

A CLINICAL STUDY TO EVALUATE THE EFFECT OF ASHWAGANDHA YOGA IN NIDRANASHA W.S.R TO PRIMARY INSOMNIAShilpa Rajan*¹, Shrilatha Kamath T.² and Dhaneshwari H. A.³¹PG scholar, Dept. of PG Studies in Kayachikitsa and Manasaroga, Sri Dharmasthala Manjunatheshwara College of Ayurveda, Kuthpady, Udupi, Karnataka.²Professor and HOD, Department of Kayachikitsa and Manasaroga, Sri Dharmasthala Manjunatheshwara College of Ayurveda, Kuthpady, Udupi.³Assistant Professor, Department of Kayachikitsa and Manasaroga, Sri Dharmasthala Manjunatheshwara College of Ayurveda, Kuthpady, Udupi.***Corresponding Author: Shilpa Rajan**

PG Scholar, Dept. of PG Studies in Kayachikitsa and Manasaroga, Sri Dharmasthala Manjunatheshwara College Of Ayurveda, Kuthpady, Udupi, Karnataka.

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ABSTRACT

Nidra is a state, when manas, jnanendriya and karmendriya get exhausted; they dissociate themselves from their vishayas, which let the individual to sleep and it is considered as one among the trayopasthambha. *Nidra nasha* happens due to aggravation of *vata*, *pitta* and *rajadosha*, later leads to the manifestation of different physical and psychological symptoms. **Objectives:** To evaluate the effect of *Ashwagandha yoga* in *Nidranasha/ Primary Insomnia*, to evaluate the effect of *Ashwagandha yoga* in Quality of life of patients in insomnia. **Methodology:** An open labelled clinical study with pre and post-test design. The 20 patients with diagnostic criteria of primary insomnia were selected from Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Kuthpady. Udupi were given with *ashwagandha yoga* for 14 days with follow up of 28 days. Outcome was measured before and after the intervention by using visual analogue scale for nidranasha symptoms like *angamarda*, *shirogourava*, *jadya*, *glani*, *jrumbha*, *apakti*, *bhrama* and *tandra*, insomnia severity index and Athens insomnia scale. To assess the quality of life of a patient WHOQOL-BREF scale has been used. All the parameters were statistically analysed with Wilcoxon signed rank test. **Results:** statistically significant results were found in parameters with p value <0.001. **Conclusion:** *Ashwagandha yoga* found to be effective in reducing the symptoms of primary insomnia and helped to improve the quality of life of patients. The efficacy of the medication has been proved with statistical analysis of the parameters.

KEYWORDS: *Nidra*, *Ashwagandha yoga*, *nidranasha*, primary insomnia.**INTRODUCTION**

Ahara, *Nidra* and *Brahmacharya* are described to be *trayopastambha* of life and so, *Nidra* is the one of the essential factors to lead a healthy life.^[1] When the mind including sensory and motor organs exhausted, they dissociate themselves from their objects, and then the individual sleeps. Happiness and misery, proper and improper growth, good strength and weakness, potency and sterility, knowledge and illiteracy and life and death of an individual depend on the quality of sleep.^[2] *Nidranasha* is a term used for loss of Sleep.

Insomnia disorder is dissatisfaction with sleep quality or quantity with complains of difficulty in initiating or maintaining the sleep. It may not be a life threatening illness, but it has a tendency to impair the person's daily life, including his occupational and social life. If it is very severe, person may develop other psychiatric illness.^[3]

Population based studies indicates that about 1/3rd of adult's report insomnia symptoms, 10-15% experienced associated day time impairments, 6-10% have symptoms that meet criteria for insomnia disorder. It is more prevalent in females and older adults. 75-90% of people with insomnia have an increased risk for comorbid medical disorders, such as conditions causing dyspnoea, gastroesophageal reflux disease, pain conditions and neurodegenerative conditions. Variety of primary sleep disorder as well as circadian rhythm disorders are frequently comorbid with insomnia. 40% of all insomnia patients have a co-existing psychiatric condition. Improper sleep can increase risk of developing obesity, diabetes, high blood pressure or heart disease.^[4]

Both *sharirika* as well as *manasika doshas* are involved in the manifestation of *nidranasha*, where *vata pitta vridhi* along with *rajo vridhi* happens in patients of *nidranasha*. Different treatment modalities are

mentioned for loss of sleep. In classics various treatment principles have been mentioned some of those are *bahya upacharas, ahara and aushada upacharas*. Treatments like *abhyanga, udwartana, mardana, nasya, karma poorana, shirolepa* and *murdhni taila* are the important treatments in *bahya chikitsa*.^[5] Meanwhile *aharas* and *aushada chikitsa* plays a vital role in *samprapti vigatana*.

In this study *Ashwagandha Yoga* is chosen.^[6] It is one such formulation which is especially indicated in *Nidra nasha*, which contains *ashwagandha, ghrita* and *sita*. All three ingredients are having *vata hara* property along with *nidra janana karma*. This is a simple and effective yoga which can be used for *Nidra nasha*.

