SHORT COMMUNICATION

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Interim Analysis of a Prospective Polysomnographic Study of Weighted Blankets in Patients with Psychophysiological Insomnia

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ABSTRACT

Background: Weighted blankets have recently introduced in the treatment on insomnia as a non-pharmacological integrative therapy. Here we prospectively evaluated the effects of weighted blankets on the sleep structure and heart rate variability (HRV) in patients with primary psychophysiological insomnia.

Methods: In this prospective polysomnographic (PSG) study between August 2021 and August 2022, patients were given weighted blankets (~10% of body weight) to use at home for 10 nights consecutively. Clinical examination and scales including Turkish Version of Basic Scale on Insomnia Complaints, Quality of Sleep (BaSIQS), and Pittsburgh sleep quality index (PSQI) were performed before and after therapy.

Results: The mean age of a total of 26 patients was 48.7 ± 9.4 years, and 69.2% were males. Sixteen patients (69.2%) showed benefit from weighted blankets as measured by BaSIQS ($P = .005$) and PSQI ($P = .003$). In objective PSG measures, sleep latency was also decreased ($P = .040$) with increased percentage of N3 sleep ($P = .034$). On the other side, obstructive apnea-hypopnea index was significantly increased ($P = .038$). Heart rate variability parameters did not show significant changes.

Conclusion: Weighted blankets should be considered as a promising non-pharmacological option in practical therapies of chronic psychophysiological insomnia. An increase in obstructive apneas/hypopneas necessities a screening for sleep apnea.

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INTRODUCTION

Insomnia is a growing health problem due to social stress, increasing demands, industrialization, and increased stressor factors associated with modern lifestyles. The overall prevalence of chronic insomnia was found to be 12.2% in Türkiye in a prospective survey of 4758 participants.[1] Chronic insomnia is associated with a variety of daytime consequences (such as impaired school/work performance and work/traffic accidents) as well as with serious health problems (such as psychosomatic disorders and cardiovascular diseases).[2] It is therefore of crucial importance to efficiently treat chronic insomnia.

Both pharmacological and non-pharmacological behavioral therapies are used in the treatment of insomnia.[3] The number of drugs approved by the Food and Drug Administration (FDA) is scarce, and FDA-approved drugs usually have the potential for side effects and addiction. Cognitive and behavioral methods are strongly recommended for these patients, but they require long treatment sessions to achieve satisfactory results.[4] Integrative therapies are therefore being increasingly used as an alternative therapy to stabilize sleep in adult patients with chronic insomnia. The European Insomnia Guideline was very recently published by the European Sleep Research Society in 2023,[5] in which cognitive-behavioral therapy was suggested as a non-pharmacological treatment. Other options included exercise, light therapy, music, and non-invasive brain stimulation, for which the authors mentioned that it was premature to recommend any of these treatments due to lack of evidence. The use of weighted blankets was not included in this guideline, probably due to the lack of randomized controlled clinical studies.

Weighted blankets have recently been introduced in the treatment on insomnia,[6] although promising results have been shown in decreasing anxiety levels in insomnia associated with psychiatric disorders.[7,8] While the exact mechanisms underlying the possible sleep-improving effects of weighted blankets are not known, decreased electrodermal activity via deep pressure stimulation[9] decreased physiological

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reactions to stressors,[10] and increased melatonin release at bedtime[11] have been hypothesized. There is still a need for systematic polysomnographic studies to demonstrate the potential benefits of weighted blankets in patients with chronic insomnia. Here, we aimed to evaluate the effects of weighted blankets on sleep structure with polysomnographic data and heart rate variability (HRV), which was analyzed for the first time here to understand the changes in the sympathetic nervous system as a possible underlying pathophysiology of the weighted blankets on treating insomnia.

