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**EVALUATION OF THE EFFECTIVENESS OF THE PRODUCT BABUNA IN
THE TREATMENT OF INSOMNIA, IN PATIENTS OF THE MALE WING OF
THE ECUADORIAN HEALTH MINISTRY'S HOSPITAL OF INFECTIOUS
DISEASE**

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SUMMARY

Objective: To evaluate the effectiveness of Babuna in the treatment of insomnia in patients of the male wing of the Ecuadorian Health Ministry's Hospital of Infectious Disease.

Materials and methods: Type of study: Group Case Study; carried out in August 2005. A validated questionnaire of 4 questions was utilized.

Results: 7 male patients were diagnosed with insomnia, 5 patients responded to the treatment, 2 did not respond.

Conclusions: 71 percent of the patients treated with Babuna responded to the proposed therapy. There is an elevated frequency of insomnia in patients in the men's wing of the Ecuadorian Ministry of Health's Hospital of Infectious Disease, the chronic form being most prevalent. Many insomniacs do not seek medical care for this problem. The natural product Babuna showed effectiveness in treating insomnia. Although the present study certainly provides us with encouraging data, it is imperative that we carry out a broader study that provides conclusive results with regard to the effectiveness of Babuna.

Key words: Insomnia, occasional insomnia, chronic insomnia.

INTRODUCTION

Insomnia is the complaint of inadequate sleep, and is the symptom of a biological, physical, psychological, or environmental condition that interferes with a person's sleep. Insomnia has traditionally been classified according to its nature: difficulty initiating sleep, repeated or lengthy awakenings, early awakenings, or poor quality of sleep in spite of having slept an adequate number of hours. It is important to note that the majority of insomniacs suffer from more than one category (1).

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In 1984 the National Institute of Mental Health (NIMH) Consensus Conference divided insomnia into three categories: transitory (lasting less than one week), occasional or short-term (between one and three weeks) and chronic (three or more weeks) (1).

Insomnia is the most common sleep disturbance in the United States. The prevalence has been estimated at approximately one third of the adult population. Insomnia is 1.3 times more frequent in women than in men. The incidence increases with age, with those over 65 suffering 1.5 times more than those younger (1).

Insomnia is a heterogeneous condition and may be caused by a variety of factors. Among the causes of transitory and occasional insomnia are changes in the sleep environment, change in work hours, excessive noise, stress-inducing events such as the loss of a partner or family member, job loss, acute illness or surgery and medication. Chronic insomnia may be caused by chronic drug or alcohol use, or a variety of medical or psychiatric problems. For this reason it is essential to seek therapy to find the underlying cause of the problem (1).

The consequences of insomnia have been widely studied. Deterioration in the quality of life is associated with insomnia. Most affected persons complain of decreased productivity, fatigue, difficulty concentrating, memory loss, and mood changes. Insomniacs are at an increased risk for problems with their studies, work, and interpersonal relations (1).

Persons who experience symptoms of insomnia experience:

- Difficulty falling asleep
- Waking with frequency during sleep time
- Waking too early and not being able to get back to sleep
- Waking without feeling rested

Babuna is a natural medication, originating from the extraction of the active ingredients of the chamomile plant (*Matricaria recutita*), the same that is credited with sedation properties and for the treatment of insomnia. The literature reports that the chamomile flower is a safe product and there are no side effects or drug interactions (2).

Toxicity tests performed with rodents show that Babuna is a non-toxic product, and applied orally does not demonstrate signs or symptoms of inflammation of the oral tract in rodents. These studies were conducted in the Department of Chemical Sciences at the University of Guayaquil. In addition, the sedative effect of the product was demonstrated (3, 4).

There are reported cases of persons experiencing significant results in the treatment of insomnia after taking Babuna. Given that it is a non-toxic product, and with pre-clinical

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tests that show its safety and effectiveness, its application can be expanded to all types of patients.

