IAMJ

INTERNATIONAL AYURVEDIC MEDICAL JOURNAL

Research Article ISSN: 2320-5091 Impact Factor: 6.719

AN OPEN LABELLED CONTROLLED CLINICAL TRIAL ON THE EFFICACY OF VEDOKTA RATRISUKTAM AND SARPAGANDHA VATI IN NIDRANASHA W.S.R. TO PRIMARY INSOMNIA

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https://doi.org/10.46607/iamj1011102023

(Published Online: October 2023)

Article Received: 08/08/2023 - **Peer Reviewed:** 25/08/2023 - **Accepted for Publication:** 10/09/2023.

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ABSTRACT

Objective: To compare the efficacy of *Vedokta Ratri Suktam* and *Sarpagandha Vati* in *Nidranasha* w.s.r. to Primary Insomnia. **Methodology:** A open labelled randomized controlled clinical study was conducted to evaluate the effect of *Vedokta Ratri Suktam* and *Sarpagandha Vati* in *Nidranasha* w.s.r to Primary Insomnia. The study was conducted on the patients of the Shri Dharmasthala Manjunatheshwara Hospital of Ayurveda, Udupi diagnosed with Nidranasha (Primary Insomnia). Regardless of their gender, cast, or creed, a total of 30 participants who have a confirmed diagnosis – that is, who meet the diagnostic inclusion criteria for *Nidranasha*/ Primary Insomnia were chosen for the study. Permuted block randomization was done, through which the participants were divided into 2 groups comprising 15 participants each. Group A (Trial group) listening to the audio of *Vedokta Ratri Suktam* for a duration of 28 days was advised and Group B (Control group) received *Sarpagandha Vati* 1 tablet twice a day with warm water after food was advised for a duration of 28 days. Assessment was done on 0^{th},14^{th},28^{th} and 56^{th} day. Parameters were scored in both Subjective and Objective aspects and were assessed on 0^{th} and 28^{th} day i.e., before and after treatment. The data obtained was statistically analyzed by Wilcoxon signed rank test within the groups and Mann-Whitney U test in between the groups. **Results:** When looking at the interventions given for Group A and Group B, Group A showed a significant improvement in relief by a mean per-

centage of 60.33% and Group B showed improvement in relief by a mean percentage of 37.06%. **Conclusion:** *Vedokta Ratri Suktam* showed significant efficacy in reducing signs and symptoms of *Nidranasha* and improving the quality of sleep when compared to *Sarpagandha Vati*.

Keywords: *Nidranasha*, Primary Insomnia, *Vedokta Ratri Suktam*, *Sarpagandha Vati*.

INTRODUCTION

Ahara (food/nutrition), *Nidra* (sleep) and *Brahmacharya* (control over senses) are described as the *Trayopastambha* of life, which means they are the three pillars of life that support and sustain human existence[1]. *Nidranasha* is classified as a *Vataja nanatmaja vyadhi*[2]. Insomnia disorder is a common sleep disorder characterized by difficulty in initiating or maintaining sleep or experiencing dissatisfaction with sleep quality or quantity. It can significantly impair an individual's daily life, including occupational and social functioning, and may lead to the development of other psychiatric illnesses. Chronic sleep deprivation has also been associated with an increased risk of various health conditions such as obesity, diabetes, cardiovascular disease, and depression[3]. Therefore, it is essential to prioritize sleep and ensure that one gets adequate and restful sleep on a regular basis in order to maintain optimal health and well-being. Insomnia disorder is a common sleep disorder characterized by difficulty in initiating or maintaining sleep or experiencing dissatisfaction with sleep quality or quantity. It can significantly impair an individual's daily life, including occupational and social functioning, and may lead to the development of other psychiatric illnesses. Studies suggest that about 1/3rd of adult's report insomnia symptoms, and 30% meet the criteria for insomnia disorder. Insomnia is more prevalent in females and older adults. Insomnia is often comorbid with other medical and psychiatric conditions, such as dyspnoea, gastroesophageal reflux disease, pain conditions, neurodegenerative conditions, and circadian rhythm disorders. Improper sleep can also increase the risk of developing other health problems such as obesity, diabetes, high blood pressure, and heart disease[4]. It is important to seek medical attention if one experiences persistent insomnia symptoms or daytime impairments. Several treatments are available, including lifestyle modifications, cognitive-behavioral therapy, and medications, to improve sleep quality and quantity and alleviate the associated impairments. There is not much focus on *Daivavyapashraya chikitsa*, hence choosing the two groups for the study. One group *Vedokta Ratri Suktam* and other group *Sarpagandha Vati*. In this study, *Vedokta Ratri Suktam* is used in comparison with *Sarpagandha Vati*. The study aims to investigate the effectiveness of *Vedokta Ratri Suktam* and *Sarpagandha Vati* in managing *Nidranasha*. *Vedokta Ratri Suktam* is believed to have a calming effect on the mind and promote restful sleep through spiritual and metaphysical means[5]. *Sarpagandha Vati* is believed to have sedative and antihypertensive properties and is used to calm the mind and promote restful sleep[6].

