Effectiveness of Valerian on insomnia: a meta-analysis of randomized placebo-controlled trials


CRD summary
The review concluded that the evidence suggested that valerian would be effective for a subjective improvement for insomnia, although its effectiveness was not demonstrated with quantitative or objective measurements. The authors' cautious conclusions reflect the evidence presented and are likely to be reliable.

Authors' objectives
To evaluate the effectiveness of valerian (Valeriana officinalis) for the treatment of insomnia.

Searching
MEDLINE, the Cochrane Library, EMBASE and BIOSIS Previews were searched to September 2008 for published articles. No language restrictions were applied. Search terms were reported. Reference lists of selected articles and reviews were scanned for additional articles.

Study selection
Randomised controlled trials (RCTs) of valerian preparations compared with a placebo for the treatment of insomnia were eligible for inclusion. Outcomes of interest were improvements in sleep quality quantified using visual analogue scales, and latency time in minutes getting to sleep. Trials that included valerian combined with other substances were excluded.

In included trials, valerian was administered as aqueous extract, aqueous root, alcoholic extract, and valerian acid; the dosage varied widely between trials. Duration of treatment ranged from four to 56 days. Participants in the included trials met a variety of diagnostic criteria with a range of insomnia scores. Some trials included participants with no sleep problems. The average age of participants ranged from 26 to 69 years. Measurement of outcomes was by encephalogram, self-reported questionnaires, or visual analogue scales.

Two reviewers independently selected studies for inclusion. Discrepancies were resolved through discussion.

Assessment of study quality
Validity was assessed using the Jadad Scale, which assessed randomisation, blinding and withdrawals and drop-outs with a maximum possible score of 5 points.

Two reviewers independently assessed validity.

Data extraction
Data on latency time (in minutes) were extracted and used to calculate the mean difference (MD) and corresponding 95% confidence intervals (CI). Data on sleep quality measured using visual analogue scales were extracted; mean differences were estimated using Hedges adjustment to account for differences in units of measurement between scales. Dichotomous data on sleep quality were extracted and used to calculate risk ratios (RR) and corresponding 95% confidence intervals. When results of more than one dose of valerian were reported, the result with the highest dose was used in the analyses.

The authors did not state how many reviewers extracted the data.

Methods of synthesis
Data were combined. Pooled weighted mean differences (WMD), standardised mean differences (SMD) and risk ratios,
together with 95% CIs, were calculated as appropriate. Heterogeneity was assessed using the $I^2$ statistic.

Subgroup analyses were used to look at the individual effects of trial quality and latency time measurement technique; meta-regression was used to examine interactions between the two.

Sensitivity analyses were conducted omitting each trial in turn.

Publication bias was assessed using visual inspection of funnel plots.

**Results of the review**

Eighteen RCTs were included in the review (n=1,317 participants). Sample sizes ranged from 5 to 434 participants. Only eight RCTs obtained the maximum score of 5 points; three RCTs scored 3 points and seven RCTs scored 2 points.

There were no significant differences between valerian and placebo for latency time (WMD 0.70 min, 95% CI -3.44 to 4.83; $I^2=57%$; 10 RCTs), or for sleep-quality measured using visual analogical scales (SMD -0.02, 95% CI -0.35 to 0.31; $I^2=62%$; seven RCTs). However, there was substantial heterogeneity for both analyses. Neither trial quality nor latency time measurement technique were significant in the regression analysis. Results did not change significantly for sensitivity analyses, although heterogeneity was reduced for some analyses.

There was a significant improvement in sleep quality with valerian compared to placebo (RR 1.37, 95% CI 1.05 to 1.78; six RCTs) when assessed dichotomously (self reported yes/no), but there was substantial heterogeneity for this analysis ($I^2=60%$). When only trials of greater methodological rigour (4 or more points on Jadad scale) were included in the analysis, effectiveness was reduced (RR 1.31, 95% CI 1.00 to 1.77; $I^2=35%$), but moderate heterogeneity remained. Results did not change significantly for other sensitivity and subgroup analyses.

Only one trial reported on adverse effects, with a greater frequency of diarrhoea in patients taking valerian compared with those taking a placebo (18% versus 8%; p=0.02).

There was no evidence of significant publication bias.

**Authors’ conclusions**
The results suggested that valerian would be effective for a subjective improvement for insomnia, although its effectiveness was not demonstrated with quantitative or objective measurements.

**CRD commentary**
The review question was broad with adequate inclusion criteria. Several relevant sources were searched without language restriction, reducing the potential for language bias. However, only published studies were eligible for inclusion, so there was the potential for publication bias; formal assessment of publication bias found no evidence. Appropriate methods were used to reduce reviewer error and bias in the selection of studies and assessment of validity, but it was unclear whether similar methods were used for data extraction.

Trial quality was assessed using an appropriate tool, although only the composite score was reported. Most of the included trials were of poor quality. The methods of synthesis were appropriate; heterogeneity was assessed. Subgroup and sensitivity analyses were used to explore reasons for heterogeneity. The authors appropriately reported some limitations of the review, including trials with small sample sizes, different doses and types of valerian, variable follow-up times, lack of standardised measurements, limited data and limited reporting of adverse events. In addition, some participants may not have had sleep problems, which limits the generalisability of the data.

The authors’ cautious conclusions reflect the evidence presented and are likely to be reliable.

**Implications of the review for practice and research**

**Practice**: The authors did not state any implications for practice.
Research: The authors stated that further research should focus on "more promising" treatments for improving insomnia than Valerian.

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