

Multipronged Treatment of Insomnia – Outcomes from an Apex Sleep Disorders Clinic in India

Shivani Poornima, Garima Shukla, Anupama Gupta, Afsar Mohammed, Priya Agarwal

Department of Neurology, All India Institute of Medical Sciences, New Delhi, India

Abstract

Introduction: A large proportion of the population suffers from disturbed sleep and a majority of these present to clinicians with the complaint of insomnia. Many of these people possibly suffer from other primary sleep disorders such as sleep apnea; however, insomnia disorder also remains an extremely common condition directly impacting the quality of life and work efficiency of affected people. While a number of approaches are used for treatment by many clinicians, a much smaller percentage can seek help from specialty sleep clinics. Since very little data are available regarding the effectiveness of treatment offered, this retrospective study aims at examining the outcome of chronic insomnia patients attending to a quaternary care specialty sleep center. **Methods:** Consecutive patients with the presenting complaint of and diagnosis of insomnia, during a study period of 2 years between 2013 and 2015, were identified and analyzed. Patients were classified based on the comorbidity and types of treatment received. Life stressors were also identified and analyzed. Outcomes were reviewed for those who had follow-up data available. **Results:** Based on the defined inclusion criteria, 102 patients could be analyzed. Among these, at least 3-month follow-up was available for 48 patients. It was observed that among patients for whom at least 3-month follow-up was available, 91.4% (43/48) showed a good response to treatment with physician-administered cognitive behavioral therapy for insomnia along with treatment for comorbid conditions. **Conclusion:** With correct diagnostic classification, as well as appropriate and easily available treatment strategies, excellent treatment outcomes are observed at specialty sleep clinics.

Keywords: Cognitive behavioral therapy, insomnia, treatment

INTRODUCTION

Since most pharmacological agents used for insomnia treatment are associated with problems of tolerance, dependence, and adverse effects, cognitive behavioral therapy for insomnia (CBT-I) has been evaluated and proven to be the first-line treatment for most patients with insomnia, either primary^[1] or comorbid to various conditions.^[2] At the same time, pharmacotherapy used carefully complements CBT-I and targeted pharmacotherapy can be extremely useful, especially in patients with insomnia comorbid with psychiatric disorders.^[3]

Meta-analyses have shown the sustained positive effect of CBT-I in most patients of not only primary insomnia^[4] but also insomnia comorbid with various psychiatric and medical conditions.^[5]

At the same time, various methods for administering CBT-I have been evaluated over the last decade or more, for maximizing outreach to most people suffering from insomnia. These have included group CBT-I and Internet-based CBT-I administration.^[6] These approaches were devised to address the problem of large number of patients, who require several sessions; while there are a limited number of trained psychologists.^[7,8]

Minimal information has been published regarding the outcome of chronic insomnia with various comorbidities in regular setup of sleep disorder clinic. In addition, outcomes of treatment provided in an unstructured format; are not known.

There are even fewer trained personnel for effective implementation of a structured CBT-I program from patients with chronic insomnia. At our center, we have routinely adopted a stepped approach in both pharmacological and nonpharmacological treatments of insomnia.

This study aims to evaluate the outcomes of patients with chronic insomnia having been treated at our apex sleep disorder clinic.

METHODS

A retrospective chart review was carried out for consecutive patients presenting to the comprehensive sleep disorders clinic with complaints of insomnia symptoms (persistent difficulty with sleep initiation, duration, consolidation, or quality that occurs despite adequate opportunity and circumstances for sleep

Address for correspondence: Dr. Garima Shukla,
Department of Neurology, Room #2, 6th Floor, Neurosciences Center,
All India Institute of Medical Sciences, New Delhi, India.
E-mail: garimashukla@hotmail.com

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and results in some form of daytime impairment), during a study period of 2 years between 2013 and 2015. Charts of patients who had a known or clear diagnosis of primary sleep disorders such as restless legs syndrome (RLS), circadian rhythm sleep disorders, or that of serious psychiatric or medical illness for which they were already on stable treatment, were excluded. All data about presenting complaints, duration, frequency, and other details were tabulated and a prestructured questionnaire of insomnia, “All India Institute of Medical Sciences (AIIMS) Insomnia Evaluation Questionnaire” (under publication process), had been used for etiological classification of all patients.

