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 Trayopasthambas1 (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 efficacys, increase the chances of various types of accident and ultimately it may drag the individual towards several severe psychosomatic disorders3.

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.r.t. 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 the trial. 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 properties.

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 Shatrikia 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. Siradhshoolu (Headache), 6. Manodourbalya (Lack of concentration), 7. Smritidourbalya (Loss of Memory), 8. Indriya Karmanahani (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 IIrd treated with Shirodhara and in the patients of Ird 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 | Withania somnifera          | Root       | 100 mg.                          |
| 2.    | Sarpagandha | Rauwolfia serpentina        | Root       | 100 mg.                          |
| 3.    | Jatamansi   | Nordostachys jatamansi      | Root       | 100 mg.                          |
| 4.    | Tagara      | Veleriana wallichi          | Root       | 100 mg.                          |
| 5.    | Parasika Yavani | Hyoscyamus niger     | 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        |
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 3: Clinical recovery of symptoms in 10 patients of Anidra (Insomnia) treated with Tab. Insomrid in Group I |
|----------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Sr. No. | Symptoms | Mean score (BT) | Mean score (AT) | Difference | Relief % | SD± | SE± | t | p |
|--------|----------|----------------|----------------|------------|----------|-----|-----|----|---|
| 1      | Jrimbha  | 2.5            | 0.8            | 1.7        | 68.0     | 0.48 | 0.15 | 11.12 | <0.001 |
| 2      | Tandra   | 2.0            | 1.0            | 1.0        | 50.0     | 0.66 | 0.21 | 4.74  | <0.01  |
| 3      | Angamarda & Angasada | 1.6 | 0.6 | 1.0 | 62.5 | 0.47 | 0.14 | 6.70 | <0.001 |
| 4      | Arati & Klama | 1.6 | 0.9 | 0.7 | 43.7 | 0.48 | 0.15 | 4.58 | <0.01  |
| 5      | Sirahshool | 2.1 | 0.9 | 1.2 | 57.1 | 0.63 | 0.2 | 6.0 | <0.001 |
| 6      | Manodourbalya | 1.1 | 0.7 | 0.4 | 36.3 | 0.51 | 0.16 | 2.44 | <0.05  |
| 7      | Smritidourbalya | 1.1 | 0.6 | 0.5 | 45.4 | 0.52 | 0.16 | 3.0 | <0.05  |
| 8      | Indriya Kamahani | 2.0 | 2.0 | 0.0 | 0 | 0 | 0 | 0 | <0.10  |
| 9      | Ajima & Agrimandya | 2.2 | 1.0 | 1.2 | 54.5 | 0.42 | 0.13 | 9.0 | <0.001 |
| 10     | Malabaddhata | 2.1 | 0.6 | 1.5 | 71.4 | 0.52 | 0.16 | 9.0 | <0.001 |
| 11     | Dhatukshaya | 0.8 | 0.2 | 0.6 | 75.0 | 0.69 | 0.22 | 2.71 | <0.05  |
| 12     | Kantikshaya | 1.3 | 0.6 | 0.7 | 53.8 | 0.48 | 0.15 | 4.58 | <0.01  |

| Table 4: Recovery in Sleep Diary assessment in 10 patients of Anidra treated with Tab. Insomrid in Group I |
|----------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Sr. No. | Symptoms | Mean score (BT) | Mean score (AT) | Difference | Relief % | SD± | SE± | t | p |
|--------|----------|----------------|----------------|------------|----------|-----|-----|----|---|
| 1      | Time to fall asleep | 2.2 | 0.9 | 1.3 | 59.0 | 0.48 | 0.15 | 8.51 | <0.001 |
| 2      | No. of awakenings | 2.2 | 0.8 | 1.4 | 63.3 | 0.69 | 0.22 | 6.33 | <0.001 |
| 3      | Naps - Day Time | 1.3 | 0.7 | 0.6 | 46.1 | 0.51 | 0.16 | 2.71 | <0.01  |
| 4      | Rate how you felt today | 2.3 | 0.9 | 1.4 | 60.8 | 0.51 | 0.16 | 8.57 | <0.001 |
| 5      | Irritability | 1.6 | 0.7 | 0.9 | 56.25 | 0.31 | 0.1 | 9.0 | <0.001 |
| 6      | Total time of sleep | 2.3 | 1.1 | 1.2 | 52.17 | 0.42 | 0.13 | 9.0 | <0.001 |
| 7      | Sleep Quality | 2.4 | 1.1 | 1.3 | 54.1 | 0.48 | 0.15 | 8.51 | <0.001 |

