

Clinical Researches

Evaluation of Insomrid Tablet and *Shirodhara* in the management of *Anidra* (Insomnia)

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Abstract

The study was conducted in 30 clinically diagnosed patients of *Anidra* (Insomnia) with an objective of clinical evaluation of the efficacy of *Shirodhara* and *Tab. Insomrid* (proposed herbal formulation) in the management of *Anidra* (Insomnia). These patients were randomly divided into three groups of 10 patients each. It was observed that the patients of Group III treated with *Tab. Insomrid* and *Shirodhara* with milk showed highly significant improvements, whereas the Group II treated with *Shirodhara* and Group I treated with *Tab. Insomrid* also showed significant improvements. No adverse effects were noted in any of the patients during the trial period.

Key words: *Anidra*, *Nidranasha*, *Shirodhara*, Insomnia.

Introduction

Tridoshas i.e. *Vata*, *Pitta* and *Kapha* are described as *Tristhuna* (Three main pillars) of *Ayurveda*- the science of life. Similarly *Aahara* (food), *Nidra* (Sleep) and *Bramhacharya* (Abstinence) are described to be the *Trayopasthambas*¹ (Three supportive pillars). Hence forth, Sleep is one of the essential factors to lead a healthy life. It has been rightly stated by *Acharya Charaka* that happiness & misery, proper & improper growth, good strength & weakness, potency & sterility, knowledge & ignorance and life & death of an individual depend on proper and improper sleep².

Insomnia (inadequate quality and quantity of sleep) may be a symptom of stressful lifestyle, depressive illness, anxiety disorders, any psychiatric conditions or any other pathological conditions. Whatever may be the cause of insomnia it needs immediate attention in present day lifestyle. It is affecting nearly 1/3rd of population (especially youth) in western developed countries and the incidences are increasing day by day in the developing countries like India, Nepal, Sri Lanka, Bangladesh etc. If insomnia is left untreated, it may reduce mental capacity of an individual, reduce efficacy, increase the chances of various types of accident and ultimately it may drag the individual towards several severe psychosomatic disorders³.

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Need of the study

Present day modern medical doctors prescribe different types of tranquilizers for the management of insomnia. Even though initially the tranquilizers give considerable relief in insomnia but continuous and long term use may induce various toxic effects including drug dependency⁴. In such a scenario there is an immediate need for the efficient management of insomnia in a natural way with good counseling, usage of herbal medicines, following the proper life style and eradicating the problems from root itself. Need has always been felt to develop certain *Ayurvedic* treatment modalities for the management of *Anidra* (Insomnia) which could be safe, effective, readily available, cost effective without any side effects. In comparison to the therapeutic procedures of different systems of medicine, *Ayurveda* has a potent approach towards the treatment of *Anidra* by both internal and external medications. With these backgrounds an effort is made to evaluate the efficacy of a herbal compound drug and the administration of *Shirodhara* (pouring of the medicated liquid on the forehead) in a series of patients suffering from insomnia.

Aims & Objectives

The present research trial was undertaken with the following main objectives-

- ◆ Conceptual and clinical studies on *Anidra* w.s.r. to insomnia and its management with time tested *Ayurvedic* principles.

- ◆ To evaluate *Nidrakara* (Anti insomnic) effects of the proposed herbal compound preparation and *Shirodhara* in a series of patients suffering from insomnia on various scientific parameters.
- ◆ To compare the efficacy of *Nidrakara* (Anti insomnic) effects of the proposed herbal compound preparation and *Shirodhara*.

Material & Methods

Selection of Cases

The study recruited a population of 30 clinically diagnosed patients of *Anidra* selected from O.P.D. / I.P.D. unit of P.G. Department of *Kayachikitsa*, National Institute of *Ayurveda*, Jaipur. A regular record of the assessment of all patients was maintained according to performa prepared for the purpose. Following inclusion and exclusion criterias were used for registration of the patients for present clinical trial.