Along with a history for signs and symptoms of insomnia, comorbid primary sleep disorders, psychiatric disorders, and physical disorders, associated life stressors and possible precipitating factors for all patients, had also been noted.

Routine treatment procedure was used at the comprehensive sleep disorder clinic: Based on the AIIMS Insomnia Questionnaire, patients are routinely divided into “primary insomnia” and “comorbid insomnia” groups. (Comorbid conditions mainly included psychiatric problems such as substance-use disorders and mood disorders.) The routine treatment strategy has usually been as follows:

- i. Physician-administered CBT-I: It includes sleep hygiene, relaxation training, stimulus-control therapy, sleep restriction therapy, and some components of cognitive therapy (unstructured). Prestructured printed educational material for sleep hygiene and important CBT measures also be provided to all patients.
- ii. Pharmacological measures: As ours is an apex referral center and patients have generally been on multiple pharmacological agents already, the treatment strategy has been to minimize the number of pharmacological agents. Furthermore, following meticulous evaluation for diagnostic category, appropriate use of medication targeting identified etiology is routinely initiated with CBT-I (e.g., for depressive disorder or dysthymia, anxiety, RLS, and others.)
- iii. Psychologist-administered CBT-I: Structured CBT-I, based on the guidelines proposed by Schutte-Rodin *et al.*,^[9] has routinely been administered after thorough customization, keeping in mind the unique social and environmental as well as personal circumstances that patients shared with the clinical psychologist (SP, MA).

The interventions include a combination of sleep hygiene, relaxation exercises, stimulus control, sleep restriction, supportive sessions, psychoeducation, and CBT targeting comorbid conditions. These are administered depending on the need as well as the feasibility of the patients to follow-up for more sessions. Cognitive therapy seeking to change the patient’s overvalued beliefs and unrealistic expectations about sleep is also administered. Common cognitive distortions are identified and addressed in the course of treatment. Dysfunctional thoughts and beliefs are identified and reconstructed with positive and appropriate concepts about

sleep and its effects. Supportive sessions have routinely been provided for the stressors found to be a major part of worrying interfering with sleep initiation.

Data entry and statistical analysis

All pertinent data were entered into Microsoft® EXCEL (2007) spreadsheets and rechecked for accuracy. Statistical analysis was mostly descriptive and carried out either on Microsoft EXCEL (2007)® or SPSS® Statistics for Windows, Version 17.0.

RESULTS

A total of 102 patients were screened wherein 43 could be categorized as primary insomnia and 69 as secondary insomnia. Outcome data of 48% of patients were analyzed as adequate follow-up data for the rest was unavailable.

Of the 102 patients, 43 could be categorized as primary insomnia and 69 as secondary insomnia. The mean age of included patients (58% male) was 45.09 ± 14.52 years. The age distribution is shown in Figure 1.

Among those with secondary insomnia, 13 patients had insomnia alone and the rest all had comorbidities also. There were 24 patients with comorbid sleep disorders such as RLS and obstructive sleep apnea, 32 with comorbid psychiatric disorders such as depression and anxiety, 24 patients who had both sleep disorders and psychiatric disorders, and 6 who had comorbid physical illness such as headaches and epilepsy [Table 1].

The common categories of stressors observed were: (a) loss due to breakup/divorce/death of loved one, (b) financial loss, (c) interpersonal relation issues due to adjustment problems/anger issues/personality traits/domestic violence, (d) major illness of near ones, and (e) shift duty.

