THE STUDY OF SIGNIFICANCE OF ANTIMIASMATIC TREATMENT IN PATIENTS OF INSOMNIA

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Abstract

One of the most prevalent psychiatric conditions impacting people globally is insomnia. Patients with insomnia struggle to fall asleep, stay asleep, or wake up early in the morning with or without a drowsy mood. It often interferes with daily activities. Numerous studies conducted worldwide indicate that 10% to 30% of people suffer from insomnia. Sleep disorder can either occur for few days or for longer period, known as primary and secondary insomnia. Anxiety, stress and depression are the commonest causes of insomnia. In Homoeopathy Miasm means an obstacle to cure. Dr Samuel Hahnemann (Father of Homoeopathy) used the term "miasm" to describe the causes to disease and to remove the cause Homoeopathy has Antimiasmatic treatment. This study supports the importance of Homoeopathic Antimiasmatic treatment for insomnia. Here we intended to investigate whether Homoeopathic remedies are effective in treating patients of insomnia.

OBJECTIVE: The objective of this study was to investigate the significance of antimiasmatic homoeopathic medicines for the treatment of insomnia.

METHODS: It is a single-blind, non-randomized clinical trial, conducted at the OPD of Bharati Vidyapeeth (deemed to be university) Homeopathic college and research Centre, Pune. The study includes 33 clinically diagnosed cases of insomnia of which 30 cases were administered the homoeopathic medicine selected on the basis of miasmatic background and totality of symptoms. The improvement of symptoms based on severity and intensity of insomnia was checked according to the Insomnia severity scale.

RESULTS: The results of the study indicate the effect of homoeopathic medicines prescribed based on the theory of miasm. Analysis was done using Student paired “t” test. A significant reduction was observed in the insomnia severity scale after treatment & the patients showed symptomatic relief as well and no adverse effect were noted. Mean reduction in intensity of symptoms in insomnia Before treatment Insomnia Index was 21.36 $\pm$ 2.09(mean$\pm$ SD) which reduces to 10.20 $\pm$ 3.61 after treatment. T-statistic value is 16.67 with a p-value of 0.00 ** highly significant. use of the antimiasmatic homeopathic does have an effect over a 4-5wk period.

CONCLUSION: From the above observations, it can be concluded that homeopathic(antimiasmatic) medicines have effect in the treatment of patients with insomnia. It can also be concluded that the comorbid conditions and associated complaints can also be treated along with the insomnia with homoeopathic medicines.

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1.INTRODUCTION

Patients with insomnia frequently have difficulties getting asleep, many night-time awakenings and difficulty falling back asleep, early morning awakenings, and/or restless sleep. [1,2] In the modern environment, insomnia is one of the most prevalent health issues. However, it is commonly disregarded. Numerous studies conducted worldwide indicate that 10% to 30% of people suffer from insomnia. 25% of all chronic insomniac patients are thought to experience primary insomnia [3,4,5]. 10%-16% of adults suffer from chronic insomnia, which is more common than transient or occasional insomnia for another 25%-35% of adults [6]. Insomnia is frequently brought on by stressed, hurried lifestyles.

The most typical causes of insomnia are listed below:

Stress, Anxiety, Day time sleep, Lack of exercise, Environmental noise, Extreme heat or cold, Jet lag, Use of too much caffeine, alcohol, drugs while sleeping, Use of electronic gadgets while sleeping, Job Shift changes.[7]

1.1TYPES

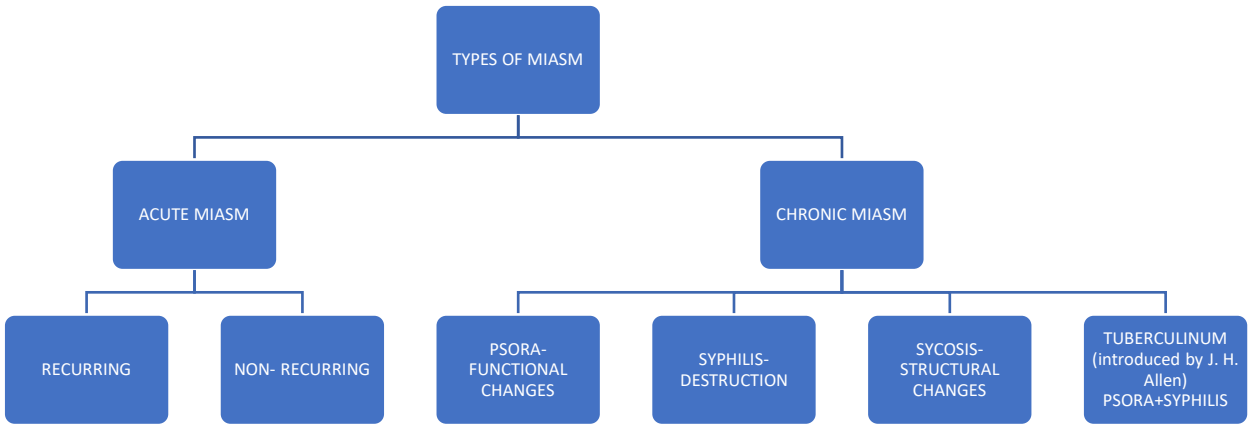
There are numerous classifications for insomnia based on the reasons, however insomnia may be categorised into two categories in a straightforward manner. either chronic for years or short-term for a month. Although the incident may have been a single incident, it is typically thought to be a recurring issue. [8]

