

Sleep Quality and Insomnia in Patients with Alcohol Dependence: Association with Severity of Alcohol Dependence



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Abstract

Background: Sleep disturbances are common in patients with alcohol dependence and may be associated with the severity of alcohol dependence. Previous studies have reported substantial sleep disturbance and insomnia in alcohol-dependent populations.¹⁻³ This study aimed to assess sleep quality and insomnia in patients with alcohol dependence and examine their association with severity of alcohol dependence.

Methods: A cross-sectional study was conducted over a period of 1.5 years in the Department of Psychiatry, Victoria Hospital, Bangalore Medical College and Research Institute. Patients aged 18–65 years diagnosed with alcohol dependence syndrome according to ICD-10 were included. Patients with other substance use disorders except nicotine dependence, psychiatric or medical conditions likely to affect sleep, delirium, significant recent withdrawal, or use of medications affecting sleep were excluded. Severity of alcohol dependence was assessed using the Severity of Alcohol Dependence Questionnaire,⁴ sleep quality using the Pittsburgh Sleep Quality Index,⁵ and insomnia severity using the Insomnia Severity Index.⁶ Associations were assessed using Spearman correlation and chi-square tests.

Results: A total of 62 patients were included. The mean age was 42.87±9.89 years, and 61 (98.4%) were males. The mean SADQ score was 21.44±10.79, with mild, moderate and severe dependence observed in 41.94%, 35.48% and 22.58% of participants, respectively. The mean PSQI score was 5.97±3.55, with poor sleep quality (PSQI ≥5) present in 58.06% of participants. The mean ISI score was 10.00±6.13, and 59.68% had clinically significant insomnia (ISI ≥8). SADQ score showed a significant positive correlation with PSQI score ($\rho=0.394$, $p=0.002$) and ISI score ($\rho=0.426$, $p=0.001$). Severity of alcohol dependence was also significantly associated with PSQI category ($p=0.005$) and ISI category ($p=0.027$).

Conclusion: Poor sleep quality and clinically significant insomnia were common among patients with alcohol dependence. Greater severity of alcohol dependence was significantly associated with poorer sleep quality and greater insomnia severity. Routine assessment of sleep quality and insomnia may therefore be useful in the comprehensive clinical evaluation of patients with alcohol dependence.

Keywords: Alcohol dependence; sleep quality; insomnia; Pittsburgh Sleep Quality Index; Insomnia Severity Index; Severity of Alcohol Dependence Questionnaire.

Introduction

Alcohol use is an important public health concern because of its associated medical, social and economic consequences. In India, alcohol is one of the commonly used psychoactive substances. The National Survey on Extent and Pattern of Substance Use in India reported that about 5.2% of Indians were estimated to have harmful or dependent alcohol use.^{7,8} Repeated alcohol use can lead to alcohol dependence. Alcohol dependence syndrome is a cluster of behavioural, cognitive and physiological symptoms that may develop after repeated alcohol use. It typically includes a strong desire to consume alcohol, impaired control over its use, persistent drinking despite harmful consequences, increased priority given to drinking over other activities and obligations, increased alcohol

tolerance and a physical withdrawal reaction when alcohol use is discontinued.⁹ Alcohol misuse is associated with several social and psychological consequences and is also associated with substantial medical morbidity. Individuals with alcohol dependence are more likely to experience psychiatric disorders such as depression and anxiety, in addition to various alcohol-related medical complications.^{10,11} Sleep is an important phenomenon affected by alcohol use. It is generally assumed that alcohol improves sleep in users. Acute alcohol intoxication generally decreases sleep latency; however, with chronic use, changes in sleep regulation can occur. Long-term alcohol use is associated with decreased rapid eye movement sleep and deep sleep, increased sleep

