Efficacy of Sattvavajaya Chikitsa in the form of relaxation techniques and Guda Pippalimula Churna in the management of Anidra (insomnia) - An open labelled, randomized comparative clinical trial

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Abstract

Background: Condition of insomnia may not be a life-threatening illness, but it has tendency to damage the person’s daily life. In the current era of modernization, most of the person are is suffering from stress either it is personal or professional. Stress may cause sleeping problems or make existing problems worse. Sattvavajaya Chikitsa is a specialized type of treatment influencing the psychological aspect of body. It can be applied in the form of Yogic practices and other mind control techniques. With this research interest, the present study has been undertaken to assess the efficacy of the Sattvavajaya Chikitsa in the form of relaxation techniques (RT) and Guda Pippalimula Churna in Anidra (insomnia).

Objectives: The objective of the study was to evaluate the efficacy of Sattvavajaya Chikitsa in the form of RT and Guda Pippalimula Churna in Anidra.

Materials and Methods: The study was an open-labelled randomized clinical trial in which sixty patients having symptoms of Anidra belonging to the age group of 20–60 years were enrolled and received Sattvavajaya Chikitsa (RT) and Guda Pippalimula Churna orally in 2gm dosage with jaggery for 28 days. The assessment of symptoms was done on the basis of relief in the scores given to signs and symptoms according to their severity.

Results: Both the groups showed significant results in chief as well as associated symptoms of disease. Regarding overall effect of therapy in both the groups, marked improvement is high followed by moderate improvement. No adverse reactions were documented.

Conclusion: Sattvavajaya Chikitsa and Guda Pippalimula Churna are effective on Anidra, but Sattvavajaya Chikitsa was found more effective in reducing Manasa symptoms such as Chinta (tension), Bhaya (fear) and Krodha (anger).

Keywords: Anidra, Guda Pippalimula Churna, relaxation techniques, Sattvavajaya Chikitsa

Introduction

In this modern era of civilization, everyone is trying to gain good financial status and to fulfill all the physical desires; therefore, today’s metaphysical society is facing unsteady, hard, weakened and everyday changing lifestyle. Due to this type of lifestyle, everyone appears to be stressed and confused. In this competitive and stressful era, sleep is proved as a divine gift to human beings, which refreshes and recharges an individual for the further struggle for survival. However, sound sleep in a peaceful state of mind is hardly possible in this modern world. It is one of the burning problems not only in India but also all over the world.

According to the statistics, 20%–40% of adults encounter insomnia problems during a year. Especially persons between 15 and 55 years of age are more affected.[1]

Ayurveda has considered sleep as one of the most important dimensions of health associated with happiness and good health and is considered as outcome of relax mental state.[2] In the Ayurvedic literature, three factors, namely Ahara (diet), Nidra (sleep) and Brahmacarya (abstinence) have been compared with the three pillars of a sub-support and have been termed as the three Upasthambha.[3] There is no definite treatment in modern medical science for insomnia. Sedatives

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and hypnotics used are having huge side effects after long-term use rather than relief. Here comes the relevancy of Ayurvedic principles to treat the disease insomnia. As, it is a disorder of stressful life and faulty dietary habits also, Sattvavajaya Chikitsa was planned in the form of relaxation techniques (RT) such as Asana Yoga, Pranayama and meditation with particular time and duration according to cause of disease found in patients. Psycho and soma are always interrelated. They interact and influence each other and jointly venture in the manifestation of a very large group of disorders very aptly known as psychosomatic disorders. Sattvavajaya, in short, is a psychophysical exercise designed to achieve a regulatory mechanism over the human psyche in dealing with environmental stressors (Indriyarthas) and subduing and balancing emotional stressors (Mano-Arthas), as improper incorporation of Artha is one of the three basic causes of disease. Among several indigenous plants used in the treatment of insomnia, Pippalimula (root of Piper Longum Linn.) is one of those plants used to treat insomnia and digestive disorders. In addition to this, piperine present in these plants used to treat insomnia and digestive disorders. In addition to this, piperine present in Piper Longum Linn. elicits positive modulatory effects on GABA<sub>A</sub> receptors. The whole study was designed with the hypothesis of finding out the effect of Sattvavajaya Chikitsa in the form of RT and Guda Pippalimula Churna in the management of Anidra (insomnia).

