

## **Extent of sleep problems and relationship with severity of chronic pain using three validated sleep assessment tools**

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**Running title:** Sleep disturbances and chronic pain

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## **Abstract**

### **Objective**

Chronic pain can impact on sleep but the extent and nature of sleep problems in patients with chronic pain are incompletely clear. Several validated tools are available for sleep assessment but they each capture different aspects. We aimed to describe the extent of sleep issues in patients with chronic non-malignant pain using three different validated sleep assessment tools and to determine the relationship of sleep issues with pain severity recorded using the Brief Pain Inventory (BPI), a commonly used self-assessment tool in pain clinics. The BPI has a single question on the interference of pain on sleep and we also compared this with the validated sleep tools.

### **Design**

Prospective, cross-sectional study.

### **Setting**

Pain management clinic at a large teaching hospital in the UK.

### **Subjects**

Adult patients (with chronic non-malignant pain of at least 3 months' duration) attending clinic during a 2 month period.

### **Methods**

Participants completed the Pittsburgh Sleep Quality Index, the Pain and Sleep Questionnaire-3 and the Verran Snyder- Halpern sleep scale, plus the BPI. Duration and type of pain, current medications and demographic data were recorded.

### **Results:**

We recruited 51 patients and 82% had poor sleep quality as shown by PSQI scores above 5. PSQI ( $p=0.0002$ ), PSQ-3 ( $p=0.0032$ ), VSH sleep efficiency ( $p=0.012$ ), sleep disturbance ( $p=0.0014$ ) and waking after sleep onset ( $p=0.0005$ ) scores were associated with worse BPI pain scores. BPI sleep interference scores concurred broadly with the validated sleep tools. Median [range] sleep duration was 5.5 [3.0-10.0] hours and was also related to pain score ( $p=0.0032$ ).

### **Conclusion**

Chronic pain has a marked impact on sleep regardless of the assessment tool used. The sleep interference question in the BPI could be used routinely for initial identification of sleep problems in patients with chronic pain.

[285 words]

## **Introduction**

Sleep is a behaviourally regulated drive which is vital for maintaining physiological functioning (1). Issues with sleep are perhaps one of the most common complaints of chronic pain patients, and are known to contribute to the severity and maintenance of chronic pain symptoms. Both pain and sleep are major health problems worldwide, and an interaction between them can lead to impairment in biological functioning and behaviour (1,2). In a large survey, 50% chronic pain patients reported feeling tired all the time (3). Experimental studies and cross-sectional surveys have suggested that the relationship between sleep disturbances and pain could be reciprocal, in which pain disturbs sleep quality and latency, and poor sleep exacerbates pain (1). Few identified risk factors are modifiable, and sleep has been identified as one of the modifiable risk factors. It is clear that there is an association between chronic pain and poor sleep (4,5), but the extent and nature of sleep quality issues in patients with chronic pain and the relationship between pain severity and sleep problems is less clear.

There are several dedicated sleep assessment tools available for the evaluation of sleep parameters and each provides information on different aspects of sleep over different time periods. In this prospective clinical study, our aim was to investigate the extent and nature of sleep issues in patients with chronic pain and the relationship between sleep parameters and pain severity in our patients, using three different sleep assessment tools. The commonly used pain questionnaire, the Brief Pain Inventory (BPI), recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) group, has only one question on sleep in the section on interference (6,7). We also investigated the utility of this single question on sleep interference in the BPI to reflect the findings of the three dedicated sleep assessment tools to see whether it could be used as a simple way to assess sleep issues routinely.

## **Methods**

### Study Design

This was a prospective cross-sectional study of self-reported sleep quality in patients with chronic pain who were attending a chronic pain management clinic. We aimed to investigate the extent and nature of sleep issues in a local population of patients with chronic non-malignant pain and the relationship between sleep quality and pain severity.

