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Sleep Disturbance in Patients with Burning Mouth Syndrome: A Case-Control Study

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Aims: To examine sleep complaints in patients with burning mouth syndrome (BMS) and the relationships between these disturbances, negative mood, and pain. Methods: Fifty BMS patients were compared with an equal number of healthy controls matched for age, sex, and educational level. The Pittsburgh Sleep Quality Index (PSQI), the Epworth Sleepiness Scale (ESS), the Hamilton Rating Scales for Depression (HAM-D) and Anxiety (HAM-A) were administered. Descriptive statistics, including the Mann-Whitney U test and hierarchical multiple linear regression analyses were used. Results: BMS patients had higher scores in all items of the PSQI and ESS than the healthy controls (P < .001). In the BMS patients, a depressed mood and anxiety correlated positively with sleep disturbances. The Pearson correlations were 0.68 for PSQI vs HAM-D (P < .001) and 0.63 for PSQI vs HAM-A (P < .001). Conclusion: BMS patients reported a greater degree of sleep disorders, anxiety, and depression as compared with controls. Sleep disorders could influence quality of life of BMS patients and could be a possible treatment target. J OROFAC PAIN 2013;27:304-313. doi: 10.11607/jop.1109

Key words: anxiety, depression, insomnia symptoms, pain, sleep

Burning mouth syndrome (BMS) is an idiopathic, chronic pain condition that affects more than 1 million individuals in the United States alone,1 with an estimated prevalence ranging from 0.7% to 4.6%.2-3 It usually occurs in the fifth to seventh decade of life and is more common in females than in males, with a ratio of approximately 3:1.2-4

The International Association for the Study of Pain and the International Headache Society define BMS as a “distinctive nosological entity,” including all forms of burning sensation in the mouth and complaints described as a stinging sensation or pain, in the absence of specific oral lesions and without alterations in blood tests and/or instrument findings.5

In almost all patients, BMS is characterized by sensory symptoms (burning, pain, a foreign-body sensation such as sand granularity, a decrease of salivation, and itching) involving mainly the tongue and lips, followed by the hard palate, alveolar ridges, cheeks, and floor of the mouth,6 which are not attributable to any organic pathologies and are not supported by clinical findings. The discomfort may range from minimal to severe and may significantly affect the patient’s quality of life. It tends to persist for at least 4 to 6 months, to be constant and bilateral, and to be relieved with food consumption. Other complaints may be associated with the burning, such as dyseusia, hyposmia, and/or dysosmia, which supports its designation as a syndrome.7 The pathogenesis of BMS remains poorly understood, although both physiological and psychological factors have been hypothesized to be involved. Several studies have shown
Rectal analgesia between insomnia and pain.

The incidence of insomnia, with a dose and bid, for rectal pain, was an important predictor for rectal pain. In patients with insomnia, a common symptom of chronic pain, as opposed to insomnia in patients with insomnia, there is a common symptom of chronic pain, as opposed to insomnia, with a higher prevalence of sleep.

The lack of research in this area may reflect the common occurrence of insomnia and other disorders, which in turn may cause a higher prevalence of sleep disorders.

In contrast to the prevalence of insomnia, with a higher prevalence of sleep disorders, the incidence of insomnia is lower in patients with insomnia, with a higher prevalence of sleep disorders.

Previous studies on association between pain...

Rectal analgesia between insomnia and pain.
Materials and Methods

Participants and Procedure

This was a case-control clinical study carried out at the Oral Medicine Unit, Federico II University of Naples. Sixty-six BMS cases and 57 healthy subjects were screened to participate between May 2010 and December 2010. Fifty BMS patients (response rate 76%) and 50 healthy control subjects (response rate 88%) were included in the trial in accordance with the inclusion/exclusion criteria, undergoing a simple randomization procedure with IBM SPSS software. Both groups were frequency-matched for sex, age, and educational level. All patients received written information and provided their written informed consent for the management of personal data before their participation. The study was approved by the local Ethical Committee.

