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ORIGINAL RESEARCH

Assessment of Lumbar Spinal Stenosis as a Risk Factor for Development of Sleep Disorder: The Locomotive Syndrome and Health Outcome in Aizu Cohort Study (LOHAS)

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Purpose: Insomnia has been reported to coexist with various musculoskeletal disorders. Although lumbar spinal stenosis (LSS) is the most frequently operated on spinal disease, the causal relationship between LSS and development of sleep disorders remains unclear due to lack of longitudinal studies. This study aimed to determine whether LSS was a risk factor for developing new sleep disorders, primarily insomnia, using a prospective cohort of community residents.

Patients and Methods: This study was a prospective cohort study. Participants aged ≥65 years from the "Locomotive Syndrome and Health Outcomes in Aizu Cohort Study (LOHAS)" conducted in 2008 formed our study population. LSS was diagnosed using the self-administered, self-reported history questionnaire, a validated diagnostic support tool for LSS. Sleep disorder was investigated using a questionnaire during the 2-year follow-up. The impact of LSS on sleep disorder onset was analyzed after adjusting for potential confounders, such as age, sex, obesity, hypertension, diabetes, depression, and smoking habits, using propensity score matching.

Results: Of the 489 participants who were followed up for two years, 38 (7.8%) had newly developed a sleep disorder in 2010. After adjusting for confounding factors, a comparison of 133 participants each in the control and LSS groups showed significantly higher frequency of new-onset sleep disorders (19 [14.3%] in the LSS group versus 6 [4.5%] in the control group).

Conclusion: LSS was found to be an independent risk factor for sleep disorders.

Keywords: lumbar spinal stenosis, sleep disorder, insomnia, cohort study, musculoskeletal disorder, locomotive syndrome

Introduction

Insomnia is a widespread problem affecting almost one-third of the adult population.[1,2] It is associated with functional impairment and increased use of medical services and products.[3] Patients with insomnia incur various socioeconomic costs, including outpatient visits, prescriptions, and transportation, which are estimated to range from $2.9 billion to $51.2 billion annually in the United States.[4,5] More than 30% of patients with this disorder have refractory chronic insomnia.[1] The disease was once classified as primary and secondary insomnia,[6] but the concept of comorbid insomnia has been put forward, in which insomnia and comorbidities interact with each other, and insomnia is known to exaggerate comorbidities.[7] Insomnia has been reported to coexist with various musculoskeletal disorders such as neck pain, low back pain, and osteoarthritis.[8–10]

Lumbar spinal stenosis (LSS) is a musculoskeletal disorder, and the most frequent condition requiring spine surgery.[11] The prevalence of LSS in the Japanese population is 5.7%, and it has been reported that this prevalence increases with age.[12] More than 200,000 adults in the United States have LSS, resulting in approximately 38,000 surgeries performed annually for Medicare patients and more than $1.5 billion in claims for hospitalization alone.[13] LSS causes pain and numbness in the lower extremities, which can lead to secondary insomnia.

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In this study, we focused on insomnia, including insomnia caused by LSS. Both LSS and insomnia have been associated with a high risk of falls[14,15] and depressive symptoms.[12] Pain and numbness in the lower extremities caused by LSS may result in insomnia. In such cases, concomitant insomnia may lead to depressive symptoms in patients with LSS, and taking sleeping pills may further increase the risk of falling. Therefore, insomnia should be evaluated for LSS management. If insomnia is confirmed, intensified treatment options for LSS, including pharmacotherapy, blocking therapy, and surgery, should be considered.

There have been no longitudinal studies assessing LSS as a risk factor for insomnia, and the causal relationship remains unknown. The aim of this study was to determine whether LSS is a risk factor for new-onset sleep disorders, primarily insomnia, in a cohort of community residents.

Patients and Methods

Ethical Considerations

The study was conducted in accordance with the tenets of the Declaration of Helsinki, after obtaining approval from the research ethics committee of Fukushima Medical University (No. 673). The recruitment period for this study was from May 2 to July 11, 2008. Written informed consent was obtained from all the participants prior to the commencement of the study.

