

## POLYSOMNOGRAPHIC EVALUATION OF THE EFFECT OF SHIRODHARA AND CAP. ASHWAGANDHA ON SLEEP IN OLDER ADULTS SUFFERING FROM INSOMNIA

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### Abstract

**Background:** Insomnia in the older adults is associated with significant morbidity and mortality. There is an urgent need to employ certain ayurvedic modality of treatment which is safe, cost-effective, readily available and still effective. Effect of shirodhara and cap. Ashwagandha on different aspect of sleep in insomniac older patients has not yet been objectively evaluated using polysomnography (PSG). Hence, the present study has been proposed to study the effect of Shirodhara and cap. Ashwagandha on sleep in older subjects and to compare their effect objectively using PSG. **Materials and Methods:** It was a quasi experimental study. A total of 63 subjects of age 60 years and above of both sexes were enrolled. All the study subjects were allocated in three groups (each group n = 21) to assess their sleep characteristics objectively at baseline and after intervention (of 21 days), using PSG. Three groups were – Group S (Shirodhara), Group A (Ayurveda) and Group SA (Shirodhara plus Ayurveda). Their socio-demographic, anthropometric and polysomnographic features were studied. Statistical analysis was done by using descriptive and inferential statistics. **Result:** We found that PSG parameters like sleep latency, total sleep time, wake after sleep onset, arousal index and sleep efficiency exhibited significant improvement after intervention in all the three groups. Pittsburgh Sleep Quality Index, Insomnia Severity Index and Epworth Sleepiness Scale also showed significant improvement in sleep quality in these three groups. Overall, Shirodhara plus Ayurveda group patients performed better in all the PSG parameters post intervention. **Conclusion:** We concluded that Shirodhara procedure along with Cap. Ashwagandha administration is very effective in management of Insomnia in older population.

## INTRODUCTION

Sleep is one of the essential factors to lead a healthy life. The prevalence of sleep disorders increase with age. When older patients have sleep disorders, they often present with insomnia. Insomnia in the older adults is associated with significant morbidity and mortality.<sup>[1]</sup> The present pharmacological treatment for insomnia brings along with it the untoward adverse reactions and hence risk associated with it outweighs the benefit.<sup>[2]</sup> Therefore, there is an urgent need to employ certain ayurvedic modality of treatment which is safe, cost-effective, readily available and still effective. Hence, the present study

has been proposed. Morbidity associated with insomnia is mainly because of the exacerbations of this age dependent sleep disruption. Though the need for sleep does not change with age, the ability to get the needed sleep decreases with advancing age. Insomnia portrays the major health problem in older population which needs immediate attention in the present-day lifestyle. If left untreated, Insomnia may reduce mental capacity of an individual, reduce efficacy, increase chance of various types of accident and ultimately it may drag the individual towards several severe psychosomatic disorders.<sup>[3]</sup> Recent studies have shown that behavioral treatments are more effective in insomnia. Therefore, need of the

hour is to develop certain ayurvedic treatment modalities for the management of insomnia which would be safe, effective, readily available, cost effective and without any side effects. The effect of shirodhara and ayurvedic herbal preparation (Ashwagandha) on different aspect of sleep in insomnia patients has not yet been evaluated objectively using polysomnography. The proposed study was an endeavor to evaluate the effect of these ayurvedic modality of treatment on sleep individually and objectively so as to use them with better efficiency as complementary systems.

## MATERIALS AND METHODS

It was a quasy experimental study to evaluate the effect of shirodhara and ayurvedic herbal preparation (cap Ashwagandha) on sleep using polysomnography in older adults. A total of 63 consecutive patients of insomnia of both sexes (27 males and 36 females) over the age of 60 years were prospectively recruited for the study after getting their informed written consent to participate. Participants were required to meet the general criteria for insomnia disorder in the Diagnostic and Statistical Manual of Mental Disorder, 4th edition (DSM-IV).<sup>[4]</sup> Insomnia assessment was obtained during thorough history taking and medical examination by the medical physician and clinically diagnosed cases were referred from Geriatric clinic, Department of Medicine. Patients with major psychiatric illness like Schizophrenia, depressive psychosis, epilepsy, alcohol dependency or drug dependency, chronic illness like asthma, malignancy, liver cirrhosis, chronic renal failure etc., uncontrolled DM, uncontrolled HT, cardiovascular accident, CCF, MI, COPD, meningitis, acute pain conditions or similar other disorders; patients using sedative-hypnotics; Patients with Periodic limb movement disorder, Restless leg syndrome and Obstructive sleep apnea were excluded. The 63 subjects were randomized as three groups (Groups 1,2, and 3) using standard random number table. Allocation of a group to a particular intervention was carried out by the lottery method. They are allocated in 3 different groups and introduced to interventions - Shirodhara, Cap. Ashwagandha, Shirodhara along with Cap. Ashwagandha. There were 21 subjects in each group. Their baseline demographic and Anthropometric data was collected. The baseline PSG (Polysomnography) was done before intervention and PSG data recorded. After intervention, PSG was repeated and data recorded.

