



REPORT
on
Influence of the Subtle Energetic Changes on
Treatment Response in Patients with Insomnia

Saint-Petersburg
2016

Content

Introduction	3
Materials and methods	5
Results.....	7
Conclusion	11

Introduction

Insomnia is one of wide prevalence of diseases - the symptoms of insomnia suffer 28-45% of the world population. Women are prone to insomnia 1.3 times more often than men. People over 65 years meet difficulties with sleeping 1.5 times often than younger ones. Complaints about the poor quality of sleep in people older than 60 years 3-4 times often than at the average ages. For the treatment of insomnia are widely used sleeping pills (hypnotics) of nonprescription group, which, during uncontrolled constant reception cause significant secondary changes in sleep patterns and adversely affect the quality characteristics of the waking period.

Quality of sleep is a component of quality of life. Often chronic sleep disorders can cause the use of nootropics, psychostimulants, antidepressants, antipsychotics, antihypertensives and antimalarial drugs, antibiotics, hormones, certain antiarrhythmic drugs and vitamins (vitamin C).

The history of pharmacotherapy of sleep disorders has undergone some changes. Before the beginning of the XX century in the treatment of insomnia used bromine and opium. In 1903, there were barbiturates, and in the early 1950s. They began to use neuroleptics (mainly phenothiazine derivatives), and antihistamines. All of these drugs can be attributed to the first generation of sleeping pills, which are currently used are extremely limited as a hypnotic. With the advent in 1960 of diazepam and oxazepam the era of benzodiazepine hypnotics second generation.

However, a group of benzodiazepines brought certain problems in clinical practice of insomnia: addiction, the need to increase the daily dose, increased manifestations of sleep apnea during sleep as a result of muscle relaxant features of benzodiazepines.

The third generation of hypnotics include the relatively new drugs developed in 1980-1990 years.: derivative of tsiklopirrolana - zopiclone (imovan) and derivatives of imidazopyridine - zolpidem (ivadal) are meets the requirements for the ideal sleeping pills. A new direction in the treatment of insomnia is the use of synthetic analogues of the hormone melatonin. Third generation hypnotics

(zopiclone, zolpidem and zaleplon), and melatonin is rarely used as the main features of the expected clinical effect is not widely known.

In the appointment of hypnotics should take into account the half-life of drugs.

Hypnotics with a short half-life is most often used for therapy of presomnial disorders among working people engaged in potentially hazardous activities. Drugs with long half-life is used only for the normalization of sleep in violation of ones duration. Among the third generations of sleeping pills the greatest danger from the point of view of the risk of toxic effects are barbiturates.

Potentially the possible severity of barbiturate intoxication can be determined by taking the drug dose:

- Mild poisoning occurs when receiving an amount of barbiturates, which is 3-4 times exceeds the therapeutic (hypnotics) dose;
- Poisoning of moderate and severe degree develops when barbiturate therapeutic dose exceeds 5-10 times.

The development of acute poisoning by hypnotic drugs dependent on the dose of the drug and its mechanism of action, combination with other agents, reinforcing effects of sleeping pills, as well as the individual the body's reaction.

With an overdose of hypnotic drugs the polysynaptic brain structure is oppressed and weakens impulses which are activating the reticular formation on the cerebral cortex.

In large doses, barbiturates depress the respiratory and vasomotor centers.

Therefore, it is relevant to the study of non-drug treatment of insomnia. Earlier, in the “Study of the Influence of Subtle Energetic Changes in Environment on the Productivity of the Process of Sleep” work published in Open Journal of Ecology, 2014, 4, 693-702 by the authors Edward V. Krizhanovsky and Lim Kwong Choong was shown the results of the study of changes of healthy people state under the influence of specialized mattresses, with a basis of cotton eco-friendly materials of filler and cover which basis was exposed to activation (AM) in the area of natural energy fields.

This work is devoted to revealing the differences between the states of patients with psychophysiological insomnia using an ordinary mattress (OM) with a basis of cotton eco-friendly materials of filler and cover, and also ones analog which basis was exposed to activation (AM) in the area of natural energy fields in Malaysia within 1 day (figure.1) (so called AM therapy).



Figure.1. Activated mattress.

Materials and methods

The study was conducted on the basis of Sports Medicine Clinics of Russian State University of Physical Education, Sport, Youth and Tourism in Moscow. Evaluation of the subjective state of clinical parameters was performed in 18 patients with psychophysiological insomnia without comorbidities.

In order to obtain the most reliable data, the following patient selection parameters was used:

- age from 22 to 50 years (mean age 36 years).

The criterion for exclusion from the study was the presence of arrhythmias, pacemakers, injuries and brain tumors, mental illness, thyrotoxicosis. Among the patients, women accounted for 61% (n = 11), men - 39% (n = 7).

All patients - volunteers are matched to one type of sleep disorders - psychophysiological insomnia.

All patients have signed the informed consent to participation in a research.

We divided patients in 2 groups with 9 people in each one.

Group 1 was TRULY informed that they took influence with AM during the sleep.

Group 2 was WRONGLY informed that they took influence with AM (in fact they used placebo cover) during the sleep.

The mattress is placed under the patient (Figure 2).



Figure 2. The process of patient sleeping on AM.

The analysis of human state was done with the help of next methods: Polysomnography, blood pressure, heart rate, the estimation of a psychophysiological state by Voll, psychological testing.

EEG study was conducted on "Neurosoft" electroencephalograph, made in Russia, Ivanovo.

