

Spinal pain—good sleep matters: a secondary analysis of a randomized controlled trial

Kari Paanalahti^{1,4} · Maria M. Wertli² · Ulrike Held² · Torbjörn Åkerstedt^{1,5} · Lena W. Holm¹ · Margareta Nordin^{1,3} · Eva Skillgate^{1,4}

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Abstract

Purpose The estimated prevalence of poor sleep in patients with non-specific chronic low back pain is estimated to 64 % in the adult population. The annual cost for musculoskeletal pain and reported poor sleep is estimated to be billions of dollars annually in the US. The aim of this cohort study with one-year follow-up was to explore the role of impaired sleep with daytime consequence on the prognosis of non-specific neck and/or back pain.

Methods Secondary analysis of a randomized controlled trial, including 409 patients.

Results Patients with good sleep at baseline were more likely to experience a minimal clinically important difference in pain [OR 2.03 (95 % CI 1.22–3.38)] and disability [OR 1.85 (95 % CI 1.04–3.30)] compared to patients with impaired sleep at one-year follow-up.

Conclusion Patients with non-specific neck and/or back pain and self-reported good sleep are more likely to experience a minimal clinically important difference in

pain and disability compared to patients with impaired sleep with daytime consequence.

Keywords Impaired sleep · Spinal pain · Back pain · Neck pain · Naprapathy

Introduction

The prevalence of insomnia symptoms (defined as difficulty initiating sleep, difficulty maintaining sleep, early morning awakenings or non-restorative sleep) varies from 17 to 38 % in different countries [1]. In Sweden the prevalence of insomnia with daytime consequences is reported to be 9.7 % (i.e., problems sleeping for the past three months during at least three nights per week with daytime symptoms or problems in daytime functioning) [2]. In that study, 44 % of the persons with insomnia at baseline reported persistent insomnia after one year indicating a persistent nature of this condition [2]. The life-time prevalence of spinal pain is reported to be about 80 % [3]. The annual costs for insomnia are estimated to be 107 billion US\$ [4] and for spinal pain 90.7 billion US\$ annually in the United States [5]. The prevalence of poor sleep in chronic neck and/or low back pain patients is suggested to range up to 64 % [6, 7]. Both poor sleep and spinal pain are of importance for development of other health-related problems like psychological distress and impaired function on different levels, and thus expanded costs for the society [8, 9].

Several studies suggest that persons with musculoskeletal pain were prone to suffer from poor sleep, others show that poor sleep could affect pain perception negatively [10]. Further, persons with chronic pain and poor sleep experienced higher pain levels than persons with chronic pain without sleep problems [11]. Not only poor

✉ Kari Paanalahti
kari.paanalahti@ki.se

¹ Institute of Environmental Medicine, Karolinska Institutet, Box 210, SE-17177 Stockholm, Sweden

² Department of Internal Medicine, Horten Center for Patient Oriented Research and Knowledge Transfer, University of Zurich, Pestalozzistrasse 24, 8032 Zurich, Switzerland

³ Occupational and Industrial Orthopaedic Center (OIOC), NYU Hospital for Joint Diseases, New York University Langone Medical Center, 63 Downing Street, New York, NY 10014, USA

⁴ Scandinavian College of Naprapathic Manual Medicine, Kräftriket 23A, SE-11419 Stockholm, Sweden

⁵ Stressforskningsinstitutet, Stockholms universitet, SE-10691 Stockholm, Sweden

sleep but also excess sleep duration is shown to be associated with increased pain experience. Experimentally induced sleep deprivation has been found to increase pain experience but there is a need for longitudinal studies to explore the effect of poor sleep on pain in clinical populations [10]. There is lack of knowledge regarding poor sleep as a prognostic factor for spinal pain. In the current cohort study we have access to longitudinal data to study the association between sleep and recovery in spinal pain in patients treated for non-specific neck or low back pain.

The aim of this study was to explore the role of impaired sleep with daytime consequence on the prognosis of non-specific neck and/or back pain.