### Measures

Three different sleep assessment tools were used; each of these provides information on a different aspect of sleep issues and their duration. The Pittsburgh Sleep Quality Index (PSQI) is a 19-item self-report questionnaire used for the assessment of sleep quality over the last month, with a overall global score above 5 indicating poor quality of sleep; sleep duration is also captured. The Pain and Sleep Questionnaire-3 (PSQ-3) evaluates the impact of pain on sleep over the previous week. It is an abbreviated version of the original PSQ and focuses specifically on sleep issues related to pain. Three visual analogue scales (VAS) are used, with one end of the scale being bounded by "never" and the other by "always". A score for each component (falling asleep, awakening during the night and awakening in the morning) is determined by measuring the scale from the left end of the line, and an algebraic sum is then calculated to give a score of 0-300. A higher score indicates a greater level of sleep disturbance due to pain. The PSQ-3 has been psychometrically tested for its reliability and validity (8). The Verran Snyder-Halpern (VSH) scale considers sleep in the last 24h and uses VAS to answer 15 questions to evaluate sleep parameters in three different domains: sleep disturbance, sleep efficiency and sleep supplementation (9). Latency and wake after sleep onset is also captured. Each question is scored from 0 to 100, with 0 indicating the sleep behaviour or quality is not present and 100 indicating that it is consistently experienced. Reverse scoring is also used in the VSH scale.

The Brief Pain Inventory (BPI) is a well validated self-assessment tool used for chronic pain patients, requiring patients to rate their pain and the level of interference of pain with activities and sleep on a scale of 0 to 10. Its reliability and validity has been shown for use in both cancer pain and non-malignant chronic pain, and it has been translated into multiple languages for use worldwide (4). It is recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) group, and has a single question on the interference of pain on sleep. We also aimed to assess the utility of the single sleep question in the BPI compared to the three dedicated sleep assessment tools and its association with the severity of pain.

Ethical approval for this study was obtained from the Leicester South Research Ethics Committee (reference number 16/EM/04) and written informed consent was obtained from all participants before the study.

### Recruitment

All patients scheduled to attend the pain clinic during the recruitment period were sent an invitation letter and participant information sheet by the clinical care team in advance of their appointment. Any patient with chronic non-malignant pain of at least 3 months' duration and who expressed an interest in taking part was screened by the healthcare team for eligibility. The inclusion criteria were as broad as possible: age over 16, able to give written, informed consent and neurologically stable enough to report on health and pain status. Patients were excluded if they had insufficient English to be able to understand what was required of them. A formal sample size calculation was not performed due to the absence of pre-existing data, but we aimed to recruit around 50 patients in a fixed recruitment period of 2 months and each patient completed the sleep assessments on a single occasion. The CONSORT diagram (Figure 1) summarises recruitment. Of the 90 patients not recruited, 35 declined to participate, 43 had conflicting clinic appointment issues, 3 were not eligible and a researcher was not available for 9 patients.

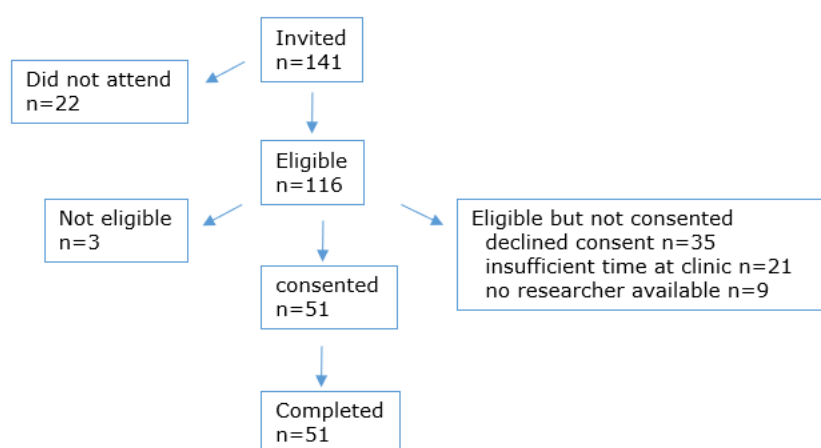


Figure 1

CONSORT diagram showing recruitment.

