

Ginkgo Biloba Is Found Ineffective for Dementia and Age-Associated Memory Impairment in the Elderly

Researchers from the Netherlands reported in the October 2000 issue of the *Journal of the American Geriatrics Society* that a standardized extract of the widely hyped herb ginkgo biloba has been found ineffective for older adults with dementia and age-associated memory impairment. The results of this study contrast sharply with those of previous ginkgo biloba trials.

The trial lasted 24 weeks and involved 214 residents of homes for the elderly. Their average age was greater than 80 years. Of these 214 patients, 63 were demented and 151 were not but had substantial cognitive decline. The trial was randomized, placebo-controlled, and double blind. This type of study design is the scientific “gold standard” for testing a hypothesis about the effectiveness of drugs or other medical interventions.

Potential trial subjects were screened to ensure that those who participated had dementia, either mild to moderate Alzheimer’s dementia or vascular dementia, or

age-associated memory impairment. A battery of eight rating scales were used to compare 160 milligrams or 240 milligrams of ginkgo biloba extract per day to an inactive placebo used as the control.

A unique feature of this trial was the special effort made to improve similarities between the ginkgo biloba and placebo tablets with respect to appearance, color, smell, taste, granularity, and solubility. In order to imitate the distinct taste of ginkgo biloba extract, 2 milligrams of quinine was added to the placebo tablets. Quinine is a very old drug, first used to treat malaria, that has an exceptionally bitter taste. (More later on why we think this is so important.)

The researchers had three questions they wanted to answer: (1) How effective is ginkgo extract? (2) Does increasing the dose of ginkgo also increase its effectiveness? (This is called a dose-response effect and is very important in showing if, in fact, an agent has biological activity.) And (3) Does the effect of ginkgo biloba persist?

After 24 weeks of treatment, the ginkgo biloba was found to be statistically superior to placebo in only two of the eight rating scales used in the study. The first concerned the subject’s self-perceived level of activities of daily living and the second was based on a test in which 30 numbers were to be connected in the right sequence as quickly as possible. (This latter scale measures cognitive speed, planning and organization.) Both of these effects were not impressive and disappeared after adjustment for other factors that may have led to a positive finding for the ginkgo extract. After adjustment, only a 12-week difference between ginkgo and placebo in the activities of daily living score persisted. The placebo was found to be statistically superior for self-perceived memory status after 12 weeks. When corrected for other factors that might have led to this result the positive effect of the placebo also disappeared.

The results of this trial led the *continued on page 16*

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antipsychotic drugs, both atypical and conventional, that could provide information on safety and effectiveness that would make prescribing more rational. In the absence of evidence, it seems more likely that the shift to the atypical drugs is largely “a victory of clinical hope and marketing hype.”

Comparative safety and effectiveness studies between old drugs and new ones are not required in the United States for approval of a new

drug. This makes it possible for new drugs to be approved without a showing that they are more effective than those already on the market; in fact, they can be less effective or perhaps more dangerous.

The review’s final recommendation—that conventional antipsychotics should usually be used first in treating an episode of schizophrenia—is sound advice both scientifically and economically. But this recommendation does not, and should not, preclude the use of an atypical antipsychotic first if

there is a sound reason for doing so.

What You Can Do

You should carefully discuss the adverse effects of various antipsychotic drugs with your doctor if you must make the decision for yourself or a family member to begin treatment. Because there is little evidence available to differentiate the effectiveness of these drugs, the choice may best be made on the basis of their potential toxicity.

GINKGO BILOBA, from page 15 researchers to conclude “... that treatment with ginkgo is not efficacious, irrespective of dose, in older patients with mild to moderate dementia or age-associated memory impairment.”

Why did the results of this trial contrast so sharply to several recent randomized, placebo-controlled, double blind trials showing a benefit for ginkgo biloba? There are some differences between this study and those showing a positive effect for the herb, including the diagnosis of the patients, severity of disease, age, and the rating scales used to test ginkgo’s efficacy.

There are other possible explanations for the results of this study. As was mentioned above, careful steps were taken to ensure the similarities between the placebo and the ginkgo pills that included giving the placebo a bitter taste. This was done to ensure that both patients and researchers were “blind” as to who was receiving the placebo or the ginkgo. This is important because if patients in a clinical trial detect a taste this may lead them to believe they are taking the active drug and this could bias their responses on some rating scales.

To verify that patients and researchers were, in fact, blinded to

which drug was being used, all were asked to guess if the placebo or ginkgo was given. This check did not show any association between actual and perceived type of treatment.

This is by far the most rigorous clinical trial we have seen of ginkgo biloba. But, as the researchers correctly point out, any time statistics are used to interpret the results of a clinical trial it is possible that the results were due to chance.

Manipulation of data is also a possible reason for the different results seen in the ginkgo trials. The boundaries between published research and promotion have become blurred and the manipulation of data and putting a spin on clinical trial results can explain, in part, the different results seen in ginkgo biloba trials. Journal editors must accept the veracity of the studies submitted to them for publication. They have neither the authority nor resources to ensure that data have not been “cooked.” This is one reason why the Food and Drug Administration’s (FDA) review process is so critical. The FDA has the authority and does audit clinical trials to ensure that the data used in making a decision about the safety and efficacy of a product are valid. This trial was

sponsored by a German ginkgo producer and we have no reason to believe that the German company influenced the results of this study.

Consumers should not be misled into believing that ginkgo biloba has undergone regulatory scrutiny for safety and efficacy, similar to an FDA review, in Germany because this herb is listed in the German Commission E Monographs. The Commission E was created in 1976 to protect the herbal drug industry when German law was changed to require proof of safety and efficacy before a product could be marketed. The law required that products, including herbals, already on the market be reviewed according to modern scientific standards to determine their safety and efficacy. This has never been done.

As dietary and herbal supplements, such as ginkgo biloba, are subjected to more rigorous scientific scrutiny, it is becoming clearer that their success in the marketplace in many cases is a result of misleading advertising rather than any type of proven benefit to consumers.

What You Can Do

Save your money. Any benefit of ginkgo biloba extract for any purpose remains dubious at best.

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