Polysomnography (PSG) was done in Sleep lab placed in Dept of Physiology with the help of PSG machine (Sleepcare system, Medicaid). PSG consisted of continuous polygraphic recording from surface leads for Electroencephalography, Electrooculography, Electromyography and Electrocardiograph, thermistors for nasal and oral airflow, thoracic and abdominal impedance belts for

respiratory efforts, pulse oximetry for oxyhemoglobin level, a tracheal microphone for snoring and leg and sleep sensors for leg and sleep position. Sleep metrics determined were - sleep latency, sleep duration, sleep efficiency, wakefulness after sleep onset, total sleep time etc. The Pittsburgh sleep quality index (PSQI) was used to provide a global measure of overall sleep quality. The insomnia Severity Index (ISI) was used to assess the level of insomnia symptoms. The Epworth sleepiness scale (ESS) was used to provide information regarding level of sleepiness in a common situation that are relevant to daily life.

Shirodhara was performed in morning session using Tila oil (2 liters of oil at temperature-98-1050 F). Duration for Shirodhara was 45-60 min. The procedure was continued for the period of 21 days. Capsule Ashwagandha was administered to the subjects of Ayurveda group in dose of 500 mg twice in a day. The Capsule was given with lukewarm milk for a period of 21 days.<sup>[5]</sup>

**Statistical Methods:** Statistical analysis was done by using descriptive and inferential statistics. It was done using Chi-square Test, Student's paired t test, one way ANOVA and Multiple Comparison: Tukey Test. Software used in the analysis were SPSS 27.0 version and GraphPad Prism 7.0 version.  $P < 0.05$  was considered as level of significance.

## RESULTS

Comparison of PSG parameters in group where shirodhara intervention was performed is depicted in [Table 1]. [Table 2] shows the comparison of PSG parameters in a group where cap Ashwagandha was the mode of intervention and [Table 3] depicts the comparison of PSG parameters in a group where cap Ashwagandha along with Shirodhara was the mode of intervention. All sleep parameters were found to be improved significantly after intervention in all three groups. Comparison of PSG parameters in three groups after intervention is shown in [Table 4]. According to it, all sleep parameters improved significantly and maximally in the group where shirodhara along with cap Ashwagandha was given and improvement was minimal in group where only cap Ashwagandha was administered except for parameter like sleep efficiency which improved maximally and significantly in Group Shirodhara and minimally in group- Ayurveda (Cap. Ashwagandha). ESS score improved maximally in group Ayurveda and minimally in group Shirodhara. However, this improvement is non-significant. Overall, Shirodhara plus Ayurveda group patients performed better in all the PSG parameters post intervention indicating good quality of sleep experienced by them and they were benefitted most. [Table 5] reflects the distribution of patients in three groups according to their subjective improvement. Subjective improvement in quality of sleep was best experienced by the subjects enrolled under shirodhara plus ayurveda group.

**Table 1: Comparison of PSG parameters in group-S before and after intervention Student's paired t test.**

PSG Parameters	Before Intervention	After Intervention	Mean Difference	t-value	p-value
Sleep Latency (min)	41.90±7.45	17.71±4.01	24.19±8.17	13.56	0.0001,S
Total sleep time(min)	312.80±29.02	387.85±19.56	75.04±21.62	15.90	0.0001,S
WASO(min)	77.23±17.55	45.09±9.13	32.14±11.87	12.40	0.0001,S
Arousal Index (per hour of sleep)	18.28±3.62	10.71±2.17	7.57±2.90	11.93	0.0001,S
Sleep Efficiency	70.38±6.56	83.28±3.30	12.90±5.50	10.74	0.0001,S
PSQI	12.19±2.58	4.57±1.07	7.61±2.24	15.54	0.0001,S
ISI	19.33±3.38	9.90±1.57	9.42±3.13	13.76	0.0001,S
ESS	8.95±1.96	6.71±1.82	2.23±1.78	5.74	0.0001,S