METHODOLOGY:

Ethical committee clearance has been done with Reference number:

SDMCAU/ACA-49/ECH 12/2020-21.

Objective of the Study

1. To evaluate the effect of *Vedokta Ratri Suktam* in *Nidranasha* w.s.r. on Primary Insomnia.
2. To evaluate the effect of *Sarpagandha Vati* in *Nidranasha* w.s.r to Primary Insomnia.
3. To compare the efficacy of *Vedokta Ratri Suktam* and *Sarpagandha Vati* in *Nidranasha* w.s.r. to Primary Insomnia.

Design of the Study:

Study Type	: Interventional
Estimation enrolment	: 30 participants
Allocation	: Randomized
Endpoint Classification	: Efficacy study
Intervention Model	: Double group
Primary Purpose	: Treatment
Masking	: Open label

Setting: Shri Dharmasthala Manjunatheshwara Ayurveda Hospital, Kuthpady, Udupi.

Participants: Regardless of their gender, cast, or creed, 30 participants with a confirmed diagnosis – that is, who meet the diagnostic inclusion criteria for *Nidranasha*/ Primary Insomnia were chosen for the study.

Intervention: A total of 30 patients were divided into 2 groups, Group A and Group B comprising 15 patients each using permuted block randomization.

Group A (Trial group)

Treatment advised: Vedokta Ratri Suktam

Time taken: 8 minutes audio.

Duration of the intervention: 28 days

Time of treatment: 90mins after dinner, while going to bed.

Group B (Control group)

1 tablet *Sarpagandha Vati* twice a day, after food.

Anupana: Warm water

Duration of intervention: 28 days

Follow up: After 28 days.

Duration of the study: 56 days

Diagnostic criteria:

- ICD- 10 criteria -F.51.0 Nonorganic insomnia[7].
- With or without the association of other *lakshana*s of *Nidranasha*.

Inclusion criteria:

1.Patients who fulfill diagnostic criteria.

2. Patients were selected for the age group between 18-60years.

3. Patients who were willing to sign informed consent.

Exclusion criteria:

1. Patients suffering from other systemic illness and other metabolic disorders interfering with the treatment protocol were excluded.

2. Patient suffering from any other psychiatric illness or disorder were excluded.

3. Pregnant and lactating women were excluded.

4. Patient suffering from Substance abuse, Circadian rhythm disorder, Parasomnia were excluded.

Assessment criteria

Both subjective and objective criteria were assessed by standard methods before and after the treatment i.e., on 0^{th} day and 28^{th} day. The data was statistically analyzed by Wilcoxon signed rank test within the groups and Mann-Whitney U test in between the groups.

Subjective criteria

1. Athen's insomnia scale[8]

The scale comprises of 8 questions with a total score of 24. For each question the scoring ranges from 0 to 4, where 0 indicates no problem and 4 indicates severity with interference in their daily routine.

2. Insomnia severity index[9]

The scale comprises of 7 questions with scores ranging from 0 to 4. Questions from 1 to 3 have scoring 0 to 4 with options of symptoms being "None, Mild, Moderate, Severe, very severe"; 4^{th} question deals with the satisfaction of the observed sleep pattern. While questions from 5 to 7 comprise the scoring options from "Not at all noticeable" to "Very much worried".

Total score ranging from 0–7 result in No clinically significant insomnia, 8–14 result in Subthreshold insomnia, 15–21 indicate Clinical insomnia (moderate severity) and 22–28 indicate Clinical insomnia (severe). The patients were included who were coming in the scoring range from 8-24.