### Study data

Sleep parameters were assessed using three sleep assessment tools: the Pittsburgh Sleep Quality Index (PSQI) to assess sleep over the previous month (7); the Pain and

Sleep Questionnaire 3 Item Index (PSQ-3) to assess sleep related to pain over the previous week (8) and the Verran Snyder-Halpern (VSH) sleep scale to assess sleep over the previous 24-hour period (9). Each sleep assessment tool was completed once by each patient after the clinic visit during a one-to-one session with a researcher. The BPI was also completed at the same time (4). Basic demographic information was collected from medical notes and included age, sex, chronic pain duration, chronic pain type and diagnosis, and current medications.

#### Data Management and Statistical Analysis

Data was collected using a paper-based case record form. Scores were calculated independently by two researchers and cross-checked to minimise errors then transcribed into Microsoft Excel, with further analysis. Statistical analysis was undertaken using Analyse-It add-in for Excel. None of the data were normally distributed and all data are presented as median [range]. BPI average pain and sleep interference scores were divided into a convenience grouping of tertiles: mild: scores of 4 or less, moderate: 5-6 and severe: scores of 7 or over. Data in relation to these tertile groupings were analysed using Kruskal-Wallis testing. Correlations were undertaken using Spearman. A p-value of <0.05 was considered to be statistically significant.