1. Primary Insomnia	2. Secondary Insomnia
It is a very short form of insomnia, showing no direct link to any other disease or health condition [9]. The Diagnostic Criteria is the fourth edition, text revision (DSM-IV-TR) [10]. The most common causes of primary insomnia are; taking nap in daytime, extreme heat and cold, consumption of alcohol or caffeine before bedtime, changes in job shift, high altitude and environmental noise [11].	It is the most common type of insomnia which is seen, in both patients and the general population. The causes of chronic insomnia include; side effect of drug, psychiatric, environmental and behavioral, whereas medical causes include chronic pain, thyroid disease, coronary artery disease, GERD, pulmonary problems and any other long-term disease [12].

1.2 Homeopathic Approach in Insomnia

The Insomnia can be treated and managed with homoeopathic antimiasmatic medicines very effectively with long-term treatment and a suitable individualised medicine. Anxiety, depression, and other psychiatric conditions have all been treated with homoeopathy. Miasms are attributed as the primary cause of all ailments. [13] Every disease has a background miasma.

Miasms have been split into two classes, including acute and chronic miasms. [13,14,15,16]



Acute miasm is an acute disease-causing agent which causes the specific infectious diseases having almost fixed manifestations. These come in 2 varieties:

a) Recurrent acute miasm These conditions reoccur in the several times in a lifetime in the same manner.

b) Non-recurrent acute miasm: This is also known as fixed miasm. These kinds of miasm only ever affect a person once in their lifetime.[14]

All chronic diseases have **Chronic miasms** as their underlying aetiology. This miasmatic cause the naturally occurring chronic miasmatic disorders.

Psora, sycosis, and syphilis are the three forms of miasms that Dr Hahnemann distinguished. Psora is the true underlying cause of almost all disease with the exception of syphilis and sycosis. [15,16] He also explained how psora causes sleeplessness and requires the patient to get out of bed and move around. When closes his eyes or doesn't get any sleep around three in the morning. [13] A different sort of miasm known as a tubercular miasm was first described by J. H. Allen.

The following table, describe the relation of insomnia with different types of Miasms.[17]

TUBERCULINUM	PSORA	SYCOSIS	SYPHILIS
Unrefreshing sleep with great exhaustion is the characteristic of tubercular sleep.	unrefreshing sleep with fearful dreams and dreams of anxiety. sleeplessness is experienced due to the abundance of ideas.	Disturbed sleep, sleep only for short period of time, wakes, then returns to sleep again. Sleeplessness caused by mental and physical disturbance.	Sleepless because of tormenting ideas. Unrefreshing sleep along with depression and melancholia.

Unfortunately, there have been no studies conducted to date to determine whether homoeopathic Antimiasmatic is beneficial for treating insomnia.

2. OBJECTIVES

The most effective treatment, according to the most recent clinical studies, requires the use of well selected homoeopathic medications. There is currently little information available about how homoeopathic insomnia therapy works in India. The goals of this study were to investigate the significance of antimiasmatic homoeopathic medicines for the treatment of insomnia and to evaluate the improvement of insomnia using the Insomnia Severity Index (ISI) in patients with insomnia in order to advance the current knowledge in the field of clinical research. The study's secondary goals were to review the homoeopathic literature on the " *The Chronic Diseases, their peculiar nature and their homeopathic cure* " in relation to insomnia and to determine the efficacy of homoeopathic medicine in treating insomniac patients.

3. MATERIALS AND METHOD

1.1 Theoretical Study: Numerous publications, including the fifth and sixth editions of Dr Hahnemann's Organon of Medicine, The Chronic Diseases, Their Peculiar Nature and Their Homoeopathic Cure, Dr S. K. Banerjea's Miasmatic Prescribing, and various philosophy books by different Stalwarts were recommended for study. For the section on modern medicine, numerous Psychology books were recommended in addition to the book's earlier research papers or meta-analyses by other authors.

