Research Article

RANDOMIZED COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF *MAMSYADI KWATHA* (ORALLY) *ANDTAKRADHARA* IN *ANIDRA* – PRIMARY INSOMNIA

Shikha Sikri[1]*, R. V. Shettar[2]

*[1]Lecturer, Dept. of Kayachikitsa, Shri Satya Sai Muralidhar Ayurvedic Medical College, Moga, Punjab, India.

[2]Professor, Dept. of Kayachikitsa, Shri DGM Ayurvedic Medical College, Gadag, Karnataka, India.

ABSTRACT

Sleep is a periodic functional state of human being, it is an essential phenomena for maintenance and restoration. That is why Ayurveda stresses on sleep and described as *Trayopasthambia*. *Anidra* vis-à-vis Primary insomnia is one of the important diseases pertaining to the *Vata* disorder affects the people of all age groups. It is particularly relevant to psychiatric illness and frequently part of diagnostic criteria for specific disorder. All the cases with the clinical symptoms of *Anidra* are selected for the study. In the proposed study, *Mamsyadi kwatha* which is helpful in producing sleep that is *Nidra janak* is to be given internally and *Takra* is to be used for external *Dhara* which is supposed to be non-invasive process, very simple in administration which can be done for 30 minutes is selected. Based on the earlier studies *Jatamamsi, Ashwagandha, Khurasani Yavani* are the ingredients of *Mamsyadi Kwatha* and are well known sleep producing drugs with anti- anxiety and anti-stress qualities. In *Dharas*, *Takradhara* is specific procedure for sleep disorders. The constant flow of liquid is continuously poured over the forehead which relaxes the mind, calm and tranquilizes the patients. Assessment is done on the basis of subjective parameter like *Jrumbha, Tandra, Angamardia, Shirashool*, *Manodourbalya, Smritidourbalya, Indriyakarmaheenta, Kantikshya* and objective parameter like Athens insomnia scale.

The study revealed a noteworthy efficacy of the trial drug in relieving almost all the clinical features within the study duration of 30 days, establishing the versatile action of the drug.

*Address for correspondence
Dr. Shikha Sikri
Lecturer, Dept of Kayachikitsa,
Shri Satya Sai Muralidhar
Ayurvedic Medical College, Moga,
Punjab.
Email: drshikhasikri@gmail.com
Mob-8558922455

INTRODUCTION

"Sleep is that golden chain that ties health and our bodies together."-Thomas Dekker

Ayurveda, the holistic science believes mainly on preventing from diseases and curing the diseases. According to Ayurveda, life sustains on three basic pillars *Ahara, Nidra* and *Brahmacharya.*[1] This aphorism of *Charaka* exemplifies the necessity of *Nidra*.

Anidra (Insomnia)

Our Ayurveda Acharyas have visualized this scenario centuries ago. They prescribed a natural and refreshing line of approach to this lack of sleep problem –*Anidra*, Acharya charaka has mentioned *Anidra* as one among the *Vataja Nanathmaja* vyadhi.[2] *Nidra* is induced due to *Kapha* and thamobhava.[3] The symptoms of *Anidra* are *Angamarda, Shirogaurava, Jrimbha, Jadya, Glani, Bhrama*. Acharya Charka has explained *Sukha, Dukha, Sthoola, Krusha, Bala* and even *Marana* depends on the *Nidra. Anidra* is also one of the important *Lakshana* in many diseases. [4]

