Prevalence of Respiratory Disorders during Sleep among Subjects of Methadone Maintenance Therapy Program

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Abstract

Background: Respiratory disorders during sleep are considered a health problem affecting the life quality. There is some evidence indicating the higher prevalence of apnea in substance-dependent patients. However, there is no information on the prevalence of the disease in people under methadone maintenance therapy (MMT). Therefore, the present study was designed to estimate the disease rate in these patients and consider the relationship of the increasing risk of apnea with some psychiatric problems.

Methods: Study group included 152 individuals under the MMT program. Baseline data were collected with the interview, and patients were considered using the STOP-BANG questionnaire to evaluate the risk of apnea. Furthermore, Epworth Sleepiness Scale (ESS), Fatigue Severity Scale (FSS), Hamilton Anxiety Rating Scale (HAM-A), and Hamilton Depression Rating Scale (HDRS) tests were performed for all participants. Data were analyzed using SPSS software.

Findings: Based on the STOP-BANG score categories, 37.5%, 40.1%, and 22.4% of patients indicated low, intermediate, and high risk of apnea, respectively. Moreover, severe daytime sleepiness, fatigue, depression, and anxiety were observed in 5.3%, 5.5%, 6.0%, and 21.1% of participants, respectively. Sex (P = 0.007) and daytime sleepiness (P = 0.048) were significantly different between low and high-risk groups of apnea after adjustment. Besides, age (P < 0.001) and fatigue (P = 0.007) were factors predicting the STOP-BANG score.

Conclusion: These findings revealed the higher prevalence of apnea in MMT patients compared to the general population of Iran and rising of the risk of apnea along with an increase in age and fatigue score. However, attention to the sleep disorders in MMT is a prominent factor that should be considered as a route of therapy.

Keywords: Respiration disorders; Apnea; Opiate substitution treatment; Substance-related disorders

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**Introduction**

Respiratory disorders during sleep in adults are a relatively common disease with many complications resulting in a decreased quality of life (QOL) and subsequently, increased morbidity and mortality. Similar to the general population and some other conditions, apnea is one of the major causes of physical and psychological problems in substance users, too. A recent systematic review study has reported that almost 936 million adults suffer from obstructive sleep apnea (OSA) in the world. Furthermore, a high rate of variation was observed based on the geographical area. The evaluation of the general population in Iran also indicated that almost 38.6% of people were in the high-risk group of OSA. However, in the latest systematic research, the prevalence of sleep apnea has been reported 44% [95% confidence interval (CI): 35-53] in a heterogeneous pooled sample. Based on the multifactorial origin of the disease, apnea highly affects socioeconomic factors like social function, employment, and income levels. Therefore, more studies are needed to investigate the disease rate in different ethnic groups and health issues.

Prolonged sleep disorders may cause symptoms such as anxiety, depression, excessive euphoria, delirium, and movement disorders to take place or exacerbate in substance abusers. Besides psychophysiological complications, death caused by opioids occurs often because of respiratory arrest during sleep. Currently, the management of sleep-related disorders in substance-dependent patients is one of the most central evaluations during the therapy procedure. The assessment, diagnosis, and appropriate treatment of these disorders in addicts improve their QOL. Moreover, it plays a crucial role in increasing the success of treatment and withdrawal and reducing the recurrence frequency and the tendency to use substances. It can also help patients improve their cognitive function.

Based on the previous studies, apnea has been detected in 53% of substance abusers who did not receive special treatment, and 78.5% of methadone maintenance therapy (MMT) patients suffer from sleep disorders. Furthermore, sleep-disordered breathing (SDB) induced by methadone or buprenorphine was observed in replacement therapy. These findings indicate a significantly higher prevalence of sleep-related breathing in substance abusers than the general population. However, to our knowledge, no study has been undertaken in this field on MMT patients in Iran. Therefore, this project was conducted to assess the prevalence of such disorders in substance abusers in the Iranian population.

**Methods**

**Study population:** This study was approved by the Ethics Committee of Mashhad University of Medical Sciences, Mashhad, Iran, with the ethical number: IR.mums.REC.1395.221. After signing the informed consent, all participants with at least two months of MMT were invited to interview, and demographic data including sex, age, occupation, and addiction time were collected. In addition, some health problems were evaluated including mental and chronic disorders, medication use, and medical allergy.