Inclusion Criteria

- ◆ Individuals between the age group of 16 to 60 years of both sexes having insomnia of minimum one month duration were selected randomly for the study.
- ◆ Patients of Insomnia with mild hypertension, mild depression and anxiety disorders without any complications of any other diseases were included for the present study.

Exclusion Criteria

- ◆ Patients below 16 years and above 60 years of age.
- ◆ Patients with major psychiatric illness like schizophrenia, depressive psychosis, epilepsy etc were not registered.
- ◆ Patients with alcohol dependency or drug dependency were excluded from the study.
- ◆ Patients having chronic illness like asthma, malignancies, liver cirrhosis, chronic renal failure, diabetes etc. were excluded.
- ◆ Patients with acute illness like Cardio Vascular Accident, Congestive Cardiac Failure, Myocardial Infarction, Chronic Obstructive Pulmonary Disorders, meningitis, acute pain conditions and similar other disorders were excluded.

Selection of Drugs

Taking the symptoms and the *Samprapti* of *Anidra* into consideration, a proposed compound drug formulation namely "*Insomrid Tablet*" was selected. The drug selected for the study were mainly having *Tikta*, *Kashaya Rasa*, *Laghu Guna*, *Ushna Virya* (except *Jatamamsi*), *Katu Vipaka* (except *Ashwagandha - Madhura Vipaka*) *KaphavatAhara* properties. All the selected drugs were having *Nadibalya*, *Mastishka Shamaka*, *Nidrajanaka* and *VatAhara* properties⁵.

Method of preparation of tablet

All the five crude drugs (Table 1) were taken in equal quantity and made into *Yavakuta Churna* (coarse powder). Then the decoction was prepared by classical method i.e. considering total drug as 1 part, 16 parts of water was added and boiled on mild flame. When 1/4th of the water was remaining, the obtained decoction was filtered through the fine cotton cloth. This filtered decoction was again heated on mild flame until *Ghanasattwa* (semi solid form) is obtained. Finally the tablets each of 500 mg were prepared from the *Ghanasattwa*. The medicine was prepared in the pharmacy of N.I.A., Jaipur.

Dose and Anupana

Dose of *Insomrid* tablet was 2 tab (each of 500 mg) in the morning after breakfast and night after the dinner with luke warm milk for 30 days.

Pre Treatment Observations

All the patients have been studied along with the registration by noting down their demographic profile including their age, sex, address, occupation, education, socio economic status, marital status, life style, addictions, dietary habits etc. After preliminary registration, patients were subjected to detailed case history taking, physical, general and systemic examinations. In history and examination importance was given to mental status examination. During this all other relevant informations like *Ashtavidha Pariksha* and *Dashavidha pariksha* including assessment of *Sharirika Prakriti* and *Manasika Prakriti* (based on the features described in classical texts) etc. were noted.

Administration of Drug & Treatment Schedule

Total 30 registered, clinically diagnosed and confirmed patients of *Anidra* (Insomnia) were selected for the present clinical trial and randomly divided into following three groups of 10 patients each-

Group-I: Total 10 patients of *Anidra* (Insomnia) were recommended Tab. *Insomrid* in the dose of 2 gms per day (2 Tab. BD) with luke warm milk for a period of 30 days.

Group-II: Total 10 patients of *Anidra* (Insomnia) were administered *Shirodhara* with luke warm milk (the temperature of milk was approximately 38°- 40° C, which is easily tolerable and cozy to touch) for a period of 15 days.

Group-III: Total 10 patients of *Anidra* were recommended both Tab. *Insomrid* and *Shirodhara* simultaneously in the dose and schedule as discussed above.

All the patients were advised to undergo following laboratory investigations before starting the trial to rule out any other illness if present and to exclude them from the trial.

- ◆ Blood - Hb%, TLC, DLC, ESR, FBS, PPBS
- ◆ Urine - Routine and Microscopic examination

Patients were followed up after 15 days and 30 days and changes, improvements, deterioration and any other effects produced after the therapy were noted down.