Materials and Methods
A total of 64 patients irrespective of gender, caste, religion and socioeconomic status who were diagnosed with Anidra (insomnia) were selected from the outpatient department of Basic Principle, IPGT and RA, Jamnagar, Gujarat. The study was approved by Institutional Ethics Committee (No—PGT/7/A/Ethics/2015-16/1470, Dt. 25/08/15). The study has been registered in Clinical Trial Registry, India (No. CTRI/2017/01/007742). Written informed consent from each patient was obtained before starting the course of treatment. The study was an open-labelled randomized clinical trial. Sampling technique was simple random sampling by computer generated method.

Diagnostic criteria
Patients were diagnosed and assessed thoroughly on the basis of Ayurvedic classical signs and symptoms of Anidra (insomnia) and were examined on the basis of specially prepared proforma along with a detailed history. All the patients were subjected to routine hematological examination (hemoglobin%, total white blood cell, differential leukocyte count and total red blood cell count) and biochemistry investigations (random blood sugar, S. G. P. T, S. G. O. T, serum bilirubin, cholesterol, blood urea, creatinine and uric acid) and urine (routine and microscopic examinations) to rule out any other pathology before treatment.

Inclusion criteria
- Patients suffering from signs and symptoms of Anidra (insomnia)
- Patients aged between 20 and 60 years
- Primary insomnia such as insomnia without identifiable cause
- Recent changes in sleep pattern
- Patients were selected without any bar of race, religion and sex.

Exclusion criteria
- Patients aged <20 years and >60 years
- Patients having insomnia due to severe illness such as cardiac diseases, hypertension, diabetes and other chronic disorders
- Patients with secondary insomnia, alcoholism, exaggeration of previous psychiatric illness (major depression and mania)
- Acute systemic pathological conditions such as fever associated with insomnia, due to severe pain and orthopnea were excluded from the study.

Grouping and posology
Patients were randomly divided into two groups. In Group A, patients were treated with RT and counselling, whereas in group with Guda Pippalimula Churna with the Anupana (vehicle) of Mahishi Ksheera (buffalo milk). Pathya-Apathya (do’s and don’ts) were advised in both the groups. Details of the treatment protocol are mentioned below.

Group A (relaxation techniques)
Withdrawal of mind from unwholesome objects (Ahita Artha) is known as Sattvavajaya Chikitsa or it is a treatment by self-control. Sattvavajaya is not only victory over mind but also victory with upliftment of mind. Indulgence of mind in unwholesome objects plays a pivotal role in the manifestation of insomnia. Control of mind from Ahita Artha (unwholesome objects) can be done by practices of Ashtanga Yoga or relaxation technique adopted here. Relaxation training triggers the relaxation response in the body and promotes a sense of mastery and control. All the procedure used here are nothing but applied aspect of Sattvavajaya Chikitsa having ultimate goal of Manasa Shuddhi or upliftment of mind. This protocol was decided with the help of Yoga expert.

Relaxation therapy/Yogic techniques:
1. Shithilikarana Vyayama (relaxation exercise) - (3–5 min)
2. Surya Namaskara (sun salutation) - (2 rounds)
3. Nadi Shuddhi Pranayama (alternate nostril breathing) - (9 rounds)
4. Bhamari Pranayama (bee breathing technique) - (5 rounds)
5. Aum chanting - (9 times)
6. Yoga Nidra (Yogic sleep) - (20 min).

Time: Morning, total duration: 40 min.

Group B (Guda Pippalimula Churna)
Pippalimula is one of the established medicines for insomnia. In Vangsen Samhita chapter 2 Jwaradikara, Guda Pippalimula Churna is mentioned for the patients of chronic insomnia. Acharya Bhavamishra has suggested the use of Pippalimula...
under innumeration of Nidrakara (sedatives) drugs in Chikitsa Sthana. Authors of Yogaratnakara and Bhaishajya Ratnavali also appreciated the use of Pippalimula with jaggery at night, for the person who suffers from chronic insomnia.