**Inclusion criteria:** 152 substance-dependent individuals treated with MMT who were over 18 years old and referred to Ibn-e-Sina and Hejazi academic psychiatry hospitals were enrolled in the study. In addition, included patients had no positive history of aggressiveness, severe psychosis, history of seizures, and history of severe head trauma.

**Exclusion criteria:** Patients who did not want to participate in the project, those who did not carefully complete the questionnaires, and patients who were aggressive while completing the questionnaires were excluded from the study.

**Questionnaires:** Epworth Sleepiness Scale (ESS), Fatigue Severity Scale (FSS), and STOP-BANG tests were performed, respectively, to assess the general level of daytime sleepiness, daytime fatigue, and classification of patients at high risk of OSA. Moreover, the Hamilton Depression Rating Scale (HDRS) and the Hamilton Anxiety Rating Scale (HAM-A) questionnaires were filled out by psychologists to evaluate depression and anxiety.

**STOP-BANG:** This test is to classify patients at high risk of OSA. It is an 8-item questionnaire with a "yes" or "no" answer, and for each "yes", a point is considered. Patients who acquire score more than 3 are at high risk for OSA and need to be evaluated by more accurate methods of OSA. The Persian version of the survey has been validated in Iran with the area under the curve (AUC) for identifying mild, moderate, and severe...
OSA of 0.805, 0.779, and 0.755, respectively, in comparison with 0.806, 0.782, and 0.822 reported by main study.\textsuperscript{14,15}

**ESS**: The ESS is a self-administered 8-question questionnaire that evaluates daytime sleepiness. Each question should be scored ranging from 0 to 3 based on the probability of dozeen during daily activities with a total score of 0 to 24 that a higher score indicates a higher rate of sleepiness. Furthermore, it is categorized as normal (0-10), moderate (11-15), and severe (16-24) daytime sleepiness.\textsuperscript{16,17} A high sensitivity (93.5\%) and high specificity (100\%) have been reported with a cut-off score > 10. Cronbach’s alpha coefficient of the Iranian version of ESS has been calculated to be 0.82 in comparison with 0.88 reported by main supplier.\textsuperscript{16,18}

**FSS**: FSS is a self-report 7-point Likert scale scored with 1 as "strongly disagree" and 7 as "strongly agree" to measure fatigue severity. The total score is the mean score of all items ranging between 1 and 7, where the higher scores indicate more severe fatigue.\textsuperscript{19} Moreover, a total score of 0-35, 36-52, and 53-63 is defined as none/mild, moderate, and severe fatigue, respectively.\textsuperscript{20} Cronbach’s alpha of the Iranian version test has been reported 0.93 in patients with neurological conditions.\textsuperscript{19} In the first report, Cronbach’s alpha was 0.89, 0.81, and 0.88 for systemic lupus erythematosus (SLE), multiple sclerosis (MS), and healthy people, respectively.\textsuperscript{21}

**HDRS**: HDRS is a 24-item test consisting of 10 items from 0 to 2 (none, mild/moderate, and severe), and 14 items from 0 to 4 (none, mild, moderate, severe, and very severe). Higher scores are equal to more severe symptoms. A total score is categorized into 4 classes including no depression (0-7), mild depression (8-17), moderate depression (18-24), and severe depression (25 and more).\textsuperscript{22} The reliability of the test has been reported 0.89 in the Iranian population.\textsuperscript{23} Retest reliability for the HDRS has been indicated in a range from 0.81 to 0.98.\textsuperscript{24}

**HAM-A**: HAM-A is a 14-item test with a 5-point Likert scale (0-4) that should be administered by a professional clinician. This questionnaire evaluates the severity of anxiety symptoms, where a higher score represents more severity of a patient's anxiety. A total score range of 0-56 is categorized as mild (\leq 17), mild to moderate (18-24), moderate to severe (25-30), and very severe (\geq 30).\textsuperscript{25} Inter-rater reliability has been reported as an intraclass correlation coefficient (ICC) of 0.74-0.96.\textsuperscript{26} The reliability of the survey has been reported to be 0.81 in Iran.\textsuperscript{27}