Method

Study design

This cohort study is a secondary analysis of data from the Björn-trial, a randomized controlled trial [12], with the aim to compare naprapathic manual therapy to evidence-based care given by a physician for patients with non-specific neck and/or back pain.

Patients and recruitment

The details of the design and data collection in the interventional study are described in detail elsewhere [12]. Briefly, subjects with non-specific pain and disability in the back and/or neck lasting for at least 2 weeks ($n = 409$), recruited at public companies in Sweden, were included in a randomized controlled trial. The two interventions compared were naprapathic manual therapy such as spinal manipulation/mobilization, massage and stretching, (Index Group), and evidence based provided care by a physician (Control Group). In the index group patients received a maximum of 6 treatments by a licensed and experienced naprapath. The control group contained evidence-based care with advice to stay active, pain coping strategies by the general practitioner up to two times. Baseline information including sleep and general information (e.g., education, marital status, duration of pain) and disease specific measures were collected before randomization. All outcomes were self-administered patient questionnaires at three, seven, 12, 24 and 52 weeks.

Exposure

At baseline, the patients reported how they experienced their sleep. The definition of impaired sleep in the present

study is based on international diagnostic criteria and available literature as follows: difficulty initiating and/or maintaining sleep accompanied by daytime consequence [9].

Patients had impaired sleep (reference group) when they reported difficulties to fall asleep (“Do you have trouble falling asleep?”) or to maintain sleep (“Do you wake up several times at night and sometimes have difficulty going back to sleep?”), and reported daytime consequence (“Do you feel very tired during your work day (shift)?”) several times per week or every day. The first two questions were derived from the Karolinska Sleep Questionnaire [13] and the last question, from “unwinding and recovery” questions by Aronsson et al. [14].

Patients who reported, having no problems or having problems less than several times per week initiating and maintaining sleep, were defined as having good sleep.

Patients who reported having problems several times per week or every day initiating and maintaining sleep but had no daytime consequence, were defined as having impaired sleep without daytime consequence.

Primary outcome

The primary outcome was Minimal Clinically Important Difference (MCID) in pain and disability from baseline to follow-up at 3 and 12 months.

Pain and disability was measured with a modified Chronic Pain Questionnaire (CPQ) [15]. Patients rated their pain by three pain items (current pain, worst pain, average pain) measured with a numeric rating scale, 0–10 (0 = no pain, 10 = pain as bad it could be). Daily activities affected by pain were measured by three disability items (interference with daily activities, recreational and social activities and work activities) on numeric rating scales. Items were rated from no pain/no interference (=0) to worst pain/unable to carry on with these activities (=10). To evaluate changes after treatment and follow-up, the original scale that was based on recall of the last 6 months was changed to the past 4 weeks.

A MCID on the pain score was defined as a decrease of at least two points compared to the baseline value. A MCID in the disability score was defined as a decrease of at least one point compared to the baseline value. These definitions are based on the results in previous studies [12, 16, 17]. The calculation for the mean pain and disability score was based on three self-administrated questions regarding pain and disability measured by numeric rating scale (NRS 0–10). If only two pain or disability questions were accessible, the calculation was based on those questions ($n = 3$).

Potential confounding factors

Potential confounding factors for the analyses of the association between back and/or neck pain and impaired sleep were identified a priori by the authors, (MW, KP, ES, UH, TÅ, LH) and are based on current available literature [18, 19].

The following potential confounding factors were identified: the treatment modality (design variable), age (continuous), gender, education (dichotomized), pain-related factors (continuous), lifestyle (dichotomized), obesity (dichotomized), work-related factors (dichotomized), major life events (dichotomized), and health-related factors (dichotomized).

Low education was defined as having completed elementary school for 9 years. Pain-related factors included pain intensity at baseline (continuous), duration of the current pain episode (continuous), and the main pain site (self-reported: neck and upper back, lower back or both). Potential confounding concerning health-related factors were; the presence of depression (current vs. had or never had), anxiety (current vs. had or never had), obesity, marital status and one or more major life event during the previous year (e.g., serious conflict with spouse or partner, or serious illness of a close person). Obesity was defined according to the WHO classification as a BMI of 30 kg/m² or higher.

