



A Randomised Comparative Clinical Study to Evaluate the Effectiveness of Shiro Basti and Lalata Basti with Tungadrumadi Taila in Nidranasha (Primary Insomnia)

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ABSTRACT

Insomnia is a common condition seen now a days. In ayurveda it is being correlated to vataja nanatmaja vyadhi. There are two types of insomnia mainly primary and secondary insomnia. The term primary indicates that the insomnia is not caused by any known physical or mental condition but it is characterised by consistent set of symptoms, a defined disease course, and a general responsiveness to its treatment. To compare the effectiveness of shirobasti and lalata basti in nidranasha (Primary insomnia). Materials and methods: The study was carried out with 30 diagnosed patients of primary insomnia of age group 30-70 year and was divided into two groups. Group A was given shirobasti with tungadrumadi taila and Group B was given lalata basti with tungadrumadi taila for seven days. Assessment was done both for subjective and objective parameters. Assessment criteria for objective parameter was insomnia severity index scale which contained seven self-rated questions. Man whitney U test for objective parameter assessment showed that there was no any statistically significant difference between group A and group B with p value >0.05. Chi-square test for subjective parameters assessment showed statistically significant result with p value <0.05 between group A and group B. Conclusion: It has been found that shirobasti and lalata basti was equally effective in nidranasha.

Keywords: Nidranasha, Primary Insomnia, Shirobasti, Lalata basti

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INTRODUCTION

Sleep is one among the common requirement of life. Hence Ayurveda mentioned importance of sleep and explained under thrayopasthambas[1]. Sleep disorders are common now a days. Stress, pain, illness, mental illness, elderly age are some of the causes. Nidranasha is characterized by qualitative and quantitative derangement of sleep. The results of nidranasha are jumbha, angamarda, tandra, akshigaurava and shirogaurava[2]. Nidranasha is a vataja nanatmaja vyadhi[3]. This can be related to insomnia, a condition where there is difficulty in sleep initiation, maintenance of sleep and non-restorative sleep[4]. The prevalence rate of primary insomnia is 33% in general population globally[5], 16% in India and 18.6% in South India[6]. Sedative and hypnotic drugs are frequently prescribed as insomnia therapy[7]. Lalata basti is a procedure where sneha is made to retain over the forehead for a stipulated period of time. Lalata basti is conceptualized from shirobasti. Shirobasti is one among the murdhni taila, a bahirparimarjana snehana chikitsa done over the shiras. It is said to have bahuguna karma when considered to other procedures of murdhni taila. Shirobasti is indicated in prasupti, ardita and jagara[8]. Shirobasti is difficult to perform because of the presence of hair. Patients do not agree for shaving of hair. Therefore there is a need for modification in treatment which may be attained through lalata basti. Tungadrumadi taila contains vatapittahara and shitaveerya property and hence will help in inducing nidra. From this perspective study has been undertaken to compare the effect of shirobasti and lalata basti with tungadrumadi taila in nidranasha (Primary Insomnia).

MATERIAL AND METHODS

SOURCE OF DATA: A total of 30 subjects of nidranasha (Primary insomnia) were recruited from the Inpatient Department of Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan.

SOURCE OF DRUG :Drugs were collected from CKKM pharmacy, Ernakulam and authentication was obtained from Department of Dravyaguna of Sri Dharmasthala Manjunatheshwara College of Ayurveda & Hospital, Hassan and CKKM pharmacy, Ernakulam .Taila was prepared in Sri dharmasthala manjunatheshwara teaching pharmacy, Hassan.

METHOD OF DATA COLLECTION: The subjects were screened for diagnostic, inclusion and exclusion criteria from OPD and IPD of Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital,Hassan.The enrolled subjects were examined and recorded in the CRF.

DIAGNOSTIC CRITERIA: Based on ICD -10 guidelines-

A) Difficulty in falling asleep, maintain sleep or non-refreshing sleep

.B) The sleep disturbance occurs atleast three times per week for atleast one month.

C)The sleep disturbance results in marked personal distress or interference with personal functioning in daily living.

D)Absence of any unknown causative organic factor, such as neurological or other medical condition , psychoactive substance use disorder or a medication.

Subjects were enrolled even if any of the above two conditions are appreciated.

- Based on clinical symptoms like jrumbha, angamarda ,thandra, shirogourava, akshigourava.

INCLUSION CRITERIA

- Subjects fulfilling diagnostic criteria.
- Subjects aging between 30 to 70 years.
- Subjects of all gender.
- Subjects willing to sign informed consent form.

EXCLUSION CRITERIA

- Known cases of alcoholism.
- Known cases of psychiatric illness.
- Previously diagnosed medical or surgical disorders.
- Patients suffering from ajeerna.

