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A Clinical Study to evaluate the management of Anidra with special reference to Insomnia with Pippali Moola Churna

Dr. Pankaj Kumar Verma¹, Dr. Pratap G², Dr. Veeraj Hegde³

¹Post Graduate Scholar, ²Professor, ³Associate Professor, Dept. of Kayachikitsa, Muniyal Institute of Ayurveda Medical Sciences, Manipal, Udupi, Karnataka, INDIA.

ABSTRACT

Sleep is a serious health ailment that affects millions of people. It is one of the most significant human behaviour occupying roughly one third of human life. Sleep occupies a greater portion of our life and is considered as one among the three *Upastambhas* of existence. *Charaka* has explained the management of *Nidranasha* (Insomnia) with both external and internal treatments. Presently people are not getting sufficient hours of sleep because of busy life schedules and overload, as a result of which, work hours have replaced time of sleep. Recent studies have shown that anxiety and stressful environment has created an imbalance in the physiological activity of the body leading to disturbed sleep and other anomalies. A Randomized comparative clinical study of 40 patients suffering with classical signs and symptoms of *Anidra* (Insomnia) of either sex divided into two groups viz. Group A - (Study group) - Treated with *Pippali Moola* (Root of *Piper Longum*) with *Guda* (Jaggery), Group B - (Placebo Group) - Acacia resin with a study duration of 14 days, including follow-ups. The data during the study was recorded and analyzed statically.

Key words: Acacia resin, Anidra, Insomnia, Pippali Moola, Root of Piper Longum.

INTRODUCTION

Anidra (Insomnia) is a serious health ailment that affects millions of people. It is one of the most significant human behavioral occupying roughly one third of human life. *Nidra* (Sleep) occupies a greater portion of our life and is considered as one among the three *Upastambhas* of existence.^[1] Lack of sleep or improper sleep causes *Dukkha*, *Karshya*, *Abala*, *Klibata* and *Akala Mrityu*.^[2] The causes of *Anidra* are

explained by *Charaka* includes *Karya*, *Kala*, *Vikara*, *Prakriti* and *Vaya*.

Presently people are not getting sufficient hours of sleep because of busy life schedules and overload, as a result of which, work hours have replaced time of sleep. Recent studies have shown that anxiety and stressful environment has created an imbalance in the physiological activity of the body leading to disturbed sleep and other anomalies.

Sleep appears necessary for our central nervous system to work properly. Insomnia refers to the difficulty in initiation, maintenance, duration or quality of sleep. Going by the statistics, 20% of people around the world are sleep deprived. Sleep disorders make people pop sleeping pills for a sound sleep. To understand the frequency of people taking these sleeping pills, Curofy (India's largest community of verified doctors) opined about the percentage of patients demanding sleeping pills, to which they said "On an average 20.3% patients examined by doctors

Address for correspondence:

Dr. Pankaj Kumar Verma

Post Graduate Scholar, Dept. of Kayachikitsa, Muniyal Institute of Ayurveda Medical Sciences, Manipal, Udupi, Karnataka, INDIA.

E-mail: pankaj1990verma@gmail.com

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ask for sleeping pills, which is almost 1 out of 5 of the patients who are suffering from sleeping disorders." This indicates that for almost 6.5% doctors more than 2 out of every 5 patients ask for sleeping pills.^[3]

When treatment of insomnia is concerned, the contemporary medicine includes antidepressants which are having adverse effects, like nausea, increased appetite and weight gain, further increase of anxiety and dizziness. Allopathic hypnotic drugs are useful for short term treatment in insomnia which is due to acute stage. Long term uses of certain classes of sedatives cause physical dependence and withdrawal symptoms also have a number of side effects.^[4] Complaints of insomnia tend to be persistent or recurrent over time. Thus, it seems that patients with chronic insomnia need some form of treatment.^[5] So in search of a potent therapy to manage *Anidra*, we can consider medicines mentioned in our classics. Our Acharya's have mentioned many drugs for management of *Anidra* one of which is *Pippali Moola*.^[6] Hence here an attempt has been made to evaluate the efficacy of *Pippali Moola* by placebo control in The management of *Anidra*.

MATERIALS AND METHODS

Source of data

Literary sources

All the Ayurvedic text, modern literatures and contemporary texts including the journals, websites etc. will be reviewed pertaining to the drug and the diseases in the intended study.

Drug sources

Ingredient was procured from authentic vendor, and approved by Dravya Guna expert from Muniyal Institute of Ayurveda Medical Sciences, Manipal. Preparation of the medicine was done in Muniyal Pharmacy Manipal.

Clinical sources

OPD and IPD Muniyal Institute of Ayurveda Medical College and Hospital, Special camps were also arranged for the purpose.

