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File: ■ Lavender (*Lavandula angustifolia*)

- Anxiety
- Silexan®

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RE: Effectiveness of a Lavender Oil Preparation in Treating Anxiety Disorder

Kasper S, Gastpar M, Müller WE, et al. Silexan, an orally administered *Lavandula* oil preparation, is effective in the treatment of 'subsyndromal' anxiety disorder: a randomized, double-blind, placebo controlled trial. *Int Clin Psychopharmacol.* 2010;25(5):277-287.

The German Commission E has approved lavender flowers (*Lavandulae flos*) for the [non-oral] treatment of restlessness and insomnia. Lavender (*Lavandula angustifolia*) may be a safe alternative treatment for people with anxiety; however, there has been little research or experience with oral formulations of the essential oil. There have been no adverse side effects reported, except for very rare cases of allergic reactions and gastrointestinal complaints after excessive intake. According to the authors, all clinical trials published to date that evaluated lavender as a treatment for anxiety were performed in highly specific patient populations (e.g., patients with a terminal illness, in intensive care, or who have situation provoked anxiety), and many of the studies were methodologically flawed. Hence, the purpose of this randomized, double-blind, placebo-controlled multicenter study was to evaluate the efficacy and tolerability of an oral preparation of lavender essential oil.

Male and female outpatients (n = 221, aged 18-65 years) with anxiety disorder, according to criteria of the Diagnostic and Statistical Manual of Mental Disorders-IV, were recruited from 27 general and psychiatric primary care centers in Germany. Included patients had a Hamilton Anxiety Scale (HAMA) total score of ≥ 18 points and ≥ 2 points for items 'Anxious mood' and 'Insomnia', as well as a total score > 5 points for the Pittsburgh Sleep Quality Index (PSQI). Patients were classified as having subsyndromal anxiety disorder not otherwise specified (NOS), which is different from generalized anxiety disorder (GAD) in that patients tend to report less worry, negative affect, depression, and comorbidity than those with GAD. All patients had sleep disturbances. Patients were excluded if they had: (1) a HAMA total score decrease ≥ 25% during run-in, (2) any psychiatric or neurological diagnosis other than anxiety disorder, (3) risk of suicide, or (4) substance abuse disorder. The use of psychotropic medications, muscle relaxants, or psychotherapy was not allowed during the study. After a 3-7 day placebo run-in phase, patients were treated with lavender oil (80 mg/day

Silexan®; W. Spitzner Arzneimittelfabrik GmbH; Ettlingen, Germany) or placebo (containing 0.08 mg of lavender oil/capsule to blind the smell of the placebo) for 10 weeks. The primary outcome measures were changes of the total scores of the HAMA (observer-rating of anxiety level) and of the PSQI (self-rating of sleep quality) between the baseline and 10-week visit. Patients with scores that decreased $\geq 50\%$ of baseline were considered treatment responders. Those who showed a HAMA total score of < 10 points or a PSQI total score of < 6 points at treatment end were classified as being in remission. Secondary outcome measures were the Clinical Global Impressions (CGI) observer-rating scale, the Zung Self-Rating Anxiety Scale (SAS), and the SF-36 Health Survey Questionnaire. The assessments of safety and tolerability were based on spontaneous reports of adverse events (AEs), physical and electrocardiogram (ECG) examinations, vital signs, and routine laboratory measurements.

Approximately 75% of the patients were women. At baseline, each group had $> 50\%$ of the patients with HAMA total score ≥ 26 and/or a PSQI total score ≥ 12 points. For CGI item 1 (severity of illness), a greater percentage of patients had more severe impairment in the placebo group, whereas all other psychiatric self- and observer-rating scales showed only negligible baseline treatment group differences.

At 10 weeks, the lavender group had a significant reduction in HAMA score compared with baseline ($P < 0.001$), but the placebo group did not. The lavender-treated patients had a total mean score decrease of 16.0 ± 8.3 points (59.3%) for the HAMA. In contrast, the placebo-treated patients had a decrease of 9.5 ± 9.1 points (35.4%) on HAMA. The anxiolytic effect of lavender was clinically detectable after 2 weeks of treatment and was statistically significant at week 4 and all later visits ($P < 0.05$). Extrapolating the HAMA total score time course beyond 10 weeks suggests that additional improvements might occur if treatment were to be continued beyond 10 weeks. Lavender treatment was superior to placebo regarding the percentage of responders (76.9% vs. 49.1%, $P < 0.001$) and remitters (60.6% vs. 42.6%, $P = 0.009$).

Sleep disturbances frequently accompany anxiety disorders. The lavender treatment had a significant beneficial influence on the patients' duration and quality of sleep and reduced their daytime tiredness. The lavender-treated patients had a total mean score decrease of 5.5 ± 4.4 points (44.7%) on the PSQI, whereas the placebo-treated patients had a decrease of 3.8 ± 4.1 points (30.9%). The sleep improvement was detectable after 2 weeks of treatment and became statistically significant after 6 weeks of treatment ($P \leq 0.01$).

For all secondary efficacy variables, the lavender group had significant improvements compared with the placebo group ($P < 0.001$). The lavender and placebo treatments had a similar incidence and profile of AEs during the study, and AEs specific to lavender were not observed.

According to the authors, Silexan is currently the only lavender essential oil that is intended for oral use. They conclude that Silexan, at a dose of 80 mg/day, had a clinically meaningful and statistically significant anxiolytic effect. The product also alleviated anxiety-related sleep disturbances while improving physical and mental well-being. The authors state that Silexan may be a good alternative treatment for anxiety considering the good tolerability, the absence of unwanted sedative effects that occur with other anxiolytics, and the convenient once-daily administration.

The results of this study cannot be generalized to patients with GAD or other defined anxiety disorders. The authors do not address the point that according to the CGI item 1, the placebo group had a greater percentage of patients with more severe impairment. It is possible that the placebo effect was smaller than the lavender effect because the patients were more impaired. A study with an active comparator (i.e., an efficacious pharmaceutical anxiolytic) is needed to truly determine whether the lavender oil product is a good alternative treatment.

—Heather S. Oliff, PhD

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