Anidra can be co-related with *Insomnia*. Insomnia is the most common health complaints in medical practice and most prevalent of all sleep disorders (Handbook of clinical neurophysiology).[5] In this modern era also called "Era of Anxiety and stress", *Nidra* is the most common neglected part of life where one gives least importance to the timing, duration and quality of sleep with stress playing an important role in inducing Insomnia. This

negligence leads to *Vata prakopa* and in turn causing various physical and psychiatric illnesses. Sleep is sensitive to disturbances by many internal influences, such as excessive worry, excessive anxiety and a depressed mood. Sleep can also be disturbed by many external influences, for example, transient stress, an important life event, excessive noise, high or low room temperature, a uncomfortable bed, unfamiliar surroundings and drug withdrawal (Atlas of sleep medicine). Several types of etiological factors can cause chronic difficulty sleeping, including circadian rhythm disorders, psychiatric disorders, physical illness, sleep related physiological disorders and negative conditioning effects (psychoneuroimmunology). Recent studies have shown that about 40% of women and 30% of men are suffering from Insomnia. Population studies have revealed that 10 to 18% of adults considered sleep to be a serious chronic problem with higher prevalence problem in women and elderly. In 1/3rd population of the world suffering from various sleep disorders out of which 10 to 20 % belongs to Insomnia. [6]

Since *Anidra* is caused by the vitiation of *Vata dosha* predominant, followed by *Pitta* and *Kapha*, the proposed drugs are well known for *Vata shaman* and *Nigraha,* along with *Medhya* and *Rasayana* properties. As such these are likely to cause *Samprapti vightana* of *Anidra*. In *Dhara, Takradhara* is specific procedure for sleep disorders. The constant flow of liquid is continuously poured over the forehead which relaxes the mind, calm and tranquilizes the patients.[7]

Objective of the Study

To evaluate the effect of *Takta Dhara* and *Mamsyadi Kwatha* in *Anidra*.

Materials and Methods

Study Design: Simple randomized comparative clinical study.

Source of Data: Patient suffering from *Anidra* were selected from O.P.D and I.P.D. of D.G.M.A.M.C & H., Gadag after following the Inclusion and Exclusion criteria.

Sample Size: A total number of 30 Patients suffering from *Anidra* were selected.

Diagnostic criteria: According to Ayurvedic and modern clinical methods, medical history and physical examination will be done for diagnosis. Based on classical signs and symptoms of *Anidra* as described under subjective and clinical assessment diagnosis will be made.

Inclusion Criteria

1. Patients presenting with complaints 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 3 months or more.
2. Patient of either sex in the age group of 30- 60 years.

Exclusion Criteria

1. Patient below 30 and above 60 years*.*
2. Pregnant women and Lactating women.
3. Patient with moderate and severe hypertension, Stroke, Haemorrhagic disorders, Epilepsy.
4. Patient with alcohol dependency or drug dependency will be excluded from study.

Posology

Takra Dhara for 10 days followed by *Mamsyadi Kwath* internal 40ml per day in two divided doses for 20 days.

Total study duration

30 days treatment

30 days follow up

Screening and diagnosis of *Anidra* Patient

Doctor may ask many questions about sleep pattern such as:

1. How long the patient is experienced with symptoms?
2. Whether symptoms occur every night or not?
3. How well does the patient function during the day?
4. Whether patient is taking any medication?
5. Whether patient is having any other health disorder?

Table 1: *Pradhana Vedana*

S.No	*Lakshana*	*Kalapakarsha*			
		<3months	<6months	< 1 year	> 1 year
1	Difficulty in falling Sleep				
2	Sleep interruption				
3	Reduction in sleep time				
4	Day time nap				
5	Others				

Table 2: *Anubhandhi vedana*

S.No	*Vedana samucchaya*	*Kalapakarsha*
1	*Jrimbha*	
2	*Tandra*	
3	*Angamarda*	
4	*Klama*	
5	*Shirashoola*	
6	*Manodourbalya*	
7	*Smriti dourbalya*	
8	*Indriya karma heenata*	
9	*Kanthikshaya*	