fragmentation and longer episodes of awakening.¹²⁻¹⁴ Sleep disturbance may therefore become an important clinical problem among individuals with alcohol dependence. Alcohol users are also at risk of developing sleep disorders such as parasomnias and sleep-related movement disorders. Parasomnias are disorders of partial arousal and include non-rapid eye movement-related parasomnias such as confusional arousals, sleepwalking, sleep terrors and sleep-related eating disorder, as well as rapid eye movement-related parasomnias such as nightmare disorder and other REM-related phenomena.^{15,16} There are relatively few studies examining the association between alcohol dependence and sleep disturbance, and studies from India are scarce. Most previous studies have been conducted in Western populations, and many included patients with co-morbid psychiatric disorders that could independently affect sleep. The present study therefore aimed to assess sleep quality and insomnia among patients with alcohol dependence and to examine the relationship between severity of alcohol dependence and sleep disturbance. The study also evaluated selected sociodemographic and clinical variables that may influence sleep quality.

Objectives

1. To assess sleep quality and insomnia in patients with alcohol dependence syndrome.
2. To assess the association between severity of alcohol dependence and sleep quality and
3. insomnia.
4. To evaluate selected sociodemographic and clinical determinants of sleep quality.

Materials and Methods

Study design and setting

This was a cross-sectional study conducted over a period of 1.5 years in the Department of Psychiatry, Victoria Hospital, Bangalore Medical College and Research Institute (BMCRI), Bengaluru.

Study population

The study included patients attending the Psychiatry outpatient department and patients admitted to the Psychiatry ward of Victoria Hospital, BMCRI, with a diagnosis of alcohol dependence syndrome according to ICD-10 criteria.

Inclusion criteria

1. Age between 18 and 65 years.
2. Diagnosis of alcohol dependence syndrome according to ICD-10 criteria.
3. Active use of alcohol at the time of assessment.
4. Willingness to participate and provision of written informed consent.

Exclusion criteria

1. Were unwilling to provide informed consent.
2. Had substance use other than alcohol dependence syndrome, except nicotine dependence.

3. Had psychiatric disorders causing sleep disturbance.
4. Had medical comorbidities likely to cause sleep disturbance.
5. Had neurological disorders such as Parkinson's disease, other neurodegenerative disorders,
6. multiple sclerosis, stroke, epilepsy or CNS tumours.
7. Had major organic illnesses such as congestive heart failure, chronic renal failure, liver failure or malignancy.
8. Had primary central nervous system hypersomnia such as narcolepsy or Kleine-Levin
9. syndrome.
10. Were receiving psychotropic medications likely to affect sleep, including sedatives,
11. antidepressants, antipsychotics or antiepileptic medications.
12. Were currently experiencing delirium.
13. Had experienced alcohol-withdrawal features lasting more than 2 days during the preceding month.

Sample size

The calculated sample size according to the study protocol was 75 participants. However, because of difficulties in recruitment during the COVID-19 pandemic, 62 participants were ultimately recruited.

Study procedure

After obtaining approval and clearance from the Institutional Ethics Committee, Bangalore Medical College & Research Institute, participants fulfilling the inclusion criteria were recruited after obtaining written informed consent.

Sociodemographic and relevant clinical information was collected using a semi-structured proforma. A psychiatric assessment was performed using the Mini International

Neuropsychiatric Interview (MINI) for screening of psychiatric diagnoses.¹⁸

The severity of alcohol dependence was assessed using the Severity of Alcohol Dependence

Questionnaire (SADQ).⁴ Nicotine dependence was assessed using the Fagerström Test for

Nicotine Dependence (FTND).¹⁷ Sleep quality was assessed using the Pittsburgh Sleep Quality Index (PSQI)⁵ and insomnia severity using the Insomnia Severity Index (ISI).⁶

Study instruments

Severity of Alcohol Dependence Questionnaire (SADQ): The SADQ was used to assess the severity of alcohol dependence.⁴

Pittsburgh Sleep Quality Index (PSQI): The PSQI was used to assess subjective sleep quality over the preceding one month. A global PSQI score of ≥ 5 was considered indicative of poor sleep quality.⁵

Insomnia Severity Index (ISI): The ISI was used to assess the severity of insomnia symptoms over the preceding two weeks.⁶

Fagerström Test for Nicotine Dependence (FTND): The FTND was used to assess the severity of nicotine dependence among participants with comorbid nicotine use.¹⁷

Ethical considerations

The study was approved by the Institutional Ethics Committee, Bangalore Medical College & Research Institute (BMCRI), under approval number BMCRI/PG/352/2019-20, dated 19 November 2019. Written informed consent was obtained from all participants.

