



Research Article

ADDED EFFECT OF PRATIMARSHA NASYA WITH KSHEERABALA TAILA (14 AAVARTITA) OVER SELECTED YOGA TECHNIQUES IN INSOMNIA

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ABSTRACT

Insomnia is a prevalent psycho physiological sleeping disorder, included in the International Classification of Sleep Disorders-2 (ICSD-2). By definition insomnia is a difficulty in initiating or maintaining sleep, or both or the perception of a poor quality sleep. Insomnia leads to various social, interpersonal and occupational impairments. Clinical studies have proven that *Yoga* is effective in insomnia. Present study was to find out the added effect of *Pratimarsha nasya* with *Ksheerabala taila* (14 *Aavartita*) over selected *Yoga* techniques in relieving insomnia. As per *Acharya* Susruta in *Chikitsa Sthana*, doing *Pratimarsha nasya* daily during evening hours (*Sayamkala*) renders *Sukhanidraprabhodanam*. A pre-post interventional study was performed in 40 participants both male and female, satisfying the inclusion and exclusion criteria. Out of 40 participants, 20 each were randomly allocated to Group I and Group II. In Group I, *Pratimarsha nasya* using *Ksheerabala taila* (14 *Aavartita*) was administered 1ml in each nostril at evening time along with the practice of selected *yoga* techniques during morning hours. In Group II, only selected *Yoga* techniques were advised. The study period was for 30 days. The pre & post changes in mean score value was assessed using Pittsburgh Sleep Quality Index (PSQI) score. The data was analyzed using unpaired t test, and was statistically significant with a p value ≤ 0.01 . Thus the added effect of *Pratimarsha nasya* with *Ksheerabala taila* (14 *Aavrtita*) over selected *Yoga* techniques in insomnia is more effective than selected *Yoga* techniques alone.

INTRODUCTION

Sleep is an important part of daily routine, a human being spends about one-third of time doing it. Getting quality sleep for the adequate duration is as essential to survival as food and water.

Insomnia is the inability to obtain an adequate amount or quality of sleep. The difficulty can be in falling asleep, remaining asleep or both. Its prevalence is about 30-50% in general population, in which 10% has chronic insomnia^[1]. Chronic insomnia can adversely affect the health, quality of life, academic performance; increase the risk of motor vehicle accidents, decrease productivity at work, irritability

and increase daytime drowsiness. Insomnia also considered a contributing risk factor for medical problems like cardiovascular diseases, chronic pain syndrome, depression, anxiety, obesity, diabetes etc^[2].

Hypnotics like benzodiazepines and non-benzodiazepines are the most frequently used drugs in insomnia. Studies revealed that BZD is associated with increased risk of dementia^[3].

Ayurveda has recognized *Nidra* as one of the most important dimensions of health associated with happiness, good health and is an outcome of relaxed mental state^[4].

Yoga is one among the *Shatdarshanas*. The definition of *yoga* is '*Yoga citta vritti nirodhah*', which means *Yoga* is the removal of oscillatory thoughts from mind and making it steady. Through the intervention of *Yoga* at both physical and mental level it encourages one to relax, slow the breath and focus on the present, down regulates the sympathetic activity via Hypothalamic Pituitary Axis (HPA) and activates the

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para sympathetic activity. Through many studies *Yoga* has proven to bring down Insomnia to certain extent (via change in certain psychological variables)^[5].

Pratimarsha nasya is a *Dinacharya* technique where nasal medication is advised as a daily routine procedure. It's done with reduced medicinal dose i.e., 1ml per nostril. Among the 14 *Kalas* of *Partimarsha nasya* explained by *Acharya Susruta* the one done during evening provides sound sleep (*Sukhanidra prabhodanam*)^[6]. *Ksheerabala tailam* (14 *Aavartita*), an important *Sneha-kalpana* mentioned in Ayurveda classics, prepared from cow milk (*Go-ksheera*), *Bala* (*Sida cordifolia*) and *Tila taila* (sesame oil).

Ksheerabala taila is being utilized as a *Rasayana* drug in conventional Ayurveda treatment for epilepsy. The continuous administration of this formulation prevents the release of abrupt electric discharges and improves the physical and mental condition of the patient. It has profound soothing and relaxing effect on mind^[7].

AIMS AND OBJECTIVES

To compare the combined effect of *Pratimarsha Nasya* with *Ksheerabala Taila* (14 *Aavartita*) and selected *Yoga* techniques in insomnia to the effect of selected *Yoga* techniques alone in Insomnia.