**Table 2: Comparison of PSG parameters in group-A before and after intervention Student's paired t test**

PSG Parameters	Before Intervention	After Intervention	Mean Difference	t-value	p-value
Sleep Latency (min)	43.57±6.39	21.80±3.38	27.76±5.83	17.08	0.0001,S
Total sleep time(min)	345.14±43.97	386.04±23.26	40.90±25.05	7.48	0.0001,S
WASO(min)	87.57±22.36	62.52±17.41	25.04±11.31	10.14	0.0001,S
Arousal Index (per hour of sleep)	18.71±4.32	14±4.07	4.71±3.21	6.72	0.0001,S
Sleep Efficiency	71.14±5.74	77.19±5.74	6.04±5.09	5.44	0.0001,S
PSQI	12.52±1.99	4.71±1.10	7.80±2.15	16.57	0.0001,S
ISI	18.09±3.40	10.42±1.69	7.66±3.08	11.37	0.0001,S
ESS	8.57±1.69	6.71±1.73	1.85±1.10	7.67	0.0001,S

**Table 3: Comparison of PSG parameters in group-SA before and after intervention Student's paired t test**

PSG Parameters	Before Intervention	After Intervention	Mean Difference	t-value	p-value
Sleep Latency (min)	40.52±7.48	17.57±5.40	22.95±6.19	16.98	0.0001,S
Total sleep time(min)	339±35.72	405.33±22.63	66.33±25.46	11.93	0.0001,S
WASO(min)	85.90±17.43	42.42±11.12	43.47±11.90	16.73	0.0001,S
Arousal Index (per hour of sleep)	17.71±4.78	9.85±2.17	7.85±3.05	11.78	0.0001,S
Sleep Efficiency	69.28±6.01	82.90±4.38	13.61±4.81	12.97	0.0001,S
PSQI	11.76±1.99	4.28±0.90	7.47±1.47	23.30	0.0001,S
ISI	19.57±3.44	9.52±1.83	10.04±2.85	16.13	0.0001,S
ESS	8.80±1.83	6.71±1.76	2.09±1.51	6.34	0.0001,S

**Table 4: Comparison of PSG parameters in three groups after intervention One Way ANOVA**

PSG Parameters	Group-S	Group-A	Group-SA	F-value	p-value
Sleep Latency (min)	17.71±4.01	21.80±3.38	17.57±5.40	6.42	0.003,S
Total sleep time(min)	387.85±19.56	386.04±23.26	405.33±22.63	4.97	0.010,S
WASO(min)	45.09±9.13	62.52±17.41	42.42±11.12	14.70	0.0001,S
Arousal Index (per hour of sleep)	10.71±2.17	14±4.07	9.85±2.17	11.56	0.0001,S
Sleep Efficiency	83.28±3.30	77.19±5.74	82.90±4.38	11.62	0.0001,S
PSQI	4.57±1.07	4.71±1.10	4.28±0.90	0.94	0.396,NS
ISI	9.90±1.57	10.42±1.69	9.52±1.83	1.49	0.233,NS
ESS	6.71±1.82	6.71±1.73	6.71±1.76	0.00	1.000,NS

**Table 5: Distribution of patients in three groups according to their subjective improvement**

Subjective Improvement	Group-S	Group-A	Group-SA	p-value
Yes	19(90.48%)	17(80.95%)	20(95.24%)	0.32,NS
No	2(9.52%)	4(19.05%)	1(4.76%)	
Total	21(100%)	21(100%)	21(100%)	

## DISCUSSION

Charaka has considered sleep as one of the pillars for maintenance of healthy life. He stated that pleasure or grief, being fat or thin, strength or weakness, potency or impotency, to be wise or unwise depend on sleep and sleeplessness consequently.<sup>[6]</sup> Healthy and sound sleep has unique place in human life. Lack of it leads to various morbidities, insomnia is one of them.

We observed more number of female patients affected by Insomnia during the screening. Our findings are in contrast with observation by Pokharel S and Sharma AK who recorded male dominance in Insomnia.<sup>[7]</sup> However, these findings are consistent with observations by Ohayon MM et al.<sup>[8]</sup> Female

dominance in Insomnia incidence might be due to more household stress females face in older age group as most females were housewives. We found that Polysomnographic (PSG) parameters like sleep latency, total sleep time, wake after sleep onset (WASO), arousal index and sleep efficiency exhibited significant improvement after intervention with shirodhara. Pittsburgh Sleep Quality Index (PSQI), Insomnia Severity Index (ISI) and Epworth Sleepiness Scale(ESS) also showed significant improvement in sleep quality after undergoing Shirodhara therapy. Our observations are in accordance with previous studies.<sup>[7,9]</sup> They reported moderate improvement of insomnia with shirodhara. We observed significant improvement of insomnia in study subjects objectively using Polysomnography

(PSG). PSG parameters were objectively compared before and after shirodhara treatment.