INVESTIGATION:

Blood and Urine routine

RESEARCH DESIGN: Open labelled double arm randomized clinical trial

Ethical clearance: Clearance was taken from ethical committee of our institute.

Written consent:Written consent was taken from all the thirty patients included in the study.

METHODOLOGY

A total of 30 diagnosed subjects of Nidranasha (Primary Insomnia) was taken in 2 groups(15 in each group).

Group A- Subjects were given shiro basti with tungadrumadi taila.

Group B- Subjects were given lalata basti with tungadrumadi taila.

1. Purva karma
2. Pradhana karma
3. Paschat karma

GROUP	PURVA KARMA	PRADHANA KARMA	PASHCHATH KARMA
Shirobasti group	The hair on the scalp was shaved. Patient was advised to pass the natural urges. Blood pressure and pulse were checked.	A special cap was prepared from thick and firm leather opened at both ends having a height of about 9 inches and the circumference was equal to the subjects head,cap was sealed with masha flour .The subject was then asked to get seated on a knee	Tungadrumadi taila which was indirectly heated was poured slowly over the scalp inside the Shiro basti yantra. The quantity of the oil poured was 2 angulas over the scalp. Temperature was maintained constant throughout the procedure. When

		height chair erect, Then the cap was kept over the head at the level above the eyebrows and earlobes, which was sealed with masha pishti. Thereafter cap was tied at the lower end with a bandage.	the oil cooled down warm oil was replaced. The procedure was carried out for a duration for fifty three minutes till samyak shiro basti lakshana appeared.
LALATA BASTI GROUP	<ul style="list-style-type: none"> Preparation of patient;:Patient was adviced to pass the natural urges. Blood pressure and pulse was checked. 	<p>Patient was asked to lie down in supine position. Dough was prepared with godhuma by adding sufficient quantity of water and was placed over the forehead at the level above the eyebrows and below the hair root in oval shape with 5.5 cm height and circumference equal to forehead of subject. Proper sealing was done to avoid the leakage. Tungadrumadi taila was indirectly warmed over a vessel. The taila was then poured along the inner sides of the dough after ensuring that the temperature is tolerable. The temperature of the taila was maintained at 39 degree celsius . When the taila cooled it was replaced after indirectly heating it again. The procedure was carried out for 53 minutes.</p>	Dough kept over the forehead was removed and gentle massage was done on the forehead.

DRUG	DOSAGE	ROUTE OF ADMINISTRATION	TIME OF ADMINISTRATION	DURATION OF PROCEDURE	DURATION OF STUDY
Tungadrumadi taila	500 ml	Shirobasti	Evening(4:00 pm)	53 min	7 days
	40 ml	Lalata basti	Evening(4:00 pm)	53 min	7 days

ASSESSMENT PERIOD

Before treatment - Day 0

After treatment - Day 7

Follow Up - Day 23(After 15 days)

ASSESSMENT CRITERIA:

This is a clinical study. The progress was noted on the basis of assessment parameters (both subjective and objective) before treatment, after treatment and follow up in a specially prepared case sheet.

SUBJECTIVE PARAMETER

- Jumbha –Present/Absent
- Angamarda-Present/absent
- Thandra-Present/Absent
- Akshigourava-Present/Absent
- Shirogourava-Present/Absent

OBJECTIVE PARAMETER

Insomnia severity index scale will be used to assess the quality and quantity of sleep.

1. 0-7-No clinically significant insomnia
2. 8-14-sub threshold insomnia
3. 15-21-clinical insomnia (Moderate severity)
4. 22-28-Clinical insomnia(severe)

INSOMNIA SEVERITY INDEX

	None	Mild	Moderate	Severe	Very severe
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1.Difficulty in falling asleep	0	1	2	3	4
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2.Difficulty in staying asleep	0	1	2	3	4
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3.Problem waking up too early	0	1	2	3	4
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4.How satisfied or dissatisfied are you with your current sleep pattern?

Very satisfied(0) Satisfied(1) Moderately satisfied(2) Dissatisfied(3) Very dissatisfied(4)

5.How noticeable to others do you think your sleep problem in terms of impairing the quality of your life?

Not at all noticeable(0) A little(1) Somewhat(2) Much(3) Very much noticeable(4)

6.How worried or distressed are you about your current sleep problem?

Not at all worried(0) A little(1) Somewhat(2) Much(3) Very much worried(4)

7.To what extend do you consider your sleep problem to interfere with your daily functioning (e.g. day

time fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc) currently?

Not interfering (0) A little(1) Somewhat(2) Much(3) Very much interfering (4).

