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Moderating Laboratory Adaptation with the Use of a Heart-rate Variability Biofeedback Device (StressEraser®)

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Abstract Difficulty sleeping is a common problem with laboratory polysomnograms. This affects both polysomnograms that are used as a clinical tool to investigate sleep pathology or as an outcome variable in research. The goal of this study was to use a handheld biofeedback device (StressEraser®) to improve sleep quality in the laboratory. Ten subjects without a history of sleep disorders were randomly assigned to either a StressEraser® or no-treatment control condition. A sleep disturbance scale derived from sleep efficiency, REM latency, minutes of stage 1 sleep, and wake after sleep onset was created to evaluate the differences between these groups. Subjects in the StressEraser® group had significantly lower scores on the sleep disturbance scale compared to the no-treatment control group ($p = 0.003$). Sleep latency was not improved. In conclusion, the StressEraser® significantly improved sleep quality compared to a no-treatment control group. This suggests that the StressEraser® may be an effective tool to help reduce the first-night effect in nighttime laboratory sleep studies.

Keywords Transient insomnia · StressEraser® · Biofeedback · Heart-rate variability · First-night effect

Introduction

Several studies have shown that the first night in the sleep laboratory is different from subsequent nights on a variety of measures (Agnew et al. 1966; Browman and Cartwright 1980; Hartmann 1968; Mendels and Hawkins 1967; Schmidt and Kaelbling 1971; Toussaint et al. 1995, 1997). The effects include decreased sleep efficiency and REM sleep, and increased wake after sleep onset (WASO), stage 1 sleep, REM latency, and stage 2 sleep (Agnew et al. 1966; Hartmann 1968; Toussaint et al. 1995, 1997). This phenomenon is generally referred to as the first-night effect or transient insomnia and has been attributed to the novelty of the sleep laboratory (Sharpley et al. 1988; Wauquier et al. 1991). Sleep studies therefore often discard data from the first night in the laboratory.

In a clinical setting, it is a common occurrence for patients who report no difficulty sleeping at home to have difficulty sleeping on their diagnostic sleep recording. Transient insomnia has been shown to be improved with the use of hypnotic medication (Rosenberg et al. 2007; Roth et al. 1995). Therefore, patients who cannot sleep on their initial PSG are often restudied with a hypnotic medication to help them sleep. However, this may not be an ideal option for a variety of reasons (for example: history of drug or alcohol abuse, risk of fall in elderly patients, or simply the refusal of a patient to take medication). In addition, it is expensive and inconvenient to perform two diagnostic studies on the same patient.

Investigating the "first night effect" would require multiple nights in the laboratory, which was not done in this study. Therefore, the goal of this study was to test the ability of an ambulatory heart rate variability biofeedback device (StressEraser®, SE) to help improve sleep quality in normal participants on the first night polysomnogram. We hypothesized that the (SE) would help subjects adapt to the sleep laboratory, resulting in increased sleep efficiency and decreased WASO, REM latency, and minutes in stage 1 sleep.

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Methods

Participants

Ten subjects were enrolled (three males and seven females). Mean age was 20 (range was 18–23). The inclusion criteria were as follows: must be between the ages of 18–55, able to read English, demonstrating a sleep onset latency between 5 and 30 min (as determined by self-report), sleeping on average more than 6 h per night. Exclusion from the study was also based on: participating in more than two studies in the past 2 years; meeting current criteria for a sleep disorder of any kind including primary insomnia; terminal, progressive, and/or unstable medical illness; a self-reported sleep–disruptive medical disorder; a current Axis I psychiatric disorder; nicotine use; drug or alcohol use (determined by on-site saliva drug screen); Raynaud's Disease; a regular intake of anti-anxiety medications, beta blockers or other heart medications that regulate heartbeat, bronchodilators, respiratory stimulants, simulating antidepressants, sedating antidepressants, thyroid supplements, anti-psychotics, and/or steroids; intake of any medication to counter sleep difficulties in the past month; symptoms of sleep apnea [BMI $>$ 30 and/or an Epworth Sleepiness Scale score of $>$10 (The Epworth Sleepiness Scale is an 8-item subjective scale that measures situational sleepiness (Johns 1991); a score of $<$10 is generally considered within normal limits)]; consumption of more than 3 (8 oz) caffeinated drinks per day; regular night-time shift work and/or rotating night-time shift work; and sleeping 2 h longer than the mean sleep duration the week prior to enrolling.

