

## AN OPEN LABEL TWO-ARM STUDY ON THE EFFECT OF PĀDĀBHYAÑGAM AND MUD APPLICATION ON SPINE IN NIDRĀNĀŚAM AMONG GERIATRIC COMMUNITY

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### ABSTRACT

**Background:** Sleep is a universal need of all life forms including human beings. A chronic lack of sleep increases the risk of obesity, diabetes, hypertension and other cardiovascular disease, infections and even cause mood problems. Insomnia is the most common sleep disorder, affecting nearly one-third of geriatric community. *Padābhyañgam* has been widely used in the management of *Nidrānāśam* but the efficacy of direct application of mud on spine was not yet studied to manage *Nidrānāśam*. **Aim:** To assess the combined effect of direct application of mud on spine with *Pādābhyañgam* in *Nidrānāśam*. **Materials and Methods:** The study was conducted with 2 groups of 20 patients each who fell under the inclusion criteria. Group 1 given *Pādābhyañgam* with *Tilatailam* for 20 minutes and Group 2 given both *Pādābhyañgam* with *Tilatailam* and mud application on spine for 20 minutes each for a period of 14 days. Insomnia was assessed based on Athens Insomnia Scale. The findings were recorded and Mann-Whitney U test was used to interpret the changes between the groups. **Results:** Group 2 with *Pādābhyañgam* and mud application on spine had more effect for treatment in *Nidrānāśam*, than Group 1 with *Pādābhyañgam* alone with  $p < 0.05$ . **Conclusions:** The combined effect of *Pādābhyañgam* and direct mud application on spine showed better results than treatment with *Pādābhyañgam* alone in inducing sleep among the old age people. Hence mud application on spine can be effectively used in the management of *Nidrānāśam*.

**Keywords:** Insomnia, Mud therapy, *Nidrānāśam*, *Pādābhyañgam*, *Tilatailam*

### INTRODUCTION

A person spends 1/3<sup>rd</sup> of his life in sleep.<sup>1</sup> Sound restorative sleep is the foundation of a healthy life. Insomnia is the most common sleep disorder, affecting nearly one-third of geriatric communities in Western developed countries and the incidence is increasing in developing countries also.<sup>2</sup> 5%-6% of

people aged 50 years and above may be affected by sleep disorders in India.<sup>3</sup> Patients with co-morbid medical and psychiatric conditions are at particularly increased risk, with psychiatric and chronic pain disorders having insomnia rates as high as 50% to 75%.<sup>4</sup> Insomnia is a condition with difficulty in

sleeping, falling asleep or maintaining the sleep. Insomnia in elderly people leads to lack of enthusiasm, fatigue, irritability and deterioration of social and/or physical functioning.

According to *Ayurveda*, life sustains on three basic pillars – the *trayōpastambhas* namely, *Āhāra*, *Nidrā* and *Brahmacarya*.<sup>5</sup> *Nidrā* deals with both the psychic and somatic factors. *Āchārya Charaka* has mentioned *Nidrānāśa* as one among the *VātajāNānātmajaVyādhi* which is commonly seen in the elderly people.

*Abhyaṅga* is advocated as a routine in our classics, emphasizing its special influence on both sleep and *vata*. *Āchārya Susruta* says that *Pādābhyaṅga* helps in inducing sleep, provides health of the body and eyes, reduces fatigue and gives softness to the feet.<sup>6</sup> In *MadanapālaNighantu*, it is mentioned that *Taila Abhyaṅga* is beneficial in *Vāta Vrddhi* especially in the old age to promote sleep. *TilaTaila* has the property to penetrate deep into tissues, is hot in potency and decreases *vāta*.<sup>7</sup>

Mud therapy is used for giving coolness to the body. Cold mud packs applied over abdomen and forehead is beneficial in insomnia.<sup>8</sup> It is proved effective in improving the quality of life including sleep in old aged women suffering from breast cancer. It also has anti inflammatory properties.<sup>9</sup> Spinal application of cold mud relaxes the central nervous system and can be effective in inducing sleep. Although many drugs are available for the treatment of insomnia, they can be addictive and are associated with many side effects especially in old patients.<sup>10</sup> The present study was conducted to evaluate the combined effect of *Padābhyaṅgam* and direct mud application on spine to manage the *Nidrānāśam*.

#### **Aim and Objectives**

- To assess the combined effect of direct application of mud on spine with *Pādābhyaṅgam* in *Nidrānāśa*

- To assess the efficacy of *Pādābhyaṅga* without mud application on spine in *Nidrānāśa*

#### **MATERIALS AND METHODS**

**Method of Study:** Randomized Clinical study

**Source of Data-** Patients of *Nidrānāśam* attending out-patient and in-patient departments of Amrita School of Ayurveda, Vallikkavu, Kerala

**Study Design:** The study comprised of two groups – Each group randomly selected by Simple Random Sampling Method consists of 20 patients.

