The Effect of the Tri-Core® Cervical Pillow on Sleep Outcomes among Whiplash Associated Disorder (WAD) Patients

Jay S. Greenstein
Sport and Spine Rehab Clinical Research Foundation

Barton Bishop
Sport and Spine Rehab Clinical Research Foundation

Jean Edward
University of Louisville

Allen Huffman
Sport and Spine Rehab Clinical Research Foundation

Danielle Davis
Sport and Spine Rehab Clinical Research Foundation

See next page for additional authors

Authors
Jay S. Greenstein, Barton Bishop, Jean Edward, Allen Huffman, Danielle Davis, and Robert V. Topp
Research

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Jay Greenstein, DC, CCSP, CGFI-L1, CKTP1, Barton Bishop, PT, DPT, CSCS, SCS, CGFI-L2, CKTP2, Jean Edward, RN, BSN3*, Allen Huffman, DC, CKTP, BS4, Danielle Davis5, Robert Topp, RN, PhD6

Address: 1President, Sport and Spine Rehab Clinical Research Foundation, Rockville, MD, USA, 2Secretary, Sport and Spine Rehab Clinical Research Foundation, Rockville, MD, USA, 3Research Assistant and Doctoral Student, School of Nursing, University of Louisville, Louisville, KY, USA, 4Sport and Spine Rehab Clinical Research Foundation, Rockville, MD, USA, 5Sport and Spine Rehab Clinical Research Foundation, Rockville, MD, USA, 6Professor and Associate Dean for Research, College of Nursing, Marquette University, Marquette, WI, USA.

E-mail: Jean Edward, RN, BSN – Jsedwa03@louisville.edu

*Corresponding author

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Abstract

Objectives: The purpose of this study was to determine the effectiveness of a semi-customized orthopedic cervical pillow on sleep outcomes in Whiplash Associated Disorder (WAD) patients.

Methods: A convenience sample of forty-three WAD patients who participated in this study was randomly assigned to an intervention or control group. The intervention group was given a Tri-Core® (Core Products International, Inc., Osceola) semi-customized orthopedic cervical pillow for sleep. Both the intervention and control groups received the Funhab® rehabilitation protocol (Sports and Spine Rehab Holdings Inc., Fort Washington). Outcome measures collected at the initial visit (baseline) and at discharge in both groups included characteristics of self-reported sleep operationalized by research participants completing the Medical Outcomes Study (MOS) Sleep questionnaire. Duration in the study varied among patients depending on individual progression and needs. Data were analyzed using descriptive statistics and repeated measures ANOVA.

Results: There were no differences between the control group and intervention group in sleep problems, sleep disturbances and sleep adequacy. The only significant finding between groups
was the improvement in self-reported snoring in the intervention group.

**Conclusion:** These findings indicate that WAD patients who use a semi-customized cervical pillow in combination with a standard rehabilitation protocol did not experience improvements in most of their sleep outcomes beyond those experienced by a control condition that used the rehabilitation protocol alone. The single variable which did decline among patients who used the TriCore® pillow and increased in the control condition was self-reported snoring. Future research is warranted to further examine other sleep characteristics associated with snoring as a result of using the TriCore® cervical pillow and the Funhab rehabilitation program.

**Introduction**

Whiplash-associated disorders (WADs) commonly occur as a result of motor vehicle accidents (MVAs) and can lead to substantial long-term negative effects on health. WADs are soft-tissue injuries characterized by hyperextension, hyperflexion or lateral movements of the head. As a result of these injuries, individuals experience multiple clinical manifestations of WADs including changes in posture, pain, disability, headache, fatigue, and sleep disturbances. Berglund et al. found that individuals who were exposed to whiplash injury as a result of rear-end collisions reported substantial changes in health outcomes including headaches, back pain, fatigue and sleep disturbances when compared to an unexposed comparison group.

Sleep disturbances predominantly occur during the initial period following the whiplash injury. In a study by Schlesinger et al. research participants with whiplash injuries experienced delayed sleep latency and poorer sleep quality when compared to controls. Additionally, symptoms such as neck pain and tension headaches that worsen with extended periods of poor posture, especially during night-time sleeping, are known to cause significant sleep disturbances. The literature identifies the importance of modifying night-time sleeping positions in conjunction with physical therapy and postural exercises to alleviate sleep disturbances and other related WAD symptoms.

