

Efficacy of *Passiflora Incarnata* Mother Tincture in Treatment of Insomnia

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ABSTRACT

Insomnia is one of the most common sleep disorders with a prevalence rate of 20-30% worldwide. Insomnia is a condition of unsatisfactory quality and/or quantity of sleep, with difficulty falling asleep, remaining asleep, or waking early and being unable to return to sleep. Factors like stressful life events, changes in work shifts, night watching, smoking, alcohol drinking and other mental disorders are the common predisposing factors which are leading to sleeplessness commonly in youngsters and middle-aged people. As use of sedatives may lead to dependency, impaired memory etc., so the Homoeopathy has a good scope in sleep disorders with minimal effects. *Passiflora Incarnata* is one of the frequently used remedies in Homoeopathy for insomnia. Its use in sleep disorders have been dated back to ancient periods. From ancient times in India, Africa, Europe, Turkey, America, Brazil, Iraq, Poland etc. it was used as traditional medicine for inducing sleep i.e., as a hypnotic. It is indicated for sleeplessness arising from exhaustion, over work, mental worries. As the above mentioned factors are frequent causes for sleeplessness now a day, *Passiflora incarnata* has been selected as medicinal intervention. This study aims at establishing the effectiveness of *Passiflora Incarnata* mother tincture in treating insomnia. This research is an experimental

research having no control group with a sample size of 20 between the age group of 25-50 years. Those participants in the study sample who were meeting the criteria according to Athens Insomnia Scale (AIS) were diagnosed as insomniac. A cut-off score of greater than or equal to 6 on the AIS is used to establish the diagnosis of insomnia. The same scale (AIS) was used to assess the results after taking the medicinal intervention. The results showed that the *Passiflora Incarnata* mother tincture medicine is effective in treating insomnia.

Keywords: Athens Insomnia Scale, Insomnia, *Passiflora Incarnata* mother tincture.

INTRODUCTION

Insomnia is defined as difficulty in initiating or maintaining sleep^[1]. Insomnia is defined in the fifth edition of the Diagnostic and statistical manual of mental disorders (DSM-5) as difficulty getting to sleep, staying asleep or having nonrestorative sleep despite having sufficient time for sleep, accompanied by a corresponding decrease in daytime functioning, and symptoms that have persisted for at least four weeks [2]. It is the most typical issue related to sleep and can be either temporary or ongoing.

It is extremely common and may be a primary disorder but it is more often secondary to another medical or psychiatric conditions^[3]. The patient may present with

either or both of the following ^[3]: 1) A complaint relating to sleep: trouble getting to sleep; repeated awakenings; early morning awakening; perceived poor quality of or unrefreshing sleep or inadequate quantity of sleep. 2) Symptoms secondary to the sleep problem: daytime sleepiness, irritability, fatigue, poor attention and concentration, and substandard performance at daily activities.

Each year, up to 40% of the general population suffers from insomnia, which is a major cause of morbidity and mortality. Insomnia prevalence in the general population ranges greatly, from 6% to 33%. Primary care settings have been found to have a greater prevalence of insomnia, with rates ranging from 10 to 69% ^[4]. There are few studies on insomnia published in India. The single center, limited studies that are currently available in India suggest prevalence rates between 15 to 45% ^[4]. Population studies conducted in Australia have revealed that between 13% and 33% of adults regularly struggle to fall or stay asleep ^[2]. Population surveys show a 1-year prevalence rate of 30-45% in adults. And most of the patients suffering with insomnia were below the age of 35 years ^[5]. Increasing age is a major factor in insomnia development. Those with medical or mental co-morbidities, women, the elderly, shift workers, people with less education, and people with lower incomes are more likely to experience insomnia ^[3]. A study revealed that women were more likely than men to experience sleeplessness. And Studies on women have also shown that separated, widowed, and divorced women are more likely than married women to experience sleeplessness ^[6]. Comorbid insomnia is generally associated with Diabetes and Depression ^[2]. Insomnia is comorbid with depression in about 50% of cases, and the most frequent psychiatric causes for patient contacts in general practice are sleep disturbance and depression, respectively ^[2]. Insomnia is of two types: a) Acute insomnia, defined as sleep disturbance meeting the DSM-5 definition of insomnia,

but with symptoms occurring for less than 4 weeks ^[2]. b) Chronic insomnia, when the symptoms persisting more than 4 weeks.