RESULT

Effect of therapy on objective parameters between the group:

Table 2 showing Mannwhitney U test for Insomnia Severity Index Total Score

GROUP	PARAMETER	N	MR	SR	MAN WHITNEY U	Z VALUE	P VALUE	R
SHIRO BASTI GROUP	Day 0	15	16.8	252	92.5	-0.92	0.35	NS
	Day 7	15	15.5	232	112.5	-0.00	1	NS
	Day 23	15	16	240	105	-1	0.31	NS
LALATA BASTI GROUP	Day 0	15	14.17	212	92.5	-0.92	0.35	NS
	Day 7	15	15.5	232	112.5	-0.00	1	NS
	Day 23	15	15	225	105	-1	0.31	NS

As p value>0.05 by using Mannwhitney U test it was concluded that there was no statistical significant difference between shiro basti group and lalata basti group on insomnia severity index score on D0,D7 and D23 .Thus it can be concluded that shiro basti group and lalata basti group had similar capacity in reducing symptom. Efficacy of therapy on subjective parameters between group:

Table 3 Showing Chi square test on Jrumbha

Parameter	Shirobasti group						Lalatabasti group					
	N	mean	SD	Chi sq	P value	R	N	mean	SD	Chi sq	P value	R
Day 0	15	1.27	0.45	3.26	0.07	NS	15	1.13	0.35	3.26	0.005	S
Day 7	15	1.13	0.35	11.26	0.00	S	15	1.87	0.35	11.26	0.005	S
Day 23	15	2	0.35	11.26	0.00	S	15	1.93	0.35	11.26	0.005	S

As p value<0.05,there was statistically significant difference between shiro basti group and lalata basti group on the symptom. Thus we can conclude that both group has different capacity to reduce the symptom of jrumbha in nidranasha.

Table 4 showing Chi square test on Angamarda

Parameter	Shirobasti group						Lalatabasti group					
	N	mean	SD	Chi sq	P value	Remark	N	mean	SD	Chi sq	Pvalue	R
Day 0	15	1.73	0.45	3.26	0.07	NS	15	1.47	0.51	0.06	0.07	S
Day 7	15	2	0.00	11.26	0.00	S	15	2	0.00	8.06	0.00	S
Day 23	15	2	0.00	11.26	0.00	S	15	1.87	0.35	8.06	0.00	S

As p value<0.05,there was statistically significant difference between shirobasti group and lalata basti group on the symptom.Thus we can conclude that both group has different capacity to reduce the symptom of angamarda in nidranasha.

Table 5 showing Chi square test on Tandra

Parameter	Shirobasti group						Lalatabasti group					
	N	mean	SD	Chi sq	P value	Remark	N	mean	SD	Chi sq	Pvalue	R
Day 0	15	1.47	0.51	0.06	0.79	NS	15	1.20	0.41	5.4	0.79	NS
Day 7	15	2	0.00	8.06	0.00	S	15	1.87	0.35	8.06	0.00	S
Day 23	15	1.87	0.35	8.06	0.00	S	15	1.80	0.41	8.06	0.00	S

As p value<0.05,there was statistically significant difference between shiro basti group and lalata basti group on the symptom. Thus we can conclude that both group has different capacity to reduce the symptom of tandra in nidranasha.

Table 6 showing Chi square test on Akshigourava

Parameter	Shirobasti group						Lalatabasti group					
	N	mean	SD	Chi sq	P value	Remark	N	mean	SD	Chi sq	Pvalue	R
Day 0	15	1.6	0.50	0.60	0.43	NS	15	1.73	0.45	3.26	0.07	NS
Day 7	15	1.9	0.25	11.26	0.00	S	15	1.93	0.25	11.26	0.00	S
Day 23	15	2	0.00	11.26	0.00	S	15	1.73	0.45	11.26	0.00	S

As p value<0.05,there was statistically significant difference between shirobasti group and lalata basti group on the symptom. Thus we can conclude that both group has different capacity to reduce the symptom of akshigourava in nidranasha.

Table 7 showing Chi square test on shirogourava

Parameter	Shirobasti group						Lalatabasti group					
	N	mean	SD	Chi sq	P value	Remark	N	mean	SD	Chi sq	P value	R
Day 0	15	1.07	0.25	11.26	0.00	S	15	1.33	0.48	1.66	0.19	NS
Day 7	15	1.80	0.41	5.4	0.02	S	15	1.87	0.35	8.06	0.00	S
Day 23	15	1.87	0.35	8.06	0.00	S	15	1.93	0.25	11.26	0.00	S

As p value<0.05,there was statistically significant difference between shirobasti group and lalatabasti group on the symptom. Thus we can conclude that both group has different capacity to reduce the symptom of shirogourava in nidranasha.