Criteria of Assessment

Both subjective and clinical improvements were employed for assessment of the impact of the therapy. Subjective criteria of evaluation included the observations of both patients and assessment of the physician.

Subjective Improvement

All the patients registered for the trial were specially asked for any changes or improvement in their growing feeling of well being if any and either physical or mental fitness produced by the therapy during the trial.

Clinical Improvement

All symptoms taken for the assessment of clinical improvements were thoroughly examined and the severity of each symptom and points of sleep diary were rated before and after the trial for clinical assessment. Efforts were made to give numerical values to all symptoms depending upon their severity before and after the treatment. For this purpose the following "Symptom Rating Scale" developed by Prof. A.K. Sharma et.al. was used (Table 1).

Following symptoms of *Anidra* were assessed before and after the therapy

1. *Jrimbha* (Yawning),
2. *Tandra* (Drowsiness),
3. *Angamarda & Angasada* (Malaise),
4. *Arati & Klama* (Fatigue & Inertness),
5. *Sirahshoola* (Headache),
6. *Manodourbalya* (Lack of concentration),
7. *Smritidourbalya* (Loss of Memory),
8. *Indriya Karmahani* (Poor sensory perception),
9. *Ajirna & Agnimandhya* (Indigestion),
10. *Malabaddhata* (Constipation),
11. *Dhatu kshaya* (Weight loss),
12. *Kanti Kshaya* (Loss of luster).

Sleep Diary Assessment

A sleep diary was provided to each of the patient after the registration for the trial. Patient himself had to fill the diary. Sleep diary contained following 10 points:

Time into bed, Time of lights out, Time to fall asleep, Number of Awakenings, Time out of bed, Naps- Day time, Rate how you felt today, Irritability, Total time of sleep, Sleep Quality (Table 2).

Observations & Results

Subjective improvement: After the completion of therapeutic trial there was marked improvement in the feeling of well being, physical and mental fitness in all the three groups. The incidence of improvement was higher in IIIrd Group i.e. Mixed therapy group. Significant improvement was observed in Group IInd treated with *Shirodhara* and in the patients of Ist Group treated with *Insomrid* tablet also.

Clinical Improvement: The clinical improvements in symptoms of *Anidra* in 30 patients of all the three groups are described below in Table 3, 4, 5, 6, 7 and 8.

Table 1: Contents of proposed herbal drug "Insomrid Tablet"

S.No.	Drugs	Botanical Names	Parts Used	Appx. Quantity in 1 Tab (500 mg.)
1.	Ashwagandha	<i>Withania somnifera</i>	Root	100 mg.
2.	Sarpagandha	<i>Rauwolfia serpentina</i>	Root	100 mg.
3.	Jatamansi	<i>Nordostachys jatamansi</i>	Rhizome	100 mg.
4.	Tagara	<i>Veleriana wallichii</i>	Root	100 mg.
5.	Parasika Yavani	<i>Hyoscyamus niger</i>	Seeds	100 mg.

Table 2: Symptoms Rating Scale

S.No.	Symptoms	Grades	Number	Percentage
1.	Nil	-	0	0
2.	Mild	+	1	25
3.	Moderate	++	2	50
4.	Severe	+++	3	75
5.	Extremely marked	++++	4	100

Table 3: Clinical recovery of symptoms in 10 patients of Anidra (Insomnia) treated with Tab. Insomrid in Group I