The use of neck support pillows helps to modify night-time sleeping positions to achieve optimal physiological positioning of the spine. Several studies have explored the effects of various neck support and cervical pillows on reducing cervical pain, improving neck disability, and other WAD symptoms while consequently improving sleep quality and outcomes. Although numerous studies have attempted to explore the effects of using cervical pillows in improving sleep outcomes, there is still contradictory evidence and need for further research that delineates the relationship between the use of cervical pillows and improved WAD outcomes. Further research is warranted to further explore the effects of utilizing cervical pillows to establish effective physiotherapy in improving sleep in WAD patients.

Therefore, the purpose of this study was to determine the effectiveness of a semi-customized orthopedic cervical pillow on sleep outcomes in WAD patients. The hypothesis tested in this study was: WAD patients utilizing a semi-customized cervical pillow will have improved characteristics of self-reported sleep compared to WAD patients who did not utilize a semi-customized cervical pillow.
Methods

A convenience sample of 43 patients was recruited from an outpatient chiropractic and physical therapy clinic specializing in spinal rehabilitation. A sample size of 21 subjects per group will result in sufficient statistical power (0.80) to detect an effect size of .90 with and type I error set a priori at .05. The study was explained to interested individuals by a member of the research staff, and informed consent was obtained prior to any data collection or interventions. Research participants were included in the study if they presented to the clinic for the treatment of an injury sustained from a motor vehicle accident diagnosed with cervical spine pain, with or without radiculopathy, and between the ages of 18-65. Before inclusion in the study, a diagnosis of WAD was established by clear causation between the trauma the subject incurred based on their history, examination and subsequent cervical spine symptomatology. Furthermore, the research participant’s condition was to be treated initially through nonsurgical approaches. Exclusion criteria included patients who presented with a diagnosis which was not deemed to be amenable to conservative management by the patient’s physician. This study was approved by the University of Louisville Institutional Review Board (IRB#10.0199) and met human ethical considerations consistent with the Helsinki Declaration.

Data Collection

Data was collected from all research participants prior to randomization using coin flips into one of the two study groups at (baseline) and again following completion of their treatment (discharge). Outcome measures included characteristics of self-reported sleep operationalized by research participants completing the MOS Sleep questionnaire. The MOS sleep questionnaire is a 12-item questionnaire concerning quantity and quality of sleep, sleep habits, and waking and daytime symptoms for the previous four weeks. The literature supports the use of the MOS sleep questionnaire to evaluate many conditions causing sleep disturbances. This questionnaire was utilized to measure shortness of breath, headaches, sleep somnolence, sleep problems, sleep disturbances, sleep adequacy, sleep duration, and snoring. In addition, two summary index measure scores were utilized to measure overall sleep problems. Sleep Problem Index I is a brief summation index that includes awakening short of breath or with a headache; trouble staying awake during the day; trouble falling asleep; awakening during sleep and having trouble falling asleep; getting enough sleep to feel rested in the morning; and, getting the amount of sleep needed. Sleep Problem Index II is a more comprehensive summation index that includes all items in Index I and the time taken to fall asleep; disturbed sleep; and sleepiness or drowsiness during the day. All domain scales and index measures were scored on a transformed 0-100 metric, with higher scores on these two indices indicating more sleep problems. Once each subject had completed the MOS questionnaire, all original numbers were calculated to obtain a percentage. Higher item scores reflect more of the attribute being measured by the scale and lower scores indicate less of that attribute.
Procedures