1.2 Study Design: The first cases will be those that support the case definition. Eligible patients were selected for the trial after being screened using inclusion and exclusion criteria. Each case was properly evaluated and given its own unique treatment. Based on the similarity of the symptoms, the right antimiasmatic homoeopathic treatment was chosen. Data extraction and statistical analysis were done using a specially created Microsoft Excel spreadsheet. The study took 18 months to complete. Depending on the scenario and the patient's availability, follow-up varied from patient to patient.

1.3 Sampling Techniques: Only 30 randomly chosen cases, representing both sexes and ages ranging from 18 to 70 years old, were chosen for this study from the OPD of the B.V.D.U Homoeopathic Hospital, mobile duty, and several urban camps run by the Bharati Medical Foundation.

1.4 Selection of Remedy and Potency: The remedy was prescribed following a thorough case assessment. A proper antimiasmatic homoeopathic remedy was recommended based on the similarity of the symptoms, and references from various homoeopathic literature were also used. According to Dr Samuel Hahnemann's instructions in his book on homoeopathic philosophy and organon of medicine, the potency of the drug was chosen based on the individual's sensitivity.

1.5 Administration of drugs: Oral means are used to carry it out. The dosage will be administered in the form of globules, liquid, or powdered lactose depending on the patient's needs.

1.6 Disclaimer: All medications used in this investigation were entirely safe for human consumption.

1.7 Clinical Protocol: For this study, patients were chosen in accordance with the case description described earlier. The project's nature was described to them, and their written consent was obtained. Data was gathered and sent for statistical evaluation.

Case was handled under regular case procedure. The follow-up and Performa were adequately maintained. As permitted by our university, the entire project will be presented and submitted to the ethical committee.

Inclusion Criteria: -

1. Those cases fulfilling the diagnostic criteria.
2. Patient opting for Homoeopathic treatment for their illness.
3. Patient complying for regular follow up.
4. Patients who will written the consent form.
5. patient of age group 18-70 years.
6. Both genders of patients.
7. Patients undertaking any other mode of treatment along with homoeopathic mode of treatment for some other illnesses.

Exclusion Criteria: -

1. That does not fulfil diagnostic criteria.
2. Patients undertaking any other mode of treatment along with homoeopathic mode of treatment.
3. Patients who have not written the consent.
4. Patients requiring emergency medical care.
5. Patients of insomnia associated with known grave pathological changes.
6. Patients who have participated in any other Research study in the last 6 months.
7. recent major surgery.

Follow up Criteria: -

Depending on the situation, the follow-up period will vary from patient to patient. The patient will be monitored for the first time after 15 days of the initial visit, and subsequent follow-up visits will either be weekly, fortnightly, or monthly depending on the case assessment.

outcome evaluation

On the basis of the information gathered from the Insomnia Severity Index (ISI) score, outcome evaluation was carried out.

Index of Insomnia Severity:

The Insomnia Severity Index was developed to evaluate the kind, effect, and treatment responsiveness of insomnia in adults. Seven questions were on the index. To determine a final score, the seven responses were combined together. Based on the provided recommendations, the total score was utilised to evaluate where the sleep problem fits.

4. RESULTS-

Total 30 patients (n=30) were selected from the age group of 18-70 years, out of which 16 patients had Severe Clinical insomnia (53.33%) and 14 patients had moderate Clinical insomnia (46.67). in miasmatic distribution 70% of patients under study show Psora Miasm followed by Sycosis with 23% of patients under study (table 3). The highest percentage of patients belonged to the age group of below 30 years (46.67%) and the lowest from the age group above 50 years (16.67%) indicating that patients between the age of 18-30 years might be affected the most (Table1). In this study 18 participants were male (60%) & 12 were female (40%). More patients were 37% student (Table1).

Table1: *Distribution of patients according to age and sex*

Age Group	No of patients	Percentage	Gender	Number of patients	Percentage
below 30	14	46.67	Male	18	60.0
30-50	11	36.67	Female	12	40.0
above 50	5	16.67			

In the study, 46.6% of patients had ages below 30, 36.6% had ages between 30-50, and 17% had ages above 50, as shown in the table above. In the study, there were 60% men and 40% women.