Study Population

This prospective cohort study used data from the "Locomotive Syndrome and Health Outcomes in Aizu Cohort Study (LOHAS)". It was a population-based prospective cohort study that evaluated the risk of cardiovascular disease, quality of life, medical costs, and mortality attributable to locomotor dysfunction. Additionally, this study provided the epidemiological information required for developing policies for the detection of locomotor dysfunction. The cohort was comprised of residents of Minamiaizu and Tadami towns in the Fukushima Prefecture, who underwent regular health examinations conducted annually by their local governments between 2008 and 2010. The details of the study design have been previously described.[16] The inclusion criterion was participants aged ≥ 65 years in 2008. LSS is considered an age-related degenerative disease. We did not enroll participants aged below 65 years to avoid introducing false positives due to other lumbar spine issues prevalent in younger patients, such as lumbar disc herniation. Therefore, our age criterion aimed to maintain the study's specificity. In 2008, participants with a history of sleep disorders, spinal surgery, hemodialysis, or rheumatoid arthritis were identified using a questionnaire and excluded from the study. Sleep disorder was defined by a "yes" response to the question, "Have you ever visited a health care provider for a sleep disorder?" Participants on hemodialysis or with rheumatoid arthritis were excluded due to potential confounding effects. These conditions have been reported to increase the risk of pathological spondylolisthesis and LSS.[17,18] Additionally, they may elevate the risk of osteoarthritis, which can subsequently influence sleep patterns.[19,20]

Assessment of LSS

Using the self-administered, self-reported history questionnaire (SSHQ), a diagnostic support tool for LSS,[21] two groups of patients were established: LSS and control groups. The SSHQ defined a patient as having LSS if all answers to questions 1 to 4 were "yes". In addition, cauda equina type LSS was diagnosed if at least one of the answers to questions 1 through 4, and at least two of the answers to questions 5 through 10 were positive. This questionnaire allowed us to diagnose LSS with a sensitivity and specificity of 84% and 78%, respectively (Supplementary Table 1).

Measurement of Outcome: Definition of Sleep Disorder

The primary outcome, sleep disorder, was investigated using a questionnaire during the 2-year follow-up. A patient was diagnosed with sleep disorder if he/she answered "yes" to the question, "Have you visited a healthcare provider in the past month for a sleep disorder?"

Measurement of Potential Confounders

Potential confounders were selected based on the epidemiological definitions of variables determining exposure (LSS) and outcome (sleep disorders). Based on the clinical significance and existing evidence, the following were considered confounders of the association between LSS and sleep disorders: age, sex, obesity, hypertension, diabetes, depressive symptoms, and smoking habits. Obesity was defined as body mass index ≥ 25.[22] Hypertension was defined as systolic blood pressure greater than 140 mmHg or diastolic blood pressure greater than 90 mmHg. Diabetes mellitus was defined as random glucose concentration of ≥ 200 mg/dL, fasting glucose concentration of ≥ 126 mg/dL, or when the participant was on glucose-lowering medication. Depressive symptoms were screened using the Mental Health Inventory consisting of five items (cutoff value ≤60).[23]

Statistical Analyses

Demographic characteristics, primary exposure (LSS diagnosed using SSHQ),[21] and outcome (sleep disorders) were described as appropriate indicators. Propensity scores were estimated using logistic regression models with LSS as the exposure, and age, sex, obesity, hypertension, diabetes, depressive symptoms, and smoking habits as the explanatory variables. Participants were matched 1:1 with imputed data using the nearest neighbor matching method with a caliper of 0.20. The frequency of sleep disorders during the 2010 survey was compared between the matched LSS and control groups. The χ-square test was used for statistical analysis. We performed two sensitivity analyses to examine the robustness of the results. The first sensitivity analysis compared the two cutoff values of SSHQ. The new cutoff value[24] suggested that a total score of 3 for Q1–Q4 or a score ≥ 1 for Q1–Q4 and ≥ 2 for Q5–Q10 indicated the presence of LSS, improving the sensitivity to 79.8% compared with the initial value.[15] In contrast, specificity decreased to 68.8%. We examined the differences in the results using both cutoff values. The second sensitivity analysis assessed whether the results were affected if the response of "yes" to the question "Have you visited a healthcare provider in the past month for a sleep disorder?" changed with a response of "fairly poor" or "very poor" to the question "How would you rate the overall quality of your sleep over the past month?"

Statistical analyses were performed using JMP® Pro version 16.0.0 (SAS Institute Inc., Cary, NC, USA). Student-t and χ-square tests were used for comparisons between groups. $P < 0.05$ was considered statistically significant.