Following baseline data collection all research participants were prescribed the Funhab® rehabilitation protocol (Sports and Spine Rehab Holdings Inc., Fort Washington, MD). Patients progressed along the program at varying rates and were discharged at different times based on individual needs. Funhab® is an evidenced-based rehabilitation protocol aimed at maximizing appropriate clinical tools inclusive of spinal manipulation, soft tissue and additional articular manual therapies, physiotherapies and rehabilitative functional exercises. This protocol is comprised of an exercise treatment and progression that addresses local, regional and global neuro-musculoskeletal dysfunction of the neck by integrating both the biomechanical and neurological components of rehabilitation. In addition to manual therapy and physiotherapies, the protocol takes the patient through postural, local, regional and then full body exercise progressions in an attempt to maximize their overall level of function and correct muscular imbalances and dysfunctions. The Funhab® protocol prescription and implementation is an 11-level treatment progression and is based on the patient’s region of pain and biomechanical dysfunction or functional limitation that needs to be corrected. Patients progress to advanced exercise levels once they are able to perform exercises at their current level without any pain. Once patients reach level 11 they are discharged from care.

Research participants assigned to the control group received the usual care for WADs provided at the clinic, which consisted of the Funhab® protocol, and slept on their regular pillow. Research participants assigned to the intervention group received the same Funhab® protocol and were also provided with a Tri-Core® (Core Products International, Inc., Osceola, WI) semi-customized orthopedic cervical pillow for sleep. Following the Tri-Core® sizing guidelines (petite, midsize, and standard) the size of the pillows were customized to each subject. Customization was done to insure the patient’s head was maintained in neutral as it relates to cervical flexion and extension when the subject was lying supine. Additionally, intervention research participants were given instructions on how to properly sleep on the pillow to maximize comfort and design features.

Data Analysis

The data was used to address the aims of the study in two steps. First, the two study groups were compared at baseline on descriptors and outcome variables to determine the efficacy of the randomization procedure (See table 1). The second step in the analysis involved comparing the two study groups on the outcome measures. Since the optimal versus non-optimal sleep variable was dichotomous, a cross tabulation table was constructed, presenting the raw and percentage values of individuals within the two treatment groups who fell into these two categories (Table 2). Continuous outcome variables were analyzed to address the hypotheses by calculating repeated measures ANOVA with Tukey-Kramer post hoc comparisons to determine if the two groups differed over time.
Table 1. Description of the sample

| Variable                          | Group     | Mean ± SD | t-value | p <  
|----------------------------------|-----------|-----------|---------|------
| Reported Number of Nights Per Week Using Pillow | Pillow    | 6.36 ± 1.06 | N/A   | N/A |
|                                  | Usual Care | 0         |         |      |
| Number of Visits                 | Pillow    | 16.23 ± 4.35 | .67    | .51 |
|                                  | Usual Care | 15.52 ± 2.06 |       |     |
| Days Since Onset of Symptoms     | Pillow    | 7.55 ± 6.35 | .92    | .36 |
|                                  | Usual Care | 9.52 ± 7.74 |       |     |
| Age                              | Pillow    | 34.05 ± 11.02 | 1.55  | .13 |
|                                  | Usual Care | 39.67 ± 12.78 |       |     |
| Gender                           | Female    | 14        | .043   | .84 |
|                                  | Male      | 8         |        |     |

Table 2. Optimal vs. Not Optimal Sleep by time and treatment condition

<table>
<thead>
<tr>
<th>Condition</th>
<th>Baseline</th>
<th>Post-Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Optimal</td>
<td>Not optimal</td>
</tr>
<tr>
<td>Control</td>
<td>7 (33%)</td>
<td>14 (67%)</td>
</tr>
<tr>
<td>Intervention</td>
<td>5 (23%)</td>
<td>17 (77%)</td>
</tr>
</tbody>
</table>

Results

As table 1 indicates, the two groups presented at baseline with a similar gender distribution, age and days since onset of symptoms. The group prescribed the TriCore® pillow used the device an average of 6.36 nights (91%) per week while they were engaged in the study. Both study groups participated in a similar number of therapy sessions in the clinic (control = 15.52 ± 2.06, intervention = 16.23 ± 4.35 visits). The two study groups did not significantly differ at baseline on any of their measures of sleep (see table 3).
### Table 3. Sleep measures by time and treatment condition