MATERIAL AND METHODS

Study Population and Procedure

Patients admitted to our Sleep and Disorders Unit complaining of insomnia were prospectively and consecutively evaluated during the study period of 1 year between August 2021 and August 2022. All patients had a thorough clinical examination with psychiatric consultation, and those who were eligible for the study and gave their written informed consent to participate had a full-night video-polysomnography (PSG) in our laboratory in Istanbul University-Cerrahpasa, Cerrahpasa Faculty of Medicine, Department of Neurology, Sleep and Disorders Unit. Patients with any other associated sleep disorder (such as restless legs syndrome and sleep apnea syndromes), neurologic and/or psychiatric comorbidity, medical disorders (such as heart diseases), or those using drugs/substances that interfere with sleep were excluded. Patients diagnosed with primary psychophysiological insomnia (as a subtype of chronic insomnia) on the basis of clinical and PSG evaluations were given weighted blankets to use at their homes. A weighted blanket equal to about 10% of the patients' body weight[6] was used by the patients for 10 consecutive nights for familiarization with the therapy. On this basis, every participant had blankets appropriate to their body weights. During this time, patients were asked to sleep at home every night with weighted blankets on. Those who were not compatible with the use of weighted blankets (4 patients) were not included in the study. At the end of this period, all participants had a second full-night video-PSG in our laboratory with weighted blankets on. Turkish Version of Basic Scale on Insomnia Complaints and Quality of Sleep (BaSIQS)[12] and the Pittsburgh Sleep Quality Index (PSQI)[13] were completed by the patients in the morning following the first and second PSG investigations. The second time when the BaSIQS and PSQI were completed, the patients were asked to answer the questions regarding the time they were using the weighted blankets. TREND guidelines were used for this non-randomized evaluation of behavioral and public health intervention, and the study was approved by the Local Ethics Committee for Clinical Researches (ID: E-83045809-604.01.01-362616).

MAIN POINTS

- Weighted blankets can be used as integrative therapy in chronic psychophysiological insomnia.
- Major beneficial effects are decreased sleep latency and improved sleep quality.
- Changes in sympathetic activation by the use of weighted blankets deserve further attention.
- Attention and caution should be exercised in patients with obstructive sleep apnea.

Scales and Tests Used in the Study

BaSIQS[12] is a self-reported questionnaire to assess nighttime insomnia complaints. It contains 7 items, with total points ranging from 0 to 28 points, higher scores meaning poorer sleep. Pittsburgh sleep quality index[13] is also a self-reported questionnaire to evaluate sleep quality, regardless of underlying etiology. It contains a total of 19 questions, and points equal to or above 5 determine bad sleep quality, with increased points meaning worse sleep quality. The Cronbach's alpha coefficient of the Turkish validation of BaSIQS was reported as 0.752.

The recording and evaluation of PSG were performed based on the AASM (American Academy of Sleep Medicine) Manual for the Scoring of Sleep and Associated Events,[14] and the third edition of the International Classification of Sleep Disorders was used for the diagnosis of sleep-related disorders.[15] Total recording time, total sleep time, wakefulness after sleep onset (WASO), sleep efficiency, sleep latency, rapid eye movement (REM) sleep latency, percentages of wakefulness and sleep stages, apnea-hypopnea index (AHI), mean and minimum oxygen saturations, and the index of periodic leg movements in sleep (PLMSI) were calculated.

A single modified electrocardiography (ECG) Lead II was used for HRV analysis. The ECG signal was processed to capture beat-to-beat intervals (R-R interval) between 300 and 1600 ms, and abnormal R-R intervals related to cardiac rhythm disturbances or artifacts were removed. In the time domain, the average R-R interval (avRR) and the proportion of adjacent normal-to-normal intervals differing by more than 50 ms (pNN50) were calculated. In the frequency domain, the spectral power of low-frequency (LF) and high-frequency (HF) bands and LF to HF ratio (LF/HF) were computed by using the fast Fourier transformation.[16]

Statistical Analysis

Data were analyzed using SPSS v21.0 software. Categorical variables were reported as frequencies and percentages. Descriptive statistics were presented as median (minimum-maximum) for non-normally distributed variables and mean ± SD for normally distributed variables. Nominal (categorical) parameters between 2 groups were tested by the chi-square test. The test of normality was evaluated

using the Shapiro–Wilk test. Dependent parameters were analyzed by the independent-samples t-test for the parameters with normal distribution and by the Mann–Whitney *U*-test for those without a normal distribution. Changes between the first and second nights were analyzed by using the paired-samples *t*-test or Wilcoxon test, depending on normality. Spearman correlation coefficients were used in the correlation analysis of parameters that may play a role in the benefits from therapy. Multiple comparisons were corrected using the Benjamini–Hochberg procedure, and $P=0.05$ was accepted as statistically significant.