Depending on the assessment of the normality test, the normally-distributed continuous variables were examined using an independent samples t-test, and the Mann-Whitney U test was used to compare non-normally-distributed variables between the two groups. The categorical variables were compared appropriately with the chi-square test or Fisher’s exact test. Correlations between variables were tested using the Pearson correlation test for normally-distributed variables and the Spearman correlation test for non-normally-distributed variables. Odds ratios (ORs) and 95\% CIs were calculated for the measured risk factors. Multivariate logistic regression (LR) was applied to identify the variables with the independent association with the disease risk. The backward LR model was implemented to select variables for multivariable investigation.

Data were analyzed using SPSS software (version 16, SPSS Inc., Chicago, IL, USA), and the P-value less than 0.05 was considered significant.

**Results**

Demographic characteristics of the study population have been summarized in table 1. The mean age of MMT cases was 42.08 ± 12.44 years, and participants were in the age range of 19 and 86 years. Subjects included 121 (81.2\%) men (mean age: 42.62 ± 11.84 years) and 28 (18.8\%) women (mean age: 38.50 ± 13.90 years). Evaluation of occupation and education indicated that 49 (32.7\%) individuals were unemployed, and 90.7\% had non-academic degrees or were illiterate. 17.2\% of cases consisted of people with a history of divorce and leaving or death of their spouse. The distribution of mental disorders, chronic disorders, and allergies were 11 (7.5\%), 18 (12.3\%), and 6 (4.0\%) in subjects, respectively.

Considering the psychiatric characteristics reported in table 2, the rates of moderate/severe depression and anxiety were 14.6\% and 46.1\%, respectively. Based on the STOP-BANG test score, a high risk of apnea was observed in 62.5\% of participants. Furthermore, 42.5\% of subjects suffered from fatigue, and 14.5\% indicated daily sleepiness problems.
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Comparing demographic and psychiatric data between low and high-risk groups of apnea revealed the relationship between age (P < 0.001, OR = 1.08, 95% CI: 1.04-1.12), sex (P = 0.002, OR = 3.78, 95% CI: 1.69-8.96), and daily sleepiness (P = 0.014, OR = 1.11, 95% CI: 1.02-1.20) with the rate of risk. The mean of moderate/severe sleepiness was significantly higher in the high-risk apnea group (6.38 ± 5.28) than the low-risk one (4.28 ± 4.04). The difference was also observed in sex after adjustment for age, and in ESS after adjustment for age and sex (P = 0.048, OR = 1.10, 95% CI: 1.00-1.20). There was no association between other considered features and apnea risk categories. Results have been indicated in table 3.

### Table 1. Baseline characteristics of the subjects of methadone maintenance therapy (MMT) program

| Characteristics                | Value                  |
|--------------------------------|------------------------|
| Age (year)                     | 42.08 ± 12.44          |
| Age of first use (year)        | 23.21 ± 7.16           |
| Usage duration (year)          | 18.44 ± 11.02          |
| Sex                            |                        |
|      Men                       | 121 (81.2)             |
|      Women                     | 28 (18.8)              |
| Marital status                 |                        |
|      Single                    | 18 (11.9)              |
|      Married                   | 107 (70.9)             |
|      Leaving/divorced          | 22 (14.6)              |
|      Widow                     | 4 (2.6)                |
| Residence                      |                        |
|      Homeowner                 | 81 (54.0)              |
|      Tenant                    | 66 (44.0)              |
|      Homeless                  | 3 (2.0)                |
| Occupation                     |                        |
|      Unemployed                | 49 (32.7)              |
|      Employed                  | 101 (67.3)             |
| Education                      |                        |
|      Illiterate                | 6 (4.0)                |
|      Non-academic              | 131 (86.7)             |
|      Academic                  | 14 (9.3)               |
| History of imprisonment        |                        |
|      No                        | 123 (83.1)             |
|      Yes                       | 25 (16.9)              |
| History of mental disorders    |                        |
|      No                        | 136 (92.5)             |
|      Yes                       | 11 (7.5)               |
| History of chronic disorders   |                        |
|      No                        | 128 (87.7)             |
|      Yes                       | 18 (12.3)              |
| History of medical allergy     |                        |
|      No                        | 144 (96.0)             |
|      Yes                       | 6 (4.0)                |