Sr. No.	Symptoms	Mean score		Difference	Relief %	SD±	SE±	t	p	Result
		BT	AT							
1	Jrimbha	2.5	0.8	1.7	68.0	0.48	0.15	11.12	<0.001	HS
2	Tandra	2.0	1.0	1.0	50.0	0.66	0.21	4.74	<0.01	HS
3	Angamarda & Angasada	1.6	0.6	1.0	62.5	0.47	0.14	6.70	<0.001	HS
4	Arati & Klama	1.6	0.9	0.7	43.7	0.48	0.15	4.58	<0.01	HS
5	Sirahshoola	2.1	0.9	1.2	57.1	0.63	0.2	6.0	<0.001	HS
6	Manodourbalya	1.1	0.7	0.4	36.3	0.51	0.16	2.44	<0.05	S
7	Smritidourbalya	1.1	0.6	0.5	45.4	0.52	0.16	3.0	<0.05	S
8	Indriya Karmahani	2.0	2.0	0	0	0	0	0	<0.10	NS
9	Ajirna & Agnimandya	2.2	1.0	1.2	54.5	0.42	0.13	9.0	<0.001	HS
10	Malabaddhata	2.1	0.6	1.5	71.4	0.52	0.16	9.0	<0.001	HS
11	Dhatukshaya	0.8	0.2	0.6	75.0	0.69	0.22	2.71	<0.05	S
12	Kantikshaya	1.3	0.6	0.7	53.8	0.48	0.15	4.58	<0.01	HS

Table 4: Recovery in Sleep Diary assessment in 10 patients of Anidra treated with Tab. Insomrid in Group I

Sr. No.	Symptoms	Mean score		Difference	Relief %	SD±	SE±	t	p	Result
		BT	AT							
1	Time to fall asleep	2.2	0.9	1.3	59.0	0.48	0.15	8.51	<0.001	HS
2	No. of awakenings	2.2	0.8	1.4	63.3	0.69	0.22	6.33	<0.001	HS
3	Naps - Day Time	1.3	0.7	0.6	46.1	0.51	0.16	3.67	<0.01	HS
4	Rate how you felt today	2.3	0.9	1.4	60.8	0.51	0.16	8.57	<0.001	HS
5	Irritability	1.6	0.7	0.9	56.25	0.31	0.1	9.0	<0.001	HS
6	Total time of sleep	2.3	1.1	1.2	52.17	0.42	0.13	9.0	<0.001	HS
7	Sleep Quality	2.4	1.1	1.3	54.1	0.48	0.15	8.51	<0.001	HS

Table 5: Clinical recovery of symptoms in 10 patients of Anidra (Insomnia) treated with Shirodhara in Group II

Sr. No.	Symptoms	Mean score		Difference	Relief %	SD±	SE±	t	p	Result
		BT	AT							
1	Jrimbha	2.1	0.7	1.4	66.6	0.51	0.16	8.57	<0.001	HS
2	Tandra	1.7	0.5	1.2	70.5	0.42	0.13	9.0	<0.001	HS
3	Angamarda & Angasada	1.6	0.5	1.1	68.7	0.73	0.23	4.71	<0.01	HS
4	Arati & Klama	1.5	0.4	1.1	73.3	0.31	0.1	11.0	<0.001	HS
5	Sirahshoola	2.0	0.5	1.5	75.0	0.70	0.22	6.70	<0.001	HS
6	Manodourbalya	1.5	0.5	1.0	66.6	0.81	0.25	3.87	<0.01	HS
7	Smritidourbalya	2.0	0.5	1.5	75.0	0.52	0.16	9.0	<0.001	HS
8	Indriyakarmahani	0.3	0.3	0	0	0	0	0	<0.10	NS
9	Ajirna & Agnimandya	1.7	0.7	1.0	58.8	0.81	0.25	3.87	<0.01	HS
10	Malabaddhata	1.6	0.4	1.2	75.0	0.78	0.24	4.81	<0.001	HS
11	Dhatukshaya	1.1	0.3	0.8	72.7	0.63	0.2	4.0	<0.01	HS
12	Kantikshaya	0.9	0.4	0.5	55.5	0.52	0.16	3.0	<0.05	S

Discussion

The clinical study of 30 patients carried out in the present series revealed that majority of these cases were of age between 31-40 years and 51-60 years. This incidence shows that the complaints of insomnia rise as the age advances. In the trial urban people of middle class were

found more affected and there was slight dominance of patients of male sex. It may be due to work stress and struggle for better life. The majority of patients registered were Hindu by religion and were on vegetarian diet. This may be due to the reason that the hospital is located in Hindu dominant area.