RESULTS

Twenty-six patients [69.2% males (n=18)] with a mean age of 48.7 ± 9.4 years completed the study. Sixteen patients (69.2%) showed subjective benefit from the weighted blanket, and 6 of them (6/26, 23%) stated a substantial benefit. The results of BaSIQS and PSQI are given in Table 1. It was observed that total scores of both tests were significantly decreased ($P=.005$ and $P=.003$, respectively). Questions 1 and 2 in BaSIQS (related to sleep latency), and questions 3, 6, and 7 (related to sleep latency, overall sleep quality, and need for medications to sleep, correspondingly) in PSQI showed significant changes following therapy (see Table 1).

Table 1. BaSIQS and PSQI Parameters Before and After the Use of Weighted Blankets in Whole Study Population

Questionnaires	Pre-Treatment (Mean ± SD) [Median (95% CI)]	Post-Treatment (Mean ± SD) [Median (95% CI)]	*P*
BaSIQS			
Q1	1.0 (1.3-2.8)	1.0 (0.8-2.3)	.016*
Q2	2.5 ± 0.8	1.8 ± 1.0	.001*
Q3	2.0 (1.7-2.4)	2.0 (1.4-2.2)	.214
Q4	2.0 (1.6-2.3)	2.0 (1.2-2.1)	.234
Q5	2.0 (1.7-2.6)	2.0 (1.5-2.2)	.135
Q6	1.0 (0.6-1.6)	1.0 (0.6-1.6)	.090
Q7	1.0 (1.0-1.6)	1.0 (0.6-1.4)	.135
BaSIQS-total	13.1 ± 3.0	10.6 ± 4.5	.005*
PSQI			
Q1	2.0 (1.2-2.2)	1.0 (1.0-1.8)	.055
Q2	2.0 (1.4-2.0)	1.5 (1.2-1.7)	.163
Q3	2.0 (1.4-2.2)	1.0 (1.0-1.8)	.042*
Q4	1.5 (1.2-2.1)	1.0 (1.1-2.9)	.186
Q5	0 (0.2-1.4)	0.5 (0.2-1.2)	.494
Q6	2.0 (1.3-2.6)	2.0 (1.0-2.0)	.014*
Q7	1.9 ± 1.2	1.3 ± 0.8	.010*
PSQI-total	11.6 ± 3.7	9.2 ± 2.8	.003*

BaSIQS Q2 and total scores and PSQI Q7 and total scores were normally distributed, and paired *t*-test was performed. The others were not normally distributed, and the Wilcoxon test was performed.
BaSIQS, Basic Scale on Insomnia complaints and Quality of Sleep; PSQI, Pittsburgh sleep quality index.
*Statistically significant.

Polysomnographic parameters (Table 2) showed that sleep latency was decreased ($P=.040$) and the percentage of N3 sleep was found to be increased ($P=.034$). Nevertheless, we observed that the obstructive AHI was increased on the second night with weighted blankets on ($P=.038$).

Age, sex, body mass index, or PSG parameters of the first night did not show any association with the patients stating therapeutic benefit (Table 3). Correlation analysis between age, sex, PSG parameters, and BaSIQS and PSQI also failed to reveal significant determinants of the benefit from weighted blanket.

Changes in HRV analysis failed to reach statistically significant levels, but a trend for decreased average RR duration, LF band, and LF/HF ratio was observed on the second night with weighted blankets on (not shown).

DISCUSSION

Weighted blankets are increasingly drawing attention as an integrative therapy for chronic insomnia. In our prospective PSG-based study, we demonstrated that the use of weighted blankets resulted in improvements in symptomatology in about 70% of the patients with chronic psychophysiological insomnia, as demonstrated by significant decreases in subjective scores of BaSIQS and PSQI. Also, we objectively demonstrated that sleep latency was decreased and the percentage of N3 sleep was found to be increased even after 10 days of therapy, which were not influenced by sociodemographic factors, including age and sex. Correlation analyses, on the other hand, failed to show the determinant factors of which subgroup of patients will benefit from weighted blankets the most. Some changes in heart rate variability were not found to be statistically significant. On the other hand, the obstructive apnea-hypopnea index was observed as significantly increased with the use of weighted blankets.