Data are presented as mean ± standard deviation (SD) or number and percentage

Analysis of STOP-BANG score in relation to the age, duration of use of a substance, and different psychiatric scores revealed a moderate positive correlation between apnea risk and anxiety (r = 0.659, P < 0.001). Other factors were correlated with the mentioned score in lower levels. Results have been indicated in table 4.

Based on multivariate linear regression data reported in table 5, the regression model predicted 33.5% of apnea score variances. Furthermore, age (P < 0.001) and fatigue (P = 0.007) were factors that significantly expected the rate of apnea risk. Results indicated that a one-unit increase in age and fatigue caused the rise of STOP-BANG score by 42.0% and 23.4%, respectively.

### Discussion

As well as decreasing QOL and increasing the relapse rate, there is some evidence reporting the higher frequency of respiratory disorders during sleep in substance-dependent patients. Therefore, we conducted the present study to assess the apnea prevalence in substance-dependent patients treated with MMT. Based on our findings, 62.5% of subjects were at a high risk of apnea, with the STOP-BANG score equal to or more than 3.
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In addition to the association between age, sex, and daily sleepiness with the high risk of apnea, age and fatigue were predictor factors of the risk score. To the best of our knowledge, the present study was the first assay to evaluate the apnea prevalence in Iranian MMT subjects. Our result indicated that 62.5% of considered population were in the high-risk apnea group. A previous study has indicated the rate of apnea almost 38% in the general population of Tehran, Iran.3 Recently, a meta-analysis study also revealed that the overall prevalence of apnea in Iran was 44%. However, subgroup analysis pointed out the highest prevalence of apnea in the patients suffering from sleep disorders (74%), diabetes mellitus (DM) (61%), and cardiovascular disease (CVD) (55%).4 Our results indicated a higher prevalence of apnea in patients under MMT than in the general population. However, the prevalence is similar to the reported values in some other common health problems like in diabetic and cardiovascular patients. It has been reported that apnea causes an increased risk of death and CVD by 2.5% and 4.5%, respectively.30

**Table 3. Prevalence of different problems in low and high-risk groups of obstructive sleep apnea (OSA) in subjects of methadone maintenance therapy (MMT)**