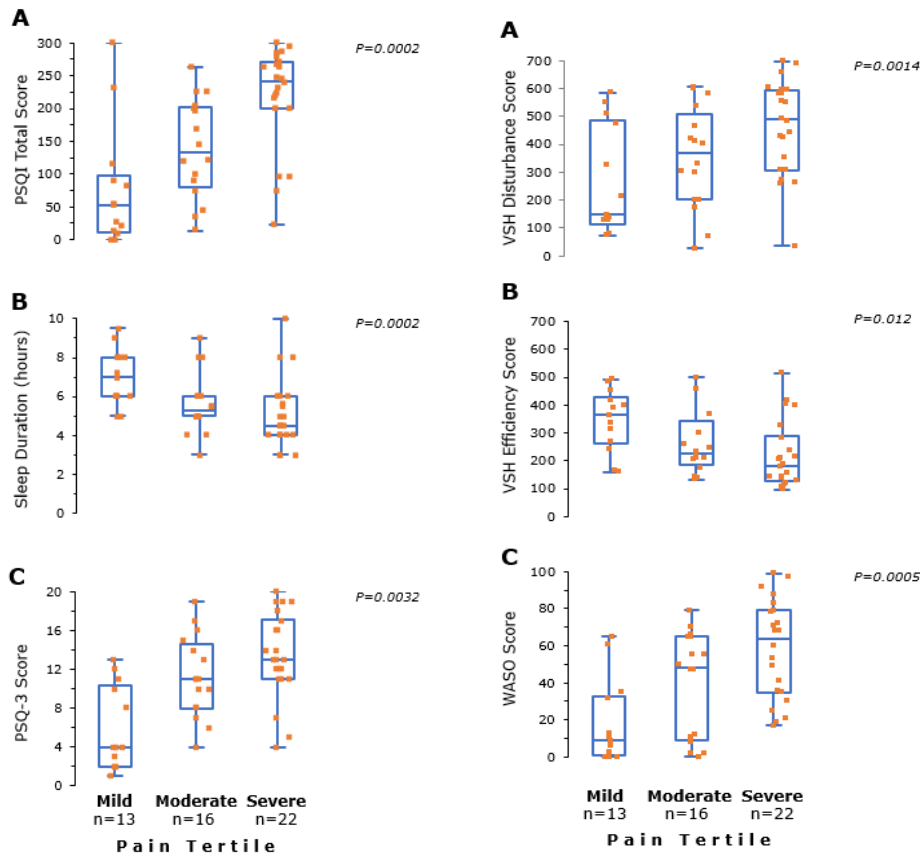
#### **Results:**

The total number of patients invited to take part was 141. Of these, 51 participants were recruited and there were no withdrawals after consenting. The reasons for non-participation are shown in Figure 1. Baseline data are shown in Table 1. The majority of the participants were female (n=37, 73%). The median [range] age was 53 [18-88] years and the median duration of chronic pain was 6 [1.8-33] years. Twenty-three (45.2%) participants were taking simple analgesia, 19 (37.3%) were taking opioids and 16 (31.4%) were taking neuropathic painkillers at the time of the study (Table 1).

#### Sleep assessment

The average pain and sleep interference scores from BPI and the other sleep assessment tools are shown in Table 2. The overall median [range] pain score from the BPI was 6 [0-10] whilst the sleep interference score was 8 [0-10]. There was a significant correlation between average pain and sleep interference scores ( $p < 0.0001$ ). The BPI average pain and sleep interference scores were grouped into convenience tertiles of 4 or less for mild pain/sleep interference, 5-6 for moderate pain/sleep interference and 7 or more for severe pain/sleep interference. Thirteen participants scored their average pain as mild, 16 as moderate and 22 as severe. In terms of sleep interference, 15 participants gave a score equating to mild, 7 as moderate and 29 as severe interference with sleep.

PSQI and PSQ-3 scores are presented in Table 2; 41 (80%) of participants had a total PSQI score over 5, indicating poor sleep quality and 39 (76.5%) had a PSQ-3 score above 75. Median [range] sleep duration captured by the PSQI was 5.5 [3.0-10.0] hours, with 37 (72.5%) of participants reporting sleeping 6h or less. Total PSQI scores were associated with BPI average pain score tertiles ( $p = 0.0002$ , Figure 2A) with higher scores seen in those with higher pain scores. Sleep duration decreased ( $p = 0.0002$ , Figure 2B) and PSQ-3 scores decreased as BPI average pain score increased ( $p = 0.0032$ , Figure 2C).



**Figure 2**

A. PSQI total quality score, B PSQI sleep duration and C. PSQ-3 score by BPI average pain score tertile. Data shown as median, interquartile and full range with individual data points overlaid. BPI sleep interference score tertiles: mild = 0-4, moderate = 5 or 6 and severe = 7-10. P values shown are from Kruskal-Wallis analysis.

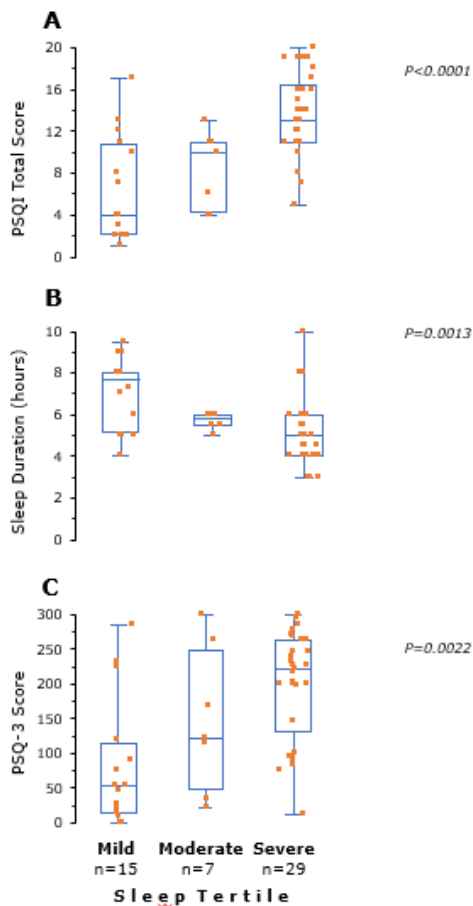
**Figure 3**

A. VSH sleep disturbance score, B VSH sleep efficiency score and C. VSH wake after sleep onset (WASO) score by BPI average pain score tertile. Data shown as median, interquartile and full range with individual data points overlaid. BPI average sleep interference tertiles: mild = 0-4, moderate = 5 or 6 and severe = 7-10. P values shown are from Kruskal-Wallis analysis

