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A multi-center, double-blind, randomised study of the Lavender oil preparation Silexan in comparison to Lorazepam for generalized anxiety disorder

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Abstract

Generalized and persistent anxiety, accompanied by nervousness and other symptoms (Generalised Anxiety Disorder, GAD) is frequent in the general population and leads to benzodiazepine usage. Unfortunately, these substances induce sedation and have a high potential for drug abuse, and there is thus a need for alternatives. As the anxiolytic properties of lavender have already been demonstrated in pharmacological studies and small-scale clinical trials, it was postulated that lavender has a positive effect in GAD. A controlled clinical study was then performed to evaluate the efficacy of silexan, a new oral lavender oil capsule preparation, versus a benzodiazepine. In this study, the efficacy of a 6-week-intake of silexan compared to lorazepam was investigated in adults with GAD. The primary target variable was the change in the Hamilton Anxiety Rating Scale (HAM-A-total score) as an objective measurement of the severity of anxiety between baseline and week 6. The results suggest that silexan effectively ameliorates generalized anxiety comparable to a common benzodiazepine (lorazepam). The mean of the HAM-A-total score decreased clearly and to a similar extent in both groups (by 11.3+/-6.7 points (45%) in the silexan group and by 11.6+/-6.6 points (46%) in the lorazepam group, from 25+/-4 points at baseline in both groups). During the active treatment period, the two HAM-A subscores "somatic anxiety" (HAM-A subscore I) and "psychic anxiety" (HAM-A subscore II) also decreased clearly and to a similar extent in both groups. The changes in other subscores measured during the study, such as the SAS (Self-rating Anxiety Scale), PSWQ-PW (Penn State Worry Questionnaire), SF 36 Health survey Questionnaire and Clinical Global Impressions of severity of disorder (CGI item 1, CGI item 2, CGI item 3), and the results of the sleep diary demonstrated comparable positive effects of the two compounds. In conclusion, our results demonstrate that silexan is as effective as lorazepam in adults with GAD. The safety of silexan was also demonstrated. Since lavender oil showed no sedative effects in our study and has no potential for drug abuse, silexan appears to be an effective and well tolerated alternative to benzodiazepines for amelioration of generalised anxiety.

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