- Group 1 – 20 patients were given *Padābhyaṅgam* with *TilaTailam* of required quantity for 20 minutes for 14 days.
- Group 2– 20 patients were given both *Padābhyaṅgam* with *TilaTailam* of required quantity for 20 minutes and direct mud application on spine for 20 minutes for 14 days. Mud was prepared with clay obtained from about 3ft – 4ft below the surface of the earth. The clay was then filtered properly and made into a fine paste with water (27°Celsius) and was applied directly on the whole spine from neck to coccyx at a thickness of 2.5cm and a width of 7cm.

#### **Inclusion Criteria:-**

- Patients presenting with the complaint of *Nidrānāśam*
- Patients of either sex aged between 60-75 years
- DSM-5's major criteria for a diagnosis of insomnia

#### **Exclusion Criteria:-**

- Patients unfit for *Padābhyaṅgam* and mud therapy
- Patients affected with medical conditions such as breathing difficulties, lung disorders, stroke, cancer

#### **Assessment Criteria:**

Athens Insomnia Scale (AIS)

### ATHENS INSOMNIA SCALE

1. SLEEP INDUCTION ( <i>time it takes you to fall asleep after turning-off the lights</i> )			
<b>0</b> No problem	<b>1</b> Slightly delayed	<b>2</b> Markedly delayed	<b>3</b> Very delayed or did not sleep at all
2. AWAKENINGS DURING THE NIGHT			
<b>0</b> No problem	<b>1</b> Minor problem	<b>2</b> Considerable problem	<b>3</b> Serious problem or did not sleep at all
3. FINAL AWAKENING EARLIER THAN DESIRED			
<b>0</b> Not earlier	<b>1</b> A little earlier	<b>2</b> Markedly earlier	<b>3</b> Much earlier or did not sleep at all
4. TOTAL SLEEP DURATION			
<b>0</b> Sufficient	<b>1</b> Slightly insufficient	<b>2</b> Markedly insufficient	<b>3</b> Very insufficient or did not sleep at all
5. OVERALL QUALITY OF SLEEP ( <i>no matter how long you slept</i> )			
<b>0</b> Satisfactory	<b>1</b> Slightly unsatisfactory	<b>2</b> Markedly unsatisfactory	<b>3</b> Very unsatisfactory or did not sleep at all
6. SENSE OF WELL-BEING DURING THE DAY			
<b>0</b> Normal	<b>1</b> Slightly decreased	<b>2</b> Markedly decreased	<b>3</b> Very decreased
7. FUNCTIONING (PHYSICAL AND MENTAL) DURING THE DAY			
<b>0</b> Normal	<b>1</b> Slightly decreased	<b>2</b> Markedly decreased	<b>3</b> Very decreased
8. SLEEPINESS DURING THE DAY			
<b>0</b> None	<b>1</b> Mild	<b>2</b> Considerable	<b>3</b> Intense

**Ethical considerations:** Ethical clearance was obtained from the institutional ethical committee (IEC) of Amrita School of Ayurveda. Consent was obtained from the patients.

Assessment was conducted before the treatment, during the 7<sup>th</sup> day and after the treatment period of 14 days and after the follow up period of one week. The data were collected by interrogation and physical examination and recorded in the case proforma.

**Statistical analysis:** Statistical analysis was done using SPSS version 20. Mann-Whitney U test is done on parameters, to interpret the changes between the groups.

### RESULTS

The clinical study conducted on 40 patients showed following improvements.

Table.1 shows the overall improvement in the treatment clinically for *Nidrānāsam* in two groups, before and after the treatment, considering the assessment criteria. Group 2 showed better improvements compared to Group 1. Statistically significant improvement was observed in Group 2 with *Pādābhyāṅga* and mud application compared to Group 1 with *Pādābhyāṅga* alone, in Sleep Induction (Table.1), Awakening Earlier Than Desired (Table.3), Total Sleep Duration (Table.4), Overall Quality Of Sleep (Table.5), Sense Of Well Being During The Day (Table.6), Physical And Mental Functioning During The Day (Table.7) And Sleepiness During The Day (Table.8) occurring after the treatment with  $p < 0.05$ . But no statistically significant change was observed in the Awakenings during the Night in the two groups (Table.2)

**Table 1: Sleep Induction**

	GROUP	Mean Rank	Mann-Whitney U	Asymp. Sig. (2-tailed)
BT	GROUP- 1	24.50	120.00	0.012
	GROUP- 2	16.50		
7TH DAY	GROUP- 1	24.65	117.000	0.002
	GROUP- 2	16.35		
14TH DAY	GROUP- 1	29.50	20.000	0.0001
	GROUP- 2	11.50		
FU	GROUP- 1	29.55	19.000	0.0001
	GROUP- 2	11.45		

