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The Potential Usefulness of Peripheral Somatosensory Stimulation in Improving Sleep Quality in Patients with Insomnia

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Abstract

Background

Insomnia and other sleep disorders represent a major cause of disability and impaired productivity. We evaluated the impact of peripheral somatosensory stimulation (PSS) on sleep quality in 12 patients with varying degrees of insomnia.

Methods

Twelve adult patients underwent daily PSS therapy for a 4-week period and were evaluated using the Insomnia Severity Index at baseline (prior to initiation of therapy) and then at the conclusion of the treatments. All data were obtained through a self-reported 7-question survey evaluating overall severity of insomnia symptoms and the impact of sleep patterns on satisfaction with sleep, daily functioning, and overall quality of life. Changes from baseline insomnia scores were analyzed using cumulative link mixed models (CLMMs).

Results

Seven men and five women completed one month of PSS therapy. Mean age was 55.1 (range 29 to 80 years). No adverse events were described by the patients. The average total change from baseline score was -10.3 points (baseline: 16.5 vs. week 4: 6.2). Patients had statistically significant improvements for every individual survey question by week 4. The median composite score was improved from baseline, with an overall median score of 2 (IQR: 1.25 – 2.75, min-max: 1-4) at baseline compared to 0.5 (IQR: 0 – 0.25, min-max: 0-2) by week 4 (MD = -1 [95% CI: -2; -1], $p < 0.001$), signaling typically moderate insomnia at baseline vs. typically minimal to no symptoms by week 4. The predicted probability of obtaining the best outcome (score=0) was 9% at baseline vs. 53% by week 4. The overall cumulative odds ratio was 11.9 ($p < 0.001$), suggesting that on average, the odds of moving from one score to a lower (improved) score at week 4 compared to the baseline are approximately 12 times higher than moving to a neutral or worse score.

Conclusions

PSS stimulation appeared to have a significantly favorable effect on sleep quality

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in this group of patients. Symptoms related to ability to fall asleep, remain asleep, and overall quality of sleep were all improved with PSS therapy. We suggest that further investigation into the potential usefulness of PSS therapy in patients with sleep disorders is warranted.

Introduction

The importance of proper sleep in maintaining general health and well-being has become increasingly recognized. (1-5) At the same time, there has been a growing appreciation for the negative consequences of sleep deprivation and sleep disorders on health and work productivity. (6-8) Common sleep issues include difficulty falling asleep, staying asleep, early or repeated awakenings, and a lack of restful or rejuvenating sleep. (1-3) It has been estimated that up to 70% of the U.S. population struggles with some form of sleep difficulty, and the problem appears to be worsening over time. (3,6-7) In addition to pharmacological interventions, treatment for sleep disorders has included various methods of relaxation and meticulous sleep hygiene. (8-12) Peripheral somatosensory stimulation (PSS) therapy is a non-invasive technique which may be beneficial to patients with a variety of neurological disorders. (13-16) This report focuses on our experience with the impact of PSS therapy on sleep quality in a group of patients with varying degrees of insomnia.

Methods

Twelve patients who suffered from anxiety, depression, and/or PTSD and also had varying degrees of insomnia were treated with PSS using the NeuroGlove device. NeuroGlove is a non-invasive device that provides PSS stimulation in the form of pneumatic puffs of air directed at the volar surface of the distal forearm, the palm, and the fingers. Subjects used the device at home for 1 hour of therapy per day (30 minutes using each hand) for 4 weeks and were directed to synchronize their breathing to the firing (on/off cycle) of the machine to encourage relaxation during device use. The results of the PSS therapy on symptoms of anxiety, depression, and PTSD in this group of patients have been previously reported. (17,18)

In this study, we analyzed the impact of PSS therapy on sleep quality using the Insomnia Severity Index. (19) This scale surveys patients based on difficulties associated with falling asleep, staying asleep, and waking up too early. Patients are also assessed for their degree of satisfaction with their sleep, the extent to which their sleep issues interfere with daily functioning, how noticeable the problem is to others, and how worried they are about their sleep problems. Each of these 7 areas is graded based on an ordinal response ranging from 0 (no problem or concern) to 4 (very problematic). The corresponding survey questions are provided in Table 1.

Table 1. List of Survey Questions.

Question	Description
Q1	Please rate the current severity (last 2 weeks) of your insomnia problem(s)
Q1A	*Difficulty falling asleep*
Q1B	*Difficulty staying asleep*
Q1C	*Problem waking up too early*
Q2	How satisfied/dissatisfied are you with your current sleep pattern?
Q3	To what extent do you consider your sleep problem to interfere with your daily functioning (e.g. daytime fatigue, ability to function at work/daily chores, concentration, memory, mood, etc.)?