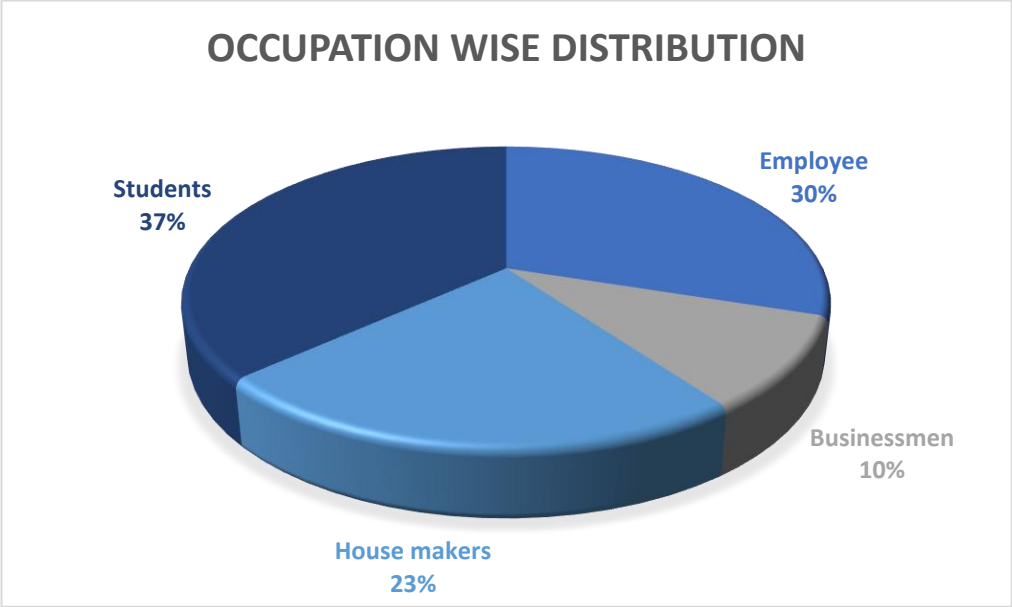


Figure 1: *Occupation wise Distribution of patients.*

Table2: *Distribution of Patients according to occupation*

Occupation	Number of patients	Percentage
Employee	9	30.0
Businessmen	3	10.0
House makers	7	23.3
Students	11	36.7

Table 2 and Fig. 2: Distribution of patients according to their occupation show that 37% of the patients were students, 30% were employees, 23% were Housemakers, and 10% were Businessmen in the study.

Table 3: *Distribution of Patients according to MIASM*

Miasmatical analysis	Number of patients	Percentage
Psora	21	70.0
Syphilis	2	6.70
Sycosis	7	23.3
Tubercular	0	0.0

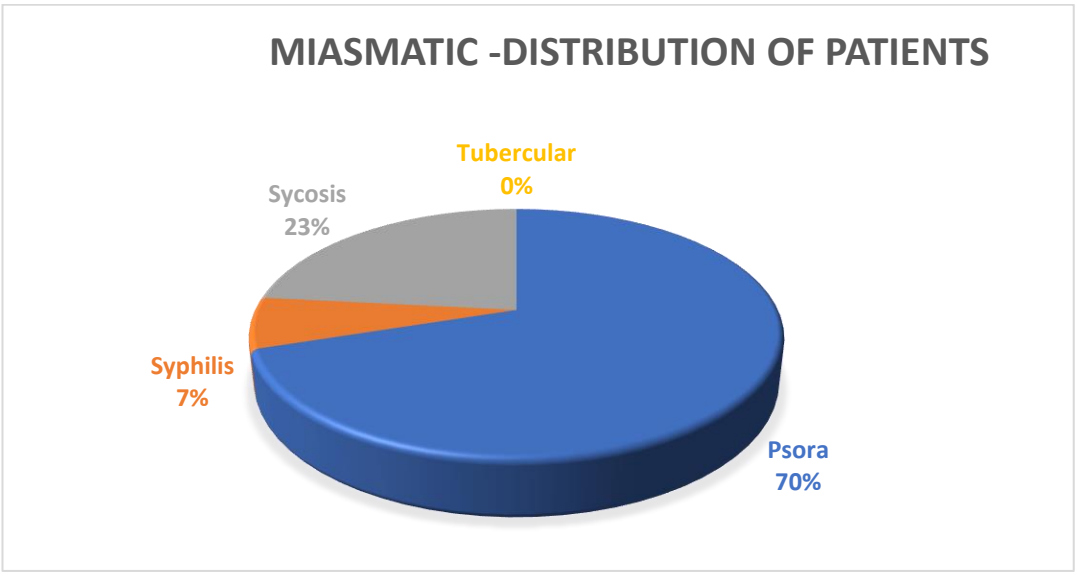


Figure 2: *Miasmatical- distribution of patients.*

Table 3 and Fig.2 show that 70% of patients under study show Psora Miasm followed by Sycosis with 23% of patients under study.