Screening

Participants were recruited through flyers and other advertisements posted in the New York City area. Responders were initially screened over the phone for basic qualifications. If they passed, they were then interviewed face-to-face at the Center for Sleep Medicine, Weill Medical College.

Participants were first screened for use of alcohol, amphetamine, methamphetamine, marijuana, phencyclidine, cocaine, and opiates. No participants were rejected for failing the drug or alcohol screen. Participants were screened for psychiatric disorders with the MINI. Five neuropsychiatric questionnaire (Sheehan et al. 1998). The study design was explained, and the participants were provided with an informed consent form.

Intake Procedure

The participants' subjective sleep parameters were evaluated using the Pittsburgh Sleep Quality Index (Buysse et al. 1989). The Pittsburgh Sleep Quality Index (PSQI) is a subjective questionnaire comprised of nineteen questions, which assesses sleep quality and disturbance over a 1-month period. The participants were then randomized. Condition was chosen based on random pick from two sets of five indistinguishable envelopes, five envelopes were designated the SE condition and five envelopes were designated the control condition. SE participants were shown a 15 min instructional video explaining basic physiological concepts behind the SE, defining the slow breathing technique that the device aids, allowing the participants to practice the breathing technique without the device, and describing the technical operation of the device. After viewing, the participants were shown the device and allowed to obtain a pulse rate wave. The researcher then demonstrated the use of the device. The training consisted of the determination of the subject's breathing rate and the use of numerical or affirmative focus phrases that match exhalation length. The participants were then tested in their ability to use the device. The requirement for continuation in the study was the ability to obtain 30 points in 10 min. Points were earned if the subject was able to match the SE targeted breathing rate. One subject was not able to achieve this benchmark and was rejected from participation.

Once the participants had shown competence in SE use, an assessment of adverse effects experienced at the end of use was conducted. Any adverse effects were recorded. The severity was judged on a scale of 1 to 4 (1 = very mild, 4 = severe), and relationship to the treatment was determined on a scale of 1 to 5 (1 = unrelated, 5 = definitely related). One subject experienced slight light-headedness after Stress Eraser use. The adverse effect was judged as one on the severity scale and five on the relationship to treatment scale. Exposure to the Stress Eraser was not performed in the control group. At the end of the intake, both participant groups were presented with a sleep log and an actigraph, and were scheduled for a follow-up PSG.

Ambulatory Heart Rate Variability Biofeedback Device

The SE is a class II 510(k) premarket notification-exempt medical device. It is an over-the-counter non-invasive biofeedback device which measures real-time pulse by pulse activity via an infrared finger sensor (Heilman et al. 2008). The finger sensor has a built-in pulse detector to identify every pulse the moment it occurs. Each time a new pulse occurs, the device calculates a new pulse rate based upon the amount of time that has elapsed between the last two pulses. Based on the pulse rate, the SE has an algorithm that creates a wave like pattern called respiratory sinus arrhythmia (RSA) and teaches users to inhale until their heart rate peaks and exhale until it begins to rise again. This breathing rate varies from individual to

individual but is typically between 4.5 and 7 breaths per min. When done correctly, it creates a resonance between respiratory and baroreflex rhythms, the two primary sources of cardiac stimulation (Vaschillo et al. 2004). The device offers two types of feedback to the user. It uses triangles, found above the pulse rate wave, to signal the optimal exhale time, and squares, found below the pulse rate wave, to relate the effectiveness of the breathing technique. One square translates into zero points and signals that the technique needs to be revised. Three squares translate into one point and signals that the breathing is sufficiently slow. Each subject in the experimental condition received a personal SE identified by a serial number.

Sleep Log and Actigraphy

A daily log of bed time, subjective sleep latency, subjective times for awakenings, final wake time, and time out of bed was kept for a minimum of 3 days prior to PSG night. The log also determined use of sleeping pills or alcohol, subjective time in bed, subjective number of awakenings, subjective total sleep time (TST), and alertness. The log was to be filled out every morning. The subjective reports obtained from the logs were checked against actimeter data (Respironics Actiwatch). The actimeters utilized in this study were worn by the participants on the non-dominant wrist at all times except when bathing. Actimeter data were recorded using 1 min sampling intervals and processed using proprietary (Actiware 5) software.