The inclusion criteria for BMS were (1) either sex, aged 18 or older; (2) the presence of chronic pain in the oral mucosa in the absence of hard and soft tissue lesions of any kind; (3) pain lasting more than 6 months, continuous throughout the day, with no paroxysm and not following any unilateral nerve trajectory; and (4) the absence of any abnormalities from the following laboratory investigations: salivary flow rates, laboratory tests, and tests for the detection of Candida. The exclusion criteria encompassed patients presenting with organic conditions that could be considered a causative factor, such as diabetes, anemia, thyroid disease, iposocialia-related systemic disorders (eg, Sjogren’s syndrome), contact allergies, psychotic illness, organic brain syndrome, or neurological disease; subjects with signs of parafunctional habits; or patients regularly treated with anxiolytic, antidepressant, anticonvulsant, or psychotropic drugs. Even in the absence of mucosal lesions, a local effect of dental materials related to contact hypersensitivity was excluded by means of patch tests when the symptoms had started after any dental rehabilitation. A final diagnosis of BMS was established only after all other possible causes of the oral complaints had been ruled out.

The inclusion criteria for healthy subjects were (1) either sex, aged 18 or older; (2) the absence of oral mucosal lesions; (3) no history of psychiatric disorder; and (4) consultation at the department exclusively for dental disease (dental caries or periodontal disease). Conversely, the exclusion criteria encompassed (1) patients with unstable medical conditions or debilitating pathologies (eg, cancer, osteonecrosis, or autoimmune blistering disease) and (2) patients regularly treated with anxiolytic, antidepressant, anticonvulsant, and/or psychotropic drugs.

Sociodemographic data, age, education, occupation, and marital status were recorded for both BMS patients and healthy subjects. At admission, each subject underwent a medical anamnesis (including history, clinical features, and treatment), a general medical examination, an intraoral and extraoral examination, and laboratory tests (eg, full blood cell count, and serum levels of iron, ferritin, folate, vitamin B12, and glucose).

Three oral medicine specialists were responsible for determining the eligibility of the BMS patients and of the healthy individuals as controls, and for collecting all the demographic and medical data from both groups. After screening, the BMS patients and controls were evaluated by a psychiatrist from the Department of Neuroscience of the same University Hospital.

Upon admission, the BMS patients and healthy controls were assessed in accordance with the following evaluation battery scales: the Pittsburgh Sleep Quality Index (PSQI) and the Epworth Sleepiness Scale (ESS) for the assessment of sleep, the Hamilton Rating Scale for Depression (HRSD or HAM-D) and the Hamilton Rating Scale for Anxiety (HAM-A) for the evaluation of depression and anxiety, and the Numeric Rating Scale (NRS) for the measurement of oral pain symptoms.

All these scales were reviewed for completeness before collection and were administered in their Italian versions.

Sleep Scales

The Pittsburgh Sleep Quality Index. The PSQI is considered an essential measure of sleep and insomnia symptoms in treatment research, and it is a recommended assessment tool for epidemiological studies; it is a self-report questionnaire assessing sleep quality and disturbances over a 1-month time interval, and is designed to be used in clinical populations.18 This instrument comprises 19 items, generating 7 “component” scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction. Sleep pattern data (eg, bedtime, wake time, sleep onset latency, and sleep quantity) are also provided. Each item is scored from 0 to 3, with higher scores indicating poorer sleep or more frequent sleep problems. Items are combined to yield the 7 components (scores ranging from 0 to 3), and the sum of the scores for these 7 components yields 1 global score ranging from 0 to 21. Global scores above 5 distinguish poor sleepers from good sleepers with a high sensitivity (90% to 99%) and specificity (84% to 87%).19 The psycho-
the variance explained by the specific set of contributing structural, regression, and demographic factors.