Table 3: Subjective parameter

S.No	Parameter	Grading
1	*Jrumba*	Grade 0 – no yawns
		Grade 1 – occasional yawns
		Grade 2 – periodical yawns
		Grade 3 – often yawns
2	*Tandra*	Grade 0 – no
		Grade 1 – occasionally
		Grade 2 – often
		Grade 3 – frequently
3	*Angamarda*	Grade 0 – no body ache
		Grade 1 – occasionally body ache
		Grade 2 – periodical body ache
		Grade 3 – prefectural body ache
4	*Klama*	Grade 0 – begins and finish work quickly
		Grade 1 – decreased interest in work
		Grade 2 – delayed and decreased work capacity
		Grade 3 – unable to begin work
5	*Shirashoola*	Grade 0 – no symptoms
		Grade 1 – mild degree (occasional symptoms)
		Grade 2 – moderate degree (Once/twice in 2-3 days)
		Grade 3 – severe (daily complaints)
6	*Smriti dourbalya*	Grade 0 – good recall and memory
		Grade 1 – delayed recall and remember with confusion
		Grade 2 – recall and remember with difficulty
		Grade 3 – Unable to recall and remember
7	*Mano dourbalya*	Grade 0 – No fear or sorrow at any cost
		Grade 1 – Fearful only at reasonable causes
		Grade 2 – Fearful occasionally
		Grade 3 – Always fearful and depressed emotions
8	*Indreyakaramaheenata*	Grade 0 – No deviations
		Grade 1– Rare deviations
		Grade 2 – Often deviations and impaired knowledge Perception
		Grade 3 – Disturbed deviation and perception
9	*Kantikshya*	Grade 0 –Normal functioning in routine

		Grade 1 – Impaired motivation towards functioning oftenly
		Grade 2 – Gradually hampered performance in functions
		Grade 3 – Loss of pace and motivation in functioning

Table 4: Objective parameter

S.No	Symptoms	Grading
1	Sleep induction (time it takes you to fall asleep after turning off the lights)	0: No problem
		1: Slightly delayed
		2: Markedly delayed
		3: Very delayed or id not sleep at all
2	Awakenings during the night	0: No problem
		1: Minor problem
		2: Considerable problem
		3: Serious problem or did not sleep at all
3	Final awakening earlier than desired	0: Not earlier
		1: A little earlier
		2: Markedly earlier
		3: Much earlier or did not sleep at all
4	Total sleep duration	0: Sufficient
		1: Slightly Insufficient 2: Markedly insufficient 3: Very insufficient or did not sleep at all
5	Overall quality of sleep (no matter how long you slept)	0: Satisfactory
		1: Slightly unsatisfactory
		2: Markedly unsatisfactory
		3: Very satisfactory or did not sleep at all
6	Sense of well being during the day	0; Normal
		1: Slightly decreased
		2: Markedly decreased
		3: Very decrease
7	Functioning (physical and mental) during the day	0: Normal
		1: Slightly decreased
		2: Markedly decreased
		3: Very decreased
8	Sleepiness during the day	0: None
		1: Mild
		2: Considerable
		3: Intense

Investigation

- Hb%
- TLC
- DLC
- ESR
- RBS (if necessary)

DISCUSSION

On clinical study

A total number of 30 Patients suffering from *Anidra* were selected. The diagnosis was made on the basis of parameters for obtaining the effect of therapy. As insomnia is a disorder diagnosed only on the basis of clinical features so objective and subjective parameter were considered in this study and also the investigations Hb%, TLC, DLC, ESR, RBS (if necessary) were done to rule out other possibilities and not for the purpose of diagnosis. Therefore, for assessment Athens insomnia scale was considered. Assessment was done on 0, 10th

day of *Takradhara*, 30th day of treatment and 30th day of follow up.

On observations

Age

Out of thirty patients, 60% were belonging to 30-45 years age group, 40% were from 46-60 years age group. In both the age group stress is predominant factor. In first category modified lifestyle, work stress is more where in second group physiological changes may be the cause for the stress.

Sex

Out of thirty patients 40% were male, 60% were female. In earlier researches the prevalence had made that this is more in females than in males. Despite the fact of prevalence that females might suffer from *Anidra*, here they did not turn up for the treatment. Insecurity and family bounding were triggering factors in most of females.

