Some May Help, Others Remain Unproven

By Editorial Staff

Millions of Americans utilize herbal remedies to help maintain health and promote wellness. Among the most popular herbal supplements on the market are ginkgo biloba, St. John's wort, ginseng, echinacea, saw palmetto and kava.
Together, the American Botanical Council estimates that the sales of these six herbs totaled more than $506 million in 1998 in the United States alone.[1] Yet for all of the ailments they are purported to cure, and for all of the people who believe that they work, relatively little research has been conducted that proves their effectiveness.

Dr. Edzard Ernst, a distinguished researcher from South Africa, attempted to look at the science behind supplements by conducting a literature search of the abovementioned products. Every known systematic review of randomized clinical trials involving humans was analyzed and graded for quality. The results of Ernst's investigations, published in the *Annals of Internal Medicine*[2] and summarized below, provide a brief overview of these remedies, including: a description of each herb; its active ingredients and properties; conditions it is traditionally used to treat; evidence that supports (or contradicts) its use for a particular ailment; typical dosage; and potential side-effects and interactions.

Ginkgo Biloba

Ginkgo biloba is a staple of traditional Chinese medicine; the plant's fruit and seeds have been used for thousands of years, mostly to treat asthma and chilblains (a condition characterized by itchy, painful swellings on the feet and lower legs). *In vitro* and *in vivo* studies have suggested that ginkgo reduces blood clotting; removes free radicals from the blood; improves circulation in tiny blood vessels; and affects metabolism. Many of these actions derive from its active ingredients, which include flavonoids and terpene lactones taken from ginkgo leaves.

Positive effects have been seen in the use of ginkgo biloba to treat dementia and intermittent claudication, a disease of the arteries that impairs circulation in the legs. A review of nine double-blind, placebo-controlled studies suggested that ginkgo was successful in delaying the deterioration of cognitive functions in dementia patients, while a review of four studies showed positive results for ginkgo in the treatment of Alzheimer's disease. A separate meta-analysis of eight randomized, controlled trials found that patients with circulatory problems who took ginkgo supplements could walk a greater distance without pain than patients in control groups. The authors of the meta-analysis concluded that the effects of ginkgo were "moderate, yet probably clinically relevant."

Results were less clear for memory impairment and tinnitus. Only eight of 40 controlled trials of ginkgo for impaired memory were judged to be of good scientific quality; of those eight, only one showed positive results for cognitive function. A review of five randomized, controlled ginkgo-tinnitus trials showed moderate benefits in favor of ginkgo, but because the quality of the studies was poor, the researchers said its value in treating tinnitus was "uncertain."

Most of ginkgo's adverse effects were deemed to be "mild, transient and reversible." However, some effects were noted in patients taking ginkgo supplements, particularly bleeding (because of its antiplatelet properties) and seizures, which were seen in some children after taking large quantities of ginkgo seeds. Dosages used in the trials ranged from 120-320 milligrams per day, and it took approximately four weeks for the effects of ginkgo to be noticed.

St. John's Wort

Applied topically or orally, St. John's wort has been used to treat ailments as diverse as bronchitis, hemorrhoids, insect bites and kidney disease. In modern times, it is used almost exclusively as a remedy for depression, although its means of doing so remain unclear. St. John's wort contains various potentially active substances, the most notable being hypericin and hyperforin.

Analysis of previous St. John's wort studies suggests it can effectively treat mild and moderate cases of depression. One review of 27 randomized, double-blind trials found it to work as well as several prescription medications, including amitriptyline and diazepam. A second review of six other randomized trials supported these claims and suggested that it could even be effective in some cases of severe depression. A more rigorous analysis of 14 clinical trials, all of which had been included in the two previously mentioned reviews, confirmed that St. John's wort is "more effective than placebo in the

treatment of mild to moderate depression, and is similar in effectiveness to low-dose tricyclic antidepressants."

The average dosage used in St. John's wort trials was 900 milligrams of a standardized extract, with a time span of about two to three weeks before effects could be seen. In addition, some safety issues were noted for patients using St. John's wort. Taken all by itself, the herb has an "excellent" safety record that is "clearly superior" to conventional antidepressants. When taken with other medications (such as anticoagulants, oral contraceptives, HIV drugs and other antidepressants), however, serious interactions may occur. Patients should always consult with a qualified health care provider when taking St. John's wort in conjunction with any other drug.

Asian Ginseng

Asian ginseng is often recommended by practitioners to improve stamina and physical performance; however, many people claim it can also relieve tension, increase virility and relieve symptoms of depression. This is due to its wide range of pharmacologic properties; research has shown that ginseng can stimulate the nervous system and moderate the immune system to fight fatigue and stress.

One review of 16 randomized, double-blind, placebo-controlled clinical trials "did not support the use of ginseng" for depression, improved memory and concentration, stamina or general wellness. In addition, a non-systematic review of studies of ginseng as a performance enhancer concluded that "compelling evidence on the efficacy of ginseng for this indication is lacking."

Typical dosages used in the ginseng trials ranged from 0.5-2 grams of dried root per day as a short-term treatment, which is equivalent to 200-600 milligrams of an extract. For continuous daily use, no more than one gram of ginseng root should be taken. Side-effects are rare but can be rather severe, including such conditions as insomnia, diarrhea and headaches.