**Table 2: Awakening During Night**

	GROUP	Mean Rank	Mann-Whitney U	Asymp. Sig. (2-tailed)
BT	GROUP-1	18.50	160.000	0.080
	GROUP-2	22.50		
7TH DAY	GROUP-1	19.50	180.000	0.435
	GROUP-2	21.50		
14TH DAY	GROUP-1	22.38	162.5000	0.144
	GROUP-2	18.63		
FU	GROUP-1	24.50	120.000	0.003
	GROUP-2	16.50		

**Table 3: Final Awakening Earlier Than Desired**

	GROUP	Mean Rank	Mann-Whitney U	Asymp. Sig. (2-tailed)
BT	GROUP-1	23.50	140.000	0.050
	GROUP-2	17.50		
7TH DAY	GROUP-1	25.45	101.000	0.002
	GROUP-2	15.55		
14TH DAY	GROUP-1	27.50	60.000	0.0001
	GROUP-2	13.50		
FU	GROUP-1	27.75	55.000	0.0001
	GROUP-2	13.25		

**Table 4: Total Sleep Duration**

	GROUP	Mean Rank	Mann-Whitney U	Asymp. Sig. (2-tailed)
BT	GROUP-1	19.50	180.000	0.382
	GROUP-2	21.50		
7TH DAY	GROUP-1	22.00	170.000	0.317
	GROUP-2	19.00		
14TH DAY	GROUP-1	23.60	138.000	0.021
	GROUP-2	17.40		
FU	GROUP-1	25.70	96.000	0.004
	GROUP-2	15.30		

**Table 5: Overall Quality of Sleep**

	GROUP	Mean Rank	Mann-Whitney U	Asymp. Sig. (2-tailed)
BT	GROUP-1	23.50	140.000	0.019
	GROUP-2	17.50		
OVE7TH DAY	GROUP-1	24.75	115.000	0.004
	GROUP-2	16.25		
14TH DAY	GROUP-1	29.38	22.500	0.0001
	GROUP-2	11.63		
FU	GROUP-1	29.90	12.000	0.0001
	GROUP-2	11.10		

**Table 6: Sense of Well Being during the Day**

Sense Of Well Being During The Day	GROUP	Mean Rank	Mann-Whitney U	Asymp. Sig. (2-tailed)
BT	GROUP-1	23.10	148.000	0.063
	GROUP-2	17.90		
7TH DAY	GROUP-1	24.18	126.500	0.023
	GROUP-2	16.83		
14TH DAY	GROUP-1	27.95	51.000	0.0001
	GROUP-2	13.05		
FU	GROUP-1	29.23	25.500	0.0001
	GROUP-2	11.78		

**Table 7: Physical and Mental Functioning during the Day**

	GROUP	Mean Rank	Mann-Whitney U	Asymp. Sig. (2-tailed)
BT	GROUP-1	23.83	133.500	0.021
	GROUP-2	17.18		
7TH DAY	GROUP-1	21.50	180.000	0.382
	GROUP-2	19.50		
14TH DAY	GROUP-1	26.70	76.000	0.0001
	GROUP-2	14.30		
FU	GROUP-1	29.08	28.500	0.0001
	GROUP-2	11.93		

**Table 8: Sleepiness during the Day**

	GROUP	Mean Rank	Mann-Whitney U	Asymp. Sig. (2-tailed)
BT	GROUP-1	21.35	183.000	0.544
	GROUP-2	19.65		
7TH DAY	GROUP-1	23.50	140.000	0.056
	GROUP-2	17.50		
14TH DAY	GROUP-1	26.30	84.000	0.0001
	GROUP-2	14.70		
FU	GROUP-1	26.60	78.000	0.0001
	GROUP-2	14.40		

## DISCUSSION

*Nidrānāśa* is a major health concern among the old aged. The age-related biological changes are not the only responsible factors for old age insomnia rather it is a product of several influential factors – situational, psychological and health factors related to ageing.

**Discussion on Observation:** Among the 43 patients, 58.1% of patients were under the age group of 60-65 years and 86.0% were females. Hormonal changes during menopause causing depression, anxiety and stress can be a factor for sleeplessness. 79.1% patients were married. Marital troubles might account for stress which might have induced sleeplessness. 69.8% were of middle class and 60% of patients were having sedentary works. The study published in the journal of The North American Menopause Society shows that sedentary lifestyle is linked with insomnia especially in menopausal women. Of all the patients, 86.0% had *avara satwa* who have unsteady mind which leads to *Nidrānāśa* condition.