| Problems                  | STOP-BANG ≤ 3 | STOP-BANG ≥ 3 | P     | OR (95% CI) | P     | OR (95% CI) |
|---------------------------|---------------|---------------|-------|-------------|-------|-------------|
| Age (year)                | 35.91 ± 10.01 | 45.69 ± 12.35 | < 0.001* | 1.08 (1.04-1.12) | -     | -           |
| ≤ 50                      | 50 (90.9)     | 61 (64.9)     | 0.001* | 5.41 (1.97-14.89) | -     | -           |
| > 50                      | 5 (9.1)       | 33 (35.1)     |       |             |       |             |
| Age of first use (year)   | 22.32 ± 6.20  | 23.76 ± 7.67  | 0.233 | 1.03 (0.98-1.08) | 0.410 | 0.97 (0.92-1.03) |
| Usage duration (year)     | 14.76 ± 10.07 | 20.64 ± 11.02 | 0.002* | 1.05 (1.02-1.09) | 0.698 | 1.01 (0.96-1.05) |
| Sex                       |               |               |       |             |       |             |
| Women                     | 18 (31.6)     | 10 (10.9)     | 0.002* | 3.78 (1.60-8.96) | 0.007* | 3.76 (1.44-9.83) |
| Men                       | 39 (68.4)     | 82 (89.1)     |       |             |       |             |
| Employment status         |               |               |       |             |       |             |
| Unemployed                | 19 (33.9)     | 30 (31.9)     |       |             |       |             |
| Employed                  | 37 (66.1)     | 64 (68.1)     | 0.799 | 1.09 (0.54-2.21) | 0.357 | 1.46 (0.65-3.25) |
| ESS                       | 4.28 ± 4.04   | 6.38 ± 5.28   | 0.014* | 1.11 (1.02-1.20) | 0.048* | 1.10 (1.00-1.20) |
| Normal (0-10)             | 53 (93.0)     | 77 (81.1)     | Ref.   |             |       |             |
| Moderate/severe (11-24)   | 4 (7.0)       | 18 (18.9)     | 0.052 | 3.10 (0.99-6.97) | 0.176 | 2.43 (0.67-8.76) |
| FSS                       | 30.82 ± 13.24 | 33.91 ± 12.86 | 0.165 | 1.02 (0.99-1.04) | 0.110 | 1.02 (0.99-1.06) |
| No/mild fatigue (0-35)    | 35 (62.5)     | 49 (24.4)     | Ref.   |             |       |             |
| Moderate/severe fatig(36-63)| 21 (37.5) | 31 (45.6)     | 0.339 | 1.39 (0.70-2.76) | 0.289 | 1.53 (0.70-3.37) |
| HDRS                      | 10.41 ± 8.48  | 9.85 ± 6.88   | 0.657 | 0.99 (0.95-1.03) | 0.966 | 1.00 (0.95-1.05) |
| No/mild depression (0-17) | 47 (83.9)     | 82 (86.3)     | Ref.   |             |       |             |
| Moderate/severe depression (18-52) | 9 (16.1) | 13 (13.7) | 0.688 | 0.83 (0.33-2.08) | 0.885 | 1.08 (0.38-3.08) |
| HAM-A                     | 24.25 ± 6.68  | 26.03 ± 8.32  | 0.172 | 1.03 (0.99-1.08) | 0.161 | 1.04 (0.98-1.10) |
| Mild/mild to moderate anxiety (0-24) | 33 (57.9)| 49 (51.6) | Ref.   |             |       |             |
| Moderate to severe/very severe anxiety (25-56) | 24 (42.1) | 46 (48.4) | 0.450 | 1.29 (0.67-2.50) | 0.312 | 1.49 (0.69-3.21) |

Data are presented as mean ± standard deviation (SD) or number and percentage; *Significant at the 0.05 level; **Significant at the 0.01 level; ESS: Epworth Sleepiness Scale; FSS: Fatigue Severity Scale; HAM-A: Hamilton Anxiety Rating Scale; HDSR: Hamilton Depression Rating Scale; OR: Odds ratio; CI: Confidence interval

**Table 4. Correlation between considered scores and STOP-BANG in subjects of methadone maintenance therapy (MMT)**

| Problems | Age | Age of first use | Usage duration | ESS | FSS | HRS | HAM-A |
|----------|-----|------------------|----------------|-----|-----|-----|-------|
| STOP-BANG| 0.484* | 0.172* | 0.330* | 0.272* | 0.285** | 0.464** | 0.659** |
| P       | < 0.001 | 0.036 | < 0.001 | 0.001 < 0.001 | < 0.001 | < 0.001 | < 0.001 |

*Significant at the 0.05 level; **Significant at the 0.01 level; ESS: Epworth Sleepiness Scale; FSS: Fatigue Severity Scale; HAM-A: Hamilton Anxiety Rating Scale; HDSR: Hamilton Depression Rating Scale; CC: Correlation coefficient

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Since the MMT subjects are at the risk of psychiatric disorders, facing sleep disorders and their related outcomes may lead to treatment interruption and consequently, decreasing in QOL. All of these factors together emphasize the importance of concise and more specific early assessments to diminish the impact of apnea on the mental and body health status of these patients.

On the other hand, there is some evidence highlighting the SDB induced by methadone or buprenorphine when using replacement therapy. This report can illustrate the higher rate of the disease in MMT subjects. Therefore, screening substance-dependent patients regarding respiratory sleep disorders can be an essential part of the treatment procedure.