MATERIALS AND METHODS

Patients who came to the OPD of *Swasthavritta*, Government Ayurveda Panchakrama Hospital, Poojappura, were well examined. On the basis of the inclusion and exclusion criteria, forty patients were selected with the help of Pittsburgh Sleep Quality Index (PSQI) and they were randomly allocated into 2 groups, namely Group I (study Group) and Group II (control group). In Group I, collected one bottle *Ksheerabala taila* (14 *Aavartita*) were dispensed every 10 days and total of 3 bottles for 30 days. The method of administration was demonstrated to all patients. They were advised to do the prescribed *Nasya karma* with 1ml in each nostril. Instructed to lie down in supine position with head and neck low position; instill 1ml of *Ksheerabala taila* (14 *Aavartita*) in each nostril. Along with *Nasya* they were advised to practice

Selected *Yoga* techniques every morning for duration of one hour on empty stomach. The control group (Group II), were given selected yoga techniques alone throughout the study period. The quality of sleep was assessed before and after the study period using Pittsburgh Sleep Quality Index. The consent of the study was taken from all participants through a consent form in regional language. The data were analyzed statistically.

Inclusion Criteria

1. Participants both male and female.
2. Participants in the age group of 30-60 years.
3. Participants having difficulty in initiating and maintaining sleep.

Exclusion Criteria

1. Participants with known severe systemic illness and other neurological illness.
2. Pregnant and lactating women.

Duration of the Study

30 days

Sampling Technique

Consecutive sampling

Data Collection Method

- Detailed Case Performa
- Insomnia screening Questionnaire
- Pittsburgh Sleep Quality Analysis Index.

Study Tool

Pittsburg Sleep Quality Index (PSQI)

Intervention

Study Drug

Ksheerabala taila mentioned in *Ashtanga Hridaya*, *Chikilsa Stana*, *Vatasonitha Chikilsa Adhyaya*. It contains 3 drugs- *Bala* (*Sida cordifolia*), *Tila taila* (*Seasame indicum* oil), cow's milk (*Go Ksheeram*).

Collection

The study drug was procured from Oushadi Pharmaceutical Corporation Kerala Ltd. Collected 60 bottles of *Ksheerabala Taila* 14 *Aavartita* having 10ml each.

Medicinal Form: Oil form

Dose: 1ml each nostril

Dose Schedule: Evening (4pm-6pm)

Route of Administration: Nasal route

Table 1: Yoga Schedule for Participants

S. No	Name of Practice	Repetition
1.	Prayer	1
2.	Loosening exercise	2
3.	<i>Tadasana</i>	2
4.	<i>Vrikshasana</i>	2
5.	<i>Padmasana</i>	2
6.	<i>Vajrasana</i>	2
7.	<i>Padahastasana</i>	2
8.	<i>Ardhakatichakrasana</i>	2
9.	<i>Shashangasana</i>	2

10.	<i>Bhujangasana</i>	2
11.	<i>Shalabhasana</i>	2
12.	<i>Matsyasana</i>	2
13.	<i>Nadishudhi pranayama</i>	2
14.	<i>Brahmari pranayama</i>	2
15.	<i>Sheetali pranayama</i>	2
16.	<i>Shavasana</i>	1
17.	<i>Aum khar</i>	1

Outcome Measurements

Pittsburgh Sleep Quality Analysis Scale

Plan of Analysis

Statistical analysis is done via Unpaired Students t Test

RESULTS

The global PSQI scale score was the most important parameter for assessing the efficacy of treatment on sleep quality and disturbances.

Table 2: Assessment of Effect of Treatment on Sleep Quality and Disturbance (PSQI)

PSQI	Group I				Group II			
	BT		AT		BT		AT	
	N	%	N	%	N	%	N	%
≤7	4	20	19	95	6	30	18	90
8 to 14	15	75	1	5	13	65	2	10
15 to 21	1	5	0	0	1	5	0	0
Total	20	100	20	100	20	100	20	100

Table 3: Analysis on the Effectiveness of Intervention on both the Groups using Mean and Standard Deviation of the PSQI score values before and after the test

Mean deviation	Group I		Group II	
	BT	AT	BT	AT
Mean	10.2	3.9	8.95	6.2
Standard deviation	2.72	1.8	2.5	2.26

The mean PSQI score of group I before test is 10.2 and after test is 3.9 and the mean PSQI score of group II before test is 8.95 and after test is 6.2. The standard deviation of the PSQI score of group I is 2.72 before test and 1.8 after test and the standard deviation of the PSQI score of group II before test is 2.5 and after test is 2.26.

Analysis was done using unpaired t test. The t value from the test is 3.56. Table value at degree of freedom 38 for the corresponding t value gives a P value of <0.01 i.e., the test is significant. From the above data it's concluded that the null hypothesis is rejected and alternate hypothesis is accepted i.e., the add on therapy of *Pratimarsha Nasya* with *Ksheerabala taila* (14 *Aavartita*) over the selected *Yoga* techniques is more effective than *Yoga* techniques alone in insomnia.