It may be etiologically related to Stressful life events, changes in the work shifts, depression, anxiety, mental illness, alcohol drinking, smoking, long-term conditions like diabetes, hyperthyroidism, Congestive heart failure ^[7]. Insomnia is characterized by subjective complaints about dissatisfaction with sleep quality or duration, difficulty falling asleep at bedtime, waking up in the middle of the night or too early in the morning, or inadequate or non-restorative sleep. Subjective reports of symptoms experienced during the day, such as lethargy or low energy, problems with cognitive abilities (such as focus, attention, and memory), and mood swings (such as anger and dysphoria), are frequently included in the category of insomnia, all of which can produce functional impairments and are often the primary concerns that prompt patients to seek treatment ^[8]. During the day, mood swings, irritation, poor memory, exhaustion, low energy, and a general malaise are common outcomes. One of the main medical causes of this is sleeplessness, which might show up as work absenteeism. It is also imperative to ask for risky consequences of insomnia, including accidents and sleepiness while driving ^[2].

Investigations and diagnosis include sleep study, Actigraphy and lab examinations like CBP, thyroid profile and physical examination to evaluate for secondary cause ^[9]. Insomnia can also be assessed by using certain qualitative sleep assessment scales. Among them, AIS was one qualitative scale used in this study for assessing the Insomnia. It is measured by assessing eight factors which include nocturnal sleep factors and daytime functioning factors. These factors are rated on a 0-3 scale. A cut-off score of greater than or equal to 6 on the AIS is used to establish the diagnosis of insomnia ^[10].

For a very long time, Passiflora Incarnata was used as a sedative. But the mechanism

of action of *P. Incarnata* extracts are poorly understood. Chemical research on a few *P. incarnata* species has resulted in the identification of compounds such as flavonoids, carboline alkaloids, cyanogenic glycosides, and terpene derivatives. Flavonoids, which comprise 0.25% of the plant's chemical composition, include apigenin, kampferol, isovitexin, orientin, and isoorientin. There have been detected (0.1%) indole alkaloids, including harman, harmin, harmalin, harmol, and harmalol. Additionally, extracted are maltol and ethyl-maltol (0.05%), as well as cyanogenic glycosides^[11].

The precise alkaloids and flavonoids in *Passiflora* that provide the hypnotic effect have not been proven. However, the mice were put into a hypnotic state by the extract of *Passiflora*.

Passiflora Incarnate is one of the frequently indicated remedy for insomnia due to its sedative effect. It was introduced by Hale, citing in the new remedies a paper by L-phares^[12]. *Passiflora Incarnate* was indicated for sleeplessness with great restlessness^[13] arising from overwork, exhaustion^[13], mental worries, excitement^[13] etc. The use of *Passiflora Incarnate* in this research is hoped to improve the sleep quality in insomnia patients.

MATERIALS & METHODS

Materials:

Passiflora Incarnate mother tincture, Athens insomnia scale, sample of 20 patients taken from IPD, OPD and peripheral camps of MNR Homoeopathic Medical college.

Methods:

The research was an experimental study on a sample of 20 patients with sleeplessness. The patients were taken from the IPD, OPD and peripheral camps of MNR Homoeopathy medical college. The research sample was 20 which includes the age group between the 25-50 of both sexes. The exclusion criteria

include the pregnant women, patients below 25 and above 50 years of age. The treatment was given with *Passiflora Incarnata* mother tincture on every night with 10 drops in 30ml of Luke warm water.

Passiflora Incarnata Q:

Passiflora Incarnate Q prepared from the leaves of *Passiflora* plant. The fresh and dried leaves from the plant are collected in the May. The tincture is prepared by the trituration of the leaves. It is a Fluid hydro alcoholic extract. The tincture is prepared by using the *Passiflora* coarse powder 100g, purified water 400ml, strong alcohol 635ml to make one liter of tincture^[14].

Assessment of sleep:

Sleep quality was assessed by using the AIS. The results were taken before and after the treatment using the AIS. The paired t test is used for the statistical analysis of the results.

STATISTICAL ANALYSIS

To ascertain the difference between the pre-treatment and post-treatment observation paired-t test is applied.

Paired t test:

It is also called matched pairs t test, paired difference t-test or repeated samples t-test.

As the name suggests, the paired t test is used to calculate if the mean difference between the pairs of measurable is 0 or not.

P value and statistical significance:

The two-tailed P value is less than 0.0001. By conventional criteria, this difference is considered to be extremely statistically significant.