Statistical analysis

Data were entered and analyzed using SPSS version 20. Descriptive statistics were used to summarize sociodemographic and clinical variables and the PSQI, ISI, SADQ and FTND scores. Continuous variables were expressed as mean and standard deviation, while categorical variables were expressed as frequencies and percentages. Spearman's rank correlation was

used to assess the relationship between severity of alcohol dependence and sleep-related scores. Chi-square test was used to assess associations between categorical variables. A p value ≤ 0.05 was considered statistically significant.

Results

A total of 62 patients with alcohol dependence syndrome were included in the study. The results are presented under sociodemographic and clinical characteristics, sleep quality, insomnia, and the association between severity of alcohol dependence and sleep outcomes.

Sociodemographic and clinical characteristics

The mean age of the participants was 42.87 ± 9.89 years (range, 25–62 years), with a median age of 42 years. The majority of participants were male (61, 98.4%), married (46, 74.2%), and from urban areas (43, 69.4%). Most participants were Hindu (59, 95.2%). The mean duration of formal education was 9.50 ± 3.93 years and the mean monthly family income was $\text{₹}19,935.48 \pm 8,984.26$. The mean SADQ score was 21.44 ± 10.79 and the mean FTND score was 1.89 ± 2.46 .

Table 1. Sociodemographic and clinical characteristics of study participants

Variable	n (%) / Mean $\pm$ SD	Range
Age, years	42.87 ± 9.89	25–62
Years of education	9.50 ± 3.93	0–15
Monthly family income, ₹	$19,935.48 \pm 8,984.26$	4,000–40,000
SADQ score	21.44 ± 10.79	8–47
FTND score	1.89 ± 2.46	0–9
Sex: Male	61 (98.4%)	
Sex: Female	1 (1.6%)	
Marital status: Single	12 (19.4%)	
Marital status: Married	46 (74.2%)	
Marital status: Separated	2 (3.2%)	
Marital status: Divorced	2 (3.2%)	
Locality: Urban	43 (69.4%)	
Locality: Rural	19 (30.6%)	
Religion: Hindu	59 (95.2%)	
Religion: Muslim	2 (3.2%)	
Religion: Christian	1 (1.6%)	
Occupation: Unemployed	3 (4.8%)	
Occupation: Farmer	8 (12.9%)	
Occupation: Unskilled	9 (14.5%)	
Occupation: Semi-skilled	3 (4.8%)	
Occupation: Skilled	15 (24.2%)	
Occupation: Clerical	2 (3.2%)	
Occupation: Professional	21 (33.9%)	
Occupation: Business	1 (1.6%)	
SADQ: Mild dependence	26 (41.94%)	
SADQ: Moderate dependence	22 (35.48%)	
SADQ: Severe dependence	14 (22.58%)	
FTND: No dependence	32 (51.61%)	
FTND: Low dependence	9 (14.52%)	
FTND: Low-to-moderate dependence	10 (16.13%)	

FTND: Moderate dependence	10 (16.13%)	
FTND: High dependence	1 (1.61%)	

Sleep quality

The mean global PSQI score was 5.97 ± 3.55 (range, 0–15). Twenty-six participants (41.94%) were categorized as having good sleep quality and 36 (58.06%) as having poor sleep quality according to the categories reported in the study.

Among the individual PSQI components, 45.2% of participants rated their subjective sleep quality as fairly bad. Sleep latency was scored as 0 in 59.7% of participants. Sleep duration was less than 7 hours in 75.8% of participants. Habitual sleep efficiency was below 85% in 51.6%. Most participants (88.7%) had a score of 1 for sleep disturbances. Sleeping medication had not been used during the preceding month by 93.6% of participants. Some degree of daytime dysfunction was present in 62.9% of participants.