**Sensitivities, Specificities, and Predictive Values**

The sensitivities and specificities of the HAM-D and the FSS are comparable to those of other scales, including the Hamilton Rating Scale for Depression (HRSD). The FSS has been shown to be highly correlated with the HRSD, with a Pearson correlation coefficient of 0.9 or greater. The FSS can be administered in the outpatient setting and can be completed in approximately 15 minutes. The FSS is a valid and reliable measure of anxiety in diverse clinical populations, including those with psychiatric disorders. The FSS is designed to be self-administered, allowing patients to provide a more accurate assessment of their anxiety symptoms. The FSS consists of 14 items, each scored on a 0-4 scale, reflecting the severity of anxiety symptoms. The total score ranges from 0 to 56, with higher scores indicating more severe anxiety.
Table 1  Demographic and Clinical Characteristics of BMS Patients and Control Subjects

<table>
<thead>
<tr>
<th>Demographic variables</th>
<th>BMS patients</th>
<th>Control subjects</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean ± SD)</td>
<td>57.98 ± 8.1</td>
<td>53.2 ± 8.6</td>
<td>.832</td>
</tr>
<tr>
<td>Years of education (mean ± SD)</td>
<td>8.4 ± 3.1</td>
<td>9.3 ± 2.9</td>
<td>.781</td>
</tr>
<tr>
<td>Sex (female: male)</td>
<td>38:12</td>
<td>38:12</td>
<td>—</td>
</tr>
<tr>
<td>Marital status (married:unmarried)</td>
<td>42:8</td>
<td>42:8</td>
<td>—</td>
</tr>
<tr>
<td>Job full-time (yes:no)</td>
<td>11:39</td>
<td>11:39</td>
<td>—</td>
</tr>
<tr>
<td><strong>Clinical parameters</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep quality, PSQI (median; IQR)</td>
<td>9.0; 6–14</td>
<td>4.0; 3–5</td>
<td>&lt;.001**</td>
</tr>
<tr>
<td>Depression, HAM-D (median; IQR)</td>
<td>16.0; 10–24</td>
<td>5.0; 4–6</td>
<td>&lt;.001**</td>
</tr>
<tr>
<td>Anxiety, HAM-A (median; IQR)</td>
<td>17.5; 13–27</td>
<td>5.0; 4–7</td>
<td>&lt;.001**</td>
</tr>
<tr>
<td>Daytime sleepiness, ESS (median; IQR)</td>
<td>10.0; 7–12</td>
<td>3.0; 2–3</td>
<td>&lt;.001**</td>
</tr>
<tr>
<td>Pain severity, NRS (median; IQR)</td>
<td>8.5; 8–10</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

IQR, interquartile range. The significance difference between medians was measured by Mann-Whitney U test. PSQI, Pittsburgh Sleep Quality Index. HAM-D, HAM-A, Hamilton Rating Scale for Depression, Anxiety; ESS, Epworth Sleepiness Scale; NRS, numerical rating scale.

**Significant P < .01.

significantly to the total variance in sleep quality after checking for the demographic set. A full model analysis was then computed with all the variables entered simultaneously into the model to determine the relative contributions of these variables to sleep quality.

Results

Table 1 summarizes the demographic and clinical parameters. There were 38 female patients (76%) and 12 male patients (24%).

PSQI Reliability

Table 2 shows the reliability analysis of PSQI in BMS patients. The Cronbach α measure 0.84 indicated a good overall reliability of the scale. All components presented an acceptable level of item-scale Pearson correlation. Item-scale correlation and Cronbach α index were used to verify the internal consistency, item by item, and the global reliability of the PSQI in BMS patients and controls.

Sleep Quality

The global and component scores for the PSQI were significantly different between cases and controls (Tables 1 and 3). Patients with BMS had higher mean PSQI scores, indicating a poorer sleep quality for these patients compared to the healthy controls. Forty patients (80%) were poor sleepers, with a PSQI global score of > 5.