Sample size

40 clinically diagnosed patients of *Anidra* were selected randomly based on inclusion criteria. They were equally divided into two groups A and B, 20 patients in each group. Group A was treated with *Pippali Moola* with *Guda*. Group B was treated with Acacia resin placebo. Both were oral medication.

Diagnostic criteria

The patient were diagnosed based on the following clinical symptom due to reduced sleep like yawning, body ache, fatigue, diseases of head, heaviness of eyes.

Inclusion criteria

- Patients complaining of reduction in sleep time, difficulty in initiation of sleep, wakefulness during normal sleep.
- Patients of either sex between the age group of 20 - 50 year were selected.
- Both new and treated cases were selected.
- Patients having insomnia for more than 1 month but less than 1 years.

Exclusion criteria

- *Anidra* because of *Madatyaya*, *Marmaabhighata* *Janya* and other systemic diseases were excluded.
- Insomnia with major psychiatric illness like schizophrenia, depressive psychosis, epilepsy etc.
- Patients with drug dependency were excluded.
- Patients having acute illness like cardiovascular accidents, myocardial infarction and chronic obstructive pulmonary diseases.
- Patients having insomnia for more than one years or less than one month.

Intervention

40 Clinically diagnosed patients of *Anidra* patients are selected randomly and divided into two group (Group A and Group B). Detailed clinical history will be taken and patients will be examined as per case Performa prepared for this purpose. The selected patients will be given the Test drugs for 15 days.

Test drugs - Pippali Moola Churna

Placebo control drug - Acacia resin

Dosage of medication

Group A - 4 gm/day with water in two divided doses for 15 days.

Group B - 4 gm/day with water in two divided doses for 15 days.

Follow-up study - 30 days after the completion of medicine.

Duration of medication - 15 days

Assessment Criteria

Efficacy of treatment will be assessed by the change in sign and symptoms which are recorded before and after the course of study. Assessment will be done with the help of subjective and objective parameters.

Subjective Parameters

- Disturbed sleep
- Disturbances in routine
- Associated complaints
- Duration of sleep (being normal 6-8 hours)

Objective Parameters

- Pittsburgh sleep quality index (psqi)^[7]

RESULT

In Ayurveda classics, *Anidra* is not explained as a separate disease, and also different words have been used to denote sleeplessness in different contents like *Asvapna*, *Alpanidra*, *Akalanidra*, *Avyavahita Nidra*, *Ratri Jagarana*, *Prajagara*, *Mandanidra*, *Nidranasha*, *Nidraviparyaya* or *Nidrabhigata*. Thus nowhere the Samprapti is available, depending upon the physiology of *Swabhavikanidra*, *Nidanapanchaka* of *Anidra* is emphasized. From the *Nidanas* it is clearly evident that *Vatavidhi* and *Kaphakshaya* is going to occur. As *Tamoguna Pradhana Kapha* should fill up *Sajnyavaha Srotas* to induce *Nidra*. In *Anidra* there is *Guntah*, *Dravyatah*, *Karmatah Kaphakshaya* with *Vata* and *Pitta Prakopa*. *Sushruta* has explained *Tamas* is the cause for *Nidra* and *Satva* as the cause for

Jagrutavastha. These two references suggest that when the *Satva Guna* becomes more predominant, then there will be *Kshaya* in *Tamoguna*, due to which person remains awake.

Comparison between the groups

Group A treated with study drug - Pippali Moola with *Guda* has shown significant results in inducing sleep. The drug is effective in treatment of *Anidra*.

Table 1: Overall effect of Group A on 20 patients of *Anidra*.

Total Effect	Percentage	No of Pts	%
Cured	100%	0	0
Markedly Improved	76-99%	07	35%
Moderately Improved	51-75%	11	55%
Improved	26-50%	02	10%
Unchanged	<25%	0	0

Table 2: Overall effect of Group B on 20 patients of *Anidra*

Total Effect	Percentage	No of Pts	%
Cured	100%	0	0
Markedly Improved	76-99%	0	0
Moderately Improved	51-75%	01	5.5%
Improved	26-50%	10	55.5%
Unchanged	<25%	07	38.8%

DISCUSSION

Sleep plays an integral part in the health and well-being of the individual. The quality of life and how efficiently he/she is functioning depends upon how healthy sleep the person has in the night. Having

sound sleep is very essential to replenish the energy level, to relieve the mental stress and settle down the physiological function in the rhythm or harmony. In Ayurveda, *Nidra* is considered as one of the *Trayoupastambha* i.e. basic supporting foundation or pillar of the life. It increases the *Prakrita Shleshma*, reduces the *Raukshyata* and *Chalatva* of *Vayu* and regulates the *Pitta Udirana* in *Koshtha* at *Doshika* level. *Nidra* replenishes all the *Dhatu*s in fact essential for *Dhatuparinamana* and increase in the bulk of being. Hence the *Pushti*, *Karshya*, *Bala*, *Abala*, *Sukha*, *Dukha*, *Gyana*, *Agyana*, *Vrishta* *Klaibya* and *Ayu* or *Jivita* is depending on the *Nidra*.