Table 2. Distribution of PSQI components among study participants

PSQI component	Category	n (%)
Global PSQI category	Good sleep quality	26 (41.94%)
	Poor sleep quality	36 (58.06%)
Subjective sleep quality	Very good	14 (22.6%)
	Fairly good	20 (32.3%)
	Fairly bad	28 (45.2%)
	Very bad	0
Sleep latency	Score 0	37 (59.7%)
	Score 1	14 (22.6%)
	Score 2	5 (8.1%)
	Score 3	6 (9.7%)
Sleep duration	>7 hours	15 (24.2%)
	6–7 hours	23 (37.1%)
	5–6 hours	19 (30.6%)
	<5 hours	5 (8.1%)
Habitual sleep efficiency	>85%	30 (48.4%)
	75–84%	16 (25.8%)
	65–74%	12 (19.4%)
	<65%	4 (6.5%)
Sleep disturbances	Score 0	4 (6.5%)
	Score 1	55 (88.7%)
	Score 2	3 (4.8%)
	Score 3	0
Sleeping medication	Not during past month	58 (93.6%)
	<1 time/week	3 (4.8%)
	1–2 times/week	1 (1.6%)
	>3 times/week	0
Daytime dysfunction	Score 0	23 (37.1%)
	Score 1	24 (38.7%)
	Score 2	11 (17.7%)
	Score 3	4 (6.5%)

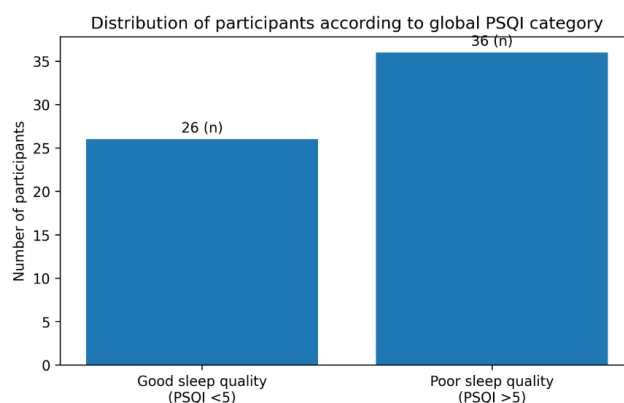


Figure 1. Distribution of participants according to global PSQI category

Insomnia

The mean ISI score was 10.005 ± 6.139 (range, 0–22). Twenty-five participants (40.32%) had no clinically significant insomnia, 17 (27.42%) had subthreshold insomnia, 19 (30.65%) had clinical insomnia of moderate severity, and 1 (1.61%) had severe clinical insomnia.

Difficulty staying asleep was common, with 87.10% of participants reporting at least mild difficulty. Some degree of early-morning awakening was reported by 58.06% of participants.

Forty percent were dissatisfied with their current sleep pattern, while 4.8% were very dissatisfied.

Sleep problems were reported as being noticeable to others to some degree in 66.13% of participants. Some degree of worry or distress about the current sleep problem was reported by 69.35% of participants, and some degree of interference with daily functioning was reported by 70.97%.

Table 3. Distribution of ISI categories and individual insomnia symptoms

ISI component	Category	n (%)
ISI category	No clinically significant insomnia	25 (40.32%)
	Subthreshold insomnia	17 (27.42%)
	Clinical insomnia (moderate severity)	19 (30.65%)
	Clinical insomnia (severe)	1 (1.61%)
Difficulty falling asleep	None	40 (64.51%)
	Mild	10 (16.12%)
	Moderate	4 (6.46%)
	Severe	6 (9.68%)
	Very severe	2 (3.23%)
Difficulty staying asleep	None	8 (12.90%)
	Mild	23 (37.10%)
	Moderate	19 (30.65%)
	Severe	11 (17.74%)
	Very severe	1 (1.61%)
Problem waking too early	None	26 (41.94%)
	Mild	11 (17.73%)
	Moderate	13 (20.97%)
	Severe	8 (12.90%)
	Very severe	4 (6.46%)
Satisfaction with sleep pattern	Very satisfied	2 (3.23%)
	Satisfied	23 (37.10%)
	Moderately satisfied	9 (14.52%)
	Dissatisfied	25 (40.32%)
	Very dissatisfied	3 (4.8%)
Sleep problem noticeable to others	Not at all noticeable	21 (33.87%)
	A little	11 (17.74%)
	Somewhat	17 (27.42%)
	Much	12 (19.35%)

