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# **Research Article**

# CLINICAL STUDY ON EFFECT OF DIFFERENT METHODS OF *SHIRODHARA* IN PATIENTS OF INSOMNIA

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## ABSTRACT

**Background:** Insomnia has a great impact on social, occupational and other functioning areas of the individual. The modern medical science is still not having a definitive and effective treatment for this disease. *Shirodhara* is considered as the highly effective treatment for this condition. Most practitioners practising oscillatory method of *Shirodhara*, Some advises to do single point *Shirodhara*. Interestingly there is no research has been done on this topic to find out which method is best and standard. **Aims:** To compare the efficacy of single point drip method *Jaladhara* and Oscillatory drip method *Jaladhara* in *Nidranasha*. **Methods and Materials:** Study was conducted in 30 diagnosed patient of *Nidranasha* with the help of symptoms of *Nidranasha* and Athens insomnia scale. The patients were randomly divided into 2 groups. i.e., Group A and Group B to compare the effect of Single point drip method and oscillatory drip method in Insomnia. **Results:** Group A (Single point drip method *Shirodhara*) provided better relief compared to Group B (Oscillatory drip method *Shirodhara*) clinically in subjective parameters Total sleep duration (48.3%), overall quality of sleep (48.3%) and Statistically provided moderately significant improvement in Functioning (physical and mental) and highly significant improvement in systolic blood pressure. **Conclusion:** Single point drip method *Shirodhara* compared to Oscillatory drip method *Shirodhara* provided better relief clinically and statistically.

**KEYWORDS:** Insomnia, *Nidranasha*, Oscillatory drip, *Panchakarma, Shirodhara*, Single point drip.

#### INTRODUCTION

*Panchakarma* becoming the fastest growing specialty discipline of Ayurveda because of its efficacy and long lasting effect. The globalization of *Panchakarma* posed issues related to efficacy, safety and standardization of procedure. There is an urgent need of standardizing the *Panchakarma* procedures in course and assessment. The dosage schedule, exact procedure, medicament, effect and side effects are to be standardized, so that an uniform schedule of practice may be developed to be practiced at all centers.<sup>[1]</sup>

*Shirodhara* is practiced mainly in psychiatric and psychosomatic disorder. In current practice different methods of *Shirodhara* are practised procedure exists. Most practitioners practising oscillatory method of *Shirodhara*, some advises to do head massage during *Shirodhara*. Some advises to do single point *Shirodhara*. Interestingly there is no research has been done on this topic to find out which method is best and standard. Hence, in this study an attempt will be made to compare different methods of *Shirodhara* and finally come to a conclusion, which method is best and standard.

Insomnia is the complaint of inadequate sleep; it can be classified according to the nature of sleep disruption and the duration of the complaint.<sup>[2]</sup> In present era due to stress of day to day life, environmental factors, over using of drugs (like fluoroquinolone, antibiotics, etc), several diseases, life style, diet pattern, human race is now facing many difficulties in maintaining natural sleep pattern.<sup>[3]</sup> Hence, substantial number of people suffer from insomnia, the most common sleep disorder. People with insomnia may have trouble concentrating, remembering or accomplishing daily tasks.<sup>[4]</sup> They also have a relatively high risk of accidents.<sup>[5]</sup> The economic consequences include the costs of increased use of health care services, work absences, and work related injuries.<sup>[6]</sup>

Application of liquid medicines by pouring continuously on any part of the body for a prescribed time is called *Seka* or *Dhara* and on head it is called Siro*Dhara* It is highly beneficial in stress and psychosomatic disorder such as IBS (Irritable Bowel Syndrome), neurological disorder (headache, epilepsy, etc. Psychiatric disorder (psychosis, neurosis insomnia etc.), convulsive disorder and also in psoriasis, eczema, hypertension and alcoholism.<sup>[7]</sup>

The main aim of this study is to evaluate the procedural effect of *Shirodhara* and hence water is selected for this study to exclude the medicinal effect of drug used for *Shirodhara*.

#### **OBJECTIVES**

1. To compare the efficacy of single point drip method *Jaladhara* and Oscillatory drip method *Jaladhara* in *Nidranasha*.

#### **MATERIALS AND METHODS**

**Research design:** Interventional, randomized, openlabelled, parallel clinical trial.

**Study Population:** An accessible population of insomnia patients in and around Ilkal, who were representative of target population, participated in the study.

