

A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF SHIRODHARA AND SHIROBASTI WITH KSHEERABALA TAILA IN ANIDRA W.S.R TO INSOMNIA

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ABSTRACT

Ayurveda has given more importance to *Nidra*, by considering it one among the *Trayo Upastambha*. The disturbance to *Nidra* includes *Anidra* which is said to be a *Vata Nanatmaja Vyadhi* which can be correlated to Insomnia. In *Anidra* both *Vata* and *Manas* play an important role. Hence *Acharyas* gave importance to *Vata* in the management of *Anidra* with *Murdhni Taila*. *Ksheerabala Taila* which is used here is having *Vatashamaka* and *Brimhaniya* action thus it enhances the *Pushti* of *Dhatus* and thus acts on *Anidra*. Objectives of this study are to evaluate the efficacy of *Shirodhara* and *Shirobasti* with *Ksheerabala Taila* in *Anidra* and also to evaluate the individual efficacy of both therapies. The 40 subjects suffering from *Anidra* fulfilling the diagnostic and inclusion criteria belonging to either sex irrespective of socio economic status and caste were selected for the clinical study. They were randomly categorized into two groups, Group A (*Shirodhara*) and Group B (*Shirobasti*) consisting of 20 subjects in each group. The Therapy under Group A provided relief ranging from 58.33% to 87.10%, while Group B provided relief ranging from 41.18% to 70.00%. In this study out of 40 subjects 09 subjects shown Marked improvement, 22 subjects shown Moderate improvement and 09 patients shown Mild improvement. It can be concluded that therapy provided highly significant results on all the parameters of *Anidra* in both groups. Even though the comparative efficacy of therapies in both groups provided statistically insignificant results, the percentage of relief was observed more in *Shirodhara* group.

Keywords: *Anidra, Manas, Trayo Upastambha, Vata, Vatashamaka*

INTRODUCTION

Charaka Acharya has mentioned *Ahara, Nidra* and *Brahmacharya* as *Trayoupastambha*¹. These three factors play an important role in the maintenance of health of a living organism. *Sukha, dukha, pushti, karshyam, vrusha, klibata, gyana* and *agyana, jivita* and *ajivata* all these factors depends on *Nidra*². *Asamyak nidra* or *Anidra* causes opposite of all these.

In modern science we can consider *Anidra* as Insomnia. It is a condition of inadequate quantity or quality of sleep. Also it is the complaint of difficulty in initiating or maintaining sleep, waking too early and not being able to get back to sleep or waking feeling unrefreshed and lethargic. Ayurveda has a very good approach towards the treatment of Insomnia by both

internal and external treatment modalities. Ayurveda has advocated *Murdhni taila*³ treatment modality which tackles both bodily and emotional factors at the same time. *Acharyas* gave more importance to *Vata* in the management of *Anidra* in which *Murdhni Taila* is mentioned as one of its treatment⁴. *Murdhni taila* includes *Shiro abhyanga*, *Shiro dhara*, *Shiro pichu* and *Shiro basti*. *Shirodhara* and *Shirobasti* comes under this were used for this current study. *Ksheerabala taila*⁵ is *vata shamaka*, *vedanasthapana* as well as *balya* and *brimhaneeya* to *shareera dhatu*s. Hence *Shirodhara* and *Shirobasti* with this *taila* provide relief from *Vataprakopa lakshanas*. In the present trial 40 subjects were randomly placed into two Groups namely Group A and Group B containing 20 subjects each. *Avipathikara choorna*⁶ 5 gm twice a day was given for *Amapachana* with *ushnodaka anupana* before food till the appearance of *Nirama Lakshnas* in both the groups prior to these procedures. The subjects of Group A were given with *Ksheerabala Shirodhara* for 14 days and the subjects of Group B were given with *Ksheerabala Shirobasti* for 14 days. Follow up was done after *parihara kala* of 28 days for 3 months.

OBJECTIVES OF STUDY:

1. To evaluate the efficacy of *Shirodhara* with *Ksheerabala Taila* in the management of *Anidra*.
2. To evaluate the efficacy of *Shirobasti* with *Ksheerabala Taila* in the management of *Anidra*.
3. To compare the efficacy of *Shirodhara* and *Shirobasti* in the management of *Anidra*.
4. To study the concept of Insomnia and *Anidra* in detail.