Beneficial effects of weighted blankets have been previously demonstrated in a small number of studies.[7,9,17] The most common effect of weighted blankets was reported as an increase in sleep quality in these studies. While the use of different scales in subjective evaluation and the lack of PSG in some of these studies make it difficult to compare the results adequately, in our study, we observed that the most prominent effect of weighted blankets was on sleep latency. Both in subjective measures (BaSIQS and PSQI) and in PSG, we observed that sleep latency was shortened significantly after the use of weighted blankets. We also observed that the duration of slow-wave sleep increased, which may explain the high rate of subjective satisfaction and increased sleep quality, as shown by decreased total scores in both questionnaires.

Table 2. PSG Parameters at First and Second Nights in Whole Study Population

PSG Parameters	Pre-Treatment (Mean ± SD) [Median (95% CI)]	Post-Treatment (Mean ± SD) [Median (95% CI)]
Total recording time (minutes)	478.0 (453.0-531.6)	475.4 (454.0-493.4)
Total sleep time (minutes)	383.2 ± 83.0	384.1 ± 36.3
Sleep efficiency (%)	78.1 ± 13.4	80.2 ± 14.2
Sleep latency (minutes)	42.6 ± 59.5	14.3 ± 9.0
REM sleep latency (minutes)	149.2 (133.8-209.6)	118.5 (98.4-196.6)
WASO (minutes)	108.0 ± 80.0	93.2 ± 67.8
Percentage of N1 sleep (minutes)	11.0 ± 7.3	9.9 ± 4.8
Percentage of N2 sleep (minutes)	50.3 ± 12.7	45.7 ± 10.4
Percentage of N3 sleep (minutes)	9.4 ± 5.6	13.5 ± 4.4
Percentage of R sleep (minutes)	14.9 ± 7.2	14.8 ± 7.7
Obstructive AHI (/hour) [Median (95% CI)]	3.0 (2.6-6.2)	5.0 (4.2-12.3)
Central AHI (/hour)	0.2 ± 0.4	0.2 ± 0.5
Mean O2 saturation (%)	95.3 ± 1.8	94.8 ± 1.7
Minimum O2 saturation (%)	89.6 ± 4.6	87.5 ± 6.6
PLMSI (/hour) [Median (95% CI)]	5.0 (4.2-16.5)	6.5 (5.0-14.9)

AHI, apnea-hypopnea index; N1, non-REM (NREM) stage 1; N2, non-REM (NREM) stage 2; N3, non-REM (NREM) stage 3; PLMSI, index of periodic leg movements in sleep; PSG, polysomnography; REM, rapid eye movement; WASO, wakefulness after sleep onset.

Table 3. The Association Between Age, Sex, Body Mass Index, and PSG Parameters of the First Night Between Patients With and Without Therapeutic Benefit

Clinical Parameters	Patients with Therapeutic Benefit (n = 16)	Patients Without Therapeutic Benefit (n = 10)	*P*
Age (years, mean ± SD)	50.8 ± 7.4	46.0 ± 10.4	.239[#]
Sex (females)	8 (50.0)	6 (60.0)	.336[¥]
BMI (kg/m^2, mean ± SD)	27.3 ± 7.2	25.8 ± 4.4	.324[#]
PSG parameters			
Total recording time [minutes, median (95% CI)]	477.9 (454.8-594.2)	472.4 (347.4-755.8)	.718[£]
Total sleep time (minutes, mean ± SD)	382.4 ± 84.2	433.2 ± 104.1	.172[#]
Sleep efficiency (%, mean ± SD)	76.2 ± 12.6	81.0 ± 14.5	.454[#]
Sleep latency (minutes, mean ± SD)	47.8 ± 54.3	56.3 ± 92.4	.841[£]
REM sleep latency [minutes, median (95% CI)]	162.8 (102.8-222.9)	196.5 (120.8-273.6)	.312[£]
WASO (minutes, mean ± SD)	107.7 ± 61.6	118.4 ± 121.8	.841[£]
Percentage of N1 sleep (%, mean ± SD)	11.8 ± 4.8	13.9 ± 12.6	.542[£]
Percentage of N2 sleep (%, mean ± SD)	48.6 ± 12.4	52.9 ± 10.7	.291[#]
Percentage of N3 sleep (%, mean ± SD)	9.3 ± 5.7	9.4 ± 7.0	.524[#]
Percentage of R sleep (%, mean ± SD)	14.8 ± 7.1	15.6 ± 8.4	.850[#]
Obstructive AHI [per hour, median (95% CI)]	4.5 (2.4-7.7)	1.6 (−1.8-7.8)	.312[£]
Central AHI (per hour, mean ± SD)	1.1 ± 0.3	1.3 ± 0.8	.841[£]
Mean O2 saturation (%, mean ± SD)	95.4 ± 2.2	95.4 ± 1.1	.992[#]
Minimum O2 saturation (%, mean ± SD)	88.8 ± 5.0	90.3 ± 4.6	.542[#]
PLMSI [per hour, median (95% CI)]	5.0 (1.1-17.9)	4.5 (-10.0-35.0)	.904[£]