Sampling: Simple random sampling

**Study sample:** patients attending the OPD and IPD of SVMVV's R.P.K. Ayurvedic Hospital, ILKAL.

Sample size: 30 patients

**Study setting:** The study was carried out in SVMVV's R.P.K. Ayurvedic Hospital, Ilkal from 2014 to 2016.

**Diagnostic Criteria:** Patients were diagnosed according to diagnostic criteria given for primary insomnia in DSM – IV.<sup>[8]</sup> A special Performa has been prepared incorporating all the sign & symptoms of the disease.

The subject reports one or more of the following *sleep* related complaints at least 1 month: difficulty initiating *sleep*, difficulty maintaining *sleep*, waking up too early, or *sleep* that is chronically non-restorative or poor in quality.

The above scale is applied exactly the same way as the comparable DSM-IV criteria (i.e., using the 3-day rule, the 30 minutes for getting to *sleep*, the 30 minutes for waking in the night and waking too early, and the  $\ge$  3 rule for number of times waking in the night (waking  $\ge$  3 and being awake  $\ge$  30 minutes are alternatives for the same sub-criteria).

#### Inclusion Criteria:

- 1. Patients having features as told in diagnostic criteria for at least 1 month.
- 2. Patients of either sex in the age group of 16-60 years.
- 3. Willing to give informed consent.

#### **Exclusion Criteria:**

- 1. Patients having severe hypertension, Stroke, DM, Haemorrhagic disorders, Epilepsy.
- 2. Patients having alcohol dependency or drug dependency.
- 3. Kaphaj Shiroroga, Pratishyaya, Tamak Shwasa, Nava Jwara, Kapha Pradhan Roga.
- 4. During *Varsha* (rainy), *Vasant*, and *Shishir* (winter season)

**Grouping:** The selected patients were randomly divided into 2 groups. i.e., Group A & Group B. Patients of Group A was administered *Shirodhara* by Single point drip method and Group B administered *Shirodhara* by Oscillatory drip method.

**Drug:** Luke warm tap water

Season: Sharad and Hemant ritu

#### Interventions:

Group-A (*Shirodhara* with Single drip method Group) Group-B (*Shirodhara* with Oscillatory drip method Group):

Drug	: Luke warm (temp 38ºc -39ºc)
Duration	: 45min.

**Course** : 14 days.

Time of administration: morning

**Follow up** : 16 days.

**Total duration**: Total 30 days (14 days therapy + 16 days follow up)

Procedure

#### Purvakarma

**Materials Required:** *ShirodharaYantra*-1, Table-1, Worm water-2.0 liter, Gauze-1, Cotton earplugs-2, Soft pillow covered with rexin-1, Hot water bath-1, Vessels-3, Soft towels-2, Therapist-1, B.P. instrument, Thermometer..

**Position of the Patient:** Patient will be advised to pass stool and urine. Then pulse, temperature and blood pressure was recorded. Patient is advised to lie on the table in *Shavasana* posture (supine posture with completely relaxed body parts, palms facing up words). The nozzle of the Pot is fixed at 4 *Angula* above the forehead. The eyes and ear will be covered with cotton to prevent the entry of liquid.

**Pradhana karma:** The Shirodhara is performed in clean therapy room, devoid of direct air flow well ventilated and very quiet. Shirodhara is done in the morning on empty stomach. Then the liquid is poured into the Shirodhara pot and start the adjusting knob for allowing the drip to fall, continuously neither very thick, nor very thin, neither very fast, nor very slow on the center of forehead of the patient in a single drip. During the procedure patient will be advised to concentrate on the point where drip is falling. The liquid is collected in another vessel and is used to refill the Pot before it becomes empty after making luke warm. This procedure was performed for 45 minutes.<sup>[9]</sup>

Duration: 45 min

**Temperature of liquid:** 38°c - 39°c temp.

#### Paschat karma:

After the *Dhara* process is completed, the scalp will be wiped and dried. This is followed by a short duration of rest. Patient was advised to avoid cold and wind, oily, *Abhishyandi Kaphakara Aahar and Vihar*.

### Group-B (Shirodhara with Oscillatory method Group) :

All intervention same as group A except some change in procedure as below-

When the liquid starts pouring then the vessel is moved in an oscillatory manner starting from one lateral side to the other. During procedure, the head of the patient will be gently massaged continuously.