Scores from the three overall domains of the VSH tool are shown in Table 2. A third of patients had disturbance scores over 500, 35% had WASO scores of >60 and 57% had efficiency scores of <250; 13 patients (25%) had disturbance scores >500, plus WASO scores >60 and efficiency scores <250. VSH sleep disturbance, efficiency and WASO were significantly associated with BPI average pain scores with increasing disturbance ( $p=0.0014$ , Figure 3A), decreasing efficiency ( $p=0.012$ , Figure 3B) and increasing WASO ( $p=0.0005$ , Figure 5C) across severity tertiles. In terms of sleep latency (the time taken to fall asleep), 22 (43%) of participants had scores above the 75<sup>th</sup> percentile but latency did not significantly increase across average pain severity or sleep interference score tertile (Table 2).

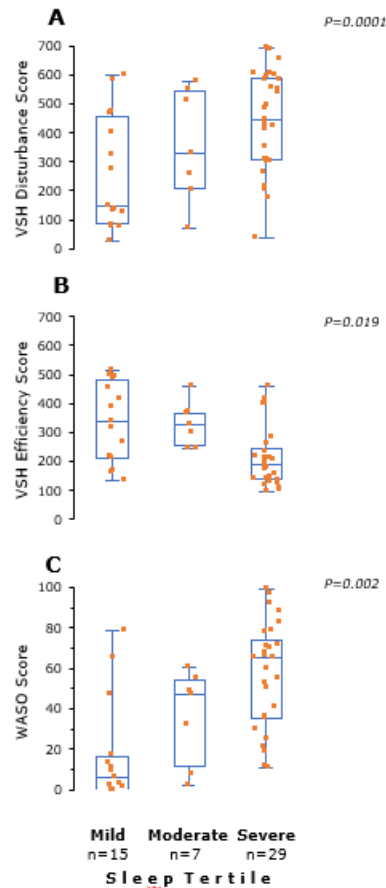
There was a concurrence between the BPI sleep interference score tertiles and the sleep assessment scores: total PSQI score increased ( $p<0.0001$ , Figure 4A), PSQI sleep

duration decreased ( $p=0.0012$ , Figure 4B) and PSQ-3 score increased ( $p=0.0022$ , Figure 4C) as BPI sleep interference scores increased. Likewise VSH disturbance was significantly increased ( $p=0.0001$ , Figure 5A), efficiency decreased ( $p=0.019$ , Figure 5B) and WASO increased ( $p=0.002$ , Figure 5C) across BPI sleep interference score tertiles.



**Figure 4**

A. PSQI total quality score, B. PSQI sleep duration and C. PSQ-3 score by BPI sleep interference score tertile. Data shown as median, interquartile and full range with individual data points overlaid. BPI sleep interference score tertiles: mild = 0-4, moderate = 5 or 6 and severe = 7-10. P values shown are from Kruskal-Wallis analysis.



**Figure 5**

A. VSH sleep disturbance score, B. VSH sleep efficiency score and C. VSH wake after sleep onset (WASO) score by BPI sleep interference score tertile. Data shown as median, interquartile and full range with individual data points overlaid. BPI average sleep interference tertiles: mild = 0-4, moderate = 5 or 6 and severe = 7-10. P values shown are from Kruskal-Wallis analysis.