Categorical variable (sex) is given as n (%).
AHI, apnea-hypopnea index; BMI, body mass index; N1, non-REM (NREM) stage 1; N2, non-REM (NREM) stage 2; N3, non-REM (NREM) stage 3; PLMSI, index of periodic leg movements in sleep; PSG, polysomnography; REM, rapid eye movement; WASO, wakefulness after sleep onset.
[¥]Chi-square test was used for nominal parameters.
[#]Independent-samples *t*-test.
[£]The Mann-Whitney *U*-test was used for continuous parameters with and without normal distribution, respectively.

Weighted blankets were also shown to be effective in decreasing anxiety in insomnia associated with psychiatric disorders.[6-8] This calming and relaxation effect of weighted blankets was hypothesized to be linked to the presence of a tactile input, which may decrease the activity of the sympathetic nervous activation and sympathetic arousals during sleep.[17,18] This hypothesis may also be one of the underlying mechanisms to explain the benefits of weighted blankets on sleep quality. In this regard, we performed HRV analysis in our patients before and after the therapy, for the first time in the literature, which shows the activity of the sympathetic nervous system via measuring the variability of heartbeats during sleep. Although we failed to demonstrate a statistically significant difference before and after the use of weighted blankets, there was a trend toward decreased sympathetic activation, which is promising for conducting a larger and longer follow-up study on this parameter.

Another original finding of our study was increased obstructive AHI with the use of weighted blankets. In the initial study of the safety of weighted blankets, vital signs of the participants, including pulse oximetry, pulse rate, and blood pressure, were traced and showed the safety of the treatment.[6] However, our results imply that the use of weighted blankets may result in an increase in obstructive hypopneas/apneas, and patients who are candidates for a treatment with weighted blankets should be screened for sleep apnea by questionnaires or should be tested by PSG to exclude sleep apnea before implementing this therapy. Nevertheless, our results need to be replicated in larger cohorts, and the use of weighted blankets in specific patient groups, such as those with sleep apnea, deserves further attention.

Besides the original and promising results of our study, it also includes some important limitations. The major limitation was the lack of a control group, which was difficult to execute due to the inability to provide a placebo weighted blanket. The interpretation of our results should therefore be made very cautiously, without conducting a placebo-controlled study. Another major limitation of this study is the low number of study participants. The room temperature adjustment was not made according to seasons and air temperature, which should be mentioned as another limitation of our study. In addition, the use of different weights of weighted blankets was unclear, as perceived heaviness of blankets may also vary considerably among subjects (due to different levels of interoceptive and sensory awareness). Only short-term effects of weighted blankets were interpreted in the current study, and long-term results should be encouraged.

CONCLUSION

Our study demonstrated the beneficial effects of weighted blankets in patients with chronic psychophysiological insomnia. The use of integrative therapies is becoming more necessary as long-lasting pharmacological therapies usually have side effects and risk of addiction. This study confirmed previous studies that weighted blankets showed beneficial effects on sleep quality, but our results offered further evidence that patients having difficulty initiating sleep would especially benefit the most from weighted blankets. In addition, changes in HRV analysis were examined for the first time in the literature, which provided promising results to be replicated in larger cohorts. Our results should be implemented with the current health care or reimbursement policies in order to advocate practitioners for the use of integrative therapies, including weighted blankets, in chronic insomnia. Only short-term effects of weighted blankets were interpreted in the current study, and long-term results should be performed. On the other hand, the risk of obstructive sleep apnea should be better elaborated before the initiation of this therapy, which deserves further studies on the use of weighted blankets in sleep apnea, as well as in other specific patient groups.

Ethics Committee Approval: This study was approved by the Ethics Committee of Istanbul University-Cerrahpasa (Approval No: 362616, Date: 18.04.2022).

Informed Consent: Written informed consent was obtained from the patients/patient who agreed to take part in the study.

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