**Guda Pippalimoola Churna**
- Dose – 2 gm, in two divided doses
- **Guda** (jaggery) – 5 gm
- Route – oral
- Time of Administration – after meal
- **Anupana** (vehicle) – Mahishi Ksheera (buffalo milk)
- Duration – 28 days.

**Criteria for assessment**
Improvement in condition was assessed on the basis of changes in scoring pattern developed for grading these clinical symptoms based on modern as well as classical symptoms of insomnia.

**Subjective criteria**
1. Difficulty in getting to sleep at bedtime

| Grade | Description |
|-------|-------------|
| 0     | No problem  |
| 1     | Slightly delayed (½-1 h) |
| 2     | Markedly delayed (1-2 h) |
| 3     | Very delayed (>2 h) or did not sleep at all |

2. Awakenings after getting sleep

| Grade | Description |
|-------|-------------|
| 0     | No problem (not at all) |
| 1     | Minor problem (total hour of awakening is in-between ½ and 1 h) |
| 2     | Considerable problem (total hour of awakening is in-between 1 and 2 h) |
| 3     | Serious problem (total hour of awakening is >2 h or did not sleep at all) |

3. Waking up too early in the morning

| Grade | Description |
|-------|-------------|
| 0     | Not earlier |
| 1     | A little earlier (½-1 h) |
| 2     | Markedly earlier (1-2 h) |
| 3     | Much earlier (>2 h) or did not sleep at all |

4. Not getting enough sleep (total sleep duration)

| Grade | Description |
|-------|-------------|
| 0     | Sufficient (>6 h) |
| 1     | Slightly insufficient (5-6 h) |
| 2     | Markedly insufficient (3-5 h) |
| 3     | Very insufficient (<3 h) or did not sleep at all |

5. Overall quality of sleep (no matter how long you slept).

| Grade | Description |
|-------|-------------|
| 0     | Satisfactory |
| 1     | Slightly unsatisfactory |
| 2     | Markedly unsatisfactory |
| 3     | Very unsatisfactory or did not sleep at all |

Associated complaint (for all associated complaints from mind not slowing down to Alasya)

| Grade | Description |
|-------|-------------|
| 0     | None |
| 1     | Mild |
| 2     | Moderate |
| 3     | Severe |

1. **Krodha** (anger)

| Grade | Description |
|-------|-------------|
| 0     | No violent tendencies |
| 1     | Violent thoughts very rarely |
| 2     | Violent, sadistic functions often |
| 3     | Frequent thoughts and functions of violence and sadistic |

2. **Bhaya** (fear)

| Grade | Description |
|-------|-------------|
| 0     | No depressed mood |
| 1     | Depressed mood only in reasonable cause |
| 2     | Depressed mood even in reasonable cause |
| 3     | Always in depressed and fearful emotions |

3. **Shoka** (mourning)

| Grade | Description |
|-------|-------------|
| 0     | No feeling of sorrowness |
| 1     | Feels inferiority and sorrow at occasion |
| 2     | Inferiority complexes and greedy often |
| 3     | Weeps and feels inferior very frequently |

4. **Chinta** (tension).

| Grade | Description |
|-------|-------------|
| 0     | No stressed mood |
| 1     | Stressed mood occasionally in reasonable cause |
| 2     | Stressed mood 3-4 days/week |
| 3     | Stressed mood more than 4 days |