Potential lifestyle confounding factors were; smoking (daily smoking, yes/no), and active lifestyle. An active lifestyle was assumed when a patient exercised three or more times a week for at least 20 min with medium to high exertion level.

Work-related factors were assessed using modified questions from the Job Content Questionnaire (JCQ) based on the demand-control-support model by Karasek-Theorell [20]. The JCQ contains questions on work strains (work regularly “very fast”, “very hard” or in a “repetitive way”, job-dissatisfaction (“he/she does not enjoy work particularly” or “not at all”) and bullying by co-workers or supervisors (“do you feel excluded by managers or co-workers, “yes, very much”).

Statistical methods

Each potential confounding factor was tested at a time by building a series of multiple regression models with the main exposure (impaired sleep) and the potential confounding factor. If the inclusion of a factor resulted in ≥ 10 % change of the effect estimate of the determinant on outcome (i.e., MCID in pain or disability), the factor was considered a confounding factor and included in the final model.

Logistic regression was used to analyze the association between impaired sleep and MCID in pain and disability at three and 12 months.

The statistics program Stata version 12.0 was used for the analysis [21].

Results

Patients with too low pain or disability score at baseline (i.e., cannot have a MCID at follow-up according to our definition) were not included in the analysis (pain $n = 4$, disability $n = 94$). From the four patients not included in the analyses of MCID in pain none were in the reference group, three in the group with good sleep and one in the group with impaired sleep without daytime consequences. From the 94 patients not included in the analyses of MCID in disability (ref. group, $n = 9$, 1. $n = 67$, 2. $n = 18$) nine were in the reference group, 67 in the group with good sleep and 18 in the group with impaired sleep without daytime consequences.

Of the patients included in the original trial ($n = 409$), 105 patients reported sleep problems consistent with the definition of impaired sleep. Of the remaining patients, 238 reported no sleep problems (good sleep) and 66 reported some sleep problems without daytime consequence (Table 1). The mean age was 46.9 (SD 10.6) years and 71 % were females. Patients with impaired sleep had lower education, were more likely to be single and smokers, had depression and anxiety more often than those with good sleep or impaired sleep without daytime consequence. Pain intensity at baseline and anxiety were found to be confounders for MCID in pain and are included in the final model. None of the covariates confounded the MCID in disability. However, we could not test for potential confounding effect of anxiety in the multivariate model for improvement in disability because all patients with anxiety ($n = 5$) showed MCID.

The final model for MCID for disability is adjusted for pain intensity at baseline to be able to report on the effect of sleep for both outcomes separately regardless of pain intensity at baseline.

Table 2 displays the odds ratios for MCID in pain and disability from baseline to follow-up for patients with good and impaired sleep without daytime consequence compared to patients with impaired sleep. Patients with good sleep were more likely to experience a MCID in pain [OR 2.03 (95 % CI 1.22–3.38)] and disability [OR 1.85 (95 % CI 1.04–3.30)] compared to patients with impaired sleep at 12 months. The odds ratio for MCID in pain in the fully adjusted model was OR 2.51 (95 % CI 1.45–4.38) at the 12 months and the corresponding figure for disability was 1.88