MATERIALS AND METHODS

Objectives

- To evaluate the effect of *Ashwagandhayoga* in *Nidranasha/ Primary Insomnia*
- To evaluate the effect of *Ashwagandha yoga* in Quality of life of patients in insomnia

Design

- Study type: Interventional
- Allocation: Non randomized
- End point classification: Efficacy study
- Interventional Model: Single group
- Primary purpose: Treatment
- Masking: open labelled, pre-test and post-test design.

Setting: Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Kuthpady, Udipi

Participants: from September 2019 to February 2020, patients with definite diagnosis fulfilling the diagnostic, inclusion criteria of *nidranasha / primary insomnia* are selected for the study irrespective of gender.

Intervention

Patients are administered *Ashwagandha yoga* consisting of 6 gm of *Ashwagandhachurna*, 6 ml of *ghrita*, and 6gm of *sita* and will be given 30 minutes before dinner for 14 days.

Duration of treatment: 14 days.

Follow up: 28 days after the treatment.

Diagnostic criteria

- ICD- 10 criteria -F.51.0 Nonorganic insomnia.^[10]
- A complaint of difficulty falling asleep, maintaining sleep or non-refreshing sleep.
- The sleep disturbance occurs at least three times per week for at least one month
- Sleep disturbance results in marked personal distress or interference with personal functioning in daily living.

- Absence of any known causative organic factor, such as neurological or other medical condition, psychoactive substance use disorder or medication.
- With or without the association of other *lakshanas* of *Nidranasha*

Inclusion criteria

1. Patient fulfilling diagnostic criteria.
2. Patients are selected of age group between 16-60years.
3. Patients willing to sign informed consent.

Exclusion criteria

1. Patients suffering from other systemic illness and other metabolic disorder interfering with treatment
2. History of other associated Psychiatric Disorder
3. Pregnant and lactating women
4. Substance abuse, circadian rhythm disorder, parasomnia

Assessment criteria

Parameters are scored by standard method and are assessed before and after treatment on 0, 7th, 14th and 42nd day, and are analysed statistically using paired 't' test for the numerical data and Wilcoxon signed rank test for ordinal data on comparing 0 to 14th day within the group.

1. Athens insomnia scale.^[7]
2. Insomnia severity index.^[8]
3. Quality of life assessment scale.^[9]
4. Baseline values of Visual analogue scale (0-10) of *Angamarda* compared with values of Visual analogue scale (0-10) on 14th day.
5. Baseline values of Visual analogue scale (0-10) of *Shirogourava* compared with values of Visual analogue scale (0-10) on 14th day.
6. Baseline values of Visual analogue scale (0-10) of *Jrumbha* compared with values of Visual analogue scale (0-10) on 14th day.
7. Baseline values of Visual analogue scale (0-10) of *Jadya* compared with values of Visual analogue scale (0-10) on 14th day.
8. Baseline values of Visual analogue scale (0-10) of *Glani* compared with values of Visual analogue scale (0-10) on 14th day.
9. Baseline values of Visual analogue scale (0-10) of *Bhrama* compared with values of Visual analogue scale (0-10) on 14th day.
10. Baseline values of Visual analogue scale (0-10) of *Apakthi* compared with values of Visual analogue scale (0-10) on 14th day.
11. Baseline values of Visual analogue scale (0-10) of *Tandra* compared with values of Visual analogue scale (0-10) on 14th day.

RESULTS

Results of the treatment were assessed by following measures.

Athens insomnia scale(AIS), Insomnia severity index scale (ISI Scale), Quality of life assessment scale by WHO(WHOQOL) Visual analogue scale for following symptoms of nidranasha Angamarda, Shirogourava Jrumbha, Glani, Jadya, Apakti, Bhrama and Tandra. Results were analyzed statistically using Wilcoxon signed rank test and the p value was obtained.

Among 20 patients 60% of patients were having moderate insomnia and 40% of patients were presenting with severe insomnia. Many of the time patients will neglect the condition without consulting the doctor, when sleeplessness is in milder form. The overall effect of the intervention shows there was moderate improvement is seen in 45% of the patients. Mild improvement seen in 30% of patients and 25% of patient showed marked improvement.

Effect of treatment in different parameters.