DISCUSSION

Probable Mode of Action of Drug: In the present study Tungadrumadi taila was used. Nidranasha is a vataja nanathmaja vyadhi, hence tungadrumadi taila was selected which contains vatapittahara and shitaveerya property[9]. Ingredients of tungadrumadi taila are- Sugandha , Lamajja , Yashtimadhu, Utpala ,Shvetachandana ,Tungadruma ,Dugdha and Tila. Sugandha is having katu rasa and laghu ruksha guna and is vatahara in action.[10] Lamajja is having madhura tikta rasa, shitaveerya , madhura vipaka and is vata pitta shamaka.[11] Yashtimadhu is having madhura and tiktara, shita veerya , madhura vipaka ,guru snigdha guna and is having vatahara properties and pittahara properties.[12] Utpala is madhura ,tikta rasa , guru guna and shitaveerya. It also has got madhura vipaka and pittahara and vatahara[13] Chandana is tikta and madhura rasa, shitaveerya and katuvipaka ,guru shita laghuguna and it is having pittahara properties [14].Tungadruma jala is having madhura rasa, guru, snigdha guna and shita veerya .It has shleshma kara property and also has got vatapittahara action.[15] Dugdha is having madhura rasa , snigdha, shlakshna, pichila, guruguna , shita veerya and madhura vipaka. It alleviates vata and pitta dosha[16].Tila taila is having madhura , tikta rasa . It has got madhura vipaka and has got vatahara action[17]. Since all the drugs are having vatahara and pittahara action, they help in alleviating nidranasha caused due to vata and pitta dosha.

Probable Mode of Action of Shirobasti Procedure: The medicine is kept over the scalp without any movement in shirobasti procedure for a particular period of time. The veerya of the medicine gets digested by the skin and through orifices present in the skin, it enters the internal organs. Veerya of medicine used in shiro basti might have entered through the tiryak dhamanis which is ramifying into hundreds and thousands of branches. The exterior orifices of these dhamanis are attached to the hair root and these dhamanis spread all over the body. Veerya is observed into the body through these orifices. Veerya (potency) circulates all over the body causing samprapti vighatana of the disease through these dhamanis. Shiro basti is one among the murdhnaitaila. It is considered as best among all the murdhnaitailas. By the power of bhrajakaagni medicine used for shiro basti undergoes pachana and deepana. Veerya of medicine used for shiro basti spread all over the body after pachana and deepana through tiryak dhamanis and action is exhibited. Through the scalp a drug could be transcranially delivered to the brain. Ayurvedic system uses special route which involves oil application to the head. Trans cranial route describes the passage of oil soluble drug across the scalp skin including the skin appendages including wall of hair follicles, sebaceous glands, through cranial bones, meninges and through the emissary veins into the brain.

Probable Mode of Action Of Lalata Basti: Acharya susruta says in sharira sthana that out of four tiryak gatha dhamanis, each dhamani divides to hundreds and thousands of times and then become innumerable. These dhamanis form a network and then spread all over the body having their openings in romakooopa. The oushadha dravya is absorbed through the openings in the skin and undergo pachana by bhrajaka pitta in the skin. Vagbhata also told the same mode of drug absorption. Drug response is produced by absorption of taila through the skin. When liquids are poured from height sthapani marma located in centre of forehead is stimulated and frontalis muscle gets relaxed. Pituitary gland is also stimulated and activity of sympathetic nervous system is decreased. By penetrating through layers of skin certain property of drugs get into systemic circulation. If the drug is having high solubility in lipid the absorption of drug across skin is increased. Penetration of some of the drugs are increased by hydration of cornified layer of epidermis. Suspending the drug in oil vehicle can enhance the drug absorption through skin as hydrated skin is more permeable than the dry skin. So systemic drug response is produced by absorption of taila through the skin. Heat application helps to promote local circulation and opens the skin pores to permit the transfer of nutrients and medicaments towards the needed sites. Thus through this mode of action lalata basti is helpful in nidranasha[18].

CONCLUSION

In the present study, Shiro basti group (Group A)- Shiro basti was done with Tungadrumadi taila and in lalata basti group (Group B)- Lalata basti was done with Tungadrumadi taila. On comparing both the groups by Mann whitney U test results were statistically not significant in both the groups for objective parameters with p value >0.05. Chi square test showed statistically significant results for the subjective parameters on comparing both the groups with p value <0.05. Thus shiro basti and lalata basti with tungadrumadi taila was equally effective in the management of nidranasha. So we can conclude that nidranasha can be treated with lalata basti also as an alternative to shiro basti as many of the patients do not agree to shave hair in shiro basti procedure. Lalata basti procedure can be done without any oral medications.

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