<table>
<thead>
<tr>
<th></th>
<th>Control Group</th>
<th>Intervention Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Post-Treatment</td>
</tr>
<tr>
<td>SOB/Headache</td>
<td>16.19 ± 2.33</td>
<td>17.14 ± 3.05</td>
</tr>
<tr>
<td>Sleep Somnolence</td>
<td>42.84 ± 2.79</td>
<td>31.09 ± 2.64*</td>
</tr>
<tr>
<td>Sleep Problems</td>
<td>45.42 ± 1.90</td>
<td>32.51 ± 2.14*</td>
</tr>
<tr>
<td>Index I</td>
<td>48.39 ± 1.87</td>
<td>33.33 ± 2.21</td>
</tr>
<tr>
<td>Sleep Disturbance</td>
<td>50.12 ± 2.50</td>
<td>31.74 ± 2.87*</td>
</tr>
<tr>
<td>Sleep Adequacy</td>
<td>64.76 ± 2.94</td>
<td>47.14 ± 3.23*</td>
</tr>
<tr>
<td>Duration of Sleep</td>
<td>6.10 ± 1.81</td>
<td>6.38 ± 1.50</td>
</tr>
<tr>
<td>Snoring</td>
<td>34.29 ± 3.80</td>
<td>40.00 ± 4.20*</td>
</tr>
</tbody>
</table>

* indicates a significant change within a study group over time (p<.05)

Shading indicates differences between groups at a specific time

Chi square analysis indicated that neither group significantly changed their perceptions of obtaining optimal or non-optimal sleep over the duration of the study. Depending on the data collection time (baseline or at discharge post-treatment), table 2 indicates that between 23% and 38% of the sample reported getting adequate sleep. Table 3 indicates that neither group significantly changed their reports of shortness of breath or headache (SOB/headache) or duration of sleep over the course of the study, although the intervention group decreased 21% on SOB/headache, while the control group increased on this variable by 6%.

Additionally, the control group significantly decreased their somnolence, while the intervention group did not significantly change over the duration of the study. However, the percentage decline in somnolence appears clinically indistinguishable between the two groups (27% to 28%). Similarly, although the intervention group exhibited a significant decline in Sleep Problems Index II (See table 3)
the percentage decline in this measure appeared clinically indistinguishable from the control group (-31% to -33%). The analysis also indicated that both the control group and the intervention group reported similar significant declines over the course of the study on the outcomes of sleep disturbance (-37% to -38%), sleep adequacy (-27%) and sleep problems on index I (-28% to -31%). Thus, sleep somnolence, sleep disturbance and sleep adequacy declined similarly within each study group over the duration of the study, while optimal sleep and SOB/headache did not change among either group during the study.

The reports of snoring indicated a significant time by group interaction effect (p<.05). The post hoc analysis indicated that the control group significantly increased their self-reported snoring by 16% over the duration of the study, while the intervention group reported significant decreases in their snoring by 21%. These significant increases in the control group and decreases in treatment group in snoring resulted in the treatment group reporting significantly less snoring than the control and the post treatment time point.

**Discussion**

Cervical and neck support pillows have been used frequently by WAD patients to assist in reducing cervical pain and consequently improving overall sleep quality and other outcomes. Previous studies indicate that WAD patients who use a cervical pillow improve their sleep outcomes including improving sleep problems, adequacy and other sleep disturbances. However, findings from this study indicate that WAD patients who use the TriCore® cervical pillow in combination with the Funhab® rehabilitation protocol did not experience improvements in sleep outcomes other than self-reported snoring beyond the improvements in sleep experienced by the control condition that used the Funhab® rehabilitation protocol alone. The single variable which did improve among patients who used the TriCore pillow, but not in the control condition, was self-reported snoring. Thus, the TriCore Pillow intervention appears to have a significant effect on reducing snoring among cervical neck patients. Despite limitations in these findings, previous studies have indicated the effectiveness of rehabilitative programs utilizing neck support pillows in decreasing pain and improving sleep outcomes. In a randomized clinical trial that studied the effects of a comprehensive rehabilitative program and sleeping neck support on patients with chronic cervicobrachialgia, findings indicated that individuals who utilized the neck support pillow had a significant decrease in sleep disturbances caused by pain. In another randomized crossover study, Lavin et al., explored the effects of three types of cervical pillows on sleep in patients with chronic neck pain. Findings from this study indicated significant improvements in overall sleep quality and significantly longer sleep duration for the water-based cervical pillow compared to the roll and standard pillow. Although sleep duration did not appear to significantly change within or between the groups in the current study the group using the cervical pillow reported sleeping 17% (54 minutes) longer at posttest compared to the control who reported sleeping 5% (17 minutes) longer at the posttest. Similarly, the use of rubber pillows have also shown to be effective in reducing waking cervical pain and improved sleep quality and pillow comfort. Valenza et al., also reported that patients with mechanical neck pain and WAD pain reported poorer sleep quality and efficiency, and higher levels of sleep latency, disturbances, and use of medication.