## Discussion

The main aim of the study was to assess the extent and nature of sleep issues and the association with pain severity in patients with chronic pain patients using three different sleep assessment tools. In addition, since the BPI is routinely used, well validated (4) and familiar to patients and clinicians alike, we investigated how well the single question on pain interference with sleep in the BPI was able to identify sleep problems and whether it concurred with results from three dedicated sleep assessment tools. We found poor overall sleep quality in 80% of patients, short sleep duration, marked sleep disturbance and waking and low sleep efficiency, with a significant effect of pain severity on these measures. Latency was an issue for almost half the participants but was not related to pain scores. BPI sleep interference scores concurred with the more complex validated sleep assessment tools and were also associated with severity of pain. This suggests that the BPI sleep interference question could be used routinely for initial identification of sleep problems in patients with chronic pain.

We used three different validated self-reported sleep assessment tools to identify sleep issues in our patients. The PSQI is one of the most widely used methods for the assessment of sleep and has been used in multiple settings (5,7,10). It was found that there was moderate to high evidence reported for sufficient structural validity and low to high evidence for sufficient internal consistency and sufficient reliability (9). A very recent systematic review reported that the PSQI was one of three most commonly used patient reported outcome measures for assessing sleep quality in adult patients with chronic pain conditions (12). The PSQI describes a wide array of sleep problems but does not directly assess the impact of pain on sleep. In a study of people with chronic non-malignant pain, it was reported that poor sleep quality identified by the PSQI was associated with low pain tolerance on the cold pressor pain task (12). We found that around 80% of our participants had a PSQI score above 5, indicating poor sleep quality, concurring with a recent systematic review (5). The PSQI sleep quality score was higher as BPI average pain score increased indicating that poor sleep quality was related to pain severity. We also found sleep duration of as low as 3 hours/night (median 5.5 h) in some participants and >70% slept for 6h or less; sleep duration decreased as BPI pain intensity score increased. Other studies have not reported the sleep duration component of the PSQI. The PSQ-3 scale specifically captures effects of pain on sleep. We found here that the PSQ-3 scores were above the 75<sup>th</sup> percentile in more than 72% of participants, concurred with BPI sleep interference scores and were worse in those with more severe pain.

The VSH scale was originally developed to assess the subjective sleep quality of hospitalised patients but has been used in a variety of populations, including healthy adults, adults with insomnia, hospitalised patients and healthy adults given melatonin (9,13-15). High scores for sleep disturbance were common in our patients with more than half of participants having a disturbance score of >350 out of 700 and 38% with a score of 500 or more, indicating profound sleep disturbance. In healthy subjects, VSH disturbance scores are reported to be around 100-200 (14,15). Conversely, more than 60% of our participants had an efficiency score of <300 out of 600, and nearly one quarter (n=12) had a score of <150. Again, these scores are considerably lower than in people without chronic pain (14,15). Both sleep disturbance and efficiency scores reflected BPI pain scores such that disturbance scores increased and efficiency scores decreased as pain was more severe. As part of the disturbance domain, a score for WASO is captured; again this was strongly associated with pain severity, such that participants with higher pain scores were awake more than those with less severe pain. Sleep latency was a problem for many patients but was not significantly associated with pain scores.

We found a marked impact of pain on and the BPI sleep interference question, and good concurrence between this and the dedicated sleep assessment tools, suggesting that BPI may be useful for initial routine screening for sleep problems in chronic pain patients.



It should be noted that all the self-reporting assessment tools used here are subjective; the gold standard method for objective assessment of sleep is polysomnography (6) but this is impractical for routine clinical use and results can be affected by medication. Future studies could include the use of actigraphy to objectively measure sleep parameters; this has good agreement with polysomnography (16). Wrist worn actigraphy 'watches' capture sleep onset and duration, latency and disturbance and also allow pain scores to be inputted contemporaneously; these have been successfully used in the context of clinical trials and broadly concur with subjective scores such as VSH (17).