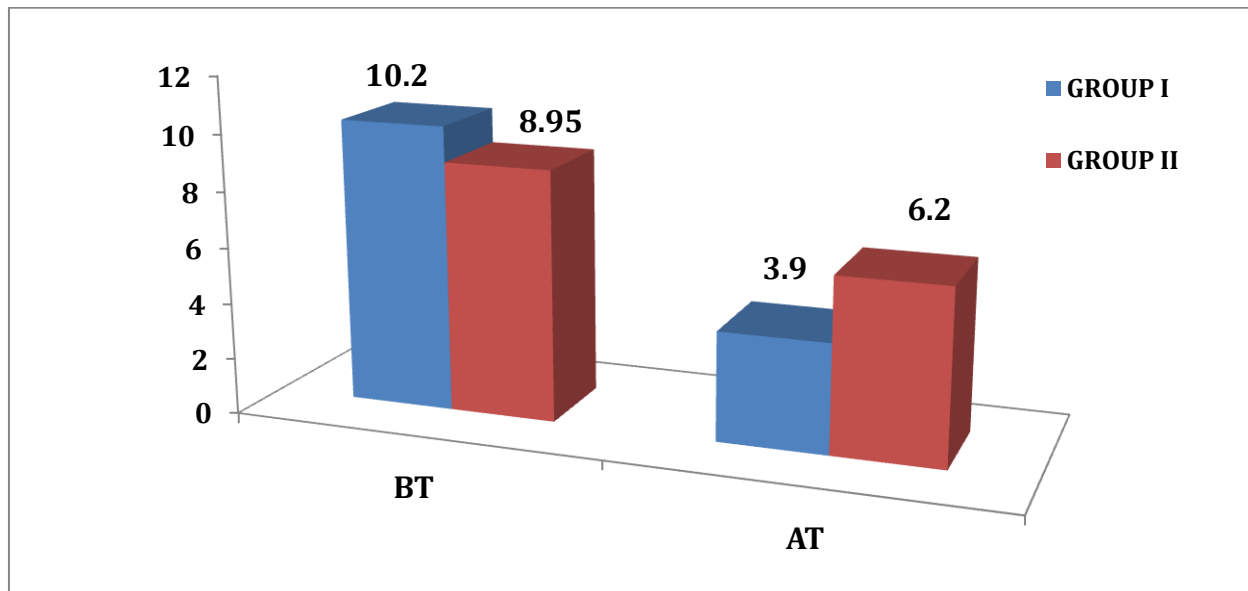
Fig No: 1- Loosening Exercise



Fig No: 2- Padahasthasana



Fig No: 3- Bhujangasana



DISCUSSION

The present research work “The added effect of *Pratimarsha nasya* with *Ksheerabala* (14 *Aavartita*) over selected *Yoga* techniques in insomnia” is having relevance in the current scenario since, 10-30% of the adults, 30-48% of older people and 23.8% of teenagers are suffering from insomnia^[8]. Modern medicine although advises both non-pharmacological and pharmacological interventions in insomnia, but are having limitations as well as side effects. Limitations being, the necessity of trained therapists to conduct non-pharmacological interventions^[9] and side effects being, dependency and memory issues in pharmacological interventions. Most of the patients with insomnia, especially non-organic insomnia rarely consider medical interventions for cure, which on the long run; end up creating other lifestyle disorders like metabolic syndromes, hypertension and type II diabetes mellitus^[10]. Considering this type of attitude by public towards this disease, an intervention which can be assimilated into once daily routine becomes an essentiality for its cure. In this wake, the current work is imbibing yoga as a non-pharmacological intervention and *Pratimarsha Nasya* with *Ksheerabala taila* (14 *Aavartita*) as a pharmacological intervention. Both these interventions can be very easily improvised into a person’s daily life without any side effects. *Yoga* being a proven non-pharmacological intervention for insomnia^[11], via this study pharmacological add on is intended since *Ksheerabala taila* has direct indication on *Vatananatmaja vikaras*. Hence this study considers *Pratimarsha nasya* with *Ksheerabala taila* (14 *aavartita*) over selected *Yoga* techniques in insomnia. Sleep quality includes quantitative aspect of sleep, such as sleep duration and latency as well as more purely subjective aspects, such as depth or restfulness of sleep.