Table4: *Distribution of Patients according to Insomnia Complaint*

Insomnia Complaint Insomnia	Number of patients	Percentage
Difficulty falling asleep	13	43.3
Difficulty sleep maintaining	22	73.3
Problem waking up too early	8	26.7
All above	2	6.7

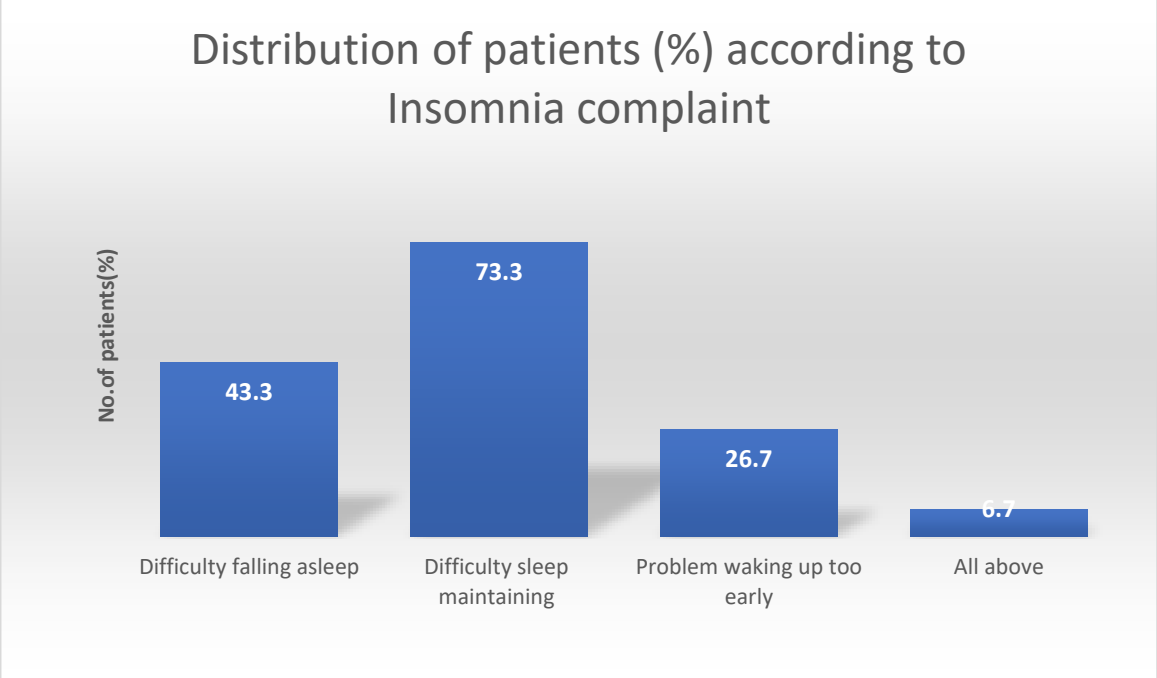


Figure 3: *Distribution of patients according to Insomnia Complaint*

Table 4 and Fig 3 display that 73.3 % of patients have difficulty maintaining sleep, whereas 43% of patients have difficulty falling asleep.

Table 5: *Remedy wise Distribution of patients*

Remedy	No. of patients	Percentage (no.of patients in %)
Arnica m	1	3.3
Ars Alb	4	13.3
Baryta c	2	6.7
Bella	2	6.7
Bryonia	3	10.0
Calc Carb	2	6.7
Calc phos	1	3.3
Canth	1	3.3
Coffea	12	40.0
Gelsemium	1	3.3
Ignatia	8	26.7
Lachesis	1	3.3
Lycopodium	4	13.3
Nat Mur	6	20.0
Nux Vom	21	70.0
Passiflora	1	3.3
Phos	4	13.3
Puls	2	6.7

