

ORIGINAL PAPER

Effect of a homeopathic-complex medicine on state and trait anxiety and sleep disorders: a retrospective observational study

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Purpose: The primary objective of this open-label, retrospective, observational study was to examine change in indicators of anxiety changed after treatment period of at least 1 month with the homeopathic-complex medicine *Datif-PC*[®]. A secondary objective was to describe the quantitative changes in the sleep pattern of the subjects included in the study.

Methods: The study population consisted of 71 subjects suffering from mild to moderate anxiety, who were treated with a homeopathic-complex medicine. The subjects had attended at least 2 consultations during the year 2010, with the second visit taking place at least 30 days after the first baseline visit. At both visits, subjects were administered the State-Trait Anxiety Inventory (STAI)-Y questionnaire (consisting of trait and state subscales) to assess their level of anxiety. Sleep quality was assessed based on the subjects' self-reported number of hours slept and number of night-time awakenings, before and after treatment.

Results: Compared to baseline, the average (STAI)-state score at visit 2 decreased by more than 6 points, while the STAI-trait score decreased by more than 3 points. This was statistically significant ($p < 0.0001$) for both subscales. These findings were stable in subgroup analyses (gender, age and anxiety level). The average number of hours slept per night increased significantly at visit 2 compared to baseline (from 5.1 ± 1.1 to 5.56 ± 0.9 h, $p < 0.0001$). A marked decrease in the average number of night-time awakenings was also observed at the second visit (-42% , $p < 0.0001$).

Conclusions: This retrospective observational study suggests that treatment of anxiety and sleep disorders with *Datif-PC*[®] can produce notable improvements even in a short period of time. Furthermore, the observed effects were not affected by sex, age or baseline anxiety. Further controlled, randomized studies are justified. *Homeopathy* (2013) 102, 254–261.

Keywords: Anxiety; Retrospective observational study; Low dose; *Datif-PC*[®]; STAI-Y; Sleep disorders

Introduction

Many sources of everyday stress (such as work, economic status, or family dynamics) can cause people to feel insecure, worried or anxious, sometimes to the point of interfering with their ability to function. Anxiety is an emotional state so deeply-rooted and widely prevalent among humans that it can sometimes be considered not just a symptom or syndrome, but a way of life marked by escalating feelings of apprehension and/or fear.¹ Anxiety

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is defined as a state of apprehension, tension and distress induced by anticipation of a future threat or negative event, accompanied by feelings of dysphoria or physical symptoms of stress.¹⁻³ The common cause of many forms of anxiety is the subjective perception that one's skills and personal strengths are inadequate for the magnitude of problems one must confront. Stress and its manifestations (anxiety and, particularly, insomnia) are becoming increasingly prevalent in both clinical practice and everyday life.^{4,5} It is therefore important to develop tools able to detect and measure anxiety, both for psychodiagnostic purposes and for evaluating the effectiveness of psychotherapeutic interventions. It is important that treatments are not only effective, but also safe and well tolerated.

Insomnia is recognized to be often related to anxiety disorders.⁴⁻⁶ Sleep can be altered by a delay in falling asleep, or by frequent nocturnal awakenings or early awakenings. Regardless of its cause, a lack of sleep or disrupted sleep will likely lead to poor concentration during daily activities. Thus far, the field of sleep medicine has made remarkable progress, and can now help people who sleep badly by identifying any organic causes, such as breathing problems or endocrine disorders, which when resolved may reduce symptoms of insomnia. The most widely prescribed drugs for the treatment of insomnia and anxiety disorders are benzodiazepines, which have been used for over 50 years.^{7,8} This class of drugs has recognized side effects such as drowsiness/sedation, disorientation, hallucinations and the possibility of causing eventual long-term drug dependence.^{8,9} A recent, large-scale observational study conducted in the US showed that patients receiving hypnotic prescriptions were associated with a more than 3-fold increase in risk of death.¹⁰

Surveys indicate that people suffering from anxiety often turn to homeopathic medicines.¹¹ Anxiety is one of the most commonly reported symptoms among French patients who consult homeopathic general practitioners.¹² One study found that 50% of Norwegian physicians take a favorable view of homeopathic treatment for certain health conditions, among which anxiety is frequently mentioned.¹³ A study on the use of homeopathic medicines for psychiatric symptoms in the general population found that homeopathy is mainly employed to reduce anxiety symptoms.¹⁴

The homeopathic-complex medicine *Datif-PC*[®] is one of the few commercially available options for treating anxiety and emotional disorders. The homeopathic-complex medicine *Datif-PC*[®] consists of 6 active ingredients diluted and dynamized to 6cH (10^{-12} of the starting substance). These ingredients are traditionally used for anxiety disorders, as reported by the homeopathic reference literature. *Datif-PC*[®] is produced in a tablet formulation and this can be an advantage in terms of treatment compliance.

The aim of the present study was to retrospectively observe how indicators of anxiety and sleep quality changed following homeopathic treatment with *Datif-*

PC[®] for a period of at least 1 month. The primary objective was to evaluate the temporal change scores for the 2 State-Trait Anxiety Inventory (STAI) subscales (STAI-trait and STAI-state).^{15,16} A secondary objective was to describe the quantitative changes in the sleep patterns of subjects included in the cohort.

Materials and methods

Study population

The study population was drawn from subjects who had been referred to our clinic (Department of Dietary Nutrition and Complementary Medicine, at the "Azienda Ospedaliera Gaetano Rummo", Benevento, Italy) and who were prescribed homeopathic treatment for anxiety. As a standard procedure for patients who complain of symptoms of anxiety, the homeopathic treatment was prescribed by the homeopath during a short consultation and data concerning anxiety (including the STAI-Y questionnaire), sleep disorders and concomitant treatments were recorded on a detailed form at each clinic visit. To select the subjects for our retrospective observational study, we reviewed those forms and recorded which patients met the inclusion/exclusion criteria on a study-specific paper case report form (CRF). The inclusion criteria were as follows:

- 1) age 18–90 years
- 2) presence of symptoms indicative of anxiety disorder during a first-contact interview
- 3) diagnosis of mild to moderate anxiety according to the STAI-Y questionnaire (score ≥ 20)
- 4) need for a new anti-anxiety medication or for a treatment to replace their previous medication (sedative-hypnotic drug) because of side effects or because the patient refused to take his/her current medication
- 5) having attended at least 2 visits between January 1 and December 31, 2010, with the second visit taking place at least 30 days after the first baseline visit.

The exclusion criteria were:

- 1) presence of other psychiatric disorders
- 2) inability to comply with the administration of a homeopathic medicine

The study was approved by the Independent Ethical Committee of the hospital "Azienda Ospedaliera Gaetano Rummo", Benevento, Italy, on January 24th, 2011. All the subjects gave their informed consent to the use of their data in this study.

Treatment and concomitant medication: The patients were prescribed the homeopathic-complex medicine *Datif-PC*[®] (Laboratoires Boiron S.r.l.) which is indicated for the treatment of anxiety states associated with sleep disorders. The components of *Datif-PC*[®] are: *Abrus precatorius* 6CH (indicated for spasms, cramps and palpitations), *Aconitum napellus* 6cH (anxiety, tachycardia, oppression), *Belladonna* 6cH (hyperalgesic spasms, tachycardia, sensory hyperesthesia), *Calendula officinalis* 6cH (spasms), *Chelidonium majus* 6cH (digestive spasms), *Viburnum opulus* 6cH (malaise, joint pain, headache).

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