Table 1 Demographic and clinical characteristics of the study population

Characteristics	Impaired sleep ^a (<i>n</i> = 105)	Good sleep ^b (<i>n</i> = 238)	Impaired sleep without daytime consequence ^c (<i>n</i> = 66)
Age, mean (SD)	49.8 (9.5)	45.5 (10.8)	47.0 (10.5)
Female, %	80 (76.2)	163 (68.5)	48 (72.7)
Low education 1–9 years, %	21 (20.0)	27 (11.3)	3 (4.6)
Marital status, single, %	43 (41.0)	27 (25.6)	17 (25.8)
Treatment allocation, manual therapy, %	49 (46.7)	124 (52.1)	33 (50.0)
Pain intensity at baseline, mean (SD)	5.9 (1.6)	5.4 (1.7)	5.1 (1.6)
Disability at baseline, mean (SD)	3.84 (2.3)	2.3 (2.0)	2.6 (2.2)
Location of worst pain, %			
Neck	66 (62.9)	137 (57.6)	35 (53.0)
Back	30 (28.6)	86 (36.1)	29 (43.9)
Neck and back	9 (8.6)	15 (6.3)	2 (3.0)
Duration of pain, >12 months, %	69 (65.7)	124 (52.3)	34 (51.5)
Obesity ≥ 30 kg/m ² , %	19 (18.1)	27 (11.2)	7 (10.6)
Depression, %	7 (6.7)	6 (2.5)	0 (0.0)
Anxiety, %	6 (5.8)	2 (0.8)	0 (0.0)
Daily smoking, %	22 (21.0)	27 (11.3)	8 (12.1)
Physical training ≥ 3 times/week on the medium or high level, %	26 (24.8)	62 (26.2)	20 (30.0)
Work demand (fast, heavy or repetitive work), %	71 (69.6)	151 (55.5)	34 (51.5)
Not enjoying work, %	15 (14.7)	20 (8.4)	1 (1.5)
Bullying, superiors or co-workers, %	5 (4.6)	3 (1.3)	2 (3.0)
Major life events, during last year, %	37 (35.2)	89 (37.4)	66 (43.9)

^a Impaired sleep: defined as difficulty initiating and/or maintaining sleep, present several nights per week or every day, and accompanied by a daytime consequence (feeling tired during work)

^b Good sleep: defined as having no problems or having problems less than several times per week in initiating and maintaining sleep

^c Impaired sleep without daytime consequence: defined as having problems in initiating or maintaining sleep several times per week or every day but having no daytime consequence

(95 % CI 1.05–3.35). The adjusted ORs for MCID in pain for patients with impaired sleep without daytime consequence in comparison to patients with impaired sleep at 12 months was OR 2.15 (95 % CI 1.05–4.46) and for disability OR 1.36 (95 % CI 0.62–2.17).

Discussion

In this longitudinal cohort study we found that patients with non-specific neck and/or back pain and self-reported good or impaired sleep without daytime consequence were more likely to experience a MCID in pain and disability compared to patients with impaired sleep with daytime consequence. The effect of good sleep was observed even after three months although the results were not statistically significant. However, at 12 months, the association of good sleep and MCID was statistically significant, both in pain and disability indicating that sleep quality is a prognostic factor in patients with neck and/or back pain.

Our results showed that the odds of experience a MCID in pain at 12-month follow-up was more than two times higher for good sleepers compared to those with impaired sleep at baseline. When this model was adjusted for pain intensity at baseline and anxiety the odds were even higher. This indicates that the sleep quality per se, regardless of anxiety and pain intensity at baseline, is important for clinical meaningful improvements for this group of patients. Concerning disability, our results imply that the odds of experience MCID in disability was almost two times higher for improvement of disability for good sleepers at 12-month follow-up compared to those with impaired sleep at baseline. When this model was adjusted for pain intensity at baseline the effect was unchanged.

The fact that 94 patients, of total 409 in this study had a disability score less than one and were therefore excluded may have induced too low statistical power for the analysis regarding MCID in disability, why the interpretation of these results may be uncertain and should be viewed with caution.

Table 2 The odds ratio for minimal clinically important difference in pain and disability from baseline to follow-up for patients with good and impaired sleep without daytime consequence compared to patients with impaired sleep

Follow-up	3 Months		12 Months	
	Crude OR (95 % CI)	Adjusted ^f OR (95 % CI)	Crude OR (95 % CI)	Adjusted ^f OR (95 % CI)
Minimal clinically important difference in pain ^a				
Impaired sleep ^b	Ref.	Ref.	Ref.	Ref.
Good sleep ^c	1.15 (0.71–1.86)	1.58 (0.93–2.70)	2.03 (1.22–3.38)	2.50 (1.44–4.32)
Impaired sleep without daytime consequence ^d	1.20 (0.63–2.29)	1.94 (0.96–3.93)	1.65 (0.84–3.24)	2.28 (1.10–4.71)
Minimal clinically important difference in disability ^e				
Impaired sleep	Ref.	Ref.	Ref.	Ref.
Good sleep	1.21 (0.69–2.13)	1.22 (0.70–2.15)	1.85 (1.04–3.30)	1.89 (1.06–3.38)
Impaired sleep without daytime consequence	1.35 (0.62–2.94)	1.37 (0.63–3.00)	1.31 (0.61–2.83)	1.37 (0.63–2.98)