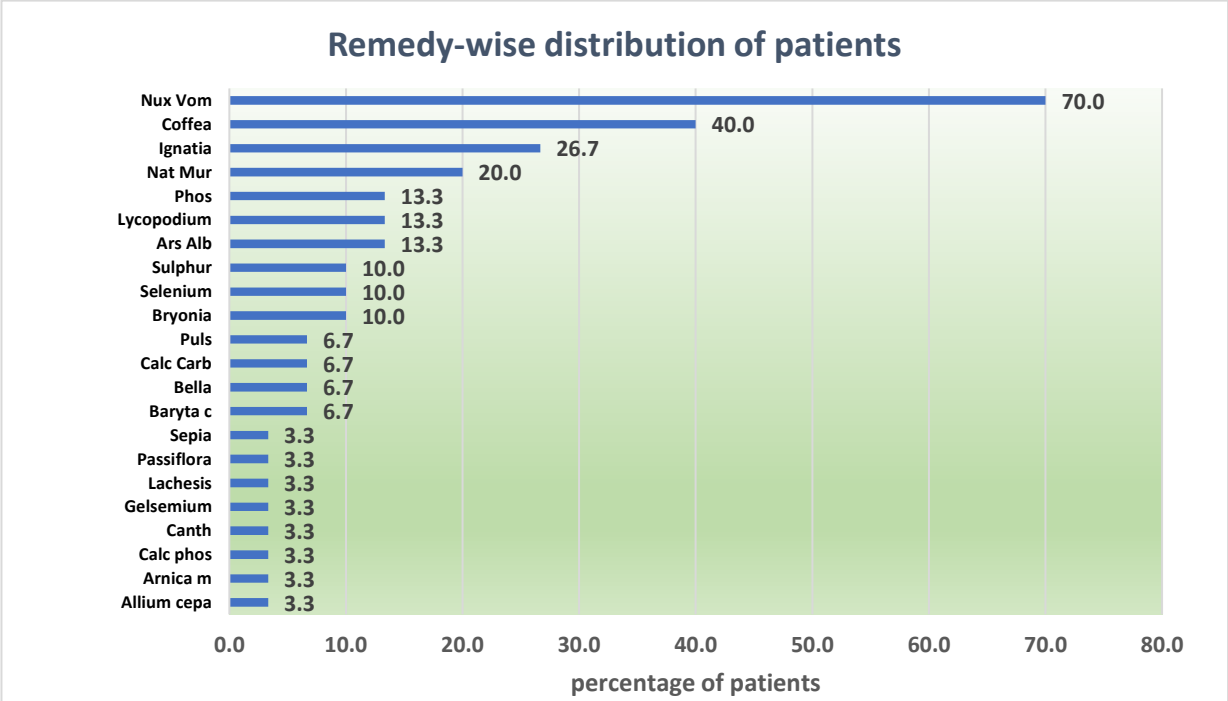


Figure 4: *Distribution of prescribed Remedy to the patients*

Table 5 and figure 4 show remedies used to treat insomnia. Nux Vomica was the most used remedy (70%) followed by coffea cruda (40%).

Table6: *Distribution of patients according to Severity of Insomnia before and after applying treatment*

Severity of Insomnia	Number of Insomnia patients before treatment	% of patients	Number of Insomnia patients before treatment	% of Patients
No clinically significant insomnia	0	0	8	26.67
Subthreshold insomnia	0	0	18	60.00
moderate Clinical insomnia	14	46.67	4	13.33
Severe Clinical insomnia	16	53.33	0	0
Grand Total	30	100	30	100