Parameter	Mean			Wilcoxon signed rank test					
	BT	AT	BT-AT	% of improvement	SD	SEM	Median	Z value	P value
Angamarda N= 15	5.450	3.500	1.95	35.77	BT- 3.486	BT- 0.780	6.000	-3.432	<0.001
					AT- 2.606	AT- 0.583	4.000		
Shirogourava N=15	3.800	2.850	.95	25	BT- 2.949	BT- 0.659	4.000	-3.153	<0.001
					AT- 2.621	AT- 0.58	2.000		
Jrumbha N = 6	1.350	0.500	0.85	62.96	BT- 2.560	BT- 0.573	0.000	-2.207	=0.031
					AT- 1.147	AT- 0.256	0.000		
Jadya N= 8	2.150	1.300	0.85	39	BT- 2.834	BT- 0.634	0.000	-2.636	=0.008
					AT- 2.003	AT- 0.448	0.000		
Glani N= 12	2.450	1.300	1.15	46.93	BT- 2.417	BT- 0.540	3.000	-2.844	=0.002
					AT- 1.593	AT- 0.356	0.500		
Bhrama N=2	0.250	0.1000	0.15	60	-	-	-	-	-
Apakti N= 2	0.650	0.450	0.2	30.76	-	-	-	-	-
Tandra N= 14	3.950	2.300	1.65	41.77	BT- 3.137	BT- 0.701	4.000	-3.086	<0.001
					AT- 2.296	AT- 0.514	2.000		
ISI scale	20.550	10.500	10.05	48.90	BT- 3.364	BT- 0.752	21.000	-3.894	<0.001
					AT- 4.249	AT- 0.950	9.500		
AIS	15.650	7.750	7.9	50.47	BT- 2.834	BT- 0.634	15.000	-3.927	<0.001
					AT- 3.432	AT- 0.767	7.500		
Physical health (WHOQOL)	11.980	14.310	2.33	16.28	BT- 1.075	BT- 0.240	12.000	3.945	<0.001
					AT- 1.061	AT- 0.237	14.000		
Psychological health (WHOQOL)	16.130	17.150	1.02	5.94	BT- 1.362	BT- 0.304	16.000	3.130	<0.001
					AT- 1.461	AT- 0.327	17.000		
Social relationship (WHOQOL)	16.850	18.065	1.215	6.72	BT- 2.007	BT- 0.44	17.000	3.482	<0.001
					AT- AT-	AT- AT-	18.000		

					1.494	0.33			
Environmental health (WHOQOL)	16.895	18.250	1.355	7.42	BT-1.884	BT-0.421	17.000	3.450	<0.001
					AT-1.232	AT-0.276	18.400		

Overall effect of treatment.

Sl no	Improvement	Scale	No of patients	% of patients
1	No	0	0	0
2	Mild	0-25	6	30%
3	Moderate	26-50	9	45%
4	Marked	51-75	5	25%
5	Excellent	76-100	0	0

DISCUSSION

Ashwagandhayoga is herbal formulation contains *ashwagandha*, *ghrita* (ghee) and *sita* (crystal sugar). *Ashwagandha* is having *tikta kashaya rasa*, *madura vipaka* and *ushna virya*. It is having *rasayana* property and can be used in *vata vyadhis* and *anidra*. *Nidranasha* is a disorder with the predominance of *vata pitta* and *rajo dosha*. *Madura vipaka* along with *ushna virya* and *snigdha guna* helps to pacify *vata*. When *vata* reduces automatically *raja* also reduces. *Tikta kashaya rasa*, *madhura vipaka* and *snigdha guna* helps to reduce *pitta*. *Ashwagandha* root extract is having a natural compound with sleep inducing potential. Withanolides have analgesic property and anti-stress property. It is having inhibitory action which inhibits the neurotransmitter in the brain. It decreases the neuron activity and inhibits the nerve cells from over firing, results in calming effect. Through this it helps to induce the sleep. It is also having tranquilizing property. *Ashwagandha* is having a CNS depressant activity, so it helps to reduce the over activity of brain.

Both *ghrita* and *sita* are having *madhura guna* and *vipaka* along with *shita veerya*. *Ghrita* is having *medya*, *rasayana* and *nidra janana* property. Ghee contains DHA and omega fatty acid. This is seen in brain cells too. It acts in normalizing the chemical changes in brain by balancing the neurotransmitters. *Ghrita* also has *samskarasya anuvartana* property which will be helpful to reduce the *nidranasha* symptoms by combining with *ashwagandha* and *sita*. Symptoms like *angamarda*, *jrumbha*, *glani*, *jadya*, *bhrama*, *apakti* were mainly due to *vata* and *pitta*, *ghrita* helps to reduce the *vata* in the body.

Thus by going through the above description it shows that all drugs of *Ashwagandha yoga* have definite action on *nidranasha*/primary insomnia.

CONCLUSION

Nidra nasha is parallel to Primary Insomnia. Intervention of *ashwagandha yoga* have provided significant improvement in insomnia severity index scale (48%) and Athens insomnia scale (50%) was noticed on analysis with Wilcoxon signed rank test with $p < 0.001$ which were statistically significant. Marked reduction were

seen in quality of life of a patient where in physical health (16%), psychological health (5%), social relationship (6%) and environmental health (7%) improvements were found in patients respectively with statistically significant value of $p < 0.001$. The efficacy of the medication has been proved with the statistical analysis of the parameters.

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