**General observation**
A total of 64 patients were registered for the present study, among them sixty patients have completed their treatment and remaining four patients discontinued. Among them, maximum number of patients, i.e., 62.5% were female. Maximum number (51.56%) of the patients were homemakers. Maximum number of patients, i.e., 87.5% were from middle class. Maximum, i.e., 60.93% of patients were taking Katu Rasa (pungent taste) dominant diet. About 54.68% of patients had poor appetite, 57.81% of patients were having Madhyam Koshtha and 40.62% were having Krura Koshtha. About 75% of patients were not performing any kind of physical exercise. About 64.06% of patients were addicted to tea, 20.31% had addiction of tobacco and 10.94% had an addiction of chewing Pan and Masala. Vata-Pitta Prakriti (Vata–Pitta Dosha dominant constitution) was observed in maximum of 73.43% patients. About 60.93% were having Avara Satva (weak mental strength). In majority of patients (82.41%), insomnia started gradually. About 14.06% of the patients had
sudden onset which was followed by 3.12% of patients with insidious onset of the disease. Progressive course of disease was reported in 84.37% of patients and stationary course of disease was reported in 9.37% of patients, whereas relapsing was found in 6.25% of patients. Stress and *Vata Vridhi* (increase of *Vata Dosha*) as a causative factor for insomnia were observed in majority (79.68%) of patients, whereas poor sleep hygiene, anxiety, *Vegadhara* (suppression of natural urges), *Dhatukshaya* (debility) and *Pitta Vridhi* (increased state of *Pitta Dosha*) was found 12.5%, 35.29%, 14.06%, 17.18% and 20.31% of the patients, respectively. About 78.12% of patients were having symptoms of vitiations of *Rasavaha Srotas*, followed by 46.87% with *Annavaha Srotodushti*.

Short duration of sleep and overall quality of sleep were found disturbed in 100% of patients.

In about 81.66% of patients, difficulty in sleep induction was found as predominant complaints, whereas awakenings from sleep during the night was found in 90% of patients and earlier awakening than desired was found in 43.33% of patients.

About 96.66% of patients had symptom that they does not fully feel refresh after sleep; reduced motivation was found in 90% of patients. *Tandra* (drowsiness) was found in 70% of patients. Fatigue was found in 93.33% of patients, *Akshigaurava* (heaviness in eyes) was found in 73.33% of patients. *Shirogaurava* (heaviness in head) was found in 90% of patients; *Apokti* (indigestion) and *Angamarda* (bodyache) was found in 78.33% and 73.33% of patients, respectively. *Jrimbha* (yawning) and *Alasya* (lethargy) was found in 73.33% and 85% of patients, respectively, whereas irritability and the symptom mind not slowing down were found in 86.66% and 85% of patients, respectively.

*Chinta* (stress) was found in maximum number of patients, that is, 85%, followed by *Krodha* (anger) in 82.81%. *Bhaya* (fear) was found in 70.31% of patients and *Shoka* (sorrow) was found in 60% of patients.

**Statistical analysis**

To find individual effect of therapy, paired nonparametric data of before and after treatment were analyzed by Wilcoxon signed-rank test, and for comparison of the effect of both therapies, unpaired nonparametric data were analyzed by Mann–Whitney rank sum test. Test was performed using Sigma Stat 3.1software (manufacturer is Systat Software, Inc., 501 Canal Blvd., Suite E, Point Richmond, CA 94804-2028, United States of America). The values were considered significant at the levels of *P* < 0.05, *P* < 0.01, and *P* < 0.001.

**Results**

In the present study, group A (relaxation technique) showed maximum (91.61%) relief in the symptom of final awakening earlier than desired. Effect of therapy on quality of sleep was 87.5%, and increase in total sleep duration was 83.87%, whereas 81.96% in awakenings during the night and increased in easy sleep induction, was observed in 74% of the patients. Statistically, all the parameters of chief complaints in group A had highly significant result.

Effect of therapy on associated symptom such as mind not slowing down (71.42%), reduced motivation (79.31%), irritability or mood disturbance (78.26%), *Akshigaurava* (heaviness in eyes) (82.35%), *Shirogaurava* (heaviness in head) (84.61%), *Jrimbha* (yawning) (97.91%) and *Alasya* (lethargy) (90.74%) was statistically highly significant.

In group B (*Guda Pippalimula Churna*), effect on major symptoms of insomnia, i.e., awakening during the night (76.59%), sleep induction (73.68%) and final awakening earlier than desired (83.33%) resulted in significant improvement of total sleep duration and overall quality of sleep. Effect of therapy on mind not slowing down (58.97%), reduced motivation (58.82%), irritability or mood disturbance 57.89%, heaviness in eyes (89.65%), heaviness in head (76.59%), yawning (100%) and lethargy (78.125%) was statistically highly significant.