Nocturnal Polysomnography

Seven electroencephalogram channels (Fp2-A1, C4-A1, O2-A1, Cz, Fp1-A2, C3-A2, and O1-A2) were collected in order to determine sleep–wake state; two electrooculogram electrodes recorded eye movements during the night; chin and anterior tibialis electrodes recorded electromyogram; two electrodes recorded the electrocardiogram, a Breaebon cTherm Cannula Thermistor and Salter Labs REF 5004 Oral/Nasal Pressure Monitoring Cannula connected to a Salter Labs BiNAPS differential pressure transducer collected a redundant measure of respiratory flow, and two piezoelectric crystal belts (one abdominal and one chest) provided a measure of thoracoabdominal effort. Polysomnographic records were scored according to the AASM manual for the Scoring of Sleep and Associated Events (Iber et al. 2007). Data were recorded on a Medcare Rembrandt digital polysomnograph.

PSG Night Procedures

Participants arrived at 8 p.m. On the day of the PSG, sleep log data were reviewed to make sure that participants' sleep had not differed significantly the night prior to entering the sleep lab for the study (>1 h from their mean TST). Participants were asked about their caffeine intake for the day in order to confirm that no caffeine was consumed after 2 p.m. Participants were asked to fill out a bedtime questionnaire, which asked: time right now, what time participants woke up on the study day; if participants were alert all day; if participants felt more tired than usual; has the day been unusual in any respect; if any naps were taken; if alcohol was consumed; if subject has or will take any medications before going to sleep; if there were any physical complaints; how anxious the subject felt on a scale of 1–5 (1-not at all, 5-extremely); whether subject felt more or less tired than usual or same as usual; and to predict the subject's sleep during the polysomnography recording would be better, same, or worse than usual, would be more or less than usual, or if no sleep is expected.

Participants in the intervention group were instructed to reacquaint themselves with the device through 10 min of use. Participants were then connected to polysomnography equipment 2 h prior to their self-reported bed time and allowed to get into bed. 20 min prior to their usual bedtime, intervention group participants were asked to use the SE for 20 min, at the conclusion of which they were to attempt sleep. Control participants were asked to attempt sleep at their average bedtime.

All participants were awakened at 7 a.m. Upon awakening, participants were instructed to get ready for their day, return the actimeter and to fill out an 18-item daytime functioning questionnaire before departure (available from author MRE upon request). The investigator completed a morning questionnaire after each subject's study night. The questionnaire established if there were any unusual circumstances during the sleep session that may have affected the results of the test and if participants experienced adverse effects. One subject in the control group experienced unifocal premature ventricular contractions during the study night. As there had been no exposure to the Stress Eraser, the condition was judged unrelated to device use. The subject was advised to consult a physician and, on follow up, the condition was judged to be benign.

Creation of the Sleep Disturbance Scale

As previously mentioned, the first night in the laboratory has been associated with decreased sleep efficiency and REM sleep, and with increased WASO, stage 1 sleep, REM latency, and stage 2 sleep (Agnew et al. 1966; Hartmann 1968; Toussaint et al. 1995, 1997). In order to develop a single scale of sleep disturbance, we performed an item analysis on these variables. We converted all items to *Z*-scores and reversed scaled sleep efficiency and minutes

in REM sleep. We then removed items which had low item-total correlations. These included minutes of REM sleep, sleep latency, and minutes of stage 2 sleep. We then created a composite scale composed of summed scores from sleep efficiency, REM latency, minutes of stage 1 sleep, and WASO. Using Cronbach's alpha we tested internal consistency and found an alpha for this scale of 0.828, indicating acceptable internal consistency. Test–retest reliability is meaningless, by definition of first-night effects.

Statistical Analyses

Statistical analysis was performed with SPSS ver. 16. A one-way analysis of co-variance (ANCOVA) test was performed to assess the difference between means. Bivariate correlations were performed separately for the dependant variable and each demographic variable (including the TST for the night before the study) to determine the appropriate covariates.

Results

The independent variable for the ANCOVA included two levels: SE and no-treatment control. The dependant variable was the sleep disturbance scale score, and the covariates were body mass index (BMI) and TST the night before the PSG (as determined by actimeter). A preliminary analysis evaluating the homogeneity-of-slopes assumption indicated that the relationship between the covariates and the dependant variable did not differ significantly as a function of the independent variable (group × BMI) $F(1,4) = 0.03$, MSE $= 0.11$, $p = 0.87$ (group × TST the day before the study) $F(1,4) = 0.22$, MSE $= 0.75$, $p = 0.67$. The ANCOVA was significant, $F(1,6) = 22.89$, MSE $= 57.83$, $p = 0.003$. The strength of relationship between SE versus no-treatment control and the dependent variable was very strong, as assessed by a partial η^2, with the treatment accounting for 79% of the variance of the dependent variable, holding constant the BMI and TST the night before the study. As expected, the adjusted mean for the sleep disturbance scale was lower in the SE group ($M = -1.79$, SD $= 3.33$) than in the no-treatment control group ($M = 1.79$, SD $= 2.15$). See Fig. 1 for the subject's individual scores on the sleep disturbance scale. The individual polysomnography findings are listed in Table 1.