Results

Study Participants and Baseline Characteristics

In 2008, there were 2254 LOHAS participants aged ≥ 65 years, of whom 263 had sleep disorders, 86 underwent previous spinal surgeries, seven were on hemodialysis, and 29 (including duplicates) suffered from rheumatoid arthritis. Seven hundred sixty-nine participants had missing LSS data. Thus, a total of 1116 patients were followed up, of which 387 and 729 were in the LSS and control groups, respectively. During the 2-year follow-up period, one patient relocated, and 16 died. A total of 610 participants had missing data on sleep disorders in 2010. Ultimately, 489 participants (21.7%) were included in the final analysis (Figure 1). Table 1 summarizes the baseline characteristics of the study participants, classified according to the LSS. The mean age of participants was 70.9 ± 3.8 years, and 61.4% were females. A total of 161 (32.9%) participants were categorized into the LSS group and 328 (67.1%) into the control group. The participants in the LSS group were significantly older ($P = 0.0023$), heavier ($P = 0.048$), and had higher rates of depressive symptoms than those in the control group ($P = 0.010$).

Outcome Data

Of the 489 study participants who were followed up, 38 (7.8%) developed new sleep disorders in 2010. Among these 38 individuals, 22 (13.7%) were in the LSS group and 16 (4.9%) in the control group. The risk of developing a sleep disorder was significantly higher in the LSS group than in the control group ($P = 0.0006$) (Table 1). After adjusting for confounding factors using propensity score matching, a comparison of 133 participants in each of the groups showed that new-onset sleep disorders were significantly more frequent in the LSS group [19 (14.3%)] than in the control group [6 (4.5%)] ($P = 0.0063$) (Table 2 and Figure 2).

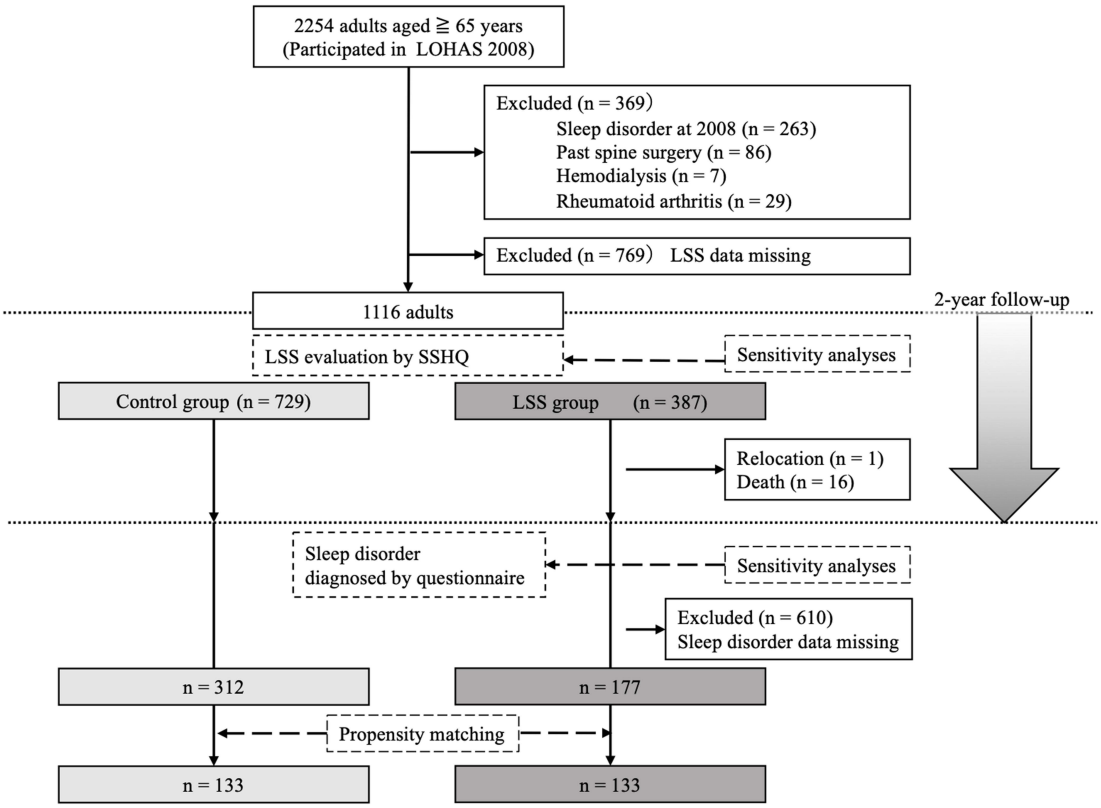

Figure 1 Flowchart of the study population. Of the 2254 study participants in the LOHAS 2008, 489 (21.7%) were included in the present study for statistical analysis.
Abbreviation: LSS, Lumbar spinal stenosis.