Table 2 Reliability Analysis of PSQI Scale in BMS Patients and Control Subjects

<table>
<thead>
<tr>
<th>PSQI Components</th>
<th>Item-Scale p correlation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjective sleep quality</td>
<td>0.58 0.51</td>
</tr>
<tr>
<td>Sleep latency</td>
<td>0.76 0.32</td>
</tr>
<tr>
<td>Sleep duration</td>
<td>0.60 0.43</td>
</tr>
<tr>
<td>Habitual sleep efficiency</td>
<td>0.62 0.36</td>
</tr>
<tr>
<td>Sleep disturbances</td>
<td>0.54 0.03*</td>
</tr>
<tr>
<td>Use of sleep medications</td>
<td>0.31 0.61</td>
</tr>
<tr>
<td>Daytime dysfunction</td>
<td>0.63 0.17*</td>
</tr>
<tr>
<td>Cronbach α</td>
<td>0.84 0.65</td>
</tr>
</tbody>
</table>

*Poor correlation between a single item and the global scale (p < 0.3).

Patients with Poor Quality of Sleep. Among BMS patients, the clinical parameters of good (PSQI < 5) and poor (PSQI > 5) sleepers were compared. Depression (P < .001), anxiety (P < .001), and daytime sleepiness (P < .001) were found to be significantly different between the two groups, while pain severity was not (P = .214) (Table 4).

Dependence of Sleep Quality. As shown in Table 5, depression (HAM-D), anxiety (HAM-A), and daytime sleepiness (ESS) correlated positively with sleep quality, while pain severity did not. In addition, the years of education correlated negatively with sleep quality.
Table 3: Comparison of Components of PSQI in BMS Patients and Control Subjects

<table>
<thead>
<tr>
<th>PSQI components</th>
<th>BMS Patients</th>
<th>Control subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep latency</td>
<td>1.1 (IQR: 0.3-2)</td>
<td>1.0 (IQR: 0.0-2)</td>
</tr>
<tr>
<td>Sleep duration</td>
<td>1.1 (IQR: 0.3-2)</td>
<td>1.0 (IQR: 0.0-2)</td>
</tr>
<tr>
<td>Habitual sleep efficiency</td>
<td>1.1 (IQR: 0.3-2)</td>
<td>1.0 (IQR: 0.0-2)</td>
</tr>
<tr>
<td>Sleep disturbances</td>
<td>1.1 (IQR: 0.3-2)</td>
<td>1.0 (IQR: 0.0-2)</td>
</tr>
<tr>
<td>Use of sleep medications</td>
<td>1.1 (IQR: 0.3-2)</td>
<td>1.0 (IQR: 0.0-2)</td>
</tr>
<tr>
<td>Daytime dysfunction</td>
<td>1.1 (IQR: 0.3-2)</td>
<td>1.0 (IQR: 0.0-2)</td>
</tr>
</tbody>
</table>

IQR: interquartile range

Table 4: Comparison Between Good and Poor Sleepers for BMS Patients

<table>
<thead>
<tr>
<th>PSQI ≤ 5 (n = 23)</th>
<th>PSQI &gt; 5 (n = 27)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression (HAMD)</td>
<td>Median: 6.0 (IQR: 1.0-9)</td>
</tr>
<tr>
<td>Anxiety (HAMA)</td>
<td>Median: 6.0 (IQR: 1.0-9)</td>
</tr>
<tr>
<td>Daytime sleepiness (ESS)</td>
<td>Median: 6.0 (IQR: 1.0-9)</td>
</tr>
<tr>
<td>Pain severity (NRS)</td>
<td>Median: 6.0 (IQR: 1.0-9)</td>
</tr>
</tbody>
</table>

IQR: interquartile range

Table 5: Dependence of Sleep Quality with Clinical Parameters and Demographic Characteristics of BMS Patients