Among all patients analyzed, 41 (89.3%) received both pharmacological and nonpharmacological treatment for comorbid conditions and physician-administered CBT-I (Level 1) and psychologist-administered CBT-I (Level 2). The remaining,

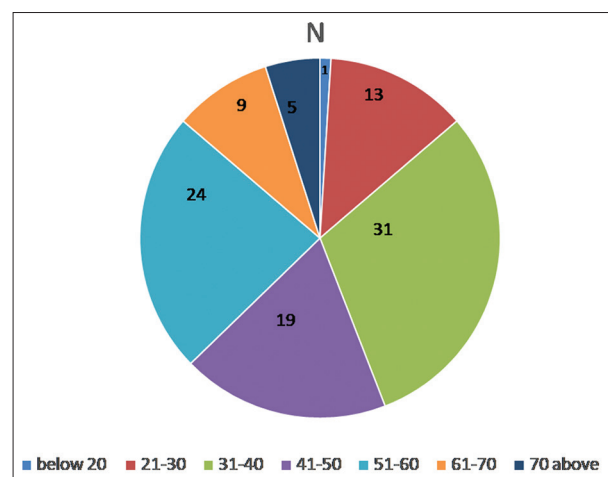


Figure 1: Age distribution for patients presenting for insomnia disorder to the sleep clinic

who were patients with insomnia without any comorbidity, were treated with both CBT-I Level 1 and CBT-I Level 2.

Medications being taken by patients were reviewed. Two or more insomnia medications were discontinued, among 7 patients.

At an average follow-up of 6.5 + 1.2 months, adequate outcome information was available for 48 patients. Table 2 represents the details of treatment outcomes for these patients. A total of 5 (10.6%) patients reported no improvement and 43 (91.4%) patients reported improvement in the symptoms of insomnia with respect to self-reported total nightly sleep time as well as initiation latency. Among these patients, 25 (53.1%) reported “subthreshold insomnia,” i.e., improvement had been noted but some symptoms had persisted; 11 (23.4%) reported “no clinically significant insomnia,” i.e., persistence of few symptoms of insomnia without distress or impairment in daily functioning due to it; and 6 (12.7%) reported “full remission,” i.e., they were able to attain functioning at premorbid level.

Eleven patients had received CBT-I at Level 2, and among these, 7 (63.6%) reported “subthreshold insomnia;” 3 (27.2%) reported “no clinically significant insomnia” and 1 (9.2%) reported “no improvement.”

DISCUSSION

This is the first study from India, reporting treatment outcomes for patients with insomnia, attending a sleep clinic. The salient observations are the high percentage of patients benefitting significantly from an unstructured but customized CBT and other nonpharmacological treatments.

Distribution of primary and comorbid insomnia

We observed the distribution of primary versus comorbid insomnia similar to that reported in other clinic-based studies.^[10] While we

found primary insomnia in about 42% of patients, Mahendran *et al.* in their insomnia clinic-based study including 141 patients found the diagnosis of primary insomnia in 47.5% of patients. In a multicenter study evaluating the distribution of various insomnia diagnoses based on the International classification of sleep disorders (ICSD), Diagnostic and statistical manual of mental disorders IV (DSM IV), and International statistical classification of diseases (ICD 10) and related health problems-version 10 criteria, Buysse *et al.* found the diagnoses of primary insomnia in approximately 20% of patients.^[11] This proportion is apparently smaller than our observation due to stringent application of various criteria in this study. In their systematic review on insomnia symptom and diagnosis prevalence, Ohayon reported the distribution of patients with insomnia as follows: primary insomnia in 16%, anxiety disorders in 24%, depressive disorder in 8%, bipolar in 2%, adjustment disorder in 2%, other sleep disorders in 5%, general medical condition in 7%, and substance-induced in 2% of patients. The percentages differ a little from our observations since the data in this review are based on various epidemiological studies from different parts of the world.^[12]

Treatment outcomes

With respect to the response to the treatment, among patients followed up for an average of four sessions, 91.4% showed improvement. Among these, 12.7% showed full remission, 23.4% showed “no clinically significant insomnia,” and 53.1% showed “subthreshold insomnia.” The presence of a comorbidity did not appear to result in any significant difference in the outcome. This finding is similar to the study by Perlis *et al.*, where it was reported that with four or more sessions, most patients showed improvement of up to 33% and that the medical and psychiatric morbidity did not influence treatment outcome.^[2] Another study by Belanger *et al.* also showed that the presence of comorbid anxiety or mild-to-moderate depressive disorder did not reduce the efficacy of CBT for insomnia.^[13]