Effect of therapy in group A on *Manasa Bhava* such as *Krodha* (anger) was 73.93%, *Bhaya* (fear) (74.29%), *Shoka* (mourning) (68.75%), *Chinta* (stress) (74.359%) which was statistically highly significant, whereas in group B improvement in *Krodha* (anger) 45.45%, *Bhaya* (fear) (42.86%), *Shoka* (sorrow) (36%) and *Chinta* (stress) (56.75%) which was statistically significant but statistically insignificant in *Shoka* (mourning).

**Comparison between effects of therapies**

**Chief Symptoms**

In Mann–Whitney rank sum test, percentage wise better results was found in all symptoms in group A than group B, but the difference between the groups was statistically insignificant [Table 1].

**Associated symptoms**

In Mann–Whitney rank sum test, statistically insignificant difference was found between the groups except the symptoms: mind not slowing down, irritability or mood disturbance and *Alasya* [Table 2].

**Manasa symptoms**

Statistically significant difference was found in *Manasa* symptoms (related to mind) such as anger, fear, sorrow and stress [Table 3].

**Overall effect of therapies**

Overall effect of *Sattvavajaya Chikitsa* and *Guda Pippalimula Churna* was 79.19% and 73.43%, respectively [Table 4].

**Discussion**

In a total of 64 patients registered for the present study, 60 patients completed their treatment and remaining four discontinued. Two patients were lazy to follow the *Yogic* techniques taught for the study and opted out after 3 days’
### Table 1: Comparison of effect of therapy on main symptoms between the groups

| Symptoms                     | Data of Group A | Data of Group B | Comparison of both groups |
|------------------------------|-----------------|-----------------|---------------------------|
|                              | n    | Df | Percentage | n    | Df | Percentage | Mann-Whitney U statistic | Probability |
| Sleep induction              | 23   | 1.66 | 74 | 26   | 1.23 | 73.68 | 493 | 0.503     |
| Awakenings during the night   | 29   | 1.66 | 81.96 | 25   | 1.66 | 76.59 | 305 | 0.02      |
| Final awakening earlier than desired | 9     | 0.366 | 91.661 | 17    | 0.4 | 83.33 | 566.5 | 0.05      |
| Total sleep duration         | 30   | 1.733 | 83.87 | 30   | 1.9 | 75.41 | 537 | 0.141     |
| Overall quality of sleep     | 30   | 1.33 | 87.5 | 30   | 1.93 | 77.41 | 312 | 0.018     |

*n*: Number of patients, Df: Difference in mean before treatment and after treatment

### Table 2: Comparison of effect of therapy on associated symptoms between the groups

| Associated symptoms                       | Group A | Group B | Comparison of both groups |
|-------------------------------------------|---------|---------|---------------------------|
|                                           | n  | Df | Percentage | n  | Df | Percentage | Mann-Whitney U statistic | Probability |
| Mind not slowing down                     | 26  | 1.66 | 71.42 | 25  | 0.766 | 58.97 | 596 | 0.012     |
| Does not fully restore after sleep        | 29  | 1.36 | 87.235 | 29  | 1.2 | 85.63 | 377.5 | 0.201     |
| Reduced motivation                        | 22  | 0.766 | 79.31 | 23  | 0.666 | 58.82 | 525.5 | 0.470     |
| *Tantra* (day time attention, concentration, memory problem) | 22  | 0.73 | 73.33 | 21  | 0.533 | 57.14 | 533 | 0.0153    |
| *Jada* (fatigue)                         | 28  | 0.56 | 76.47 | 28  | 1.2 | 76.59 | 408 | 0.047     |
| Irritability or mood disturbance          | 27  | 0.46 | 78.26 | 25  | 0.73 | 57.89 | 624 | 0.002     |
| *Akshigaurava* (heaviness in eyes)        | 21  | 0.93 | 82.35 | 23  | 0.866 | 89.65 | 426 | 0.691     |
| *Shirogaurava* (heaviness in head)        | 25  | 1.1 | 84.61 | 29  | 1.1 | 76.59 | 554.5 | 0.943     |
| *Apakti* (indigestion)                    | 21  | 0.8 | 70.58 | 26  | 0.866 | 75.41 | 476.5 | 0.020     |
| *Angamarda* (body ache)                   | 24  | 1.33 | 78.43 | 20  | 1.3 | 81.25 | 479 | 0.103     |
| *Jrambha* (yawning)                       | 24  | 1.266 | 97.91 | 20  | 0.933 | 100 | 554 | 0.808     |
| *Alasya* (laziness)                       | 27  | 1.166 | 90.74 | 24  | 0.83 | 78.125 | 322.5 | 0.671     |

