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File: ■ Ginkgo (*Ginkgo biloba*)
■ Cognitive Impairment
■ Safety/Efficacy

HC 120596-399

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RE: Safety and Effectiveness of a Traditional Ginkgo Fresh Leaves Extract Treating Mild Cognitive Impairment

Bäurle P, Suter A, Wormstall H. Safety and effectiveness of a traditional ginkgo fresh plant extract—Results from a clinical trial. *Forsch Komplementmed*. 2009;16:156-161.

Ginkgo (*Ginkgo biloba*) is used traditionally as a tea, alcoholic tincture, or extract; however, it has been most often studied as the standardized ginkgo special extract EGb 761® (Dr. Willmar Schwabe GmbH; Karlsruhe, Germany). The purpose of this study was to evaluate the safety and effectiveness of a newly developed fresh leaf extract of ginkgo in patients with mild cognitive impairment. Mild cognitive impairment is defined as having normal daily activities with complaints of decreased memory function. It is considered a precursor to Alzheimer's disease. The fresh leaf extract evaluated in this study is more comparable to the ginkgo preparations used traditionally.

Patients (n = 59) from 11 general practices in Switzerland diagnosed with mild cognitive impairment (DemTect score >12) with no obvious symptoms of dementia, but with at least 2 of the following: forgetfulness, impaired concentration, or impaired memory, participated in this open-label study. For 6 weeks, patients took 1 ginkgo tablet 2 times/day. "Each tablet contained 90 mg native extract (Drug Extraction Ratio 3-5:1, extractant 65% ethanol v/v) of fresh ginkgo leaves produced by A. Vogel Bioforce AG (Roggwil, Switzerland). The extract contained <100 ppm ginkgolic acids and its spectrum of constituents was similar to a mother tincture." Effectiveness was determined with the SF-12 quality-of-life scale, and the DemTect validated questionnaire, which measures memory, mental agility, language, attention, and memory recall. Blood was drawn to assess laboratory parameters.

The majority of patients were women (mean age 72 years). All but 6 patients had good treatment compliance. At the end of the 6-week treatment period, the average DemTect score did not change from baseline (15.9 at start vs. 16.0 at end). The mean physical component of the quality-of-life scale also did not change from baseline (44.5 at start vs. 45.3 at end). The mean mental component of the quality-of-life scale improved significantly by 3 points (P = 0.013). Forgetfulness, impaired concentration, and impaired memory subjectively improved in 41%, 43%, and 35% of the subjects, respectively. The

improvement in symptoms was rated as “good” or “rather good” by 61% of the patients and 69% of physicians. The treatment was rated as having no effect by 29% of patients and 24% of physicians.

None of the adverse events (AEs) were rated as definitively related to treatment. One case of gastrointestinal disturbance and 18 AEs (types were not reported) were rated as possibly related to ginkgo. All AEs were mild to moderate and transient. Vital signs and laboratory measurements were not adversely affected by treatment. The majority of patients and physicians considered the treatment to be well tolerated.

This study used a newly developed plant extract. The authors conclude that the formulation is safe and well tolerated in a population that was taking concomitant medications and suffering from concurrent diseases. Based on the effectiveness, the authors state that the treatment is an “interesting option” for age-related memory disorders. They acknowledge that the observed effects could be due to placebo or regression of the mean. This study should be repeated as a randomized controlled trial before efficacy can be concluded.

—Heather S. Oliff, PhD

The American Botanical Council has chosen not to reprint the original article.