Most patients reported, came for initial interview, assessment, and Level 1 intervention only. The number of follow-up and CBT sessions varied among all patients reported, from a minimum of two sessions to a maximum of eight sessions or more, with an average of four sessions. In other studies also, it was found that 5 h therapy provides reliable changes in sleep latency and time awake after sleep onset (WASO).^[13,14] In one of these studies, older adults with secondary insomnia were given four sessions of psychological treatment which comprised relaxation and stimulus control; at 3-month follow-up, in comparison to control group, the patients reported improvement in wake time during night, sleep efficiency percentage, and sleep quality ratings.^[13] A comparative meta-analysis of 23 randomized controlled trials on behavioral intervention for insomnia was carried out by Irwin *et al.*, and they found moderate-to-large effects of behavioral treatments on subjective sleep outcomes.^[15] Lacks and Kimberly analyzed data from seven outcome studies ($n = 216$), and they found that overall 39% of participants showed statistically significant improvement after 4 weeks of treatment, 47% at short-term follow-up (1–3 months posttreatment), and 49% by a year

Table 1: Distribution of patients with respect to their comorbid conditions and follow-up

Comorbid condition	Total (n)	Follow-up (n)
Sleep disorder	24	16
Psychiatric disorder	33	14
Both	24	12
Neurological illness	12	6

Table 2: Outcome of patients at follow-up

Outcome	Level 1 (n=47), n (%)	Level 2 (n=11), n (%)
No effect	5 (10.6)	1 (9.1)
Subthreshold insomnia	25 (53.1)	7 (63.6)
No clinically significant insomnia	11 (23.4)	3(27.2)
Full remission	6 (12.7)	0

Level 1 includes physician-administered CBT-I along with other treatments for comorbid conditions, and Level 2 includes psychologist-administered CBT-I after Level 1. CBT-I=Cognitive behavioral therapy for insomnia

follow-up.^[16] Similarly, in another meta-analysis on treatment effectiveness of CBT-I, 14 randomized controlled studies were identified between year 1990 and 2009 and medium-to-large effect was reported through sleep diaries and self-rating scales, which was also maintained at follow-up.^[17] In a study by Edinger *et al.*, included in the above meta-analysis, 75 adults were randomly assigned to receive CBT, relaxation training, and placebo. It was found that on both subjective and Polysomnography (PSG) findings, CBT produced larger improvements with an average 54% reduction in their WASO within 6 weeks of intervention, whereas the patients receiving Relaxation training (RT) and Placebo treatment (PT), respectively, reported only 16% and 12% reductions in this key measure.^[18] However, in a meta-analysis on insomnia pharmacotherapy and behavioral therapy, Smith *et al.* examined studies from 1966 to 2000 and found that there was no difference in the magnitude between both treatment strategies in any measures except latency to sleep onset, which was better with behavioral therapy. This is possibly because the study analyzed only short-term outcomes, but if we see in long term, it is seen that total sleep time continues to increase beyond short-term treatment levels with behavioral therapy. Moreover, studies from over four decades were included and methods of intervention have continually evolved with deeper understanding and customization of therapy.^[19] In a randomized controlled trial ($n = 46$) of CBT versus oral zopiclone, it was found that interventions based on CBT are superior to zopiclone treatment both in short- and long-term management of insomnia in older adults.^[20]

Limitations

Being a retrospective study, the biggest limitation remains the small number of patients for whom detailed follow-up information was available. Many patients would follow up without prior appointment, and this was one of the main reasons for the incomplete documentation of data. Nevertheless, this analysis provides valuable insights into planning a more structured prospective evaluation of outcomes of patients receiving treatment for insomnia in an Indian population.

CONCLUSION

With correct diagnostic classification, as well as appropriate and easily available treatment strategies, excellent treatment outcomes are observed at specialty sleep clinics.

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Conflicts of interest

There are no conflicts of interest.

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