**Assessment criteria:** For assessing the effect of therapy, Athens Insomnia scale (AIS)<sup>[10]</sup> was used.

#### Athens Insomnia scale (AIS)

- I. sleep induction (time it takes you to fall sleep after turning-off the lights)
  - 0: No problem
  - 1: Slightly delayed
  - 2: Markedly delayed
  - 3: Very delayed or did not sleep at all

- II. Awakenings during the night
  - 0: No problem
  - 1: Minor problem
  - 2: Considerable problem
  - 3: Serious problem or did not sleep at all
- III. Final awakening earlier than desired
  - 0: Not earlier
  - 1: little earlier
  - 2: Markedly earlier
  - 3: Much earlier or did not sleep at all
- IV. Total sleep duration
  - 0: Sufficient
  - 1: Slightly insufficient
  - 2: Markedly insufficient
  - 3: Very insufficient or did not sleep at all
- V. Overall quality of sleep (no matter how long you slept)
  - 0: Satisfactory
  - 1: Slightly unsatisfactory

- 2: Markedly unsatisfactory
- 3: Very unsatisfactory or did not sleep at all
- VI. Sense of well-being during the day
  - 0: Normal
  - 1: Slightly decreased
  - 2: Markedly decreased
  - 3: Very decreased
- VII. Functioning (physical and mental) during the day
  - 0: Normal
  - 1: Slightly decreased
  - 2: Markedly decreased
  - 3: Very decreased
- VIII. sleepiness during the day
  - 0: None
  - 1: Mild
  - 2: Considerable
  - 3: Intense

**Objective Parameter-** Pulse, B.P., R.R. (Recorded before and after the procedure.)

#### RESULTS

#### Table 1: Showing the effect of Shirodhara on sleep Induction

	Grade 0	Grade 1 Total		P value AF
Group A	66.7%	20%	86.7%	0.710
Group B	53.3%	26.7%	80%	0.710

When the values between the group A and group B are compared using fisher exact test, the distribution of sleep induction is not statistically significant at BT, AT and AF with p value (P<0.05)but clinically in group A (45%) improvement as compare to group B (30%).

#### Table 2: Showing the effect of *Shirodhara* on awakening during night

	Grade 0	Grade 1	Total	P value AF
Group A	33.3%	53.3%	86.6%	0.306
Group B	20%	80%	100%	0.300

When the values between the group A and group B are compared using fisher exact test, the distribution of Awakening during night is not statistically significant at BT, AT and AF with p value (P<0.05)but clinically in group A (40%) improvement as compare to group B (33.3%).

#### Table 3: Showing the effect of Shirodhara on final awakening earlier than desire

	Grade 0 Grade 1		Total	P value AF
Group A	53.3%	40%	93.3%	0.715
Group B	40%	33.3%	73.3%	0.715

When the values between the group A and group B are compared using fisher exact test, the distribution of Final awakening earlier than desire is not statistically significant at BT, AT and AF with p value (P<0.05) but clinically in group A (43.3%) improvement as compare to group B (35%).

#### Table 4: Showing the effect of Shirodhara on total sleep duration

	Grade 0	Grade 1	Total	P value AF
Group A	60%	33.3%	93.3%	0.054
Group B	20%	60%	80%	0.054+

When the values between the group A and group B are compared using fisher exact test, the distribution of Total sleep duration is suggestively significant at AF with P value P- 0.054 but clinically in group A (48.3%) improvement as compare to group B (33.3%).

#### Table 5: Showing the effect of Shirodhara on overall quality of sleep

	Grade 0	Grade 1 Total		P value AF
Group A	73.3%	13.3%	3.3% 86.6%	
Group B	46.7%	33.3%	80%	0.298

When the values between the group A and group B are compared using fisher exact test, the distribution of Overall quality of sleep is not statistically significant at BT, AT and AF with p value (P<0.05) but clinically in group A (48.3%) improvement as compare to group B (41.6%).

	Grade 0	Grade 1	Total	P value AF
Group A	60%	13.4%	73.4%	1.000
Group B	66.7%	-	66.7%	

#### Table 6: Showing the effect of *Shirodhara* on sense of wellbeing during day

When the values between the group A and group B are compared using fisher exact test, the distribution of Sense of wellbeing during day is suggestively significant at BT with P value P- 0.050 and not statistically significant at AT and AF with p value (P<0.05) but clinically in group A (36.6%) having improvement change % as compare to group B (31.6%).

#### Table 7: Showing the effect of Shirodhara on functioning (physical &mental) during day

	Grade 0	Grade 1	Total	P value AF
Group A	80%	-	80%	0.03*
Group B	40%	-	40%	

When the values between the group A and group B are compared using fisher exact test, the distribution of Functioning (Phy. &Ment) during day. is moderately significant at AT & AF with P value P- 0.033 but clinically in group A (31.6%) improvement change % as compare to group B (25%).