In a blinded study that tested the effects of four different neck pillows with different shapes and fillings on neck pain, headache, and quality of sleep among 52 patients with chronic non-specific neck pain, there were positive effects of neck support pillows on all three variables. There were no differences regarding the types of pillows used and their effects on neck pain, headache, and quality of sleep. Based
on these findings, Persson concluded that neck support pillows must be carefully selected to meet individual needs and is an important aspect of physiotherapy in patients with neck pain. Unfortunately, few of these previous studies employed a control group in the design and thus the positive finding attributable to the various pillow interventions are suspect to threats to internal validity. The current study employed a true control group and a cervical pillow group both of whom received the Funhab® rehabilitation protocol.

Although both of these groups reported similar improvements in their sleep outcomes, the intervention group reported decreases in snoring, while snoring appeared to increase in the control group. Reductions in snoring attributable to using the Tri-Core® semi-customized orthopedic cervical pillow are significant. Snoring is a common symptom of obstructive sleep apnea (OSA). OSA has been associated with a variety of significant health problems including the development of hypertension, coronary artery disease, heart failure, stroke, diabetes and other metabolic disorders. OSA is a result of obstructed airflow due to a collapsed pharynx which results in progressive asphyxia typically until the person is awakened. Misalignment of the neck among WAD patients may contribute to OSA. A possible benefit of using the Tri-Core® semi-customized orthopedic cervical pillow may be the correction of misalignment of the neck among WAD patients, resulting in less snoring. Reishtein concluded in his review of the area that effective treatment of OSA, indicated by a reduction in snoring, can reduce the risk of these health problems. Thus, further study is indicated to determine if the reductions in snoring realized among WAD patients through the use of the Tri-Core® semi-customized orthopedic cervical pillow can reduce OSA and the comorbidities associated with this condition.

Limitations

The findings of this study must be interpreted cautiously due to a number of potential threats to internal and external validity. The convenience sample likely did not represent all WAD patients, although mandating a random sample of WAD patients participate in the study would be unethical. The sample size was selected to detect a large effect size of the intervention and may not have been sufficient to detect important changes in the outcomes that in fact did result from the intervention. Important variables related to the subject’s sleep characteristics were not included in the protocol. These variables included weight, body mass index, alcohol consumption, and use of stimulants or sleeping aids. Knowledge of these variables may have provided insight into the combined effects of these factors and sleep characteristics. Sleep characteristics including snoring were collected through subject’s using an established self-report tool. This tool, although exhibiting validity in previous studies (reference 12) does not measure objective sleep characteristics.

Conclusions

With these limitations in mind the findings of this study have implications for future research and clinical practice. The results indicate that the Tri-Core® semi-customized orthopedic cervical pillow does not have any deleterious effects on sleep outcomes and appears to reduce self-reports of snoring. WAD patients who use this pillow in combination with the Funhab® rehabilitation protocol appear to improve their sleep outcomes but not at a statistically significant level beyond a control condition. The increase in sleep duration reported by the pillow group over the duration of the study (54 minutes), while not statistically significant, may be clinically important for practitioners whose WAD patients are obtaining a low duration of sleep. Future research may wish to examine other sleep characteristics which may be associated with snoring as a result of WAD patients using the Tri-Core® pillow including qualitative
remarks about restfulness and somnolence. Clinicians may wish to prescribe the Funhab® protocol with the Tri-Core® pillow with patients (or their sleeping partners) with complaints of snoring.

Acknowledgments

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References