Echinacea

Most echinacea supplements derive from one of three plant species: *E. angustifolia*, *E. pallida* or *E. purpurea*. Most herbal suppliers use echinacea root in their products; others use different parts of the plant. No single active ingredient has been found in echinacea supplements, although they contain many potentially active ingredients. Echincea is used most frequently to stimulate the immune system, prevent infections and treat conditions such as burns and eczema.

The author examined a review of 16 randomized clinical trials of echinacea for upper respiratory tract infections, which failed to provide a definitive answer. Eight of the 16 trials examined the use of echinacea to prevent colds. Six of those trials showed positive effects for echinacea; however, five different echinacea preparations were used, resulting in a lack of sufficient evidence for a particular product. The author concluded that "Echinacea may be efficacious, but the trial data are weak and inconclusive."

Most studies cited used 900-1,000 milligrams of an echinacea supplement three times per day, with anecdotal evidence that the most effective preparation comes from 6-9 millileters of pressed juice from *E. purpurea*. The author feels that systematic studies into the adverse effects associated with echinacea "are needed" given its growing popularity.

Saw Palmetto

Berries from the saw palmetto tree have been traditionally used to treat genitourinary conditions and enhance libido. Today, it is used almost exclusively for benign prostatic hyperplasia, better known as an enlarged prostate gland. How saw palmetto treats this condition is not fully known; some scientists theorize that substances in the plant halt the production of certain enzymes related to estrogen and testosterone.

A review of 16 randomized, double-blind studies involving more than 2,900 patients with enlarged prostates showed that saw palmetto significantly reduced incidences of night-time urination and peak urinary flow. One recent study from the U.S. recommended saw palmetto as "a safe and highly desirable option for men with moderately symptomatic benign prostatic hyperplasia." The results of these studies led Ernst to conclude that there is "good evidence that saw palmetto extract is efficacious short-term (and, probably, medium-term) therapy for symptoms of benign prostatic hyperplasia."

The typical dosage used in the saw palmetto studies was 320 milligrams of an extract taken daily, which is equivalent to 20 grams of saw palmetto berries. Side-effects were rare and usually mild, and no herb-drug interactions were reported.

Kava

Kava comes from the dried rhizome of the kava plant. It is wildly popular in the South Pacific, where kava is used as part of a mildly intoxicating recreational drink. The active ingredients in kava are a group of four compounds called kavapyrones, which relax muscles and reduce the severity of seizures. In the U.S., many people use kava to ease tension and reduce the feelings of anxiety.

A systematic review and meta-analysis of seven randomized, double-blind, placebo-controlled trials examined the use of kava in reducing anxiety, one of which compared kava with the prescription drug oxazepam. The collective results of that trial led Ernst to suggest that "short-term administration of kava is effective in reducing anxiety."

Dosages of kava in the trials ranged from 70-240 milligrams of dried root extract per day. Although side-effects are rare (between 1.5-2.3% in patients according to two referenced studies), there have been several recent reports of toxic liver damage in patients taking large doses of kava. Long-term use of kava at extremely high doses has been associated with hair loss; loss of appetite; partial loss of hearing; and a flaking or yellowish discoloration of the skin known as kavaism. These symptoms usually go away when people stop taking the herb.

Conclusions and Recommendations

Although some of the supplements lacked enough evidence to show effectiveness, the results for others were encouraging. Three of the six products examined in Ernst's study - ginkgo biloba, St. John's wort and saw palmetto - were all associated with positive results for the treatment of dementia and intermittent claudication, depression, and enlarged prostate, respectively. Nevertheless, there remain serious questions about the safety and effectiveness of many herbal remedies, especially for products that are used less frequently.

In Ernst's opinion, there are four major concerns that need to be addressed:

A lack in the quantity and quality of clinical trials. Only after long-term studies are conducted, Ernst believes, will practitioners truly be able to make informed, responsible decisions about herbal remedies in the care and treatment of patients. As a possible solution, he proposes creating an association of "reputable producers" that would set aside a small percentage of profits for vital herbal research projects.

A lack of quality and standardization in herbal remedies. Independent testing has shown that many herbal products either: contain much more of the product than what is listed on the label; contain much less; or are contaminated with a foreign substance. Ernst labels this situation "unacceptable" and suggests that the industry adopt new standards and controls.

The belief that research is not necessary. Many members of the herbal medicine community prefer to rely on accumulated knowledge and the "test of time" as proof that a product works, but these criteria are obviously unacceptable for establishing a product's safety or effectiveness. "The area of herbal medicine has been hindered by a tradition of regarding clinical trials as being of secondary importance," Ernst writes. "However, such investigations are the best (and perhaps the only) way to answer the question of whether herbal medicinal products cause more good than harm."

The public's attitude. Many people assume that because herbal products are not drugs and do not require a prescription, they do not produce any adverse effects. Ernst labels this assumption a "myth" perpetuated by the media and cautions that there may be many as yet unknown risks associated with herbal remedies, especially when they are used in conjunction with prescription drugs.

Because the use of herbal remedies is increasing, questions about safety and efficacy have clearly become a concern not just to patients, but to practitioners, health insurers and legislators. To address these concerns, Ernst offers several solutions to the problems facing the herbal medicine community, which include: publishing more objective (instead of promotional) information; conducting larger, more exacting clinical trials; and setting aside adequate funds for research, all of which are quintessential to the survival and growth of the herbal supplement industry in the United States. These suggestions, combined with a rigorous evaluation of all products currently on the market, are considered "the way ahead" and should be of interest to all parties involved in the production and consumption of herbal remedies.

References

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[IMAGE]

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