P.O. Box 144345 Austin, TX 78714-4345 ▪ 512.926.4900 ▪ Fax: 512.926.2345 ▪ www.herbalgram.org

HerbClip™

File: ■ Bacopa (*Bacopa monnieri*)
■ Memory
■ Elderly Health

HC 081051-408

Date: September 15, 2010

RE: Bacopa Extract Produces Evidence of Some Memory Improvements in the Elderly

Morgan A, Stevens J. Does *Bacopa monnieri* improve memory performance in older persons? Results of a randomized, placebo-controlled, double-blind trial. *J Altern Complement Med*. 2010;16(7):1-7.

Bacopa (*Bacopa monnieri*) is an aquatic plant that has been used in Ayurvedic medicine to enhance memory, intellectual function, and longevity. Several randomized, blinded, controlled clinical trials demonstrate the benefits of bacopa on memory and learning, including one that also improved depression and anxiety measures in the elderly without dementia.[1] A Phase 1 clinical trial demonstrated the safety and tolerability of BacoMind™ (Natural Remedies Pvt. Ltd.; Bangalore, India), a standardized extract of bacopa, in healthy volunteers.[2] The purpose of this randomized, placebo-controlled, double-blind study was to evaluate the efficacy and safety of BacoMind in older people (the population that experiences memory impairment).

The researchers recruited participants from the general population of Northern Rivers region, New South Wales, Australia, via radio, television, print media, and the staff at Southern Cross University, Lismore, New South Wales, Australia. The study included volunteers ≥ 55 years old who were without dementia or depression as assessed with validated scales. Participants had to be healthy and not using psychoactive medications, herbal medications, recreational drugs, or consuming more than 4 alcoholic drinks per day.

Participants (n = 98) were randomized to receive one 300 mg tablet/day BacoMind or placebo for 12 weeks. BacoMind is an alcoholic extract (herb to extract ratio, 20:1) standardized to contain total bacoside saponin content of 40%-50%. BacoMind is standardized to 9 active constituents: bacoside A_3, bacopaside I, bacopaside II, jujubogenin, bacopasaponin C, bacosine, luteolin, apigenin, and β-sitosterol-D-glucoside. The dosage evaluated was based on the manufacturer's recommendation and was taken after a meal. Compliance was assessed by counting tablets at the end of the study; > 20% of the tablets remaining was considered noncompliance.

Efficacy was evaluated with 3 validated neuropsychologic tests and a memory complaint questionnaire. The Rey Auditory Verbal Learning Test is a word list learning test to assess aspects of memory including immediate recall, delayed recall, and retroactive and proactive interference. Rey-Osterrieth Complex Figure Test assesses visuospatial ability and visual

memory. Trail Making Test measures scanning and visuomotor tracking, and involves cognitive processing (including memory) along with psychomotor speed. The Memory Complaint Questionnaire quantifies subjective memory complaints of aging.

The average age was 65 years (range 55-86 years). At baseline, there were significant differences between treatment groups in the mean scores on the Rey-Osterrieth delayed recall tasks at both 3 and 30 minutes ($P = 0.005$ and $P \leq 0.008$, respectively). There were no other baseline differences between groups. There were 17 withdrawals, including 9 in the bacopa group and 2 in the placebo group due to adverse side effects.

The Rey Auditory Verbal Learning Test consists of 15 tasks. Of these 15 tasks, BacoMind significantly improved memory function on 6 of the tasks compared with placebo: trial a4 ($P = 0.000$), trial a5 ($P = 0.016$), trial a6 (postdistraction trial; $P = 0.000$), trial a7 (delayed-recall trial; $P = 0.001$), total learning (Σ trials a1–a5; $P = 0.011$), and retroactive interference index ($P = 0.048$). For all of the other efficacy tests there were no significant differences from placebo. Stool frequency, nausea, and abdominal cramps occurred significantly more often in bacopa-treated patients.

The authors conclude that bacopa significantly improves memory acquisition and retention in older Australians as measured by the Rey Auditory Verbal Learning Test. They state that the study demonstrated an improvement in the learning rate and had no effect on the forgetting rate. Bacopa may work through the cholinergic system (possibly explaining the gastrointestinal [GI] side effects). The authors caution against concurrent use of bacopa and acetylcholinesterase inhibitor medications, which are commonly prescribed for dementia. This study reported a higher incidence of GI side effects than was reported in the Phase 1 trial of BacoMind. This difference may be due to the older age of the population included in the current study, which may have a lower tolerability to bacopa, possibly due to its high saponin content.

This study was well designed and executed; however, an improvement on 1 test does not show decisively that bacopa improves memory acquisition and retention. This study bears repeating since there was a significant difference at baseline (a study limitation). It would also be interesting to evaluate a population with memory loss.

—Heather S. Oliff, PhD

References

1. Oliff HS. Special extract of bacopa examined for safety. *HerbClip.* July 13, 2007. (No 060571-332) Austin, TX: American Botanical Council. Review of Safety evaluation of BacoMind™ in healthy volunteers: A phase I study by Pravina K, Ravindra KR, Goudar KS, et al. *Phytomedicine.* 2007;14:301-308.

2. Oliff HS. Concentrated bacopa extract improves outcomes on cognitive and affective tests in elderly. *HerbClip.* February 13, 2009. (No. 090586-370) Austin, TX: American Botanical Council. Review of Effects of standardized *Bacopa monnieri* extract on cognitive performance, anxiety, and depression in the elderly: A randomized, double-blind, placebo-controlled trial by Calabrese C, Gregory WL, Leo M, et al. *J Altern Complement Med*. 2008;14(6):707-713.

Enclosure: Referenced article reprinted with permission from Mary Ann Liebert, Inc., 2 Madison Ave., Larchmont, NY 10438; Telephone (914)834-3100; Fax (914)834-3582; email: info@liebert.com.