Sensitivity Analyses

In the first sensitivity analysis with the modified LSS cutoff, new-onset sleep disorders were found to be significantly more frequent ($P < 0.036$; Supplemental Table 2a) in the LSS group (18 [14.1%]) than in the control group (8 [6.3%]), with a similar trend. The second sensitivity analysis with a different definition of sleep disorder showed a similar trend, with 19 (14.3%) new cases of sleep disorder in the control group versus 29 (21.8%) in the LSS group ($P = 0.11$; Supplemental Table 2b).

Table 1 Characteristics of the Study Participants

	(-) LSS[a] n = 328	(+) LSS n = 161	*P* value
	Mean [SD], n (%)		
Age (years)	70.5[3.6]	71.6[4.2]	< 0.001
Female Sex	196(59.8)	104(64.6)	0.30
Obesity	116(36.6)	71(46.1)	< 0.05
Hypertension	203(64.0)	110(71.4)	0.11
Diabetes Mellitus	29(9.5)	19(13.6)	0.20
Depressive symptoms	94(28.7)	65(40.4)	< 0.01
Smoking habit (current)	30(9.4)	14(9.3)	0.96
Sleep disorder onset in 2010	16(4.9)	22(13.7)	< 0.001

Abbreviation: [a]LSS, Lumbar spinal stenosis.

Table 2 Comparison of Characteristics Between the Two Groups After Propensity Score Matching

	(-) LSS[a] n = 133	(+) LSS n = 133	*P* value
	Mean [SD], n (%)		
Age (years)	71.3[3.5]	71.4[4.2]	0.79
Female Sex	83(62.4)	82(61.7)	0.90
Obesity	55(41.4)	61(45.9)	0.55
Hypertension	102(76.7)	95(71.4)	0.96
Diabetes Mellitus	18(13.5)	15(11.3)	0.58
Depressive symptoms	49(36.8)	48(36.1)	0.90
Smoking habit (current)	15(11.3)	13(9.8)	0.69
Sleep disorder onset in 2010	6(4.5)	19(14.3)	< 0.01

Abbreviation: [a]LSS, Lumbar spinal stenosis.

Discussion

In this study, participants with LSS had a significantly higher incidence of sleep disorders, even after adjusting for confounding factors (age, sex, obesity, hypertension, diabetes, depressive symptoms, and smoking habits), using the propensity score matching method.

Relationship Between LSS and Sleep Disorders

LSS is a condition that causes lower-extremity pain, numbness, and intermittent claudication, leading to decreased activities of daily living. Previous cross-sectional studies have reported that the factors associated with LSS include obesity, abdominal circumference, diabetes mellitus, hypertension, cardiac disease, stress, and dysuria.[12,25–27] The LOHAS project was one of the few longitudinal studies conducted on patients with musculoskeletal disorders.[16] Kyphosis is associated with depression[28] and a risk factor for falls among men.[29] The study also summarized that LSS was a risk factor for the development of dementia.[30]

This study focused on sleep disorders secondary to lower-extremity pain and numbness caused by LSS. Previous cross-sectional studies have reported that patients with LSS had poor sleep quality[31] and that the risk factors for sleep disorders in patients with LSS included female sex, depression, and severe foraminal stenosis.[32] It has also been reported that surgical treatment for LSS improved sleep quality in comparison to conservative treatment, and failure to improve

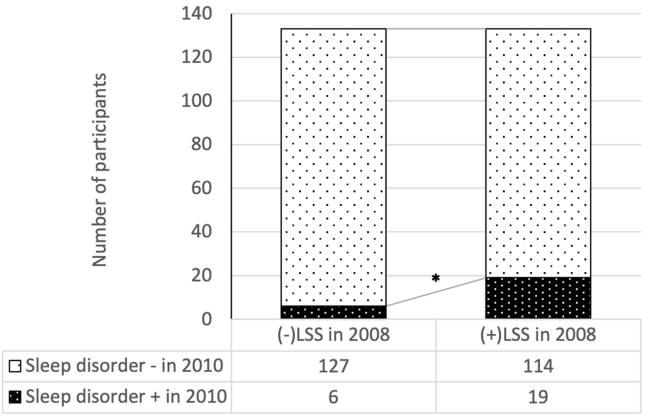

Figure 2 Relationship between presence of LSS in 2008 and occurrence of sleep disorder in 2010. **P* = 0.0063.
Abbreviation: LSS, Lumbar spinal stenosis.

sleep in the conservative treatment group was associated with depression and severe foraminal stenosis.[33] However, the causal relationship between LSS and sleep disorders remains unclear owing to the absence of longitudinal studies.