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	Grade 0	Grade 1	Total	P value AF	
Group A	60%	13%	73%	0.018*	
Group B	13.3%	53.3%	66.6%		

# Table 8: Showing the effect of *Shirodhara* on sleepiness during day

When the values between the group A and group B are compared using fisher exact test, the distribution of *sleep*iness during day is moderately significant at AF with P value P- 0.018 but clinically in group A (38.3%) improvement as compare to group B (26.6%).

Para	Gr. A	Gr. B	SE	t score	P value	Remarks
SBP	115.333	129.333	2.737	-3.350	0.002	Strongly significant
DBP	75.333	78.533	1.652	-1.308	0.202	Not significant
Pulse	71.867	75.067	1.591	-1.324	0.196	Not significant
RR	18.467	19.867	0.467	-2.367	0.025	Moderately significant

#### DISCUSSION

Insomnia is seen in many diseases as a symptom, complication or Arishta Lakshana. The Acharyas considered its independent manifestation too as a disease. *Vata* and *Manas* are interdependent and if one becomes vitiated, it vitiates the other. Charaka has given importance to Vata in the management of Insomnia. Hence, Manaha sukham, Manonukula-vishaya etc. are mentioned in the management of Insomnia.<sup>[11]</sup> Recent advancement in the field of neurophysiology, neurochemistry, and psychiatry has provided much understanding about the mechanism of sleep and sleep disorders. During sleep many physiological changes occur in cardio respiratory functions, body temperature, muscle tone, hormone secretion and blood pressure. Sleep is one of the most important physiological functions that influence the daytime activity, vigilance, concentration and performance. Hence maintaining good quality sleep would be crucial to health.

#### Effect of *Shirodhara* on Both the Groups

Single point drip method *Shirodhara* provided significantly better improvement in comparison of Oscillatory drip method *Shirodhara* in the symptoms of *Anidra* i.e. sleep induction, awakening during night, final

awakening earlier than desire, total sleep duration, overall quality of sleep, sense of wellbeing during day, functioning (physical and mental) during day, sleepiness during day. Deliberation of overall effect of therapy also showed that the effect of single point drip method *Shirodhara* was noted as far better in comparison to the oscillatory drip method *Shirodhara*. single point drip method *Shirodhara* provided better result because of, deep relaxation of mind due to fall of drip on *Ajna Chakra* area and also the person is advice to concentrate on the same area.

#### Probable mode of action of Shirodhara

*Shirodhara* produce a constant pressure and vibration which is amplified by hollow sinus present in 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 forebrain which then brings the amount of serotonin and catecholamine to the normal stage. Pressure also has an effect on impulse conduction. If prolonged pressure is applied to a nerve, impulse conduction is interrupted and part of body relaxes. Medicated oil poured on fore-head may be

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absorbed, producing Tranquilizing effect by reaching the Brain cortex. The chemical constituent of medicated oil may act as a neurotransmitter as deficiency of certain Neurotransmitter can be checked hypothetically if oil percolate in to Brain cortex as explained by Johnson while treating the patient of Angina by nitroglycerine. Shirodhara may also have Alpha Adrenergic blocking effect and can thus block certain actions of adrenaline and nor adrenaline. Shirodhara may also act on the adrenergic neuron probably produce their effects by modifying the svnthesis storage and uptake mechanisms of noradrenaline. The effect of Shirodhara on hormone secretion can also be postulated considering the effect on hypothalamus as hypothalamus is the main controller of endocrine secretions. The hypothalamic Neurons which secrete the regulatory hormones are themselves under the control of specialized monoaminergic, neurotransmitter neurons which arise in the mid brain. These latter release Dopamine, Nor adrenaline and Serotonin. In turn, these mid brain nuclei are under the control of visceral brain and are responsive to stress and emotional disturbances. Together with the limbic system with the hypothalamus regulates the feeling of rage, aggression, pain and pleasure and behavioural patterns of sexual arousal. Ultimately it can be postulated that *Shirodhara* may be having some effect on hypothalamus resulting in decrease of most of the psychic and somatic disorders.<sup>[12]</sup>

## CONCLUSION

Group A (Single point drip method *Shirodhara*) compared to Group B (Oscillatory drip method *Shirodhara*) provided better relief clinically in subjective parameters total sleep duration (48.3%), overall quality of sleep (48.3%) and Statistically provided moderately significant improvement in Functioning (physical and mental) and highly significant improvement in systolic blood pressure.

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