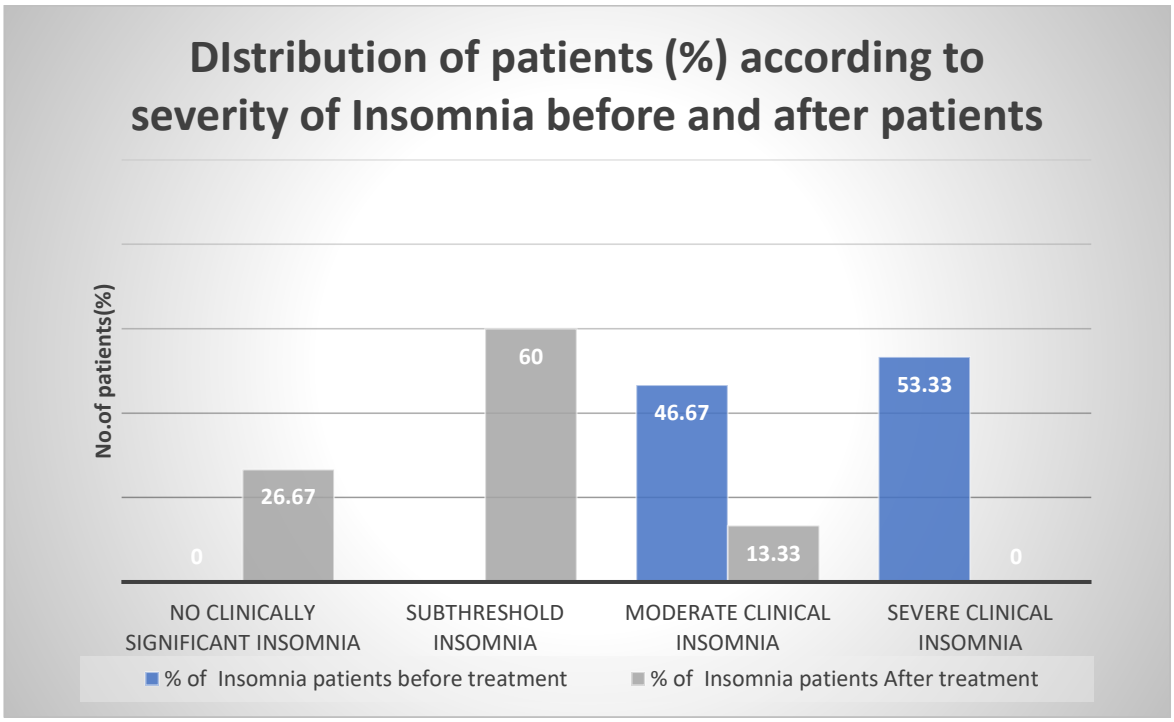


Figure 5: *Distribution of %of patients before and after treatment of Insomnia*

Table 6 and Fig. 5 show the distribution of patients (%) according to the severity of Insomnia before and after the treatment. Before treatment, almost 53% of patients had Severe clinical Insomnia and 46% had moderate Clinical Insomnia. After the treatment, almost 60% of patients were having Subthreshold Insomnia and 13% of patients were having moderate clinical Insomnia whereas 26% of patients were having no clinically significant Insomnia.

Table 7: *Distribution of patients (%) according to change in the severity of Insomnia due to treatment.*

The severity of Insomnia Before treatment	The severity of Insomnia After treatment							
	No clinically significant insomnia		Subthreshold insomnia		moderate clinical insomnia		Severe Clinical insomnia	
	Count	%of patients	Count	%of patients	Count	%of patients	Count	%of patients
moderate Clinical insomnia	5	35.71	9	64.29	0	--	0	--
Severe Clinical insomnia	3	18.75	9	56.25	4	25.00	0	--

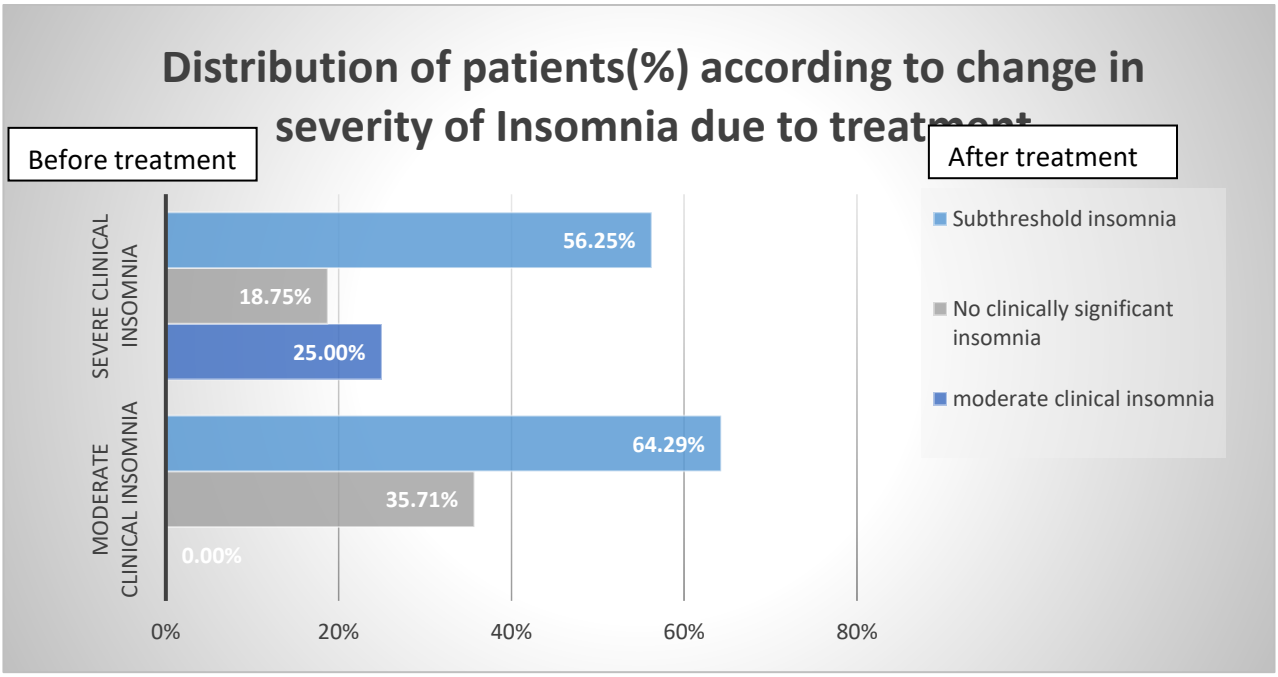


Figure 6: *Distribution of patients (%) according to changes in the level of Insomnia after treatment.*

Table 7 and Fig.6 depict the change in the severity of Insomnia due to treatment.