Before treatment, PSQI score for control group was 5% in the score 15-21, 65% in the score 8-14, 30% in the score less than 7 greater than 5. After treatment, PSQI score for control group was 0 in the score 15-21, 10% in the score 8-14, 90% in the score less than 7 greater than 5. Before treatment, PSQI score for test group was 5% in the score 15-21, 75% in the score 8-14, 20% in the score less than 7 greater than 5. After treatment, PSQI score for test group was 0 in the score 15-21, 5% in the score 8-14, 95% in the score less than 7 greater than 5. Based on the PSQI score change, the assessment of effectiveness of intervention in sleep quality and disturbance is statistically significant with P value <0.01 using unpaired t test. This result signifies that the added effect of *Pratimarsha Nasya* along with *Yoga* techniques is more effective in insomnia than *Yoga* techniques alone.

Probable Mode of Action of Treatment

Therapeutic interventions in modern medicine are available in various forms. The most widely used drug by them is benzodiazepines, which since administered orally absorption rate gets reduced, thus duration of administration increases. This creates dependence and in long period is leading to dementia^[12]. So as a therapeutic intervention *Ksheerabala taila* (14 *Aavartita*) is chosen in this study, which is administered as *Pratimarsha Nasya*.

Pratimarsha Nasya is one among the *Dinacharya* procedure (daily regimen) advised by Ayurveda from birth to old age. When done as a daily regimen, it’s stated to reduce many upper respiratory complaints and *Pratimarsha nasya* done during evening time is specifically stated as effective in sleep problems (*Sukhanidra prabhodanam*).

When medicines are administered via TNDD the dose can be reduced to minimum since rate of absorption becomes more. That's why in this study the route of administration was chosen as TNDD^[13].

Ksheerabala taila has 3 ingredients in total- *Bala* (*Sida cordifolia*), *Goksheera* (cow's milk), *Tila taila* (*Sesamum indicum* seed oil). Considering the action of drug, the main ingredient in *Ksheerabala taila* (14 *Aavartita*) is *Sida cordifolia* (*Bala*). Studies have proven that *Sida cordifolia* has properties like anxiolytic, Sedative and anticonvulsant action^[14]. Anxiolytic property accounts for the reduction in anxiety, which in turn can reduce the stress. Sedative action of *Bala* can help the patients with sleep problems to get good sleep. There are studies which have shown the effect of *Sida cordifolia* in reducing the number of epileptic episodes in epilepsy patients, which proves its anticonvulsant action.

Taking in account of all these effects and properties, it can be understood that the probable mode of action of *Ksheerabala taila* (14 *Aavartita*) as *Pratimarsha Nasya* as an added therapy over Yoga in insomnia patients for a period of 30 days must have been due to the anxiolytic, sedative, anticonvulsant and depressant action of the drug *Sida cordifolia*.

Various non-therapeutic measures are available in the Modern science to deal with insomnia. One among the most widely used one is cognitive behavioral therapy for insomnia (CBT-I). This includes cognitive interventions, behavioral interventions and psycho educational interventions. In case of insomnia the therapy usually needs a minimum of 6-8 sessions with a minimum of 20 minutes in each session. CBT-I therapy is done by a qualified therapist for the same or by a primary care doctor. Yoga in Ayurveda is an evident method to deal with stress and sleeping disorders. It can be considered as a non-therapeutic intervention in Ayurveda. There are various studies that prove its effectiveness in reducing stress and to cope the sleeping disorders especially non organic insomnia. *Yoga* has an evident action on the parasympathetic activation. When the parasympathetic activation happens automatically the person feels relaxed and calm. *Yoga* with an amalgamation of *Asana* and *Pranayama* is meant to be doing this. During this process, the inflammatory cytokines reduces and oxidative stress comes in bay.

There are clinical studies which have stated that, doing *Yoga* acts as psycho-physiological stimuli for the endogenous secretion of melatonin^[15]. That can be considered as the mode of action of yoga on insomnia.

CONCLUSION

Insomnia is the current most prevalent sleep disorder with a prevalence of 23.8% even in the teenagers. The most relevant reason for insomnia

(primary insomnia) is stress. *Nidranasam* is both a symptom and a disease, and the symptoms correlate to that of insomnia. *Ksheerabala taila* has direct indication on *Vata nanatmaja vikaras*, *Nidranasam* is one among those 80 *Vikaras*. *Ksheerabala taila* (14 *Aavartita*) can reduce the oxidative stress and relax the mind. *Yoga* practice can down regulate the Hypothalamic Pituitary Axis (HPA). The reduction in mean PSQI score of the test group was more than that of the control group. *Pratimarsha Nasya* with *Ksheerabala taila* (14 *Aavartita*) can be included as a in the daily routine (at *Dinacharya* level) for Insomnia. *Pratimarsha nasya* can be included in the daily routine (at *Dinacharya* level). Both the interventions are easy, economical and safe in practice. The effect of intervention observed in the Test group was significantly greater than that of the Control group with a P value of 0.01. No side effects were observed during and after the study period of administration of trial medicine.

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