As with other findings in this study, anxiety was the main factor correlated with the apnea risk in methadone-treated patients. Daily sleepiness indicated higher frequency in the high-risk group of apnea, and fatigue had a significant role in predicting risk score. As a direct correlation between increasing methadone dosage and anxiety score has been indicated, a higher frequency of anxiety has also been reported in apnea patients than in the general population regardless of gender. Another report has indicated the association of anxiety with poor sleep quality and high Pittsburgh Sleep Quality Index (PSQI) scores. Furthermore, daily sleepiness has been observed as a result of different sleep disorders. Fatigue has also been identified as a related item with apnea. These symptoms can be similar between apnea and substance use, MMT, and withdrawal syndrome. Therefore, differential diagnosis using complementary tests like Holter monitoring and then polysomnography (PSG) is required. Subsequently, the line of therapy is specified to the treatment of these symptoms as consequences of sleep disorders and/or MMT and withdrawal.

There were some limitations in this study. The risk of apnea was evaluated based on the STOP-BANG test that the age of more than 50 and sex are the main factors for the risk score calculation. Due to the small number of samples, there was not enough sample in sex and age subgroups. Therefore, this is necessary to continue studying with enough samples in each category to remove or diminish the confounders’ impact. Furthermore, many subjects were multidrug users, and the rate of their effect on the psychophysiological situation of the body may be diverse. Therefore, the homogenous samples produce refined results.

**Conclusion**

Based on our findings in this study, apnea has a high prevalence in patients under MMT compared with the general population. Since sleep disturbance has been identified as a factor addressing relapse in substance-dependent patients, it can be a severe challenge in the withdrawal process. Therefore, it is suggested that patients be routinely screened, and physicians employ treatment procedures to decrease the side effects of the disease in this group and diminish the risk of relapse. Besides, PSG can be used as the gold standard of sleep apnea diagnosis to confirm these findings. Moreover, further studies should be conducted to identify the mechanisms and pathways underlying respiratory disorders during
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sleep in MMT subjects and describe the reasons for the high prevalence.

Conflict of Interests

The Authors have no conflict of interest.

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Authors’ Contribution

Design the research: AT, FA, SN and RN. Data collection: AT and RN. Statistical analysis: FA and SN. Manuscript draft: FA and AT. All authors helped edit and approve the final version of this manuscript for submission. They also participated in the finalization of manuscript and approved the final draft.

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چکیده

مقدمه: اخلاق‌های تنفسی در هنگام خواب، یک مشکل سلیمانی مؤثر که شیوع زندگی محل می‌شود. برخی شواهد نشان‌گذار شیوع بالاتر آن‌ها در بیماران واژنی به‌واسطه داشته با آن‌ها در بیمارستان‌ها و آکادمی‌های سلامت و اتاق‌های درمانی نگهدارنده مبتلا به افراد، دارای ارزش معنی‌داری دارند. این تحقیق با هدف ارزیابی خطر آپنه‌های نباید از شیوع بالاتر راه‌اندازی در افراد تحت درمان نگهدارنده متادون در این مورد را بررسی کرده و از افراش خطر آپنه با برخی از مشکلات روشنی‌پذیری طراحی شد.

روش‌ها: گروه مطالعه شامل ۱۵۵ نفر تحت درمان نگهدارنده متادون بود. داده‌های اولیه به کمک مصاحبه جمع‌آوری گردید و بیماران با استفاده از Epworth Sleepiness Scale (ESS) Epworth Sleepiness Scale به معنی داری در متغیر جنسیت (P = ۰/۴) و خواب آلودگی در طول روز (P = ۰/۰۴) بین گروه‌های کم خطر و برخی از افراد پس از تعیین برای STOP-BANG شاخص سن و جنسیت مشاهده شد. تفاوت

توصیه‌گری: نتایج به‌دست آمده، شیوع بالای این‌ها در بیماران تحت درمان نگهدارنده متادون را نشان می‌دهد. با این حال، باید به اخلاق‌های تنفسی در افراد تحت درمان نگهدارنده متادون توجه کنید. اشتباهات در تحقیقات این‌ها در رابطه با موارد مشابهی ممکن است که با باید به عنوان یک مسئله درمانی در نظر گرفته شود.

واژگان کلیدی: اخلاق‌های تنفسی؛ آپنه؛ درمان جایگزین داروهای افیونی; اختلالات مرتبط با مواد

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