While the assessment of *Prakriti*, most of the patients

Table 6: Recovery in Sleep Diary assessment in 10 patients of Anidra treated with Shirodhara in Group II

Sr. No.	Symptoms	Mean score		Difference	Relief %	SD±	SE±	t	p	Result
		BT	AT							
1	Time to fall asleep	2.0	0.6	1.4	70.0	0.51	0.16	8.57	<0.001	HS
2	No. of awakenings	1.6	0.6	1.0	62.5	0.47	0.14	6.70	<0.001	HS
3	Naps - Day Time	1.6	0.5	1.1	68.7	0.73	0.23	4.71	<0.01	HS
4	Rate how you felt today	1.8	0.4	1.4	77.7	0.51	0.16	8.57	<0.001	HS
5	Irritability	1.7	0.6	1.1	64.7	0.31	0.1	11.0	<0.001	HS
6	Total time of sleep	1.9	0.6	1.3	68.42	0.67	0.21	6.09	<0.001	HS
7	Sleep Quality	2.0	0.5	1.5	75.0	0.52	0.16	9.0	<0.001	HS

Table 7: Clinical recovery of symptoms in 10 patients of Anidra (Insomnia) treated in Group III (Mixed Group)

Sr. No.	Symptoms	Mean score		Difference	Relief %	SD±	SE±	t	p	Result
		BT	AT							
1	<i>Jrimbha</i>	2.8	0.7	2.1	75.0	0.73	0.23	9.0	<0.001	HS
2	<i>Tandra</i>	1.8	0.5	1.3	72.2	0.48	0.15	8.51	<0.001	HS
3	<i>Angamarda & Angasada</i>	2.0	0.5	1.5	75.0	0.84	0.26	5.58	<0.001	HS
4	<i>Arati & Klama</i>	2.2	0.5	1.7	77.2	0.67	0.21	7.96	<0.001	HS
5	<i>Sirahshoola</i>	2.0	0.4	1.6	80.0	0.69	0.22	7.23	<0.001	HS
6	<i>Manodourbalya</i>	1.9	0.8	1.1	57.8	0.56	0.17	6.12	<0.001	HS
7	<i>Smritidourbalya</i>	1.0	0.5	0.5	50.0	0.52	0.16	3.0	<0.05	S
8	<i>Indriya Karmahani</i>	0.2	0.2	0	0	0	0	0	<0.10	NS
9	<i>Ajirna & Agnimandya</i>	2.1	0.5	1.6	76.1	0.51	0.16	9.79	<0.001	HS
10	<i>Malabaddhata</i>	1.7	0.6	1.1	64.7	0.56	0.17	6.12	<0.001	HS
11	<i>Dhatukshaya</i>	0.6	0.2	0.4	66.6	0.51	0.16	2.44	<0.05	S
12	<i>Kantikshaya</i>	1.3	0.4	0.9	69.2	0.73	0.23	3.85	<0.01	HS

Table 8: Recovery in Sleep Diary assessment in 10 patients of Anidra (Insomnia) treated in Group III (Mixed Group)

Sr. No.	Symptoms	Mean score		Difference	Relief %	SD±	SE±	t	p	Result
		BT	AT							
1	Time to fall asleep	2.2	0.5	1.7	77.2	0.48	0.15	11.12	<0.001	HS
2	No. of awakenings	1.7	0.4	1.3	76.4	0.48	0.15	8.51	<0.001	HS
3	Naps - day time	1.3	0.5	0.8	61.5	0.63	0.2	4.0	<0.01	HS
4	Rate how you felt today	1.7	0.4	1.3	76.4	0.48	0.15	8.51	<0.001	HS
5	Irritability	1.4	0.4	1.0	71.4	0.47	0.14	6.70	<0.001	HS
6	Total time of sleep	2	0.5	1.5	75.0	0.52	0.16	9.0	<0.001	HS
7	Sleep quality	2.2	0.7	1.5	68.1	0.70	0.22	6.70	<0.001	HS

HS = Highly Significant, S = Significant, NS = Not Significant.