Confidence interval:

The mean of Group One minus Group Two equals 7.55

95% confidence interval of this difference:
From 5.03 to 10.07

Intermediate values used in calculations:

t = 6.2702
 df = 19
 Standard error of difference = 1.204

| | Before treatment | After treatment |
|------|------------------|-----------------|
| MEAN | 12.90 | 5.35 |
| SD | 3.58 | 5.74 |
| SEM | 0.80 | 1.28 |
| N | 20 | 20 |

Total, 20 samples were taken for the study. Among them 10 male and 10 female samples between the age group of 25-50 years were taken for the study. Observations from the above study revealed that Insomnia was more prevalent between the age group of 25-45 years. Among the age group between the 25-35 years, the males to females affected were almost equal.

RESULT

Effect of *Passiflora Incarnata Q* in improving the sleep quality:

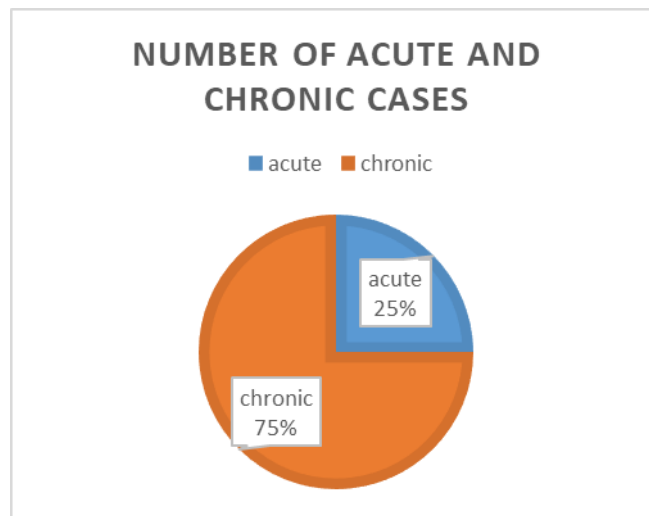


Figure. 1

From the above study it was observed that the chronic insomnia was more prevalent than the acute insomnia. Out of total 20 participants, 15 (75%) participants were

observed to be suffering from chronic insomnia. And 5 (15%) were observed to be suffering from acute insomnia.

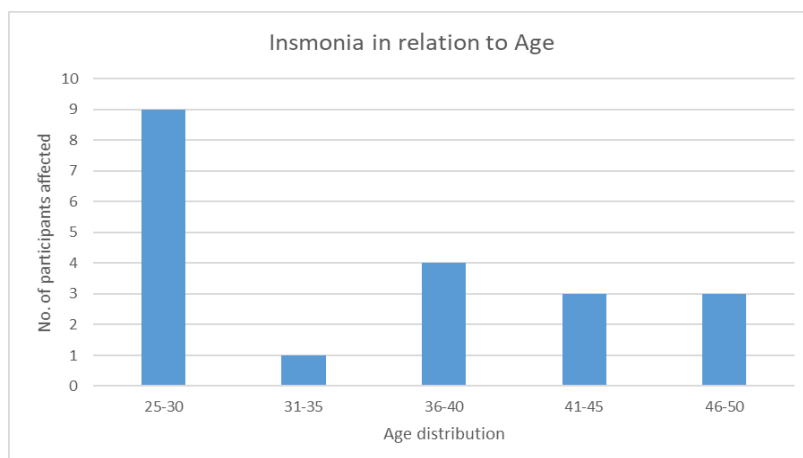


Figure.2

From the study conducted, it was observed that, insomnia was more prevalent (45%) among the age group of 25-30 years. Of total 20 samples, 9 of the participants affected with insomnia were between the 25-30 years. Next affected age group was between 36-45 years. Between the age group of 36-45 years, it was observed that 7

(35%) participants were affected with insomnia. So from the study it may be observed that the more vulnerable age group for insomnia was between 25-45 years. The results of the study were given in the table below with AIS score before and after treatment.

