The article “Critical evaluation of the effect of valerian extract on sleep structure and sleep quality”, Pharmacopsychiatry 2000; 33: 47 – 53, by F. Donath et al provokes some criticism. In contrast to the formulation in the title, a critical consideration by the authors of their patient group and their results is missing. Apart from some minor methodological issues (how many subjects started with placebo, how many with verum? Why couldn’t subjects sleep according to their usual habits and were woken up in the morning? – this may have influenced the results), we want to address the following items:

1. The diagnosis of psychophysiological insomnia was apparently based on the minimal criteria (ICSD 1990, code number 307.42- 0): subjective complaints of insomnia and decreased daytime functioning (criterion A), and indications of learned sleep-preventing associations (criterion B). There was a “control polysomnography” before the start of the trial (one night only, thus not taking into account the first-night effect), but it was not used for diagnosis. This would have required a comparison group of healthy subjects as the sleep variables reported in Table 1 (baseline, placebo) are by themselves not convincing of a notable psychophysiological insomnia. Diagnosis might have been “sleep state misperception” as well (discrepancy between objective and subjective sleep parameters).

2. The authors state that the baseline nights served for adaptation and were not used as reference to correct for the effect of time”. Nevertheless, baseline-placebo and baseline-verum differences were computed and one of the two significant effects of the study refers to these:

Fig. 2 shows that the increase in the percentage of slow wave sleep (SWS) from baseline to verum long-term is greater than that from baseline to long-term placebo. The authors fail, however, to mention that the largest increase in %SWS occurred in the placebo short-term condition. Here, the median increase above baseline amounted to 36 %, whereas under valerian long-term it was 21 % and under long-term placebo 14 %. A direct comparison between %SWS in the latter two conditions does not result in a statistically significant difference. In absolute terms, the difference is negligible, comprising not more than 0.6 % of Sleep Period Time or less than 3 minutes. The statement of a “reconstruction of slow-wave sleep” does not seem to be justified.

The other significant effect concerns SWS latency (which lacks definition as do most sleep parameters). Although this variable is shorter after long-term valerian than after long-term placebo, it cannot be overlooked that it is still longer than after short-term placebo (Table 1).

3. We conclude that neither the target variable of the study (sleep efficiency) nor other much used parameters of sleep quality or daytime functioning (sleep onset latency, wake after sleep onset, subjective sleep quality, morning feeling, daytime performance) showed any significant difference between verum and placebo treatments. In our opinion, the marginal and clinically irrelevant effects based on a questionable evaluation (%SWS, SWS latency) do not justify the conclusion that valerian can “be recommended as adjuvant therapy in... chronic psychophysiological insomnia” – the more so, as the authors claimed to remain “on a descriptive level” and therefore deliberately abstained from adjusting their level of significance to multiple testing.

Rather, the study is a further indication of the inefficiency of valerian in this dosage and for this group of patients.

Reference


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