

Phase II study of ginkgo biloba in irradiated brain tumor survivors: Effects on quality of life (QOL), mood, and cognitive function.

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Author(s):

A. Attia, L. D. Case, R. D'Agostino Jr., G. J. Lesser, K. McMullen, M. J. Naughton, S. R. Rapp, R. Rosdhal, E. G. Shaw; Wake Forest University Baptist Medical Center, Winston Salem, NC; Wake Forest University School of Medicine, Winston Salem, NC

Abstract:

Background: Ginkgo biloba can improve cognitive function in patients with Alzheimer's disease and multi- infarct dementia. We conducted an open-label phase II study of this botanical product in symptomatic irradiated brain tumor survivors. **Methods:** Eligibility criteria included: age \geq 18 years, life expectancy \geq 30 weeks, partial or whole brain radiation \geq 6 months before enrollment, no imaging evidence of tumor progression in previous 3 months, on stable or decreasing steroid dose, Karnofsky Performance Status (KPS) \geq 70, and no brain tumor treatment planned while on study. The ginkgo biloba dose was 120 mg/day (40 mg tid) for 24 weeks followed by a 6-week washout period. Assessments performed at baseline, 12, 24 (end of treatment), and 30 weeks (end of washout) included KPS, functional assessment of cancer therapy-brain (FACT-Br), profile of mood states (POMS), mini-mental status exam (MMSE), trail-making test parts A (TMT-A) and B (TMT-B), digit span test (DST), Modified Rey-Osterrieth Complex Figure (ROCF), California Verbal Learning Test Part II (CVLT-II), and the F-A-S Test. **Results:** Of the 34 patients enrolled on study, only 19 (56%) completed 24 weeks of ginkgo. Five dropped out due to perceived lack of efficacy, five had dose-limiting toxicity, and five developed either intercurrent medical illness or brain tumor progression. Of the 19 remaining patients, there were significant improvements at 24 weeks: FACT brain subscale ($p = 0.023$), executive function (TMT-B) ($p = 0.011$), attention/concentration (TMT-A) ($p = 0.006$), and nonverbal memory (ROCF - immediate/delayed recall) ($p = 0.018/0.025$). No other differences were observed. **Conclusions:** Although some improvement in QOL and cognitive function were noted with ginkgo biloba, the drop out rate was significantly higher than our published results with donepezil (Aricept) (Shaw EG et al, J Clin Oncol 24:1415, 2006). Thus, we did not pursue

further studies with ginkgo biloba. This study was supported by NIH/NCI/DCP grant 2 U10 CA 81851-09-13.