Shirodhara is a relaxation therapy which relieves mental exhaustion as well as pacifies the aggravated vatadosha in head. It helps to normalise the function of central nervous system by relaxing the nervous system and balancing the circulation of blood in the head.<sup>[10]</sup> In the procedure of Shirodhara, particular pressure and vibration is created over the forehead. The vibration is amplified by the hollow sinus present in the frontal bone. The vibration is then transmitted inwards through the fluid medium of cerebrospinal fluid (CSF). This vibration along with little temperature may activate the functions of thalamus and the basal fore brain which then brings the amount of serotonin and catecholamine to the normal stage inducing the sleep. If prolonged pressure is applied to a nerve, impulse conduction is interrupted and part of the body may go to rest. Prolonged and continuous pressure due to pouring of the medicated liquid may cause tranquility of mind and induce natural sleep.<sup>[7]</sup> The method of Shirodhara produces almost similar effect as that of yognidra technique which completely relaxes the mind and bring about the sound sleep. On the other hand, procedure of Shirodhara stimulates the supreme Chakras i.e. Aagya Chakra and Sahasrara Chakra which are situated in the head region.<sup>[11]</sup> These Chakras govern all the vital energy in the body. Due to the stimulation of these Chakras the individual gets good mental condition. Hence the condition like insomnia is really benefitted by the Shirodhara.<sup>[12,13]</sup>

Nevertheless, psychoneuroimmunological effects of this therapy, such as a decrease in noradrenaline, exhibiting a sympatholytic effect, and resulting in the activation of peripheral foot skin circulation and increase in natural killer cells, have been demonstrated by Japanese researchers.<sup>[14]</sup>

Our findings are coexistent with the results of previous studies that demonstrated effect of shirodhara on improvement of subjective sleep quality.<sup>[15-20]</sup> These studies relied mostly on various subjective indices to judge the improvement in sleep quality, however, the present study evaluated sleep betterment objectively using polysomnography.

In present study, we noticed that PSG parameters like sleep latency, total sleep time, wake after sleep onset (WASO), arousal index and sleep efficiency exhibited significant improvement after administration with tab Ashwagandha. Pittsburgh Sleep Quality Index (PSQI), Insomnia Severity Index (ISI) and Epworth Sleepiness Scale (ESS) also showed significant improvement in sleep quality. Corresponding findings are observed by Sharma UK et al.<sup>10</sup>. These effects may be noticed due to the anti-stress properties, central muscle relaxant and tranquillizing, sedative, hypnotic effect and antispasmodic effect of ashwagandha. Moreover, drugs of this formulation are mainly having properties to pacify the vitiated vata and pitta dosha in Insomnia. Furthermore, most of the drugs having mental cooling, nutritive and refreshing properties

too which acts on senses, mind and brain.<sup>[10]</sup> This might be the reason why do we get significant finding in patients administered with tab Ashwagandha.

We reported that in current study, PSG parameters like sleep latency, total sleep time, wake after sleep onset (WASO), arousal index and sleep efficiency exhibited significant improvement after intervention with shirodhara and tab Ashwagandha. Pittsburgh Sleep Quality Index (PSQI), Insomnia Severity Index (ISI) and Epworth Sleepiness Scale (ESS) also showed significant improvement in sleep quality. Similar observations were also noted by Tokinobu et al,<sup>[21]</sup> and Sharma UK et al.<sup>[10]</sup> These results are consistent with findings of previous studies.<sup>[15-17]</sup> The PSQI and ISI result in present study is supported by the findings of the previous studies that demonstrate Shirodhara is associated with decreased sympathetic nervous system tone and increased skin temperature of the hand and foot. When the sympathetic nervous system relaxes, peripheral blood circulation and skin temperature increase. This situation might induce shorter sleep latency and better sleep quality.<sup>[14,22]</sup> We observed that overall, Shirodhara plus Ayurveda group patients performed better in all the PSG parameters post intervention indicating good quality of sleep experienced by them and they are benefitted most. This may be due to the combined beneficial effect of Shirodhara and Tab Ashwagandha on sleep pattern and characteristics which we recorded through PSG. Pokahrel S and Sharma AK<sup>7</sup> reported that Shirodhara and Ayurvedic herbal preparation (tab Insomrid) combined therapy showed better improvement in patients with Insomnia than the participants who received Shirodhara or tab Insomrid alone ( $p < 0.001$ ). These finding are coexistent with our observations; however, we have used tab Ashwagandha as ayurvedic herbal preparation and we objectively analyzed the outcomes with the help of polysomnography.

We also observed that Subjective improvement in quality of sleep is best experienced by the subjects enrolled under shirodhara plus ayurveda group. This is in agreement with findings by Pokharel S and Sharma AK.<sup>[7]</sup>

## CONCLUSION

Finally, based upon the observation in this study, it may be concluded that Shirodhara procedure along with Tab Ashwagandha administration is very effective in management of Insomnia in older population. Both these modalities of treatment are safe, non-habit forming, non-invasive and potential to improve quality of sleep.

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