Q4	How noticeable to others do you think your sleep problem is in terms of impairing the quality of your life?
Q5	How worried/distressed are you about your current sleep problem?

Statistical Methods

Simple descriptive statistics were calculated for individual scores at each timepoint, including median, interquartile ranges (IQR), and range (min-max). A composite score of all questions using the pooled median value of patient-specific survey questions was also generated and compared between patient visits. Additionally, for summarizing overall severity of patient status, the following definitions were used: no clinically significant insomnia (total scores 0-7), sub-threshold insomnia (total scores 8-14), clinical insomnia of moderate severity (total scores 15-21), or severe clinical insomnia (Severe) (total scores 22-28).

We assessed changes in individual ordinal scores from patient-specific matched pairs using Wilcoxon's signed-rank test to determine if there were significant improvements from baseline to week 4. A composite score of all questions using the pooled median value of patient-specific survey questions was also generated and compared between baseline and week 4. Effect sizes from Wilcoxon's signed rank tests were reported as the median of differences alongside approximates of the 95% confidence interval. Since this nonparametric test works with ranks, it is typically not possible to derive a confidence interval with exactly 95% confidence; instead, the closest approximate was calculated, corresponding to true CIs calculated with 96.14% confidence; for simplicity these are reported as 95% CIs in text.

To formally analyze overall cumulative probability of improved scores across measurement times, we employed a Cumulative Link Mixed Model (CLMM) with a logit link function. The model was specified with the following formula using the clmm() function in the 'ordinal' package for R:

$$\text{Score} \sim \text{Week} + (1 \mid \text{Subject})$$

Where, 'Score' represents individual ordinal-scale responses, 'Visit' is the predictor variable of interest (baseline or week 4), and '(1 | Subject)' indicates the inclusion of random intercepts for individual subjects to account for within-subject variability. Laplace approximation was employed to estimate the model parameters. Predicted probabilities and 95% CIs for each score at a given timepoint were extracted from the model. Overall effect sizes from the CLMM model are reported as cumulative odds ratios.

Bar plots were used to visually show overall odds of improved insomnia outcomes and line plots were generated to show patient-specific results across timepoints.

Software

All analyses were conducted in RStudio (2023.09.0 Build 463), running on R version 4.3.1. CLMM analyses were performed using the 'ordinal' package (version 2022.11-16). Figures were generated using the 'ggplot2' package (version 3.4.3).

Results

A total of twelve patients including 7 men and 5 women completed one month of PSS therapy. Mean age was 55.1 years (range 29 to 80 years). At baseline, 1 patient (8%) had minimal symptoms (total scores: 0-7), 4 (33%) had sub-threshold insomnia (total scores: 8-14), 3 (25%) had moderately severe

insomnia (total scores: 15-21), and 3 (25%) had severe insomnia (total scores 22-28). Compliance with the treatment protocol was excellent based on patient reporting and our ability to query the devices for a log of treatment times. No adverse events were reported related to device use.

By week 4, 8 patients (75%) had overall minimal to no insomnia symptoms, 2 (17%) had sub-threshold insomnia, and the remaining 2 patients (17%) had moderate insomnia (Table 2). Except for 1 question response, all responses of dissatisfaction by week 4 came from 2 patients with severe insomnia at baseline (total scores 22 and 25 at baseline). For every question answered, all patients had either improved symptoms or at least unchanged scores by week 4. The average total change from baseline score was -10.3 points (baseline: 16.5 vs. week 4: 6.2; Table 2).

Overall, patients had statistically significant improvements for every individual survey question by week 4. The composite score was improved from baseline, with an overall median score of 2 (IQR: 1.25 – 2.75, min-max: 1-4) at baseline compared to 0.5 (IQR: 0 – 0.25, min-max: 0-2) by week 4 (MD = -1 [95% CI: -2; -1], $p < 0.001$; Table 3), signaling typically moderate insomnia at baseline vs. typically minimal to no symptoms by week 4. Overall, the predicted probability of obtaining the best outcome (score=0) was 9% at baseline vs. 53% by week 4. Conversely, the predicted probability of obtaining the worst outcome (score=3) was 12% at baseline vs. 1% at week 4 (Table 4). The overall cumulative odds ratio was 11.9 ($p < 0.001$), suggesting that on average, the odds of moving from one score to a lower (improved) score at week 4 compared to the baseline are 11.9 times higher than moving to a neutral or worse score. Overall likelihood of improved insomnia symptoms and patient-specific trends are displayed in Figure 1.