It was used the standard scheme of bipolar leads with 21channel. We used bridge type of electrodes.

Efficiency of therapy was estimated by means of clinical and psychometric methods of a research in 2 weeks of influence.

All personal cards of patients were processed by means of methods of descriptive and comparative statistics. The descriptive statistics was executed for all analyzable indices depending on variable type. In the analysis of the quantitative variables defined their arithmetic average, the minimum and

maximum values, a standard deviation, and in the analysis of qualitative variables – their frequency and part (as a percentage) from the total number.

Statistical analysis was carried out according to the distribution of sample by using of T-test and Fischer parametric criteria or Wilcoxon and Kolmogorov-Smirnov nonparametric test with help of Statistica package 10.0 statistical software.

Results

The vast majority (76.5%) of patients with insomnia associated with the beginning of some traumatic situation (caused acute financial difficulties, problems at work or in the family and other circumstances).

All patients were detected clinically registered sleep disorders, comes to the fore in the clinical picture of a neurotic state.

The most frequent complaints were difficulty falling asleep at night (72.4%), frequent (more than 3-4 times per night) nocturnal awakenings (62.3%), difficulty of morning awakening (41.6%), daytime sleepiness (39.6 %), lack of a sense of rest after a night's sleep (35.1%), sudden nocturnal awakening with difficulty falling asleep again (28.3%). Statistically significant differences between the groups as well as gender-based pre-treatment is not revealed. Analysis of the relations between subjective measures of sleep patterns showed that the difficulty morning awakening is associated with the duration of sleep ($p < 0.05$) and the lack of a sense of relaxation after sleep ($p < 0.05$).

Surface sleep significantly ($p < 0.05$) correlated with the lack of a sense of relaxation after sleep. Between sleep duration and the feeling of cheerfulness at morning didn't find statistical differences. It was revealed a link between lack of sleep and feelings of subjective sensations at morning (lethargy, fatigue, irritability, headaches). It was found that the early final awakening is not accompanied by poor health in the morning.

Subjectively, patients in this group, in most cases experienced morning alertness and working capacity.

Based on the data, it can be stated that long-term falling asleep and difficulty morning awakening is associated with feelings of lack of rest after sleep. On the contrary, the morning feeling almost connected with intrasomnial disorders.

After 2 weeks of therapy, we found a significant improvement in sleep quality by visual analog scale with the dynamics of the studied parameter in Group 1 from 3.2 to 7.5 points, and in the Group 2 - from 3.1 to 3.6 points (Table. 1).

Differences are not significant in the second group.

Table 1. Dynamics of the quality parameter of sleep on a visual analog scale of self-assessment.

Group	Parameter, points	
	before treatment	after treatment
1-я	3,2 ± 0,23*	7,5 ± 0,38*
2-я	3,3 ± 0,25	3,6 ± 0,22

* Significant differences between groups, P <0.05.

It was found that the use of AM significantly reduced the sensation of a sleep lack waking and representation postsomnial disorders such as daytime sleepiness (Table. 2, Fig. 1 and 2).

Table 2. Dynamics of sleep quality parameters in the treatment process

	Value of parameters, %			
	Group 1		Group 2	
	before treatment	after treatment	before treatment	after treatment
The inability to sleep for more than 30 minutes	70	20	72	69
Falling asleep within 20-30	3	22	3,8	4

minutes after bedtime				
Night waking up (3-4 per night)	65	12	62	58
Sense of sleep lack of sleep after a night	45	10	46	42
Daytime sleepiness	18	4,2	19	15

* Significant differences between groups, $P < 0.05$.

During the study, we have revealed a significant decrease in the level of reactive anxiety after treatment in the two groups. In group 1, after treatment the average score on a scale of reactive anxiety Spielberger-Hanin was $36,2 \pm 1,78$, in the 2nd - $39,8 \pm 1,88$, which was significantly lower than before the treatment in the first group $42,2 \pm 1,21$ and unreliable for second $40,9 \pm 1,38$, respectively. EEG changes in results are shown in the examples (Figure 3 and 4).



Figure 3. Patient P EEG data before and after two weeks of the study.

Figure 4. Patient O EEG data before and after two weeks of the study.

The process of the placement of sensors for measuring EEG displayed in Figure 5.



Figure 5. The process of EEG study.

Compared with the initial data on the EEG pattern it was observed a clear response to the process of opening-closing of the eyes. A greater representation of the beta rhythm in the anterior (front) leads. These changes indicate a full-fledged functioning of the cerebral cortex.

Conclusion

The dynamics of the individual qualitative and quantitative characteristics of sleep disorders in AM therapy tends to be a positive development for the Group 1 study. Positive changes in the Group 2 revealed due to proper sleep hygiene in the clinic, as well as the placebo effect. Thus, changes in the second group are not significant.

Action of AM therapy against manifestations of insomnia was expressed, while helps to reduce anxiety and improve of mood state. It is important to note from the occurrence of the effect AM therapy that helped patients fall asleep within 20-30 minutes.

This is manifested by the EEG pattern, which also show a clear reaction to the of eyes opening-closing process. These changes in the EEG shows a full-fledged functioning of the cerebral cortex.

Furthermore, it was found the improvement sleep quality and reduction of the number of nighttime awakenings and daytime sleepiness. AM therapy approach as a way of insomnia relief, together with the sleep hygiene can help to effectively monitor the status of sleeping and avoiding muscle relaxant and synaptic influence on patients with the same as in given research symptoms of insomnia.