were having *Vata Pittaja Prakriti* (60.00%) and *Rajasika Prakriti* (83.33%). So it can be inferred that the persons with *Vata Pittaja Prakriti* and *Rajasika Prakriti* find more difficult to get natural sleep. Out of 30 registered cases 16 patients (53.33%) were having *Vishamagni* with *Madhyama AAhara Shakti* (70.00%). This shows that *Anidra* also affects the quantity of food intake and the process of digestion is also hampered. Majority of patients were having *Madhyama Sara* (83.33%) and *Madhyama Samhanana* (73.33%) with *Madhyama Sattva* (66.66%). Out of 30 patients registered for the study 16 (53.33%)

patients were having chronic insomnia with more than 18 months duration of illness.

After completion of clinical trial it was observed that there was considerable improvement in the feeling of well being, physical and mental fitness in all the patients of all the three groups.

Regarding overall improvement in clinical features of *Anidra* (Insomnia) the results were highly significant in symptoms *Jrimbha* ($p < 0.001$), *Tandra* ($p < 0.001$), *Angamarda & Angasada* ($p < 0.001$), *Arati & Klama*

($p < 0.001$), *Shirashoola* ($p < 0.001$), *Manodourbalya* ($p < 0.001$), *Ajirna* & *Agnimandya* ($p < 0.001$), *Malabaddhata* ($p < 0.001$) and *Kantikshya* ($p < 0.01$) in patients of IIIrd Group treated with both *Shirodhara* and *Insomrid* tablet.

In IInd group treated with only *Shirodhara* the symptoms *Jimbha* ($p < 0.001$), *Tandra* ($p < 0.001$), *Angamarda* & *Angasada* ($p < 0.01$), *Arati* & *Klama* ($p < 0.001$), *Shirashoola* ($p < 0.001$), *Manodourbalya* ($p < 0.01$), *Smritidourbalya* ($p < 0.001$), *Ajirna* & *Agnimandya* ($p < 0.01$), *Malabaddhata* ($p < 0.001$) and *Dhatukshaya* ($p < 0.01$) showed highly significant results.

In trial group I treated with only *Insomrid* tablet, symptoms *Jimbha* ($p < 0.001$), *Tandra* ($p < 0.01$), *Angamarda* & *Angasada* ($p < 0.001$), *Arati* & *Klama* ($p < 0.01$), *Shirashoola* ($p < 0.001$), *Ajirna* & *Agnimandya* ($p < 0.001$), *Malabaddhata* ($p < 0.001$) and *Kantikshaya* ($p < 0.01$) showed highly significant results.

As per Table 4, 6 and 8; the results of the sleep diary assessment about the time into bed, times of lights out, time to fall asleep, numbers of awakenings, time out of bed, naps in day time, rate how you felt today, irritability, total time of sleep and quality of sleep are also highly significant in all the three groups.

All the above findings strongly suggest that Tab. *Insomrid* and *Shirodhara* with luke warm milk have potent effect on the management of *Anidra*. Various scientific parameters in the current study confirmed this observation which showed significant and highly significant improvement respectively.

Probable mode of action of *Insomrid* Tablet

Taking *Samprapti* of *Anidra* into consideration, a compound drug formulation has been selected. The herbal drugs selected for preparation of the tablet were *Ashwagandha*, *Sarpagandha*, *Jatamansi*, *Parsika Yavani* and *Tagara*.

The drugs selected for the study mainly have *Tikta*, *Kashaya Rasa*, *Laghu Guna*, *Ushna Virya* (except *Jatamansi*), *Katu Vipaka* (except *Ashwagandha-Madhura Vipaka*) and *KaphavatAhara* properties. All the selected drugs have *Nadibalya*, *Mastishka Shamaka*, *Nidrajanaka* and *VatAhara* properties.

Due to the *Tikta* and *Kashaya Rasa* the drugs are *Pitta Shamaka*. Due to the *Ushna Veerya* of the drugs they are *Vata Shamaka*. All the selected drugs have *Nadibalya*, *Mastishka Shamaka*, *Nidrajanaka* and *VatAhara* properties by virtue of which this combination showed significant therapeutic results.