	Very much	1 (1.61%)
Worried/distressed about sleep problem	Not at all	19 (30.65%)
	A little	10 (16.12%)
	Somewhat	13 (20.97%)
	Much	18 (29.03%)
	Very much	2 (3.23%)
Interference with daily functioning	Not at all	18 (29.03%)
	A little	11 (17.74%)
	Somewhat	18 (29.03%)
	Much	14 (22.58%)
	Very much	1 (1.61%)

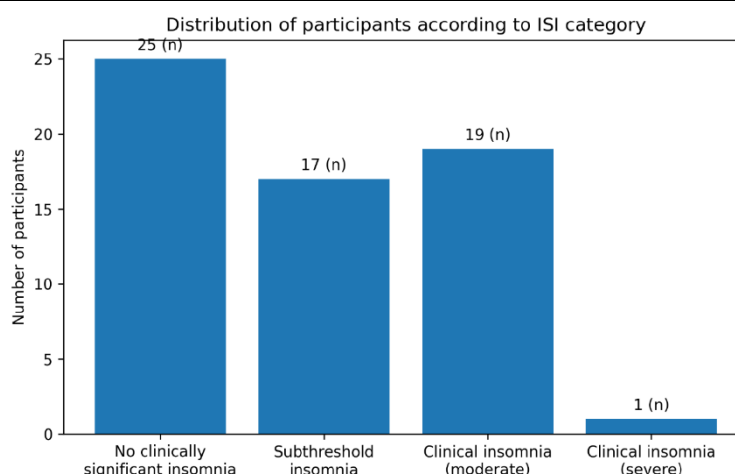


Figure 2. Distribution of participants according to ISI category

Association between severity of alcohol dependence and sleep outcomes

There was a statistically significant positive correlation between SADQ score and global PSQI score (Spearman's $\rho=0.394$, $p=0.002$), indicating that greater severity of alcohol dependence was associated with poorer sleep quality. Similarly, SADQ score showed a statistically significant positive correlation with ISI score ($\rho=0.426$, $p=0.001$). When severity of alcohol dependence was analyzed categorically, there was a statistically significant association between SADQ category and PSQI category ($p=0.005$). A statistically significant association was also observed between SADQ category and ISI category ($p=0.027$).

Table 4. Association between severity of alcohol dependence and sleep outcomes

Analysis	Test	Statistic	p value
SADQ score vs Global PSQI score	Spearman's rho	0.394	0.002
SADQ score vs ISI score	Spearman's rho	0.426	0.001
SADQ category vs PSQI category	Chi-square	—	0.005
SADQ category vs ISI category	Chi-square	—	0.027

Sociodemographic and clinical determinants of sleep outcomes

Age was not significantly correlated with PSQI score ($\rho=0.199$, $p=0.121$) or ISI score ($\rho=0.085$, $p=0.512$). Marital status was not significantly associated with PSQI ($p=0.312$) or ISI ($p=0.320$). Locality was significantly associated with PSQI category ($p=0.040$), with poorer sleep quality reported among rural participants; however, locality was not significantly associated with ISI category ($p=0.110$). Religion and occupational status were not significantly associated with PSQI or ISI scores. Total monthly family income was not significantly correlated with PSQI score ($\rho=0.057$, $p=0.662$) or ISI

score ($\rho=0.098$, $p=0.446$). Years of education were not significantly correlated with PSQI ($\rho=0.168$, $p=0.192$) or ISI ($\rho=0.247$, $p=0.053$). FTND category was not significantly associated with PSQI ($p=0.557$) or ISI ($p=0.229$).