### Discussion on Results

**Sleep induction:** 29.09% of overall improvement was observed in Group 1 while in Group 2, it was 55.31%. There is statistically significant change occurring in 7<sup>th</sup> day of treatment itself. *Abhyaṅga* decreases Beta Brainwave activity that leads to increased release of neurotransmitters viz; serotonin and dopamine as well as decreased release of cortisol levels. This type of brain activity is one which facilitates deep sleep induction. Mud application reduces stress of an individual which is an important factor for delayed sleep induction.

**Awakening during the Night:** The overall improvement in Group 1 was 39.02% while in Group 2 it was 53.33%. No statistically significant changes were noticed in between the groups. This might be due to certain other physiological factors related to the condition and daily habit.

**Final Awakening Earlier than Desired:** The overall improvement in Group 1 was 35.71% while in Group 2 it was 56%. Statistically significant change occurred in 7<sup>th</sup> day of treatment itself. Marked im-

provement was found in both Groups but between the groups, Group 2 showed better improvement. The insomnia patients awaken early in the morning due to the lower levels of adenosine. This might be due to the action of *Pādābhyaṅgam* along with Mud therapy to provoke a series of neuroendocrine reactions.

**Total Duration of Sleep:** In Group 1 the overall improvement was 42.85% while in Group 2, 61.35% of improvement was observed indicating better result in treatment of Group 2. Through *Pādābhyaṅga*, one gets good sleep and Mud therapy increases membrane electrical conductance, absorption phenomena and activation of enzymes and hormones.

**Overall quality of sleep:** 37.82% of overall improvement was observed in Group 1 whereas in Group 2, it was 71.69% showing a better result in Group 2. Previous studies have indicated the immune boosting qualities of *Abhyaṅga* and explained the same, along with its probable mode of action in terms of - increase in tryptophan further leading to increase in serotonin which gives a calm and soothing feeling promoting sleep. Mud therapy improves the quality of life including sleep in old aged. This might be the reason for better results in quality of sleep in Group 2.

**Sense of wellbeing during the day:** The overall improvement after treatment in Group 1 was 47.72% while in Group 2 it was 84.21%. This probable mode of action might be *Pādābhyaṅgam* and Mud Application on Spine which increases the level of serotonin. Serotonin is responsible for the feel good condition and has pleasant and calm effect on mind.

**Functioning during the Day:** The overall improvement in treatment of Group 1 was 47.50% while in Group 2 an overall improvement of 75.75% was observed. This can be due to the combined effect of *Pādābhyaṅgam* and Mud Application on Spine. Mud application improves the motor functions and daily activities. Studies shows that cooling of certain regions of nervous system can slow the increased metabolism causing stress, anxiety or fear and makes it easier to get a good night's rest.



**Sleepiness during the day:** The overall improvement in treatment was 33.33% in Group 1 while in Group 2 it was 65%. The probable mode of action may be due to *Pādābhyaṅgam* and Mud Application. *Abhyaṅga* directly works on the seat of *vāta* i.e. skin and it has remarkably direct influence on the *vāta-dosha* by virtue of its opposite qualities. *Abhyaṅga* with oil makes human body strong. It becomes unsusceptible to diseases of *vāta*, resistant to exhaustion and exertion. Mud application improves the motor functions and daily activities and increases membrane electrical conductance, absorption phenomena and activation of enzymes and hormones. So altogether the treatment modality adopted was found to be effective in inducing good quality sleep. *Pādābhyaṅga* when combined with mud application significantly improved quality and duration of sleep in elderly patients.

## CONCLUSION

*Nidra* is an essential phenomenon for maintenance and restoration of the life, which is considered under *Trayōpastambhas*. *Nidrānāśa* can be correlated with insomnia of contemporary science by observing the similarity in Pathophysiology as well as clinical manifestation. *Avara satwa* persons had a higher predominance of sleeplessness as they have an unsteady mind. Combined use of *Pādābhyaṅgam* and direct Mud application on spine showed better effects than treatment with *Pādābhyaṅgam* alone among the old age people. Hence *Pādābhyaṅga* with direct application of Mud on Spine can be advocated in elderly patients of insomnia since it is cheap, convenient and not associated with troublesome side effects commonly seen with sleeping pills.

## Limitations of the study

- The study sample is minimal so the same study could be done with a larger sample for more accurate results and conclusions.
- Study period was very limited. Thus similar study can be carried out with more duration of treatment.

- Sampling can be done based on the score obtained by the patients during examination for a better accuracy in results.
- Assessment was based on subjective parameters. Electronic data collection like polysomnography would improve the accuracy of daily sleep and symptom reporting.

## Suggestion:

This truly encouraging, cost effective treatment can be strongly recommended for all the affected patients, especially those belonging to the geriatric community.

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