The drugs also act by *Prabhava*. *Sarpagandha* has *Nidrajanana Prabhava*, *Jatamansi* is *Bhutaghna* i.e. *Manasa DoshAhara Prabhava* and *Parsika Yavani* is

Madaka and *Vedanasthapaka*. Due to combined effects of all these *Prabhava*, trial drug *Insomrid* tablet has shown synergistic action and encouraging results in the management of patients of *Anidra*.

Probable mode of action of *Shirodhara*

It is very difficult to explain exactly how the *Shirodhara* acts in treating *Nidranasha*. Following hypothesis may be proposed on the basis of modern physiology and Ayurvedic classical texts.-

1. According to modern physiology
2. According to Ayurvedic *Samprapti* of *Anidra*
3. Yogic concepts

1. According to modern physiology⁶

Experimental studies have variously implicated the medullary reticular formation, the thalamus and the basal forebrain in the generation of sleep. While the brainstem reticular formation, the midbrain, the sub thalamus, the thalamus and the basal forebrain have all been suggested to play a role in the generation of wakefulness.

Current hypotheses suggest that the capacity for sleep and wakefulness generation is distributed along an axial "core" of neurons extending from the brainstem rostrally to the basal forebrain. Complex commingling of neuronal groups occurs at many points along this brainstem-forebrain axis. A cluster of γ -aminobutyric acid (GABA) and galaninergic neurons in the ventrolateral preoptic (VLPO) hypothalamus is selectively activated coincident with sleep onset. These neurons project to and inhibit histaminergic cell groups in the tuberomammillary nucleus that are important to the ascending arousal system, suggesting that the hypothalamic VLPO neurons may play a key executive role in sleep regulation.

Pharmacologic studies of sleep and wakefulness suggest roles for other neurotransmitters as well. Pontine cholinergic neurotransmission is known to play a role in REM sleep generation. By this it can be said that the functions of the thalamus and the basal fore brain are diminished and the sleep promoting neurotransmitter serotonin is decreased. It is proved that the presence of catecholamines is responsible for the state of wakefulness.

In the conditions of *Insomnia* probably the functions of the structures like thalamus and fore brain might be diminished along with quantitative decrease in serotonin and increase in the quantity of catecholamines. Thus it results in to the state of *insomnia*.

In the procedure of *Shirodhara*, particular pressure and vibration is created over the forehead. The vibration is amplified by the hollow sinus present in the 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 fore brain which then brings the amount of serotonin and catecholamine to the normal stage inducing the sleep.

Again, it is explained in modern text books of physiology that pressure has an effect on impulse conduction through tactile and thermo receptors. If prolonged pressure is applied to a nerve, impulse conduction is interrupted and part of the body may go to rest. In *Dhara* therapy, prolonged and continuous pressure due to pouring of the medicated liquid may cause tranquility of mind and induce natural sleep.

2. According to Ayurvedic Samprapti of *Anidra*

Nidranasha is explained as *Vata Nanatmaja Vikara*, in *Vata & Pitta Dosha Vriddhi Lakshanas*⁷ and as *Lakshanas* of some other diseases. During the description of *Nidra Utpatti*, *Acharayas* have mentioned that *Sharirika Dosha Kapha*, *Manasika Dosha Tama*, *Chetana Sthana Hridaya* and *Sanjnavaha Srotas* are responsible for it. With the procedure of *Shirodhara*, *Vata* and *Pitta Doshas* get pacified and there is elevation in the quantum of *Kapha Dosha*. When an individual lies down in a relaxed state for longer time, *Tamasika Guna* overcomes the *Rajasika Guna*. The procedure of *Shirodhara* brings the *Sanjnavaha Srotas* in peaceful state of rest which helps in inducing sleep. The milk used for the *Shirodhara* has *Madhura Rasa*, *Snigdha Guna*, *Sheeta Veerya* and *Madhura Vipaka* which subside *Vata* and *Pitta Doshas* and increases the *Kapha Dosha*⁸. It also increases *Tamoguna* in the *Shirah Pradesha*. Hence it helps in production of *Nidra*.