<table>
<thead>
<tr>
<th>Clinical parameters</th>
<th>Pearson coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression (HAMD)</td>
<td>0.68</td>
</tr>
<tr>
<td>Anxiety (HAMA)</td>
<td>0.63</td>
</tr>
<tr>
<td>Daytime sleepiness (ESS)</td>
<td>0.65</td>
</tr>
<tr>
<td>Pain severity (NRS)</td>
<td>0.18</td>
</tr>
<tr>
<td>Age</td>
<td>0.03</td>
</tr>
<tr>
<td>Years of education</td>
<td>0.32</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Demographic characteristics</th>
<th>Female: 9.0; 6-15; Male: 9.0; 6-10.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marital status</td>
<td>Unmarried: 9.0; 6-10.5</td>
</tr>
</tbody>
</table>

HAMD: Hamilton Depression Scale; HAMA: Hamilton Anxiety Scale; ESS: Epworth Sleepiness Scale; NRS: Numerical Rating Scale; IQR: Interquartile Range. P < 0.05 (Significant).
Table 6  Multiple Linear Regression Model Predicting Sleep Quality in BMS Patients

<table>
<thead>
<tr>
<th>Predictors</th>
<th>Model 1 Beta (SE)</th>
<th>Model 1 P</th>
<th>Model 2 Beta (SE)</th>
<th>Model 2 P</th>
<th>Model 3 Beta (SE)</th>
<th>Model 3 P</th>
<th>Model 4 Beta (SE)</th>
<th>Model 4 P</th>
<th>Model 5 Beta (SE)</th>
<th>Model 5 P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>-0.02 (0.09)</td>
<td>.785</td>
<td>0.10 (0.06)</td>
<td>.131</td>
<td>0.09 (0.07)</td>
<td>1.98</td>
<td>-0.01 (0.09)</td>
<td>9.44</td>
<td>0.01 (0.06)</td>
<td>1.144</td>
</tr>
<tr>
<td>Years of education</td>
<td>-0.53 (0.23)</td>
<td>.026*</td>
<td>-0.48 (0.16)</td>
<td>.004**</td>
<td>-0.39 (0.18)</td>
<td>0.034*</td>
<td>-0.49 (0.24)</td>
<td>0.043*</td>
<td>-0.46 (0.16)</td>
<td>0.007**</td>
</tr>
<tr>
<td>Sex: Female</td>
<td>0.71 (1.63)</td>
<td>.665</td>
<td>1.15 (1.12)</td>
<td>.309</td>
<td>1.46 (1.25)</td>
<td>2.47</td>
<td>0.77 (1.64)</td>
<td>6.42</td>
<td>1.24 (1.15)</td>
<td>2.86</td>
</tr>
<tr>
<td>Marital status: Married</td>
<td>-2.72 (1.71)</td>
<td>.120</td>
<td>-0.57 (1.22)</td>
<td>.641</td>
<td>-0.64 (1.35)</td>
<td>6.37</td>
<td>-2.58 (1.74)</td>
<td>1.45</td>
<td>-0.49 (1.24)</td>
<td>6.93</td>
</tr>
<tr>
<td>Depression (HAM-D)</td>
<td>0.39</td>
<td>&lt;.001**</td>
<td>0.29 (0.05)</td>
<td>&lt;.001**</td>
<td>0.32 (0.11)</td>
<td>&lt;.005**</td>
<td>0.07 (0.09)</td>
<td>.452</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety (HAM-A)</td>
<td></td>
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<td></td>
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<td></td>
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<tr>
<td>Pain severity (NRS)</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>$R^2$ (%)</td>
<td>16.2</td>
<td>.088</td>
<td>61.5</td>
<td>&lt;.001**</td>
<td>52.7</td>
<td>&lt;.001**</td>
<td>17.3</td>
<td>.125</td>
<td>62.0</td>
<td>&lt;.001**</td>
</tr>
<tr>
<td>$R^2$ change (%)</td>
<td>45.3</td>
<td>&lt;.001**</td>
<td>36.5</td>
<td>&lt;.001**</td>
<td>1.1</td>
<td>4.40</td>
<td>45.8</td>
<td>&lt;.001**</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SE, standard errors of beta estimates. HAM-D, HAM-A, Hamilton Rating Scale for Depression, Anxiety; ESS, Epworth Sleepiness Scale; NRS, numerical rating scale. P values were obtained by hypothesis test on regression coefficients. *Significant .01 < P .05, **Significant P .01.