Religion

The area of study is free of any disturbances the religion relation does not exist. Out of thirty patients the distribution showed 80% Hindu, 16.66% Muslims, and 3.33% Christian. No religious prevalence is attributed in the present study.

Occupation

Out of thirty patients, 13.33% were agriculturist, 33.33% were labourer, 10% were Government officials, 33.33% were housewives, and 10% were businessmen. Labourer and housewives suffer from excessive mental tension and worry which may lead to *Anidra*.

Marital status

Out of thirty patients, 90% were married, 10% were unmarried. So, maximum patients were belonging to married group because of *Chinta*, which leads to *Anidra*.

Economic status

Out of thirty patients, 43.33% were poor, 53.33% were middle class, and 3.33% was rich. Though the economic status is not prevailing to present disease but the financial status of different categories of patients may have impact in stress conditions. So in the present study patients of all categories are equally affected.

Educational qualification

Out of thirty patients, 30% were uneducated, 13.33% were primary educated, 33.33% had higher secondary education, and 23.33% were graduated.

Habitat

Out of thirty patients, 10% were from rural area, 90% were from urban area. This is due to lifestyle changes in urban areas which triggers to *Anidra*.

Addiction

Out of thirty patients, 26.66% were eating tobacco, 13.33% had habit of smoking, 10% had habit of consuming alcohol and 50% had no addiction. It has been reported that alcohol, nicotine affects the sleep pattern. Despite they provide sleep initially but later affect the blood concentration which leads to arousal.

Diet

Out of thirty patients, 63.33% were non-vegetarian, 36.66% were vegetarian. This reports that non vegetarians are more towards the *Anidra*. But in *Anidra chikitsa*, diet which is advised is *Mamsa* of various animals. Although *Mams ahara* is guru but *Dravyas* which are used are *Vidahi* by nature which causes stomach discomfort so it might result in *Anidra*.

Bowel habits

Out of thirty patients, 70% were *Samyak* and 30% were *Vibhanda*. So in the study it reports that maximum number of patients had normal bowel habits.

Koshta

Out of thirty patients, 16.66% had *Mrudu koshta*, 56.66% had *Madhyma koshta*, and 26.66% had *Krura koshta*. So in the study maximum patients belonged to *Madhyma koshta* which clearly lightens the predisposing factor for *Vata*.

Prakruti

Out of thirty patients, 46.66% had *Vata pitta prakruti*, 40% had *Vata kapha prakruti* and 13.33% had *Pitta kapha prakruti*. So this reports that *Vata pitta prakruti* patients are at high risk of *Anidra*.

Satva

Out of thirty patients, 73.33% had *Madhyama satva*, 16.66% had *Avara satva* and 310% had *Pravara satva. Avara satva* persons have unstable mind due to which they have no hold on *Krodha* and *Chinta* which leads to *Anidra*.

Vyayama shakti

Out of thirty patients, 50% had *Madhyama vyayama Shakti*, 26.66% had *Pravaravyayama Shakti* and 23.33% had *Avara vyayama shakti*. Less of physical activity promotes *Anidra*.

Chronicity

Out of thirty patients, 36.66% were suffering from *Anidra* for more than three months,

30% suffered for 3-6 months, 13.33% for 6months to one year and rest 20% suffered for more than a year.

Symptoms

Out of thirty patients 63.33% had *Jrimbha*, 50% had *Tandra*, 28% had *Angmarda*, 40% had *Klma*, 90% had *Shirashoola*, 60% had *Manodourbalya*, 50% had *Smritidourbalya*, 10% had *Indriyakarmaheenata* and lastly 13.3% had *Kantikshya*.

Stress factors

Out of thirty patients 40% had work stress, 20% had financial stress, 16.66% had relationship stress and 23.33% had others stress. This study reports that due to mental tension and worry, insecurity of finances and relations leads to the cause of *Anidra*.