Figure 1 shows the sleep disturbance scale score for each subject. The data are listed in ascending order. Each bar represents the score from one subject in either the SE (black) or control (gray) condition. The sleep disturbance scale is a composite scale composed of summed scores from sleep efficiency, REM latency, minutes of stage 1 sleep, and WASO. Higher scores indicate an increased sleep disturbance.

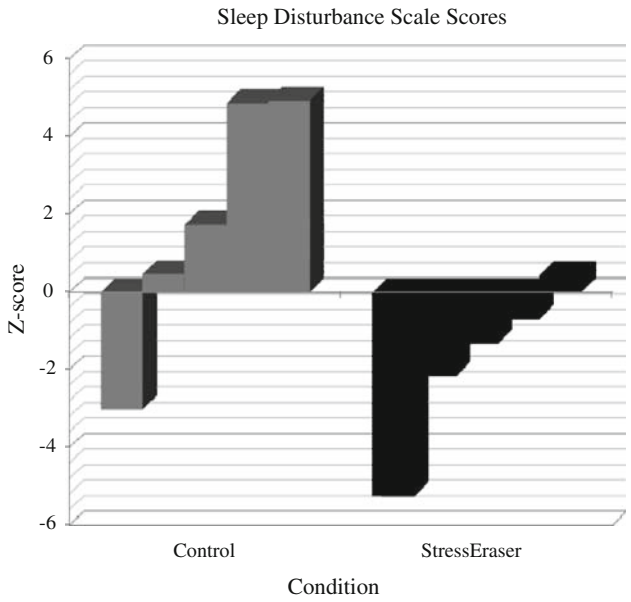

Fig. 1 Sleep disturbance scale scores

Table 1 Polysomnography data

	StressEraser® ($n = 5$)		Control ($n = 5$)	
	Mean	SD	Mean	SD
TST	361.20	19.15	389.40	37.80
Sleep efficiency	90.40	4.28	87.00	5.24
WASO	26.60	9.86	49.00	20.09
Stage 1	14.20*	4.79	23.00*	4.99
Stage 2	231.80	17.11	254.80	32.13
Delta	54.20	9.48	61.30	17.53
REM	60.70	10.46	50.00	30.92
AHI	0.82	0.53	0.92	0.53
Sleep latency	12.40	11.59	6.60	3.71
REM latency	116.40	31.98	133.20	58.05

This table shows data from the nighttime sleep study. TST, WASO, stage 1, stage 2, delta, REM, sleep latency and REM latency are listed in minutes. Sleep efficiency is shown as a percentage. AHI is the apnea/hypopnea index from the study night. The items in italic comprise the sleep disturbance scale

* Significantly different at a $p < 0.05$

Discussion

These data show that the SE significantly improved sleep quality, as measured by the sleep disturbance scale. This suggests that the SE may be useful in helping patients adapt

to the first night in the sleep laboratory. This finding is particularly important for clinical sleep laboratories because it offers a behavioral treatment for patients who have difficulty adapting to the sleep laboratory during their diagnostic sleep study. Because most sleep laboratories are prevented by law from storing and dispensing hypnotic medications at night to their patients (except in hospital based labs that have a doctor on hand to write a prescription and have a pharmacy) this may be the only option to help some patients sleep.

On many of the PSG parameters, such as sleep efficiency, WASO, total stage 1, and total REM sleep there appeared to be an improvement with the SE. The SE did not improve sleep latency, although in both groups mean sleep latency was <15 min. TST was also reduced in the SE group, but this is due to the fact that the SE group tended to have a slightly later bedtime than the control group and because both groups were awakened at 7 a.m., this artificially reduced TST for this group.

In summary, this study shows that the use of the SE device can improve sleep quality in normal participants. However, to further evaluate the degree to which SE reduces the first-night effect, it would be necessary to conduct a multiple night trial to compare the first night in the laboratory with the SE to subsequent nights in the lab without the SE. It would also be helpful to investigate the ability of the SE to reduce the first-night effect in pathological populations that are normally studied in the sleep laboratory, such as patients with obstructive sleep apnea. In addition, because the sample size used in this study is small, a large scale study verifying these findings is necessary.

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