



Phytotherapy Review & Commentary

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Valerian: A Safe and Effective Herb for Sleep Problems

Recent publications appear to have answered several important questions for valerian root:

- Does valerian impair cognitive function or cause excessive sedation?
- How does its efficacy compare to benzodiazepine drugs?
- Is valerian safe and effective for children?

In an Australian study, nine healthy volunteers received single doses of either valerian root (1000mg or 500mg), the drug triazolam (0.25mg) or placebo in a double-blind, placebo-controlled, crossover trial.¹ Results confirmed that while triazolam had a detrimental effect on cognitive processes, the valerian was without effect. Another study compared even higher doses of valerian (600, 1200 and 1800mg of a 5:1 extract) with 10mg diazepam and placebo in a clinical trial of similar design.² Again an impairment of performance occurred for the benzodiazepine drug whereas the valerian had no impact on any parameters tested. A third study found that valerian (400mg and 800mg) was not different from placebo on any measure used of psychomotor performance or sedation.³

Patients aged 18 to 73 years and diagnosed with non-organic insomnia were treated in a multicentre, double-blind, randomized parallel group comparison with either 600 mg/day of valerian extract (5:1) or 10 mg/day oxazepam taken for 6 weeks.⁴ A total of 202 outpatients with a mean duration of insomnia of 3.5 months at baseline were included. Sleep quality after 6 weeks showed that valerian extract was at least as efficacious as treatment with oxazepam. Both treatments markedly increased sleep quality compared with baseline ($p < 0.01$). Adverse events occurred in 29 patients (28.4%) receiving valerian extract and 36 patients (36.0%) under oxazepam, and were all rated mild to moderate. No serious adverse reactions were reported in either group. Most patients assessed their respective treatment as very good (82.8% in the valerian group, 73.4% in the oxazepam group).

Another smaller trial of similar design compared the effect of the same dose of valerian with 10mg oxazepam over 4 weeks in 75 patients with non-organic insomnia.⁵ The study showed no differences between the efficacy of valerian and oxazepam.

The efficacy and tolerability of a valerian extract preparation were investigated in an open, observational study on children aged to 6 to 12 years.⁶ An average daily dosage of 2 tablets (range 1 to 4) tablets containing 300mg of 5:1 extract was administered to 130 children suffering from nervous sleep disturbances and/or nervous tension over a period of 4 weeks. Therapeutic efficacy was estimated by parents and physicians as good to very good in 95% of cases. A side effect (tiredness in the morning) was reported in only one case, which disappeared after dose adjustment.

Commentary

Unlike the benzodiazepine drugs, valerian clearly does not cause sedation or impairment of functioning in healthy volunteers. But this could be attributed to valerian having no activity on the nervous system (as detractors of phytotherapy would no doubt assert). Hence, it is pertinent that a well-designed trial found valerian to be just as effective as a benzodiazepine drug in the alleviation of non-organic insomnia. (Non-organic insomnia is characterized by a chronic, psychological impairment of the ability to initiate or maintain sleep which leads to a preoccupation with insomnia and impairment of functioning during the day.) The open trial in children also provides proof of safety here, but its efficacy should now be established in a randomized, controlled trial.

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Anxiety: New Options for Herbal Treatment

A clinical trial was recently conducted in France to assess the benefits of a combination of extracts of hawthorn (*Crataegus oxyacantha*) and Californian poppy (*Eschscholtzia californica*) together with magnesium versus placebo in the treatment of mild to moderate anxiety disorders.¹ A total of 264 patients (81% female) presenting with generalized anxiety (DSM-III-R) with a Hamilton anxiety score of between 16 and 28 were included in a double-blind, randomized, placebo-controlled trial. Patients were randomly assigned to two groups: 130 received the herbal treatment and 134 a placebo.

Efficacy and safety data were recorded before first administration and at 7, 14, 30, 60 and 90 days after the start of treatment. Efficacy was assessed by a change in the Hamilton anxiety scale, a change in patient self-assessment as well as the number of responsive patients.

Total and somatic (physical) Hamilton anxiety scale scores and subjective patient-rated anxiety fell during treatment, indicating clinical improvement. The decrease was greater for the herbal treatment than in the placebo group. End results, although mild, were statistically significant. In all, 15 patients (11.5%) in the study group and 13 patients (9.7%) in the placebo

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