MATERIALS AND METHODS:

Study Design: - A comparative Clinical Study

Sample Size: - A minimum of 40 subjects suffering from *Anidra* fulfilling the diagnostic and inclusion criteria belonging to either sex irrespective of socio economic status were selected for the clinical study. They were randomly categorized into two groups namely Group A and Group B consisting of 20 subjects in each group.

Group A – *Shirodhara* with *Ksheerabala taila*,
Group B – *Shirobasti* with *Ksheerabala taila*

INCLUSION CRITERIA:

1. Subjects between the age group 20-60 years of either sex.
2. Subjects complaining of reduction of sleep time, difficulty in initiation of sleep, wakefulness during normal sleep- either any of these or all of these for the duration of three months.
3. *Anidra* along with patients complaining of *Angamarda*, *Shirogaurava*, *Jrimba*, *Jadyata*, *Glani*, *Bhrama*, *Apakthi* either some of these or all.
4. Patient already diagnosed for Primary Insomnia with duration of one month to five years.
5. Subjects satisfying the findings of DSM V and Athen's Insomnia Scale.
6. Patient fit for *Shirodhara* and *Shirobasti*.

EXCLUSION CRITERIA:

1. Subjects below twenty years of age and above sixty years of age.
2. *Anidra* due to *Madathyaya*, *Abhighata* etc.
3. *Anidra* associated with any other systemic and metabolic disorders.
4. Patient with severe Psychic diseases.
5. Subjects unfit for *Shirodhara* and *Shirobasti*.
6. Subjects with Malignant Hypertension.

SUBJECTIVE PARAMETERS: *Angamarda*, *Shirogauravata*, *Jrimba*, *Jadyata*, *Glani*, *Bhrama*, *Apakti*

Symptoms as per Diagnostic and Statistical Manual of Mental Disorders 5th Edition (DSM 5)

Difficulty in initiating sleep, Difficulty in maintaining sleep, Early morning awakening, Day time sleepiness, Lack of concentration, Fatigue, Headache.

OBJECTIVE PARAMETERS:

Through ATHEN'S INSOMNIA SCALE objective parameters will be assessed before and after treatment. Athens scale is measured by assessing 8 factors, these are rated on a 0-3 scale and the sleep is finally evaluated from the cumulative score of all factors and reported as an individual's sleep outcome. Over the period of time, AIS is considered to be an effective tool in sleep analysis. A cut off score of > 6 on the AIS is used to establish the diagnosis of insomnia.

Subjective parameters and Objective parameters before and after treatment were analyzed and compared by using appropriate statistical methods (student “t” test) and final conclusion was drawn.

OBSERVATION AND RESULT:

Comparative efficacy of therapies on subjective parameters (Lakshanas): The comparative efficacy of Group A with Group B showed Statistically Highly Significant ($p < 0.001$) result with ‘t’ value of 3.88 which means Group A showed better efficacy when compared with Group B in the treatment of *Shirogauravata* in *Anidra*. In case of other symptoms like *Angamarda* and *Bhrama* the comparative efficacy showed Statistically Significant ($p < 0.05$) result which means Group A showed better efficacy. The remaining symptoms like *Jrimba*, *Jadyata*, *Glanis* and *Apakti* the comparative efficacy showed Statistically Insignificant ($p > 0.10$) result which means Group A and Group B are equally effective in the treatment of *Jrimba* in *Anidra*.

Comparative efficacy of therapies on subjective parameters (DSM-5): The comparative efficacy of Group A with Group B showed Statistically Significant ($p < 0.10$) result which means Group A and Group B are equally effective in the treatment of Difficulty in initiating sleep, Early morning awakening and Headache in *Anidra*. The comparative efficacy of Group A with Group B showed Statistically Insignificant ($p > 0.10$) result with which means Group A and Group B are equally effective in the treatment of Daytime sleepiness, Lack of concentration and Fatigue in *Anidra*.

Comparative efficacy of therapies on Subjective Parameters (Athen’s Insomnia Scale): The comparative efficacy of Group A with Group B showed Statistically Significant ($p < 0.01$) result which means Group A and Group B are equally effective in the treatment of Sleep induction, Awakening during nights, Final awakening and Total sleep duration in *Anidra*. The comparative efficacy of Group A with Group B showed Statistically Insignificant ($p > 0.10$) result which means Group A and Group B are equally effective in the treatment of Sleep quality, Well-being

during day and Functional capacity during the day in *Anidra*.