Table 2. Patient-specific changes in total scores from baseline to week 4.

Subject	Baseline Total	Week 4 Total	Change from Baseline	Interpretation
1	19	7	-12	Moderately Severe at Baseline vs. No Significant Insomnia at Week 4
2	14	1	-13	Sub-Threshold at Baseline vs. No Significant Insomnia at Week 4
3	7	1	-6	No clinically significant insomnia at both times, though score lowered at week 4
4	17	1	-16	Moderately Severe at Baseline vs. No Significant Insomnia at Week 4
5	13	6	-7	Sub-Threshold at Baseline vs. No Significant Insomnia at Week 4
6	25	19	-6	Severe at Baseline vs. Moderately Severe Insomnia at Week 4
7	25	8	-17	Severe at Baseline vs. Sub-Threshold Insomnia at Week 4
8	11	4	-7	Sub-Threshold at Baseline vs. No Significant Insomnia at Week 4
9	15	8	-7	Moderately Severe at Baseline vs. No Significant Insomnia at Week 4
10	13	5	-8	Sub-Threshold at Baseline vs. No Significant Insomnia at Week 4

11	17	0	-17	Moderately Severe at Baseline vs. No Significant Insomnia at Week 4
12	22	14	-8	Severe at Baseline vs. Sub-Threshold Insomnia at Week 4
Summary	**Avg: 16.5**	**Avg: 6.2**	**Avg: -10.3**	**Improved Outcomes for All Patients**

Table 3. Summary of survey responses at baseline and at week 4.

Survey Question	**Baseline Median (IQR)**	**Week 4 Median (IQR)**	**Median of differences [95% CI]**	**p-value**
Q1A	2 (1 – 2.75)	1 (0 – 1.75)	-1 [-1; -1]	0.002
Q1B	2 (1 – 3)	1 (0 – 1.75)	-1 [-2; -1]	0.002
Q1C	1.5 (0.25 – 2)	0 (0 – 0)	-1 [-2; 0]	0.016
Q2	3 (2.25 – 4)	1 (0 – 1.75)	-2 [-3; -1]	<0.001
Q3	3 (2 – 3)	1 (0 – 1)	-2 [-2; -1]	0.002
Q4	1.5 (0 – 2.75)	0 (0 – 0.75)	-0.5 [-2; 0]	0.031
Q5	2.5 (1 – 4)	0.5 (0 – 2)	-2 [-2; 0]	0.004
Overall	**2 (1.25 – 2.75)**	**0.5 (0 – 1)**	**-1 [-2; -1]**	**<0.001**

Table 4. Cumulative link mixed model results for overall improvement in insomnia symptoms.

Survey Score	**Baseline Probability [95% CI]**	**Week 4 probability [95% CI]**	**Cumulative odds ratio [95% CI]**	**P-value**
Score 0	9% [2 – 15%]	53% [34 – 71%]	11.9 [6.1 – 23.3]	<0.001
Score 1	20% [9 – 30%]	30% [19 – 40%]		
Score 2	32% [22 – 41%]	12% [4 – 20%]		
Score 3	28% [15 – 41%]	4% [1 – 8%]		
Score 4	12% [3 – 22%]	1% [0 – 2%]		