In modern it can be co-related to Insomnia. It is the most commonly reported sleep problem. WHO defines it as a problem initiating and or maintaining sleep or the complaint of non-restorative sleep that occurs on at least three nights a week and is associated with day time distress or impairment. It can be grouped into primary and secondary Insomnia. Primary Insomnia is a sleep disorder not attributable to a medical, psychiatric or environmental cause and Secondary insomnia also known as comorbid insomnia which is associated with psychiatric disorder. Increased use of fast and junk food, competition, stress, workload, shift duties etc. increases the unnecessary alertness and over consciousness, which lead to disturbance in diurnal pattern of an individual. Such a diurnal changes produces loss of harmony in neurohormonal function. Ultimately there is loss of balance or homeostasis of physiological reaction of person. Sleep is one of the life activities which require harmony of various neurohormonal and other physiological functions. As discussed above in today's life different etiological factors affects sleep of an individual. In case of sleep patterns REM and NREM are two types of sleep. Whenever threshold of stress (either physical or mental) get crossed it affects the REM sleep and produces the initial symptom of insomnia.

As the management of *Anidra* is concerned, Ayurveda advocates *Nasya* and *Murdhnitaila* which include *Shiro-abhyanga*, *Shiraseka*, *Shiropichu* and *Shirobasti* for *Mano* and *Indriya Vikaras*. There are also some

drugs mentioned in classics which cause *Nidrajanana*. *Pippali Moola* and *Guda* is said to be very effective in treating *Anidra* in *Bhaisajya Ratnavali* and *Bhavaprakasha*. Since the present day management with administration of Antipsychotic and Sedatives, have its own limitations, there is a need to find an effective drug remedy from Ayurveda for *Anidra*. Hence the present study was focused to evaluate the efficacy of *Pippali Moola* in *Anidra*.

Probable mode of action of drug

Pippali Moola administered with *Guda* has shown significant improvement in the patterns of *Anidra*. *Pippali Moola* although is *Katu Rasa*, *Katuvipaka*, *Laghuguna* because of its *Snigdha* *Guna* it is *Vatahara*. *Guda* has properties like *Madhura Rasa*, *Madhura Vipaka* also having *Guru* and *Snigdha Guna*. When combine with *Pippali Moola* further enhance the property of *Nidrajanana*.

When drug shows effect according to their *Vipaka* then it suggests that substances perform their action according to their *Pratyarabdhatu*. *Arabdhatu* means the origin of any substances by its unique conjugation and configuration of *Panchamahabhutas*. The changes in *Arabdhatu* during digestion and metabolism are known as *Pratyarabdhatu*. While the substance whose *Panchabhautika* composition changes at either level of digestion one or more times and becomes different from the original substance are known as *Vichitrapratyayarbdha* substances.

The combined action of *Pippalimoola* and *Guda* will change their actions that would have occurred if individually given. *Vichitrapratyayarabdhatu* action in drugs has influenced the sleep pattern which is revealed in the results. In *Anidra*, there is vitiation of *Vata*, *Pippali Moola* might help in the *Samprapti Vighatana* by virtue of its *Vatahara* property. *Pippali Moola* its *Anushna Sheetavirya* along with *Guna* of *Guda* helps in increasing *Kapha* thus promoting sleep. From the modern pharmacological point of view, *Pippali Moola* has piperine and piplarine which are known to have sedative effect and which are also used in epilepsy for sedation.

CONCLUSION

Anidra closely resembles Insomnia. *Vata Vriddhi* along with *Kapha Kshaya* is the main reason for *Anidra*. *Vata* and *Rajas* play a key role in the pathogenesis of the body. According to modern science, sleep is said to nourish and repair the damages to the tissues caused by various catabolic activities of the body. Insomnia is more commonly seen in middle age group and more in menopausal aged women in the present study. It was observed that Insomnia manifests mostly in patients who are in unstable mind due to their personal life events - such as fear, stress, anxiety, emotional or mental tension, work problems, financial stress, lost of spouse and negative relationship of husband-wife etc. It was also noticed that Insomnia may present as a disorder on its own, but more frequently it co-morbid with hyperacidity, hypertension, sexual dysfunction, chronic pain, heart disease etc. While *Pippali Moola* with *Guda* (jaggery), it provided long lasting effect after completion of treatment. Individual effect of Group A (*Pippali Moola*) is good in all the phases of treatment

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