DISCUSSION

Discussion on Observations on Demographic Data:

Age: *Anidra* can occur in any age group but persons from age group (41-50) years are more susceptible to this because of the predominance of *Pitta* and *Vata*. Also this age period is the ending stage of *Pitta* and starting stage of *Vata* thus *Vata Pitta* predominance will be more in this stage hence they are more prone to *Vata pittaja* disorders.

Sex: A higher prevalence was seen in males (67.5%) than females (32.5%). While considering the incidence rate generally females are more prone to have *Anidra* than males but here it is seen that most of them are males this doesn’t mean the incidence rate is here more in males. It is because female patients are not willing to do proper treatment.

Religion: The maximum number of patients came were Hindus (65.0%). This is only due to the predominance of Hindu community in this surrounding area.

Occupation: Maximum subjects (30.0%) were doing some sort of business and remaining few were doing service in different sectors this reveals that sedentary life style as well as increased mental activity and stress & strain contributes in establishment of the disease.

Agni: Out of 40 subjects, maximum subjects (52.5%) had *Mandagni* and remaining others has *Vishamagni* and *Teekshnagni* which is once again proving the fact that *Agnimandhya* is the root cause for all diseases.

Discussion on Disease

Chronicity: It ranges from 3 months to more than 5 yrs. Insomnia being an under diagnosed condition, many patients do not even think that they could be having a sleep problem until they start experiencing the effects of sleep deprivation.

Nidana (Aharaja, Viharaja & Manasika): Most of the subjects were doing *Vata Pitta prakopakaraka Aharas & Viharas* so that they are more prone to *Anidra*. *Chinta* and *shoka* are the *Manasika viharas* which are seen common.

Symptoms wise (DSM -5& Athen's Insomnia Scale): All symptoms are seen in patients in whom most of the people are troubling in initiating sleep and some others for maintaining also. All eight parameters of Athens scale were seen in all subjects.

PROBABLE MODE OF ACTION OF SHIRO DHARA AND SHIRO BASTI WITH KSHEERABALA TAILA:

Ksheerabala Taila is *Vatashamaka*, *Vedanasthapana* as well as *Balya* and *Brimhaniya* to *Sharira dhatus*. Hence *Shirodhara* and *Shirobasti* with this *taila* provide relief from *Vataprakopa lakshanas*. All the ingredients of *Ksheerabala Taila* possess *VataPittahara* properties as they are *Madhura* and *Tikta rasatmaka*, *Sheeta viryayukta* and have *Madhura vipaka*. Almost all of them have *laghu*, *snigha* and *guru gunas*. These *dravyas* are absorbed by the action of *Bhrajaka Pitta*. Although these procedures are *Snigdhaswedana* in action it bestows following benefits like *vatahara*, *sleshma vardhaka*, *bala vardhaka*, *mardavakara* etc. The *dravyas* used in this *taila* are *brimhana* and *rasayana* in nature thus it enhances the *rasa* and *ojo gunas* thus it is having *dhatu* level action. In *Shirodhara* prolonged and intermittent stimulation by dripping of oil may provide afferent inputs to the cerebral cortex leading to a tranquilizing effect. It is deeply relaxing and induces a relaxant state. Detoxification of the blood circulatory channels in the brain and the rejuvenation of the nervous functioning are the main objectives of *Shirodhara*. The mode of action of *Shirobasti* depends on therapeutical effect, physical effect and application of heat. *Sneha* being a lipid material nourishes different components of nervous system by passing through blood brain barrier easily. Further, absorbed active principles of *taila* reaches up to nerves and exerts their *vataghna* effects. *Snighdhata* of this *taila* removes the *rukshata* of vitiated *Vata* which helps in nourishing the nerve functions. *Mrudu abhyanga* after the procedure also helps in improving the impulse transmission in the nerve and synapses by influencing the activity of neuro transmitters.

CONCLUSION

The comparative efficacy of Group A with Group B was not significant. This shows both groups provided good relief in various parameters of *Anidra*. The Therapy under Group A provided relief ranging from 58.33% to 87.10%, with an average of 76.03%. The Therapy under Group B provided relief ranging from 42.86% to 70.00%, with an average of 53.53%. Even though the comparative efficacy of therapies in both groups provided statistically not significant results, the percentage of relief was observed more in Group A (*Shirodhara* with *Ksheerabala Taila*).

So it can be concluded that the Comparative effects of Group A and Group B, both showed statistically insignificant results which means both *Shirodhara* and *Shirobasti* are effective in the management of *Anidra*. If considering percentage of relief on all the parameters it is more in Group A than Group B.

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