3. Yogic Concept:

In yogic sciences there are number of procedures explained for relaxation of body and mind. By these procedures like meditation and relaxation the mind comes down to a tranquil state, it reduces stress, helps in normal and better function of mind. All the benefits of meditation and relaxation are achieved by the procedure of *Shirodhara*.

In today's busy world no one gets time to lie down quietly and relax for a while. We are always exposed to lot of stress and tensions. If we lie down in a relaxed state for some time with the practice of meditation we definitely feel better. The process of *Shirodhara* also produces a meditation effect which helps to overcome the complaint of insomnia. The method of *Shirodhara* produces almost similar effects as that of *Yoganidra* technique in yogic science.

On the other hand procedure of *Shirodhara* acts on the level of *Yogic Chakras*. It stimulates the supreme *Chakras* i.e. *Aagya Chakra* and *Sahasrara Chakra* which are situated in the head region⁹. These *Chakras* govern all the vital energy in the body. Due to the stimulation of these *Chakras* the individual gets good mental condition.

Hence the condition like *Anidra*¹⁰ is really benefitted by the *Shirodhara*¹¹.

Conclusion

On the basis of the clinical manifestations and the symptoms produced, insomnia may be correlated with the term *Anidra* or *Nidranasha*. The persons of age group between 30-60 years are more prone for *Anidra* (insomnia).

Amongst various causative factors of *Anidra* the most common causes are:

- ◆ Mental Stress or *Manasika Nidanas* like *Chinta*, *Bhaya*, *Krodha* etc.
- ◆ Improper sleep timings
- ◆ Vitiating of *Vata* and *Kapha Doshas* & Reduction in *Tamoguna* and increased *Rajoguna*.

Tablet *Insomrid*, a proposed herbal formulation is safe, without any adverse effects, economical and effective remedy for the management of *Anidra*. *Shirodhara* procedure with luke warm milk is very effective in the management of *Anidra*. On comparison of the efficacy of Tab. *Insomrid* (herbal formulation) and *Shirodhara*, both seem to be equally effective in the management of *Anidra*. In combined therapy group, Tab. *Insomrid* and *Shirodhara* with luke warm milk have synergistic effects in the management of *Anidra* and the results were more pronounced.

Therefore it can be concluded that Tab. *Insomrid* and *Shirodhara* with milk are very safe and effective treatment modalities and can be used effectively in the management of *Anidra* (Insomnia).

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हिन्दी सारांश

अनिद्रा रोग में इन्सोमरिड टेबलेट एवं शिरोधारा चिकित्सा के प्रभाव का अध्ययन

संजय पोखरेल एवं अजय कुमार शर्मा

प्रस्तुत चिकित्सात्मक अध्ययन में अनिद्रा के ३० रोगियों का चयन किया गया। इस अध्ययन का मुख्य उद्देश्य विभिन्न वैज्ञानिक मापदण्डों के आधार पर अनिद्रा की चिकित्सा में “इन्सोमरिड टेबलेट” (कल्पित योग) एवं शिरोधारा के चिकित्सात्मक प्रभाव का अध्ययन करना था। अध्ययन में मिश्रित (इन्सोमरिड टेबलेट एवं शिरोधारा) समूह में सांख्यिकीय दृष्टि से अत्यधिक महत्वपूर्ण सुधारात्मक परिणाम प्राप्त हुए। प्रथम समूह (इन्सोमरिड टेबलेट) एवं द्वितीय समूह (शिरोधारा) में भी प्रतिशत के आधार पर उत्साह जनक परिणाम प्राप्त हुए। चिकित्सात्मक अध्ययन अवधि के दौरान रोगियों में किसी भी प्रकार के प्रतिकूल प्रभाव नहीं पाये गये।

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