Of patients with Severe clinical Insomnia, after treatment, 56.25% had subthreshold Insomnia, 25% with moderate clinical Insomnia, and 18% shows no clinically significant Insomnia.

In patients with moderate clinical Insomnia, after treatment, 64.29% of the patients had Subthreshold Insomnia whereas 35.71% of patients had no clinically significant Insomnia

HYPOTHESIS TESTED:

H0: Homoeopathic medicine is not effective in patients with insomnia.

Vs

H1: Homoeopathic medicine is effective in patients with insomnia.

Table 8: *Descriptive statistics of the Insomnia Severity Index before and after treatment.*

Severity Index of Insomnia	Mean± SD	T Statistic Value	P-Value	Decision
Before Treatment	21.36 ± 2.09			
After Treatment	10.20 ± 3.61	16.67	0.00**	Reject Ho
Hence there is a significant difference in the severity Index of Insomnia before and after treatment.				

A test used: Paired t-test, **: Highly Significant Difference, T Statistic-value: Test Statistic value

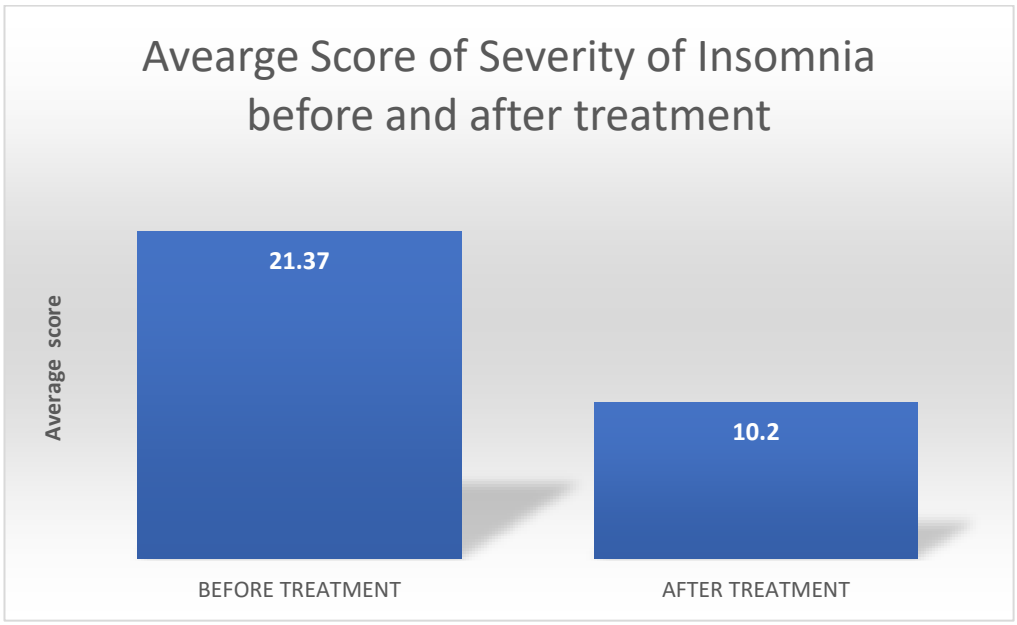


Figure 7: *Bar diagram representing Average Score of Severity of Insomnia before and after treatment*

Table 8 and Fig 7 gave descriptive Statistics of the severity Index of Insomnia before and after the treatment. Before treatment Insomnia Index was 21.36 $\pm$ 2.09(mean$\pm$ SD) which reduces to 10.20 $\pm$ 3.61 after treatment.

To test the hypothesis of whether the average Severity index of Insomnia in patients, before and after Homoeopathic medicine remains the same or not, the Paired t-test is used.

T-statistic value is 16.67 with a p-value of 0.00 ** highly significant.

We reject Ho and conclude that Homoeopathic medicine is effective in patients with insomnia.

5 CONCLUSIONS

The observations stated above lead to the conclusion that homoeopathic (antiimiasmatic) medications are effective in treating people with insomnia. We can also draw the conclusion that homoeopathic drugs can be used to treat both the comorbid disorders and the accompanying complaints as well as the sleeplessness.

A larger sample size and a longer study period will need to be considered in future research projects due to the small sample size and short study duration.

6 ETHICAL STATEMENTS:

Through a letter dated 30 June 2020, the Bharati Vidyapeeth Deemed to Be University Homoeopathic Medical College & Hospital Institutional Ethics Committee approved the project. Through the informed consent form, which was properly documented, each patient was apprised of the ethical concerns associated to the study. The study was carried out in accordance with the guidelines outlined in the Helsinki Declaration of 1964.

7 ACKNOWLEDGEMENTS

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8 CONFLICTS OF INTEREST The authors declare that there are none.

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