Clinical Implications of LSS with Comorbid Sleep Disorders

Our finding that LSS is a risk factor for sleep disorders offers clinicians two perspectives. First, orthopedic surgeons should screen for comorbid sleep disorders when treating patients with LSS; both LSS and sleep disorders are known risk factors for falls and depression,[12,34–36] and the combination of LSS and sleep disorders may increase the risk of falls and depressive symptoms. However, no studies have investigated the increased risk of developing falls and depression due to the comorbidity of LSS and sleep disorders.

Second, general physicians should screen for LSS when treating patients with sleep disorders and provide treatment, especially when they present with symptoms suggestive of LSS, such as intermittent claudication and pain or numbness in the lower extremities. Such patients can also be referred to an orthopedic surgeon if necessary. For these patients, treatment of LSS may help avoid sleep medications. If LSS is difficult to diagnose, SSHQ can be used.[21] The prevalence of LSS in patients with sleep disorders is unknown and needs further investigation.

Mechanisms of Sleep Disorders Caused by LSS

There are three possible mechanisms through which LSS may result in sleep disorders. The first is pain and numbness. Second, depressive symptoms resulting from LSS may lead to insomnia. The third is the effect of frequent urination owing to cauda equina disorders. However, the present study did not provide reasons for the sleep disorders, and further research is needed to investigate the underlying mechanisms.

Strengths of the Study

This study had several strengths. First, this was a large-scale cohort study on LSS, which is difficult to diagnose owing to a lack of established diagnostic criteria. Therefore, we developed a self-administered diagnostic support tool, SSHQ.[15] In particular, the SSHQ was designed to allow diagnosis without imaging or physical findings owing to its questionnaire-based design, which made this large-scale study possible. Second, it was a prospective cohort study with a 2-year follow-up period. Additionally, it was the first study to demonstrate a causal relationship between LSS and sleep disorders. Third, the study was conducted in a less mobile area, resulting in fewer dropouts due to moving.

Potential Limitations of the Study

This study had several limitations. The first was the definition of sleep disorder. In this study, the onset of a sleep disorder was defined by answers to a simple questionnaire asking whether the patient had visited a healthcare provider for a sleep disorder. Therefore, sleep disorders that do not require medical consultation were not considered. Also, the severity and chronicity of the sleep disorders were not evaluated. A similar trend was observed in a sensitivity analysis in which the definition of sleep disorder was changed to a sleep quality issue, and the impact was considered to be limited.

Second, sleep disorders other than insomnia could have been included. We used the 2008 questionnaire to investigate the details of sleep disorders. As a result, particular sleep disorders such as hypersomnia and narcolepsy were found in only 4 (1.1%) out of 353 cases (Supplemental Table 3). Therefore, it seems reasonable to conclude that sleep disorders were mainly caused by insomnia.

Third, the SSHQ was used to define LSS in this study. The sensitivity and specificity of the SSHQ were 84% and 78%,[21] respectively, false positives and negatives must be considered when interpreting the results. However, the results did not change when LSS criteria were changed in the sensitivity analysis, suggesting that the impact of this change was limited. In addition, this study did not evaluate the severity of LSS. Future research should elucidate the correlation between LSS severity and sleep disorders.

Fourth, no consideration was given to pharmacotherapy for LSS. In particular, use or disuse of oral medications that can affect sleep quality, such as neuropathic pain medications (pregabalin, mirogabalin), antiepileptic drugs (clonazepam), and serotonin and norepinephrine reuptake inhibitors (duloxetine), may be confounding factors when comparing LSS patients with controls. However, these are confounders that work in the direction of weakening the association between LSS and the

occurrence of sleep disorders and, although unadjusted, are not likely to have a significant impact on the interpretation of results.

Fifth, other possible confounding factors, such as alcohol intake, physical activity level, and medications, were not examined.

Finally, this study was conducted in a mountainous rural area. To improve the generalizability of our findings, similar studies should be conducted in other regions, such as urban areas with different lifestyles and activities of their inhabitants.

In conclusion, LSS was found to be an independent risk factor for sleep disorders. Participants with LSS may need to be evaluated for comorbid sleep disorders in addition to formal assessment. Patients with LSS and comorbid sleep disorders may require more intensive treatment. Further research is anticipated to verify the effectiveness of these approaches.

Data Sharing Statement

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare no competing interests.

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