3. Nidranasha Rating Scale

The scale is used by assessing the presence and absence of the lakshanas of *Nidranasha* and is scored out of a total score of 8 on 0^{th},14^{th},28^{th} and on 56^{th} day.

4. Baseline values of Visual Analogue Scale (0-10) of *Angamarda, Shirogourava, Jrumbha, Jadya, Glani, Bhrama, Apakti, Tandra* on 0^{th},14^{th},28^{th} and on 56^{th} day.

5. *Manasika Bhava* Scale was used to assess the emotional status of the patients. There were both positive and negative emotions that were assessed using this scale.

Objective criteria

1. Pulse
2. Blood Pressure

RESULTS

The initial mean scores of AIS, ISI, NRS were reduced to scores as described in the table below.

WITHIN THE GROUP

Table no.1 Effect of treatment on AIS within the group

Group	Mean		BT - AT	% of Relief	WILCOXON SIGNED RANK TEST					
	BT	AT				SD	SEM	Median	Z	P
Group A N=15	16.687	10.733	5.954	35.69%	BT	2.503	0.646	18.000	-3.422	(P = <0.001)
					AT	2.4492	0.643	10.000		
Group B N=15	16.733	13.600	3.133	18.70%	BT	2.631	0.679	17.000	-3.448	(P = <0.001)

Table no.2 Effect of treatment on ISI within the group

Group	Mean		BT - AT	% of Relief	WILCOXON SIGNED RANK TEST					
	BT	AT				SD	SEM	Median	Z	P
Group A N=15	19.667	13.867	5.8	29.49%	BT	2.743	0.646	20.000	-3.424	(P = <0.001)
					AT	0.568	0.643	14.000		
Group B N=15	20.133	16.467	3.66	18.17%	BT	2.631	0.679	17.000	-3.436	(P = <0.001)
					AT	3.122	0.804	12.000		

Table no.3 Effect of treatment on NRS within the group

Group	Mean		BT -AT	% of Relief	WILCOXON SIGNED RANK TEST					
	BT	AT				SD	SEM	Median	Z	P
Group A N = 15	5.400	2.467	2.933	54.31%	BT	0.986	0.254	6.000	-3.449	(P = <0.001)
					AT	0.990	0.256	2.000		
Group B N = 15	5.800	3.800	2.000	34.48%	BT	1.207	0.312	6.000	-3.475	(P = <0.001)

BETWEEN THE GROUP

Table no.4 Effect of treatment on AIS between the group

Group	Mean	SD	SEM	Median	Mann Whitney U Test		
Group A N=15	6.133	2.642	0.682	5.000	T value	U value	P value
Group B N=15	3.133	1.356	0.350	3.000	312.500	32.500	<0.001

Table no.5 Effect of treatment on ISI between the group

Group	Mean	SD	SEM	Median	Mann Whitney U Test		
Group A N=15	5.800	2.305	0.595	6.000	T value	U value	P value

Group B N=15	3.667	2.059	0.532	3.000	292.000	53.000	=0.013

Table no.6 Effect of treatment on NRS between the group

Group	Mean	SD	SEM	Median	Mann Whitney U Test		
Group A N=15	2.933	0.961	0.248	3.000	**T value**	**U value**	**P value**
Group B N=15	2.000	0.845	0.218	2.000	285.500	59.500	0.022

Based on Symptoms

Significant differences were observed in the mean scores of both groups. In Group A, the mean score of the Insomnia Severity Index decreased from 19.667 before treatment to 13.867 after treatment, indicating a 29.49% improvement whereas in Group B, the score decreased from 20.133 before treatment to 16.467 after treatment, showing an improvement of 18.17%. Statistically significant improvements were observed in various symptoms after the intervention. In Group A, Angamarda showed a substantial 62.90% improvement, which was statistically significant with a p-value of 0.002. Comparatively, in Group B, the improvement in Angamarda was 33.68%, also statistically significant with a p-value of less than 0.001. For Shirogaurava, Group A exhibited a noteworthy 61.22% improvement ($p<0.001$), surpassing the 38.54% improvement ($p<0.001$) seen in Group B. In Group A, Jrumbha displayed a remarkable 64.04% improvement, with a p-value of less than 0.001, while Group B showed a 33.32% improvement ($p<0.001$). Jadya showed a significant improvement in Group A, with a 56.85% increase ($p=0.002$), compared to a 29.86% improvement in Group B. In Group A, Glani demonstrated a substantial 65.70% improvement ($p=0.016$), whereas Group B showed a 33.33% improvement ($p=0.031$). Similarly, Apakti displayed a statistically significant improvement in Group A, with a 60.59% increase ($p=0.016$), while Group B showed a 37.27% improvement ($p=0.002$). Tandra exhibited a 61.60% improvement ($p=0.016$) in Group A, contrasting with a 38.54% improvement ($p=0.002$) seen in Group B. It's important to note that for Bhrama, in Group A, there was a 60.06% improvement, but no statistical test was conducted in Group B due to a low patient count.