*n*: Number of patients, Df: Difference in mean before treatment and after treatment

### Table 3: Comparison of effect of therapy on *Manasa* symptoms between the groups

| Symptoms                     | Data of Group A | Data of Group B | Comparison of both groups |
|------------------------------|-----------------|-----------------|---------------------------|
|                              | n  | Df | Percentage | n  | Df | Percentage | Mann-Whitney U statistic | Probability |
| *Krodha* (anger)             | 27  | 1.66 | 73.93 | 26  | 0.5 | 45.45 | 695.5 | <0.001     |
| *Bhaya* (fear)               | 24  | 0.867 | 74.29 | 21  | 0.4 | 42.86 | 258 | 0.001     |
| *Shoka* (sorrow)             | 19  | 0.733 | 68.75 | 17  | 0.3 | 36 | 607 | 0.009     |
| *Chinta* (stress)            | 26  | 0.966 | 74.359 | 25  | 0.7 | 56.75 | 573 | 0.062     |

*n*: Number of patients, Df: Difference in mean before treatment and after treatment

### Table 4: Overall effect of therapies

| Effect                        | Number of patients (%) |
|-------------------------------|------------------------|
|                               | Group A | Group B |
| Excellent improvement (>70%)  | 24 (80) | 19 (63.33) |
| Moderately improvement (40%<70%) | 6 (20) | 11 (36.66) |
| Mild improvement (20%<40%)    | 0 (0) | 0 (0) |
| Unchanged (<20%)              | 0 (0) | 0 (0) |
| Overall effect                | 30 (79.19) | 30 (73.43) |

Other two patients were dropped from the study due to their personal reason.

Maximum number of patients, i.e., 62.50% were female. Biological conditions unique to women such as the menstrual cycle, pregnancy and menopause can affect sleep. This is because the changing levels of hormones that a woman experiences throughout the month and over her lifetime, such as estrogen and progesterone, have an impact on sleep.[8] The present study reveals that maximum numbers (51.56%) of the patients were homemakers, this reflects that high level of physical or mental stress, strain with responsibilities causes stress, and thus insomnia has become more common in homemakers. The present study shows that maximum number of patients, i.e., 87.5% were from middle class. The middle-class economic background people may have more struggles in life, hence insomnia dominates.[9] About 60.93% of patients were taking *Katu Rasa* (pungent taste) dominant diet, it increases *Vata* and due to *Vataprakopa* (vitiation of *Vata Dosha*), insomnia occurs. *Rajasika/Vatavardhaka Ahara* (dietary items that increase *Vata Dosha*) may act as a predisposing factor in manifestation of a psychiatric disorder. In the present trial, 54.68% of patients had poor appetite. As