Note: Table and figure numbering in this manuscript has been consolidated from the original thesis tables/figures. The numerical results above are derived from the study document.

Discussion

The present study evaluated sleep quality and insomnia among patients with alcohol dependence and examined their association with the severity of

alcohol dependence. In this study of 62 patients, poor sleep quality was observed in 58.06% of participants and clinically significant insomnia in 59.68%. Importantly, severity of alcohol dependence showed a significant positive correlation with both global PSQI score and ISI score, indicating that greater severity of alcohol dependence was associated with poorer sleep quality and greater insomnia severity. Sleep quality in alcohol dependence The mean PSQI score in our study was 5.97 ± 3.55 , with 58.06% of participants having poor sleep quality. This finding is consistent with previous studies demonstrating a high prevalence of sleep disturbance among individuals with alcohol dependence. Hartwell et al. reported a mean PSQI score of 7.4 ± 3.3 , with 76% of participants having poor sleep quality.¹ The lower PSQI score and prevalence observed in our study may be related to differences in sample characteristics and recruitment. The present study included patients attending both outpatient and inpatient services, whereas Hartwell et al. studied problem drinkers recruited from the community. In addition, our study excluded psychiatric and medical conditions likely to affect sleep.

Wallen et al. reported a substantially higher mean PSQI score of 10.91 ± 4.14 and sleep disturbance in 90.4% of alcohol-dependent patients admitted for treatment.² Their sample consisted exclusively of inpatients and had substantial psychiatric comorbidity, with mood disorders and anxiety disorders being common. In comparison, the majority of participants in our study were outpatients, and patients with psychiatric comorbidities likely to affect sleep were excluded. These differences may partly explain the lower prevalence and severity of sleep disturbance observed in our sample.

The individual components of the PSQI also demonstrated clinically relevant sleep disturbances. Sleep duration was less than seven hours in 75.8% of participants, while 51.6% had sleep efficiency below 85%. Some degree of daytime dysfunction was present in 62.9% of participants. These findings are broadly consistent with previous studies reporting reduced sleep duration and disturbed sleep among patients with alcohol dependence.^{1,2}

Interestingly, difficulty initiating sleep was less prominent in our sample, with 59.7% reporting no difficulty falling asleep. In contrast, sleep-maintenance difficulties and early-morning awakening were more frequent. Alcohol may initially reduce sleep latency, whereas chronic alcohol use is associated with disruption of sleep continuity and sleep architecture.^{12,13} This may explain why patients can perceive alcohol as facilitating sleep initiation despite experiencing disturbed sleep later in the night.

Insomnia in alcohol dependence

The mean ISI score in our study was 10.01 ± 6.14 . Clinically significant insomnia was present in 59.68% of participants, with 27.42% having subthreshold

insomnia, 30.65% moderate clinical insomnia and 1.61% severe clinical insomnia.

Our findings are comparable with those reported by Chaudhary et al., who found a higher prevalence of insomnia among alcohol-dependent subjects, with a mean ISI score of 13.02 ± 7.21 .³ The somewhat lower prevalence and mean ISI score in our study may be related to differences in sample characteristics, including the predominantly moderate severity of alcohol dependence and exclusion of psychiatric comorbidities likely to influence sleep.

The pattern of insomnia in our study was characterized predominantly by difficulty maintaining sleep and early-morning awakening rather than difficulty initiating sleep. Approximately 87% of participants reported some degree of difficulty staying asleep, while 58% reported some degree of waking too early. Nearly half of the participants were dissatisfied with their current sleep pattern, and approximately two-thirds reported some impairment in quality of life related to their sleep problem.

These findings suggest that insomnia in alcohol dependence should not be assessed solely in terms of sleep initiation. Assessment of sleep maintenance, early awakening and daytime consequences may provide a more complete understanding of the sleep disturbance experienced by these patients.