On subjective parameter

Jrumbha

In this study, 63.33% were found with the symptom of *Jrumbha* which can be correlated with yawning. *Takradhara* and *Mamsyadi kwatha* was given which provided significant relief in the above symptom and it was reduced to 3.33%. The mean score of *Jrumbha* was 1.100 before treatment and reduced upto 0.0667 after treatment with 93.93% relief which was statistically highly significant. (p<0.001).

Tandra

In symptom *Tandra*, which is characterised by reduced acuity of perception, yawning and tiredness this condition is similar to intense urge of sleep. This may be correlated to stupor. This is caused by the increase of *Tamas, Vata* and *Kapha*. 50% were found with the symptom and after treatment all got significant relief in the above symptom. Initially the mean score for *Tandra* was 0.900 before treatment which reduced upto 0.667 after treatment with 92.55% relief which was statistically highly significant. (p<0.001)

Angamarda

80% were markedly noticed with the symptom. As it may be caused by *Vata dosha* so after *Takradhara* and *Mamsyadi kwatha* it was left in 20% of the patients. The mean score of *Angamarda* was 1.733 before treatment and reduced upto 0.200 after treatment with 88.45% relief which was statistically highly significant (P<0.001)

Klama

Usually fatigue occurs after physical labour. A condition of tiredness without prior physical exertion is called *Klama*. It may be roughly correlated with exhaustion. So in the present study, 40% were present with *Klama* and with the treatment 6.66% left with the above symptom. It was reported that mean score of *Klama* was 0.500 and after treatment it reduced to 0.133. This 73.40% of relief was statistically highly significant (p<0.001).

Shiroshoola

This symptom is seen due to *Vata*, *Pitta* and *Rajo guna vriddhi*. Highly significant result was found in case of *Shiroshoola*. 90% of this symptom was present which later reduced to 6.66%. This is due to *Takradhara* by calming the stressful mind, relaxes the entire physiology. Imbalance of *Prana*, *Udana* and *Vyana Vayu*, *Sadhaka Pitta* and *Tarpaka Kapha* can produce stress and tension. The mean score of *Shiroshoola* was 1.967 before treatment and reduced upto 0.133 after treatment with 94.78% relief which was statistically highly significant (p<0.001).

Manodourbalya

It was present in 60% of the patients and it showed the improvement up to 23.33% of the patients. This is due to the *Takradhara* and the drugs like *Jatamamsi* possess the *Manasdoshahara* and *Nidrajanana* quality. *Ashwagandha* is *Mastishkashamaka* and acts as a *Rasayana* which stimulates the immune system and have Antiinflammatory effects and also improve memory. *Khurasani yvani* have properties like anti spasmodic, anti inflammatory, *Madak* and *Nidrakar*. It was reported that initial mean score of *Manodourbalya* was 0.833 and after treatment it reduced upto 0.300.This 63.98% relief was statistically highly significant (p<0.001).

Smriti dourbalaya

It was present in 46.66% of patients but there was found no improvement in this area.

Indreeyakarmaheenta

This was present in 10% of the patients but all the patients were improved after the treatment in the present study. It was reported that initial mean score of *Indreeyakarmaheenta* was 0.0667 and after treatment it reduced up to 0.000. The t value of this parameter is 1.439 and p value is 0.161 which is statistically nonsignificant. Since, there were less number of patients are affected so it was came statistically non significant but the percentage of improvement is 100%.

Kantikshaya

In 13.33% of the patients were having *Kantikshaya*. Symptom was relieved in all the patients after treatment. It was reported that initial mean score of *Kantikshaya* was 0.200 and after

treatment it reduced up to 0.000. The t value of this parameter is 1.989 and p value is 0.056 which is statistically non significant. Since there were less number of patients is affected so it was come statistically non significant but the percentage of improvement is 100%.