Association with Sleep Quality. The results of the hierarchical multiple linear regression analyses predicting sleep quality are shown in Table 6. Model 1 (the demographic model) tested the contribution of demographic variables to disturbed sleep. Model 2 (the depression model) tested the contribution of depressed mood to poor sleep quality after controlling for the demographic variables. Model 3 (the anxiety model) tested the contribution of anxiety mood to poor sleep after checking for the demographic variables. Model 4 (the pain model) tested the contribution of pain severity after checking for the demographic variables. Model 5 is the standard regression analysis where all of the variables were entered simultaneously into the model to assess the relative contributions of these variables to sleep quality. This model takes into account the interrelations between the predictor variables as well as the effects of the predictor variables on the outcome variable (PSQI).

The first model testing the contributions of demographic variables to sleep quality was not found to be statistically significant ($R^2 = 16.2\%$, $P = .088$). The addition of depression (model 2) and anxiety (model 3) resulted in a significant increase in the $R^2$ value ($\Delta R^2 = 45.3\%$, $P < .001$ for depression, $\Delta R^2 = 36.5\%$, $P < .001$ for anxiety) while the addition in model 4 of pain (NRS) did not contribute significantly to poor sleep quality. The final full model (the standard multiple regression analysis) in which all of the variables were entered simultaneously could explain 62% of the variance in sleep quality.

The analysis of dependence reported in Table 5 highlights a strong correlation between the PSQI and the ESS. This result is consistent with the similar nature of the two scales, and therefore the ESS can be considered as a proxy variable of the PSQI. For this reason, the ESS was excluded from the set of predictors considered in the hierarchical multiple linear regression analysis reported in Table 6.

Discussion

Previous studies have demonstrated that sleep disorders occur in up to 27% of the primary-care population and more frequently (ranging from 51% to 75%) in the elderly and in patients with advanced medical illness.51,52 In clinical populations, the prevalence of sleep disturbance has been estimated to be about 51% of patients who experience chronic low back pain, 75% of those with fibromyalgia, and 70% of those with rheumatoid arthritis.
psychological disorders. In a recent study, pain was considered the most common factor in pain management, with a combination of poor sleep in approximately 90% of patients in opioid-requiring pain levels. However, the SPF of poor sleep in depression patients, even more so for patients with depression, has been extensively studied in patients with depression. Poor sleep in depressed patients is associated with increased risk of depression.

In the current study, the association between poor sleep and depression was considered to be the central factor in the development of depression. Poor sleep was identified as a risk factor for depression, and the risk of developing depression was higher in patients with poor sleep. This relationship was consistent across different populations and settings.

Study limitations

In conclusion, poor sleep in depressed patients is associated with increased risk of depression. However, the association between poor sleep and depression is complex and multifaceted, and further research is needed to better understand the underlying mechanisms.
Conclusions

This study has confirmed the comorbidity of sleep disturbance and psychological distress in a sample of BMS patients. In contrast, pain intensity did not correlate with sleep quality. The study has demonstrated that sleep disturbance is a common problem among BMS patients and has highlighted the importance of assessing sleep variables in clinical evaluation and, possibly, in treatment. Future studies should try to gain an understanding of the pathophysiological relationships between these sleep disturbances, anxiety and depression, and their biological background.

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Adams et al.