| Table 5: Clinical recovery of symptoms in 10 patients of Anidra (Insomnia) treated with Shirodhara in Group II |
|----------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Sr. No. | Symptoms | Mean score (BT) | Mean score (AT) | Difference | Relief % | SD± | SE± | t | p |
|--------|----------|----------------|----------------|------------|----------|-----|-----|----|---|
| 1      | Jrimbha  | 2.1            | 0.7            | 1.4        | 66.6     | 0.51 | 0.16 | 8.57 | <0.001 |
| 2      | Tandra   | 1.7            | 0.5            | 1.2        | 70.5     | 0.42 | 0.13 | 9.0 | <0.001 |
| 3      | Angamarda & Angasada | 1.6 | 0.5 | 1.1 | 68.7 | 0.73 | 0.23 | 4.71 | <0.01  |
| 4      | Arati & Klama | 1.5 | 0.4 | 1.1 | 73.3 | 0.31 | 0.1 | 11.0 | <0.001 |
| 5      | Sirahshool | 2.0 | 0.5 | 1.5 | 75.0 | 0.70 | 0.22 | 6.70 | <0.001 |
| 6      | Manodourbalya | 1.5 | 0.5 | 1.0 | 66.6 | 0.81 | 0.25 | 3.87 | <0.01  |
| 7      | Smritidourbalya | 2.0 | 0.5 | 1.5 | 75.0 | 0.52 | 0.16 | 9.0 | <0.001 |
| 8      | Indriya Kamahani | 0.3 | 0.3 | 0 | 0 | 0 | 0 | 0 | <0.10  |
| 9      | Ajima & Agrimandya | 1.7 | 0.7 | 1.0 | 58.8 | 0.81 | 0.25 | 3.87 | <0.01  |
| 10     | Malabaddhata | 1.6 | 0.4 | 1.2 | 75.0 | 0.78 | 0.24 | 4.81 | <0.001 |
| 11     | Dhatukshaya | 1.1 | 0.3 | 0.8 | 72.7 | 0.63 | 0.2 | 4.0 | <0.01  |
| 12     | Kantikshaya | 0.9 | 0.4 | 0.5 | 55.5 | 0.52 | 0.16 | 3.0 | <0.05  |
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 & Anga sada (p<0.001), Arati & Klama

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

| Sr. No. | Symptoms               | Mean score | Difference | Rel. % | 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 | Rel. % | SD±  | SE±  | t    | p     | Result |
|---------|------------------------|------------|------------|--------|------|------|------|-------|--------|
|         |                        | BT         | AT         |        |      |      |      |       |        |
| 1       | Jrimbha                | 2.8        | 0.7        | 2.1    | 75.0 | 0.73 | 0.23 | 9.0   | <0.001 | HS     |
| 2       | Tandra                 | 1.8        | 0.5        | 1.3    | 72.2 | 0.48 | 0.15 | 8.51  | <0.001 | HS     |
| 3       | Angamarda & Angasada   | 2.0        | 0.5        | 1.5    | 75.0 | 0.84 | 0.26 | 5.58  | <0.001 | HS     |
| 4       | Arati & Klama          | 2.2        | 0.5        | 1.7    | 77.2 | 0.67 | 0.21 | 7.96  | <0.001 | HS     |
| 5       | Sirahshoola            | 2.0        | 0.4        | 1.6    | 80.0 | 0.69 | 0.22 | 7.23  | <0.001 | HS     |
| 6       | Manodourbala           | 1.9        | 0.8        | 1.1    | 57.8 | 0.56 | 0.17 | 6.12  | <0.001 | HS     |
| 7       | Smritidourbala         | 1.0        | 0.5        | 0.5    | 50.0 | 0.52 | 0.16 | 3.0   | <0.05  | S      |
| 8       | Indriya Karmahani      | 0.2        | 0.2        | 0      | 0    | 0    | 0    | <0.10 | NS     |
| 9       | Ajima & Agnimandya    | 2.1        | 0.5        | 1.6    | 76.1 | 0.51 | 0.16 | 9.79  | <0.001 | HS     |
| 10      | Malabaddhata           | 1.7        | 0.6        | 1.1    | 64.7 | 0.56 | 0.17 | 6.12  | <0.001 | HS     |
| 11      | Dhatukshaya            | 0.6        | 0.2        | 0.4    | 66.6 | 0.51 | 0.16 | 2.44  | <0.05  | S      |
| 12      | Kantikshaya            | 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 | Rel. % | 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    | 2.2        | 0.7        | 1.5    | 68.1 | 0.70 | 0.22 | 6.70  | <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.
(p<0.001), Shirashoola (p<0.001), Manodourbalya (p<0.001), Ajirma & 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 IIrd group treated with only Shirodhara the symptoms Jrimbha (p<0.001), Tandra (p<0.001), Angamarda & Angasada (p<0.01), Arati & Klama (p<0.001), Shirashool (p<0.001), Manodourbalya (p<0.01), Smritidourbalya (p<0.001), Ajirma & 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 Jrimbha (p<0.001), Tandra (p<0.01), Angamarda & Angasada (p<0.001), Arati & Klama (p<0.01), Shirashool (p<0.001), Ajirma & Agnimandya (p<0.001), Malabaddhata (p<0.001) and Kantikshya (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 Kaphavat/Ahara properties. All the selected drugs have Nadibalya, Mastishka Shamaka, Nidrajanaka and Vat/Ahara 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 Vat/Ahara properties by virtue of which this combination showed significant therapeutic results.

The drugs also act by Prabhava. Sarpagandha has Nidrajanaka Prabhava, Jatamansi is Bhutaghna i.e. Manasa Dosh/Ahura 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 physiology
Experimental studies have varioulsy 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 g-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 forebrain 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 Shirodharma, 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 in 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 Vridhhi Lakshanas and as Lakshanas of some other diseases. During the description of Nidra Utpatti, Acharayas have mentioned that Sharirika Dosha Kapha, Manasika Dosha Sama, 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 elevation 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 subsides Vata and Pitta Doshas and increases the Kapha Dosha. 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. 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 region. 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 is really benefitted by the Shirodhara.

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
- Vitiation 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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