Nervoheel N vs. Lorazepam for Mild Nervous Disorders

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Introduction

Complementary and alternative medicine (CAM) is being used more often, both in Europe and in the United States. One of the main reasons for the increase in CAM is the adverse effects seen with conventional medications, leading to the withdrawal of some of these drugs from the market. It is believed that CAM medications are better tolerated than conventional medications.

One of the frequent uses of CAM is for treatment of functional nervous disorders, including insomnia, distress, anxiety, restlessness, and burnout. In this study, Nervoheel N, a CAM medication, was compared with lorazepam, a conventional benzodiazepine, for the treatment of functional nervous disorders. Specifically, the effectiveness and tolerability of the 2 medications were compared. The purpose of the study was to show the noninferiority of Nervoheel N vs. lorazepam.

Nervoheel N is a preparation based on the principles of homotoxicology. Lorazepam has a relatively short half-life and is favored over long-acting benzodiazepines for the short-term relief of anxiety. Benzodiazepines are contraindicated for long-term use because of their addictiveness and adverse effects.

The present study was a preliminary open-label prospective nonrandomized cohort investigation. To our knowledge, it is the first study to evaluate the effectiveness of Nervoheel N in a clinical setting.

Methods

This study was performed in 39 centers in Belgium and the Netherlands; these centers offer both conventional and CAM therapy. Patients enrolled were18 years or older and suffered from headache, heart palpitations, backache, indigestion, lack of appetite, mild sexual dysfunction, fatigue, listlessness, sleep disturbances, restlessness, or lack of concentration. Patients excluded were those who were unable or did not want to participate in the study and those taking both Nervoheel N and lorazepam.

The study duration was a maximum of 4 weeks. Patients were examined at the start of treatment, after 2 weeks of treatment, and after 4 weeks of treatment.

Physicians decided the treatment used for each patient (after discussion with the patient), and any other medications taken were not changed during the study. The dose of Nervoheel N given was 1 tablet 3 times a day; the dose of lorazepam given was 2 to 3 mg daily for sedation and anxiety and 2 to 4 mg nightly for insomnia. Variations in the dose were allowed if determined to be in the patient's best interest.

The effects of treatment were determined in conversation between the practitioner and the patient. The severity of symptoms was evaluated on a 4-point scale (0 indicates asymptomatic; 1, mild; 2, moderate; and 3, severe). The overall effect of the therapies was evaluated on a 5-point scale (excellent, good, satisfactory, no improvement, and worsening of symptoms). Tolerability was determined by patient-reported adverse events evaluated by the physician. Overall tolerability of the treatments was evaluated as excellent, good, moderate, or poor.

Results

A total of 248 patients were included in this study (136 in the Nervoheel N group and 112 in the lorazepam group). After 2 weeks of treatment, 128 patients in the Nervoheel N group and 106 patients in the lorazepam group were examined. At the final 4-week examination, the numbers of patients included were 134 and 111, respectively.

There were several differences between the 2 groups at enrollment: Patients in the lorazepam group were older and were more likely to be men, to smoke, and to use alcohol or coffee regularly than patients in the Nervoheel N group. However, none of these differences were statistically significant.

There was also no significant difference in the number of nervous disorders between the 2 groups (predominately 2-4 disorders). In both groups, the most common com-

Sepia, one of the ingredients of Nervoheel N, is prepared from the secretion of the inkgland of the cuttlefish (Sepia officinalis).

plaints included emotional distress, jitteriness, and anxiety; and the most common reasons given for the complaints included work-related anxiety, stress, and family-related anxiety. Most patients in both groups (> 70%) had not received previous treatment for their condition.

In both groups, there were significant differences from baseline: The sum of symptom scores improved by 4.4 points in the Nervoheel N group and by 4.2 points in the lorazepam group. However, there was not a significant difference between the 2 groups.

For both groups, the greatest symptom improvement was seen at the 2-week examination, with slight continued improvement until the 4-week examination. Even though most patients chose to maintain treatment for longer than 4 weeks, less than 10% did so for longer than 6 weeks. The average duration of treatment was 31 days in the Nervoheel N group and 29 days in the lorazepam group.

There was no significant difference between the 2 groups in overall therapeutic results (rated as excellent to good by 72.1% of the Nervoheel N group and 73.7% of the lorazepam group; $P = 0.84$).

The tolerability of both treatments was very good, with only one patient in each group experiencing an adverse event (both considered unlikely to be treatment related).

Notably, the overall patient-assessed tolerability was significantly better for the Nervoheel N group vs. the lorazepam group: Tolerability was rated as excellent in 81.9% vs. 45.5% of patients ($P < 0.001$).

There was no significant difference between the 2 groups in compliance scores ($P = 0.35$), with compliance ratings of excellent or good for approximately 90% of both groups.

Discussion

This study showed that Nervoheel N, a homotoxicological medication, can effectively treat mild nervous disorders, including aches, palpitations, indigestion, lack of appetite, mild sexual dysfunction, fatigue, listlessness, sleep disturbances, restlessness, and lack of concentration. The study indicated that Nervoheel N was better tolerated than lorazepam, a traditional benzodiazepine medication used to treat these disorders.

This being an open-label observational trial, there are limitations to such a study that are inherent in the design. First, the enrollment criteria for mild nervous disorders are somewhat subjective because there are no standardized rating scales for these disorders.

Second, the evaluations were left mostly to the physician's discretion, which could result in greater physician bias. However, the fact that the enrolling centers offer both complementary and conventional medicine may reduce this factor in this case.

Third, baseline differences between groups are inherent in the design of observational studies, as was also found in the present study.

There were also other differences between the 2 treatment groups (older patients and more male patients, with different lifestyle habits, in the lorazepam group), which were addressed with propensity score analysis but would not exclude all bias.

However, the strength of observational studies is not so much to show efficacy, but to show effectiveness in a practice-based setting and to demonstrate tolerability, in which this study succeeded.

In conclusion, this 4-week study showed that Nervoheel N (a homeopathic treatment) was not inferior to lorazepam (a conventional benzodiazepine treatment) for the short-term relief of mild nervous symptoms. In addition, significantly more patients rated the tolerability of Nervoheel N as excellent compared with the tolerability of lorazepam.

Reference

van den Meerschaut L, Sünder A. The homeopathic preparation Nervoheel N can offer an alternative to lorazepam therapy for mild nervous disorders. *Evid Based Complement Alternat Med.* Published October 25, 2007. doi:10.1093/ecam/nem144.