On objective parameter

Athens insomnia scale

The scale assesses the severity of insomnia using diagnostic criterion set forth by the international classification of diseases (ICD-10). The eight-item questionnaire evaluates sleep onset, night and early morning waking, sleep time, sleep quality, frequency and duration of complaints, distress caused by the experience of insomnia, and interference with daily functioning. A shorter version of questionnaire, consisting of the first five items may also be used.

According to Athens insomnia scale, 70% of the patients had mild *Anidra*, 26.66% had moderate and 3.33% were suffering from severe *Anidra*. After treatment only 3.33% of patient had symptoms of mild *Anidra*, 96.66% patients were normal.

Table 5: Statistical analysis percentage of relief in *Jrumbha*

Jrumbha	n	Mean score	Mean diff	% of relief	SD	SE	T value	P value	significant
BT AT	30	1.100 0.0667	1.03	93.93%	0.964	0.176	5.869	<0.001	S

Table 6: Statistical analysis percentage of relief in *Tandra*

Tandra	n	Mean score	Mean diff	% of relief	SD	SE	T value	P value	significant
BT AT	30	0.900 0.0667	0.833	92.55%	0.913	0.167	5.000	<0.001	S

Table 7: Statistical analysis percentage of relief in *Angamarda*

Angamarda	N	Mean score	Mean diff	% of relief	SD	SE	T value	P value	significant
BT AT	30	1.733 0.22	1.533	88.45%	0.900	0.164	9.336	<0.001	S

Table 8: Statistical analysis percentage of relief in *Shirodhara*

Shirodhara	N	Mean score	Mean diff	% of relief	SD	SE	T value	P value	significant
BT AT	30	1.967 0.133	1.833	93.18%	0.874	0.160	11.486	<0.001	S

Table 9: Statistical analysis percentage of relief in *Manodourbalya*

Mano dourbalya	n	Mean score	Mean diff	% of relief	SD	SE	T value	P value	significant
BT AT	30	0.833 0.300	0.533	63,98%	0.571	0.104	5.133	<0.001	S

Table 10: Statistical analysis percentage of relief in *Smritidourbalaya*

Smriti dourbalaya	n	Mean score	Mean diff	% of relief	SD	SE	T value	P value	significant
BT AT	30	0.600 0.600	0.000	0%	0.000	0.000	0.000	1.000	NS

Table 11: Statistical analysis percentage of relief in *Indreeya karmaheenta*

Indreeya karmaheenta	N	Mean score	Mean diff	% of relief	SD	SE	T value	P value	significant
BT AT	30	0.0667 0.000	0.0667	100%	0.254	0.0463	1.439	<0.161	NS

Table 12: Statistical analysis percentage of relief in *Kantikshay*

Kantikshay	N	Mean score	Mean diff	% of relief	SD	SE	T value	P value	significant
BT AT	30	0.200 0.000	0.200	100%	0.551	0.101	1.989	0.056	NS

Mode of action

Mamsyadi kwatha

Jatamamsi, Ashwagandha, Khurasani Yvani were the ingredients which were used in *Mamsyadi kwatha*. It was selected on the basis of having their tranquilizing and anti stress effect which was helpful in *Anidra. Jatamamsi* possess the *Manasdoshahara* and *Nidrajanana* quality. *Ashwagandha* is *Mastishka shamaka* and acts as a *Rasayana* which stimulates the immune system and have anti inflammatory effects and also improve memory. *Khurasani yvani* have properties like anti spasmodic, anti inflammatory, *Madak* and *Nidrakar*.

CONCLUSION

- *Takradhara* and *Mamsyadi kwatha* has significant effect on *Anidra*.

- This treatment has good effect even after stopping the treatment.

- *Takradhara* and *Mamsyadi kwatha* can be practiced in *Anidra* patients without any harmful effects.

- This treatment also has effects on symptoms associated with *Anidra* like *Jrumbha, Tandra, Angamarda, Klma* etc.

- However, *Takradhara* and *Mamsyadi kwatha* can be practiced on large samples so that more definite conclusions can be drawn as the present study consists of only 30 patients.

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