^a Minimal clinically important difference in pain was defined as at least two-point decrease from baseline to follow-up, measured with numerical rating scale 0–10 (0 = no pain, 10 = pain as bad as could be)

^b Impaired sleep: defined as difficulty initiating and/or maintaining sleep, present several nights per week or every day, and accompanied by a daytime consequence (feeling tired during work)

^c Good sleep: defined as having no problems or having problems less than several times per week in initiating and maintaining sleep

^d Impaired sleep without sleep without daytime consequence: defined as having problems in initiating or maintaining sleep several times per week or every day but having no daytime consequence

^e Minimal clinically important difference in disability was defined as at least one-point decrease from baseline to the follow-up, measured with numerical rating scale 0–10 (0 = no interference, 10 = unable to carry on with these activities)

^f Minimal clinically important difference in pain is adjusted for pain intensity at baseline (continuous) and anxiety (yes vs. no). Minimal clinically important difference in disability is adjusted for pain intensity at baseline (continuous)

Experimentally induced sleep deprivation has been found to increase pain experience but only a few of these studies have a long follow-up time [10]. Studies with longitudinal design have shown that poor sleep is a prognostic factor for decreased improvement in pain for burn injury patients at follow-up after 2 years [10]. Poor sleep at baseline was also a prognostic factor for development of fibromyalgia in the Norwegian population a study with 11-year follow-up and for the development of chronic head ache in the Danish population at 12-year follow-up [10]. Nitter et al. found in a study with 17-year follow-up that poor sleep at baseline was a prognostic factor for unfavorable course of chronic pain [22]. These results are in line with our findings suggesting that good sleep is an independent positive prognostic factor for non-specific neck and/or back pain recovery.

The mechanism behind impaired sleep possibly being a part of the increased pain perception is suggested to be on the central level of the nervous system involving the serotonergic and dopaminergic neurotransmission [10]. It has been suggested that sleep loss deregulates the central opioid system and therefore has an effect on the endogenous pain regulation [10]. Sleep deprivation is suggested to be associated with an increased inflammatory process or perhaps a decreased anti-inflammatory process leading to impaired recovery and could therefore be part of the pain syndrome [23].

In the present study we had a high participation rate, 85 %, and a large number of patients which is a strength [12]. Further, the outcome was MCID in pain and disability which emphasizes the importance of the results. The definition of a MICD has been used in other publications [12, 24] and is similar to, but not identical with, definitions recommended by others [16, 25]. To increase the validity of the results a thorough control for potential confounding factors was performed. Out of 16 a priori defined potential confounding factors only anxiety and pain intensity at baseline were found to confound the results for MCID in pain.

A limitation of the study was the lack of follow-up at all instances. If we had information of different aspects of sleep at every follow-up time point, the accuracy of the results may have been improved. Further, impaired sleep was self-reported which could have had an impact when evaluating the measurement of impaired sleep. It has been proposed that to improve the assessment of different aspects of sleep and pain, actigraphy and polysomnography should be used more frequent to increase the objectivity of these measures [10, 26]. However, the sleep questionnaire used in this study is widely used and validated for different aspects of sleep [13]. There was also lack of information about the duration of the sleep impairment in the questionnaire used to measure sleep quality at baseline.

We consider that our results are important for patients, clinicians and health care providers. The increased knowledge about the prognostic value of good sleep on improvement in spinal pain should be considered when planning the care for these patients.

Our results also encourage for more research in this field.

Conclusion

Patients with non-specific spinal pain reporting good sleep are more likely to experience a MCID in pain and disability compared to patients with impaired sleep with or without a daytime consequence.

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Conflict of interest The authors declared that they have no conflict of interest in connection with this paper.

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