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Nidra (sleep) is stated to enhance Agni (digestive power),\textsuperscript{[10]} Anidra (insomnia) may produce Mandagni (weak digestive power). Proper sleep helps for normal digestion and excretion. Some studies supported classical opinion that poor state of Agni (digestive power) is associated with sleep complaints. About 57.81% of patients were having Madhyama Koshta and 40.625% were having Krura Koshta. Madhyama and Krura Koshta are suggestive of Kapha and Vata Dosha dominancy, respectively. About 75% of patients were not performing any kind of physical exercise and were leading a sedentary life. Lack of physical exercise results in the feel that there is no need for rest and thus may lead to sleeping difficulties which can later result into insomnia. Maximum number of patients (64.06%) was having addiction of tea. Tea contains caffeine and small amounts of theobromine and theophylline, which are stimulants.\textsuperscript{[11]} Vatapradhana-Pitta Prakriti (Vata predominant Pitta constitution) was observed in maximum (73.43%) patients. Generally, person who has Vata Prakriti (Vata predominant constitution) gets poor quality of sleep due to Chala Guna (mobile property) of Vata Dosha, whereas Pitta Prakriti (Pitta predominant constitution) persons have “Klesha Asahishnuta (unable to tolerate mental stress), Krodhahikyata (excessive anger)” which leads to more stress. Hence, these Prakriti individuals are more prone to insomnia.\textsuperscript{[12]} About 96.86% were of Rajasika Prakriti. Characteristic features of this constitution are various emotional factors related to Rajoguna – keeping in mind overactive condition which causes either delayed or lesser sleep duration. About 60.93% of patients were having Avara Sattva (weak mental strength), followed by 32.81% of patients having Madhyama Sattva (moderate mental strength). Acharya Charaka has mentioned that person having moderate and weak mental strengths is more vulnerable to insomnia.\textsuperscript{[13]} Majority of patients’ (82.41%) insomnia started gradually. Progressive course of disease was reported in 84.37% of patients. Gradual and progressive nature of the disease indicates silent nature of the disease which is avoided initially and causes many physical and mental disturbances in later stage. Data revealed that stress and Vata Vridhhi (increased state of Vata Dosha) as a causative factor for primary insomnia were observed in majority (79.68%) of patients, whereas poor sleep hygiene, anxiety, Vegadarshana (suppression of natural urges), Dhatuksaya (deblity) and Pittavridhdi (aggravated Pitta) were found in 12.5%, 35.29%, 14.06%, 17.18% and 20.31% of the patients, respectively. Researchers have shown a long list of factors to be related to insomnia, ranging from physical and emotional disorders to demographic and socioeconomic characteristics. However, many of these factors are interrelated, so what seems to be a direct association may disappear when the effects of the others are taken into account.\textsuperscript{[14]}

**Mode of action of Sattvavajaya Chikitsa**

In the present study, it is found that stress is the major cause for the disease insomnia. This stress further leads to chief symptoms as well as associated.

Shithilakarana Vyayama opens the energy channels and psychic centers. Researchers have found that developing control of the body through these practices enables them to control the mind and energy. Yogasana became tools to higher awareness, providing the stable foundation necessary for the exploration of the body, breath, mind and higher states. When Prana begins to flow, the toxins are removed from the system ensuring the health of the whole body.

Surya Namaskara: These postures generate Prana, the subtle energy, which activates the psychic body. Surya Namaskar regulates Prana, Udana Vayu, Tarpaka Kapha and Alochaka Pitta which in turn enhance the functions of Buddhi (intellect). Regular practice of Surya Namaskar significantly shows reduction in pulse rate, attributed to increased vagal tone and decreased sympathetic activity.\textsuperscript{[15]} Research on Surya Namaskara concluded that it plays positive and significant role to decrease stress level of the individuals.\textsuperscript{[16]}

Collective impact of Nadi Shodhana, Bhrumari Pranayama and Aum chanting modulates the sympathetic and parasympathetic activities thereby resulting in relaxation. From the Yogic point of view, Nadi Shodhana Pranayama regulates Prana flow in the body. It helps to remove congestion or blockage of Nadi and thereby allows the free flow of Prana. When the Pingala Nadi is dominant, right nostril breathing will be there resulting in heating up of the body and increased physical activity. While Ida Nadi dominancy results in left nostril breathing, it increases mental activity. These two aspects of Prana represent the two most obvious characteristics of human, the ability to think and act. Through Pranayama, a fine balance of these two can be achieved.\textsuperscript{[17]} Pranayama results in the control on Chanchalatava Guna (instability) of Vata and also Rajas Guna. Vata Dosha is the controller of Manasa (mind), by controlling the breath; mind also gets controlled. The various Manasa Bhava (mental signs) such as Krodha (anger) and fear also come under control through the Pranayama, which are the root cause for all type of mental disorders. During Aum chanting, the first pronunciation A creates the vibrations, which affects the spinal cord to increase its efficiency, affecting intermediolateral gray column. The second pronunciation U creates the vibrations in the throat and affects the thyroid glands, whereas the last pronunciation M brings the vibrations to the brain, thereby activating the brain centers as a result of which the efficiency of a brain increases.\textsuperscript{[18]} Aum chanting helps to remove the Avarana (shield) of Rajas and Tamas.