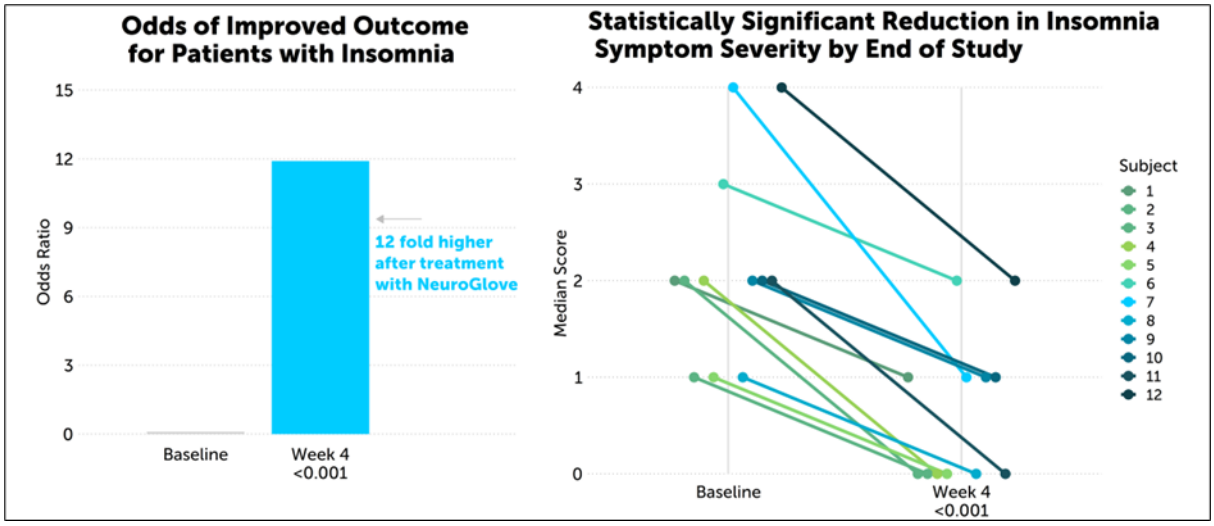

Figure 1. Change from baseline severity of insomnia symptoms. Relative odds of improved outcomes from baseline obtained from a CLMM model (left). Patient specific pooled median scores at baseline and at week 4 (right).

Discussion

The impact of normal sleep on health and wellness has been well-described. (1-5) In addition to impairing alertness and affecting ability to work, sleep disturbances have been linked to cardiovascular disorders, stroke, and cognitive decline.(1-8,20-24) Sleep is of critical importance for normal neuronal development and functioning, and lack of proper sleep has been linked to impairment of attention, memory, mood, and behavior (25-6) Although multiple pharmacological treatments have been utilized to improve sleep, many of these fail to restore normal sleep patterns, and an increasing emphasis has been placed on improved sleep hygiene and various relaxation techniques to improve sleep quality. (2,7,8, 11,12)

Our previous work demonstrated a statistically significant improvement in symptoms of PTSD, anxiety, and depression with the use of PSS. (17,18) The scientific bases for such improvements may be related to the role played by sensory processing in anxiety, depression, and PTSD. Haricharichan et al postulated that alterations in the neural pathways important for processing sensory input have a cascading effect on the ability to perform higher cognitive functions implying that abnormal sensory processing may be contributory and associated with these disorders (27). Similarly, impaired sensory processing has been implicated in sleep disturbances, and various forms of sensory stimulation have been utilized to improve sleep. These include the use of relaxing music, aromatherapy, minimizing bright lights or the use of specific lighting to restore normal circadian rhythms, the avoidance of particular foods or stimulants, and tactile input such as from massage or weighted blankets (28-38). It is noteworthy that individuals with autism, elderly nursing home residents, and dementia patients all appear to be disproportionately affected by sleep disorders and seem to respond to sensory stimulation (39-43). Based on these findings, we hypothesized that tactile PSS might be beneficial in improving sleep.

Our survey results suggest promising preliminary evidence of improved insomnia symptoms after 4 weeks of PSS therapy. All patients had overall improvements by week 4, with statistically significant improvements for every individual survey question answered. Results from our study suggest that, on average, patients had typically moderate insomnia symptoms at baseline compared to typically minimal

or no symptoms by week 4. It should be noted that two patients who initially had severe insomnia still had moderate insomnia symptoms by the end of the study. Although patients were not uniformly free of insomnia symptoms by the end of the study, this data suggests that patients of varying degrees of insomnia severity may benefit from PSS therapy.

Limitations

The main limitations of our study are the small sample size and lack of an active control group. Data are also limited only to self-reported survey questions and may not capture other clinically important outcomes. Survey responses were limited to two timepoints, thereby making it difficult to quantify and differentiate effects related to time- and device-related improvements in insomnia symptoms. Data related to patient factors such as other medications, daily routines, and lifestyle changes was unavailable and may have influenced patient outcomes.

Conclusions

We describe our experience with twelve patients with anxiety, depression, and/or PTSD who had varying degrees of insomnia and underwent one month of PSS treatment. Our survey results reveal encouraging preliminary evidence of improved quality of sleep and reduced insomnia symptoms after 4 weeks of PSS therapy. By the end of the study, most patients demonstrated minimal or sub-threshold insomnia symptoms, indicating potential benefits for individuals with varying degrees of insomnia severity. Although the small sample size limits our ability to draw definitive conclusions regarding efficacy of PSS on sleep disturbances, this study was meant to evaluate in very preliminary fashion the potential usefulness of PSS in patients with insomnia, potentially forming the basis for a larger study. All patients with sleep disturbances showed improvement in their symptoms suggesting that further investigation into the potential use of PSS in the treatment of patients with sleep disorders is warranted.

Institutional Review Board Statement: The study was approved by the Western (WCG) Institutional Review Board (protocol code: 20233103, date of approval: 7/19/2023).

Trial Registration: This study was registered with clinicaltrials.gov prior to initiation any work or patient enrollment. The trial number is NCT06050590.

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