| Case no | Age | Gender | AIS score before treatment(X ₁) | AIS score after treatment (X ₂) | d = X ₁ - X ₂ |
|---------|-----|--------|---|---|-------------------------------------|
| 1 | 26 | F | 18 | 4 | 14 |
| 2 | 26 | F | 9 | 3 | 6 |
| 3 | 46 | F | 14 | 2 | 12 |
| 4 | 25 | M | 9 | 2 | 7 |
| 5 | 36 | M | 10 | 0 | 10 |
| 6 | 28 | M | 17 | 14 | 3 |
| 7 | 35 | M | 16 | 1 | 15 |
| 8 | 45 | M | 9 | 9 | 0 |
| 9 | 28 | F | 12 | 1 | 11 |
| 10 | 40 | F | 9 | 9 | 0 |
| 11 | 42 | F | 9 | 0 | 9 |
| 12 | 28 | M | 10 | 0 | 0 |
| 13 | 29 | M | 14 | 2 | 12 |
| 14 | 40 | F | 17 | 16 | 1 |
| 15 | 50 | F | 18 | 14 | 4 |
| 16 | 27 | F | 12 | 2 | 10 |
| 17 | 46 | F | 18 | 3 | 15 |
| 18 | 26 | F | 9 | 9 | 0 |
| 19 | 37 | M | 16 | 16 | 0 |
| 20 | 42 | M | 12 | 0 | 12 |

P value and statistical significance:

The two-tailed P value is less than 0.0001. By conventional criteria, this difference is considered to be extremely statistically significant.

DISCUSSION

From this study, it was established that *Passiflora Incarnata Q* is effective in treating the insomnia (P<0.0001). the study includes 20 samples of both sexes between the age group of 25-50 years. The participants were selected from those visiting OPD, IPD and camps and peripheral centers of MNR Homoeopathic medical college and hospital by screening the patients using the questionnaire that contains AIS score. A regular follow ups were taken from the patients as far as possible. The follow ups were taken for every 15 or 30 days depending on the patient condition. Thus 3-5 follow ups were obtained from the patient. The patients were prescribed with the medicine *Passiflora Incarnata Q* regardless of symptom totality. The screening of the

patient and progress of the patient is assessed using AIS scores. The data that is obtained is then statistically analyzed using paired t test.

From the results obtained the p value is looked for which, if greater than 0.01 the value is significant, and the alternate hypothesis of the study is true.

From the test, the following conclusions are drawn:

- In this study both the sexes are equally participated i.e., 10 male patients and 10 female patients were taking part in this study.
- From the total 20 participants, it was found that the participants of age group 25-30 years (45%) and 35-45 (35%) are more affected by insomnia than those of other age groups.

- Among the total 20 participants, males of age group 25-45 years are more affected than the other male Age groups.
- Among the total 20 cases taken, it was seen that 5 (25%) of the total cases were acute and remaining 15 (75%) cases were chronic insomnia cases. Among the 15 chronic cases, females (8) were affected more than the males (7). The patients, in which the complaint persisting more than 6 weeks were taken as chronic insomnia and the patients in which the insomnia symptoms persisting form less than 6 weeks are taken as acute cases.
- Among the total 15 chronic cases insomnia, the age group that is more affected is 25-35 years than the other age groups.
- From the study we can conclude that, insomnia is slightly more prevalent in women than in men. More studies should be conducted to establish an appropriate incidence rate among gender.
- From the 20 case study, 7 cases have shown negative of the medicine intervention used. Either there is slight improvement in AIS score or not at all.
- The cases of insomnia associated with other co-morbidities like hypertension and diabetes have shown less impact of *Passiflora Incarnate Q* on them as those cases have shown slight relief or no relief at all.
- Of the total 20 cases 5 cases are with co-morbidities like HTN and DM which shown negative effect of the study medicine on them.

Limitations:

- The study sample is small therefore there may be variation in the values and results when the study is performed over a large group of patients.
- A detailed study on all the aspects of insomnia could not be studied owing to the shorter duration of study.
- The pathophysiology of insomnia and its effects are not completely studied which indicated a wide scope for research.

CONCLUSION

As Insomnia is the leading sleep disorder among the youth and middle aged, it is important to take necessary steps to tackle the condition. And as the leading causes such as overwork, mental worries, exhaustion are prevalent among the youth, *Passiflora Incarnate* can be chosen as one of the first line remedies in tackling insomnia. From the research done, it was shown that *Passiflora Incarnate Q* is effective in treating the sleep disorders especially Insomnia. The quality scale used for assessing the sleep quality was shown positive results. So *Passiflora Incarnate* mother tincture can be used as a top grade remedy for insomnia. to establish more evidence, further research to be done using more sample size.

Declaration by Authors

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Conflict of Interest: The authors declare no conflict of interest.

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