Meditation: Meditation has been defined as training in awareness which when practiced over a period of time produces definite change in perception, attention and cognition. Mindfulness meditation involves focusing on your breathing and then bringing mind’s attention to the present without drifting into concerns about the past or future. It helps to break the chain of everyday thoughts to evoke the relaxation response, which would result in sleep.\textsuperscript{[19]} Awareness is maintained by concentrating on the auditory channel. The rest of the terminals are disengaged.
and their connections in the cerebral cortex are dissociated so that no message gets through to the motor organs. When awareness is focused on the parts of the body, the feelings or the visualizations enumerated in the practice, higher centers of the brain are being monitored.

All these relaxation technique lessen the stress level in the body and activate Mana (mind) for proper function by controlling Raja Dosha and breaks the Avarana (shield) of Tamas. Raja and Vata both are interrelated by the Samyavashththa of Raja Guna (balanced state of Raja Guna); Vata also gets controlled. Ultimately, all the Avarana gets break down. There is free flow of Prana in Manovaha Srotas (Hridaya). Manasa (mind) gets activated for Swasyanigraha and Indriyaabhighra Karma. Mind gets dissociated from all the things (Ahita Artha) and prepares the body and the mind for sleep.

**Mode of action of Pippalimula**

Vitiation of Vata is the most important phase of insomnia, where Pippalimula might help in the Samprapti Vighatana (breakdown of pathogenesis) by its Vatahara (pacification of Vata Dosha) property as the drug is Dipana (stimulation of digestion), Pachana (digestion of undigested food particle), Anaha Prasamanam (releives abdominal distension) and regulates Prana-Apana Gati (movements of Prana and Apana). Hence, it was found effective in the management of insomnia. Adjuvant used in the present study is jaggery and buffalo milk. Jaggery is having Madhura Rasa (sweet taste), Madhura Vipaka (sweet postdigestive action), Dhatusupshithikara (nutritious), Shleshmavardhana (increased Kapha Dosha) and Vatapittahara (pacified Vata and Pitta Dosha) property. Due to these properties, it acts as Indriyatarka (satisfied Indriya) and increases nutritional value of drug. Buffalo milk is having Nidrajanana (sedative) property so act as excellent adjuvant as Anupana. The present study confirms that Pippalimula with Guda (jaggery) and Mahishi Ksheera (buffalo milk) induced the sleep in the patients of insomnia. It may be stated that Pippalimula along with jaggery and milk containing three potent, yet different drugs attain balanced properties in synergistic fashion and regulate the function of Apana Vayu, improve the digestion, regulate the physiology of Dhatu or body tissues, give pleasure, calmness and relieve the symptoms of Anidra.

**Pippalimula** has piperine and pilplatin which are known to have sedative effects. It may be presumed that alkaloids such as piperine and essential oils might be responsible of sedative and CNS depressant activities of Piper longum root by acting on the GABA receptor complex.

**Conclusion**

_Sattvavajaya Chikitsa_ in the form of relaxation technique and _Guda Pippalimula Churna_ provide significant result in the chief as well as associated complaints of insomnia. But the difference between these two therapies was statistically insignificant. While in psychological symptoms, group A (relaxation technique) was found more effective than group B (Guda Pippalimula Churna). In Manas symptoms like Krodha 28.48%, Bhaya (31.43%) and in Shoka (32.75%) better result was found in group A (relaxation technique) than group B (Guda Pippalimula Churna) which was statistically significant also. _Rajo_ and _Tamo Guna_ are the major predisposing factors for Krodha (anger), Bhaya (fear), Shoka (sorrow) and Dwesha (jealousy). Yogic practices bring down the _Rajo Guna_ which is the root for Manasa (mind) indulgence in Ahita Artha (unwholesome objects). Hence, from this study it can be concluded that _Sattvavajaya Chikitsa_ could be a better approach than _Pippalimula Churna_.

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