This was a small observational study restricted to a local population of patients. Nevertheless, we clearly show here that sleep issues are widespread and marked. The precise genetic and environmental risk factors which lead to the development of chronic pain are poorly understood. Although chronic pain may have a single identifiable cause in many patients, pain duration and intensity, as well as the physical, psychological and social effects of pain, are influenced by a number of other risk factors. The relationship between pain and sleep is reported to be reciprocal, with pain affecting sleep quality, and sleep disturbance exacerbating pain (1). Patients often find themselves in a vicious cycle, with worsening health, wellbeing and quality of life. There is therefore a need to identify and treat sleep problems in chronic pain patients. Not only does this have the potential to improve patients' quality of life and functioning, but also to improve pain. The extent of the sleep problems we have identified in our patients with chronic non-malignant pain suggest that intervention to improve sleep may be worthwhile. This may take various forms from promotion of sleep hygiene, good pain control to pharmacological management including exogenous administration of melatonin (17).

## **Conclusion**

The aim of this study was to assess the extent and nature of sleep issues in patients with chronic pain and to investigate whether the question on sleep interference in the BPI could be used as a simple first step to identify sleep problems by investigating whether it reflected validated sleep assessment tools. We found that the majority of patients attending the pain management clinic had poor sleep quality, high levels of sleep disturbance, short sleep duration with marked waking after sleep onset, and poor sleep efficiency, all of which were associated with pain severity. We also found that the BPI sleep interference score concurred broadly with the three validated sleep assessment tools such that the BPI could be used to routinely monitor sleep problems in the clinic. Given the extent of sleep issues in patients with chronic pain, measures to improve sleep may be worthwhile.

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**Table 1: Baseline Demographic data**

	<b>Total</b>	<b>Female</b>	<b>Male</b>
Number (%)	51	37 (72.5)	14 (27.5)
Age (years)	53 [18-88]	53 [18-88]	52.5 [33-78]
Chronic pain duration -years Median [range]	6 [1.8-33]	6 [1.8-33]	7 [2-30]
Chronic pain type – number (%)			
Neuropathic	10 (19.6)	8 (21.6)	2(14.3)
Predominantly neuropathic	5 (9.8)	4 (10.8)	1 (7.1)
Nociceptive	11 (21.6)	5 (13.5)	6 (42.9)
Predominantly nociceptive	15 (29.4)	11 (29.7)	4 (28.6)
Visceral	1 (2.0)	1 (2.7)	0
Mixed	9 (17.6)	8 (21.6)	1 (7.1)
Medication type- number (%)			
Simple analgesia	23 (45.1)	18 (48.6)	5 (35.7)
NSAIDs	22 (43.1)	15 (40.5)	7 (50.0)
Compound analgesics	10 (19.6)	7 (18.9)	3 (21.4)
Opioids	19 (37.3)	16 (43.2)	3 (21.4)
Anticonvulsants	16 (31.4)	10 (27.0)	6 (42.9)
Antidepressants	13 (25.5)	13 (35.1)	0
Other	26 (51.0)	18 (48.6)	8 (57.1)
None	6 (11.8)	3 (8.1)	3 (21.4)

**Table 2 Sleep and pain scores**

<b>Score</b>	<b>Entire cohort (n=51)</b>	<b>Males (n=14)</b>	<b>Females (n=37)</b>
<b>BPI</b> Average pain score Sleep interference score	6 [0-10] 8 [0-10]	7 [2-10] 8 [2-10]	6 [0-10] 7 [0-10]
<b>PSQI</b> Total score Duration (hours)	11 [1-20] 5.5 [3-10]	11 [4-19] 5.25 [3-10]	11 [1-20] 5.5 [3-9.5]
<b>PSQ-3</b> Total score	197 [0-295]	152 [26-300]	197 [0-300]
<b>VSH</b> Disturbance Efficiency Supplementation WASO Latency	413 [36-697] 234 [98-514] 13 [0-368] 44 [0-99] 58 [0-100]	331 [75-598] 376 [177-458] 67 [0-368] 29 [8-99] 57 [7-101]	425 [26-690] 212 [103-515] 12 [0-177] 50 [1-92] 75 [0-100]