Association between severity of alcohol dependence and sleep disturbance

The principal finding of the study was the significant association between severity of alcohol dependence and both sleep quality and insomnia. SADQ score showed a moderate positive correlation with global PSQI score ($\rho=0.394$, $p=0.002$). There was also a moderate positive correlation between SADQ score and ISI score ($\rho=0.426$, $p=0.001$). Categorical analysis similarly demonstrated significant associations between SADQ category and PSQI category ($p=0.005$) and between SADQ category and ISI category ($p=0.027$).

The finding regarding PSQI is consistent with the study by Hartwell et al., in which alcohol problem severity was associated with poorer global sleep quality.¹ The present study specifically used the SADQ as a measure of alcohol-dependence severity and demonstrated that increasing SADQ scores were associated with increasing PSQI scores.

Similarly, Chaudhary et al. reported an association between insomnia severity and greater psychosocial problem severity among alcohol-dependent subjects.³ The findings of the present study further demonstrate a significant relationship between the severity of alcohol dependence and insomnia severity as measured by the ISI.

The relationship between alcohol-dependence severity and sleep disturbance may have several possible explanations. Chronic alcohol exposure can produce neuroadaptive changes involving GABAergic neurotransmission, which may contribute to alterations in sleep architecture and sleep continuity.¹⁹ However, these mechanisms should be considered as possible explanations rather than direct findings of the present study, as objective sleep architecture and neurobiological parameters were not assessed.

Sociodemographic and clinical determinants

Most sociodemographic variables were not significantly associated with sleep quality or insomnia. Education and occupational status showed no significant association with sleep quality, consistent with findings reported by Hartwell et al.¹ Unlike some previous findings, our study did not demonstrate a significant correlation between age and either PSQI or ISI. This difference may be related to differences in sample characteristics and the relatively small sample size.

An association was observed between locality and sleep quality, with participants from rural areas having poorer sleep quality than those from urban areas. Similar findings have been reported by Tang et al., who found higher PSQI scores and a greater prevalence of insomnia among rural residents compared with urban residents.²⁰ However, this finding should be interpreted cautiously because of the relatively small sample size and the single-centre nature of our study. Nicotine dependence was not significantly associated with either PSQI or ISI in our study. The relatively low mean FTND score may partly explain the absence of a significant association.

Clinical implications

1. Sleep quality and insomnia should be routinely assessed in patients with alcohol dependence.
2. Patients with greater severity of alcohol dependence may require particular attention to sleep disturbances.
3. Early identification of sleep problems may facilitate appropriate clinical management.
4. Sleep assessment may be incorporated into the comprehensive evaluation of patients with alcohol dependence.
5. Strengths
7. 1. Use of standardized assessment tools.
8. Defined inclusion and exclusion criteria.
9. Assessment of both sleep quality and insomnia.
10. Assessment of dimensional severity of alcohol dependence.
11. Evaluation of potential sociodemographic and clinical determinants.
12. Limitations
13. 1. Small sample size (n=62).
14. 2. Cross-sectional study design.

15. Single-centre study.
16. Subjective assessment of sleep.
17. Alcohol quantity and duration of use were not assessed in detail.
18. Possible recall and interviewer bias.
19. Objective sleep measures such as polysomnography were not performed.
20. Potential confounding factors were not comprehensively assessed.
21. Longitudinal outcomes and relapse were not assessed.

Future directions

1. Larger multicentre studies are required to confirm these findings.
2. Longitudinal studies should examine changes in sleep with abstinence and relapse.
3. Objective sleep assessment using polysomnography or actigraphy may provide additional information.
4. Future studies should examine the effects of alcohol quantity, duration of use and withdrawal on sleep.
5. Intervention studies are needed to determine whether treatment of sleep disturbances improves alcohol-use outcomes.

Ethical approval

The study was approved by the Institutional Ethics Committee, Bangalore Medical College & Research Institute (BMCRI), approval number BMCRI/PG/352/2019-20, dated 19 November 2019. Written informed consent was obtained from all participants.

Conflict of interest The authors declare no conflicts of interest.

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