MATERIAL AND METHODS

Experimental study in patients of the male wing of the Ecuadorian Ministry of Health's Hospital of Infectious Disease.

The sample size corresponds to the total number of patients eligible for the study: n=7.

Inclusion Criteria

- All patients with sleep disturbances.
- All patients displaying disquiet.

Exclusion criteria

- Patients with severe neuropathies.
- Patients with severe alternations in consciousness levels
- Patients with verified hepatic insufficiency
- Patients with acute or chronic respiratory insufficiency
- Patients taking sedatives

Information was obtained via a four-question instrument that was administered voluntarily in the written format. The questionnaire was developed based on prevalent theory, expressed in terms understandable to the target population. The questionnaire had previously been tested and validated in a pilot study. The study was conducted in August 2005 in the male wing of the Ecuadorian Ministry of Health's Hospital of Infectious Disease.

A patient was defined as an insomniac if he was currently experiencing difficulty sleeping. He was classified according to the duration of the insomnia as an occasional or chronic insomniac. Those who experienced insomnia for fewer than 3 weeks were classified as an occasional insomniac, and those labeled chronic insomniac had experienced insomnia for more than three weeks.

The responses related to sleep disturbances were considered affirmative if the respondent answered “many times” or “always”.

The data was then put into an Excel 2000 database and analyzed.



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RESULTS

The sample was comprised of 7 surveys based on 7 interviews. All were men. The median age was 32 ± 8 years old. The average body mass index (BMI) was 18.11. Four patients had normal BMI (between 18 and 25) and 3 were malnourished (BMI < 18) and none were obese (BMI > 25) or morbidly obese (BMI >40).

There were 6 cases of difficulty falling asleep, 6 cases of difficulty staying asleep and 6 cases of early waking.

All patients were HIV positive, one patient with histoplasmosis, one patient with erosive gastritis, four patients with tuberculosis, and one with tuberculosis, histoplasmosis, and pneumonia.

No patient showed signs or symptoms of toxicity upon ingesting the product. Five patients reported that they always suffer from insomnia, one often, and one rarely. Two patients reported that they always wake during the night, four reported often, and one sometimes. Six patients reported that they wake too early and not able to fall back to sleep, and one reports that occurring sometimes. Three report always awakening not feeling rested, one often, one sometimes, and one never.

Soon after administering the product, five patients reported that they did not have difficulty falling asleep, that they did not wake often during the night, that they did not awake too early, and they did not awaken feeling unrested. Two patients continued with insomnia.

The effectiveness of Babuna in the treatment of insomnia in patients of the male wing in the Ecuadorian Ministry of Health's Hospital of Infectious Disease was 71.42 percent.

DISCUSION

There is a high incidence of insomnia in the male wing of the Ecuadorian Ministry of Health's Hospital of Infectious Disease. The information used to create the theoretical framework of the present study shows a 69 percent prevalence of insomnia in outpatients, 50 percent with occasional insomnia and 19 percent with chronic insomnia (1).

In general, different studies show a higher prevalence in outpatients than in the population as a whole, which may reflect the impact that medical and psychiatric illness can have on sleep patterns.



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Moreover, when the pathology is chronic, the picture becomes quite complex; that benzodiazepines show secondary effects such as the development of a tolerance to the drug, ricochet insomnia, alteration in psychomotor productivity, dependency, and respiratory depression (1).

Although the use of traditional medicine such as valerian is frequent in our midst, little scientific evidence exists on the safety and effectiveness of these products (1).

The use of a medicine of natural origin, non-toxic, with no known drug interaction, of high effectiveness and that helps in the management of hospital patients with chronic pathologies, generates the necessary construction of evidence on the side of traditional medicine.

In conclusion, there is a high frequency of insomnia in the male wing of the Ecuadorian Ministry of Health's Hospital of Infectious Disease, predominantly the chronic form. Many insomniacs do not seek medical help. The natural medicine Babuna shows effectiveness in the treatment of insomnia.



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