OVERALL EFFECT OF THERAPY:

The analysis of the treatment interventions for Group A and Group B revealed significant improvements in relief for both groups. In Group A, the mean percentage of relief was 60.33%, while in Group B, it was 37.06%. Among the patients in Group A, 6.6% experienced maximum relief, 66.66% had moderate relief, 20% had mild relief, and 6.6% had minimum relief. In contrast, none of the patients in Group B experienced maximum relief, 20% had moderate relief, 46.66% had mild relief, and 33.33% had minimum relief. These findings suggest that the interventions applied to Group A resulted in a higher degree of relief compared to Group B.

DISCUSSION

Vedokta Ratri Suktam discusses the benefits of Sound Therapy in reducing stress-related insomnia. It explains that Sound Therapy calms the mind, leading to improved sleep by addressing excessive cortical excitation. The therapy achieves this by engaging the brain, relaxing it, and enabling a natural transition to slower rhythms conducive to sleep[10]. The brain's structures, including the Insula, Anterior Cingulate Cortex, and Orbitofrontal cortices, play vital roles in various functions such as pain, behavior, cognition, and sensory processing. Sound Therapy, particularly during *Om Mantra* chanting, deactivates these areas, promoting parasympathetic activity and aiding in sleep[11]. The study focuses on the "*RatriSuktam*" from *Rigveda Samhita's* 10th *Mandala*, 8th *Ashtakam*, 127th *Sutram*[12]. The therapy involves *Vedokta Ratrisuktam* audio, 8 minutes long, before sleep, engaging 27 *shlokas*. *Mantras*, through vibrations, influence brain cells, reducing worries, and purifying the mind[13]. The *Rigveda-Samhita* comprises 10 *Mandalas*, 85 *Anuvaka*, 1028 *Sukta*, and 10552 *Mantra*[14].

The chosen "*RatriSuktam*" is a hymn to the goddess *Ratri* (night) as protection from darkness. The prayer seeks safety from night-related challenges, with verses describing the goddess, activities during the night, and a plea for protection. This hymn is also interpreted as a spiritual journey from darkness to light, ignorance to knowledge[15].

Overall, the passage underscores the benefits of Sound Therapy, the effects of chanting *Mantras* on the brain, and the significance of the "*RatriSuktam*" as both a practical and spiritual guide for dealing with challenges related to the night.

Sarpagandha comprises of *Tikta, Kashaya rasa* along with *Ruksha guna*. It is of *Ushna veerya* and of *Katu vipaka*. *Sarpagandha* is *Kapha-Vata hara*[16,17]. *Nidranasha* being a *Vataja nanatmaja vyadhi*, *Sarpagandha* has an impact on this condition based on the characteristics mentioned above.

CONCLUSION

- No adverse effects were observed in any of the patients during the treatment period or follow-up. None of the patients reported any adverse drug reactions to the medication.
- *Vedokta Ratrisuktam* showed significant efficacy in reducing signs and symptoms of *Nidranasha* and improving the quality of sleep when compared to *Sarpagandha Vati*.

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Source of Support: Nil

Conflict of Interest: None Declared

How to cite this URL: Pata Anusha & Shrilatha Kamath T: An open labelled controlled clinical trial on the efficacy of vedokta ratrisuktam and sarpagandha vati in nidranasha w.s.r. to primary insomnia. International Ayurvedic Medical Journal {online} 2023 {cited October 2023} Available from: http://www.iamj.in/posts/images/upload/2456_2461.pdf