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# A randomized comparative clinical study to evaluate the efficacy of *Ashwagandha Churna* over *Tagara Churna* in the management of *Nidranasha* (insomnia)

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## ABSTRACT

Ayurveda is known for its holistic approach. It has emphasized to lead a healthy lifestyle, and *Nidra* is one among the important factor to remain healthy. *Nidra* is the most neglected part of modern lifestyle where one gives least importance to the timing, duration and quality of sleep with stress playing an important role in inducing insomnia. Aim of present study was to evaluate efficacy of *Ashwagandha Churna* over *Tagara Churna* in the management of *Nidranasha*. Study was conducted on 40 clinically diagnosed patients of *Nidranasha*. On the basis of observed data, it was concluded that *Ashwagandha Churna* has highly significant effect on *Nidranasha* when compared to *Tagara Churna*.

**Key words:** *Nidra, Nidranasha, Ashwagandha Churna, Tagara Churna, Insomnia.*

## INTRODUCTION

*Aahara, Nidra, Brahmacharya* are collectively known as *Tryopasthambha* of life in our Ayurvedic classics.<sup>[1]</sup> Happiness and misery, nourishment and emaciation, strength and debility, virility and impotence, knowledge and ignorance, life and death, all are dependent upon sleep.<sup>[2]</sup>

In the present day, we come across various patients who complain about *Nidranasha* (Insomnia). People who have rotating shifts in their work have trouble sleeping as the sleep timings will keep on changing, which may lead to *Nidranasha*.

Most people need 6-8 hours of sleep a day. But, this

requirement varies in accordance to physical exertion, illness and age also. It is not a rare condition i.e. 20-30% of the population have insomnia of one or the other type. It is difficult to initiate or maintain sleep or its non-restorative nature leading to intense distress and impairment of functioning.<sup>[3]</sup>

The man of this techno-world is trying to get overcome such harmonious features by elaborating his mental dimensions. But the biological clock which is mandatory for the well-being of human life's rhythm, is not ready to recognize these upsetting created by him. If once this harmony is violated, of course his health as well as his sleep will be hampered, because sleep exactly runs according to biological clock. That's why Ayurveda stresses on sleep and described it as one among the primary tripod of life. (Ch. Su. 11/35).

In the context to relation between body and mind, Ayurveda emphasizes that *Sharira* and *Satva* - both interacts with one another in all spheres of life (Ch. Sha. 4/36). We find a rich material which establishes that the Ayurvedic approach to the disease is definitely psychosomatic in nature. It has been shown that somatic humors also affect the psychic conditions. For example, with increasing of Vata there

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happens insomnia (Su.Su.15/17). On the other hand the effect of psychic disorders on the body have been also mentioned: *Vayu* is provoked by *Kama*, *Shoka*, *Bhaya*, *Pitta* is deranged by *Krodha* (Ch. Chi. 3/115).

If *Nidranasha* is not treated, there is high risk to suffer from several psychosomatic disorders.

Loss of sleep causes vague pains all over body, feeling of heaviness of head, yawning, laziness, tiredness, giddiness, indigestion, stupor.<sup>[4]</sup>

Classic Ayurvedic herbs have been selected for this study in the management of *Nidranasha*.

*Ashwagandha Churna* (*Withania somnifera*) is indicated in the management of *Nidranasha* in *Jaladoshadi Yogadhikar* of *Vangasena Samhita*.<sup>[5]</sup>

*Tagara* (*Valeriana wallichii* DC) has been said as *Svapajanaka* in *Bhavaprakasha Nighantu Karpuradi Varga*. The research works done on *Tagara* shows that it is an effective and powerful drug to cure *Nidranasha* caused by any reason. It also showed significant activity as hypotonic, sedative and nervine tonic.<sup>[6]</sup>

Hence, the present study was undertaken to evaluate the efficacy of *Ashwagandha Churna* over the standard drug *Tagara Churna* in the management of *Nidranasha*.

## AIMS AND OBJECTIVES

To evaluate the efficacy of *Ashwagandha Churna* over *Tagara Churna* in the management of *Nidranasha*.

## MATERIALS AND METHODS

Total 40 patients fulfilling the criteria for the diagnosis of *Nidranasha* irrespective of their gender, religion were selected by randomly sample technique for the present study from OPD of Kayachikitsa department, after seeking the permission of Institutional ethical committee. The materials required to conduct study were *Ashwagandha Churna*, *Tagara Churna*, *Mahisha Ksheera*.

### Inclusive Criteria

- Patients of either sex and age between 20-60 years.

- Patients who are suffering from *Nidranasha* from one month and above.

### Exclusive Criteria

- Sutika*, *Garbhini* and any serious systemic illness.
- Patients who are not on anti-histamines and narcotics.
- Patients who are alcoholic.

### Criteria for diagnosis

- Presence of signs and symptoms of *Nidranasha Vyadhi* as per text was essential for diagnosis.
- The routine hematological investigations such as Hb, TC, DC, ESR and RBS were carried out to exclude any other pathology.
- Sleep Efficacy Index was calculated to support the diagnosis. An index of less than 80% indicates poor sleep.

### Assesment Criteria

#### 1. Objective parameter

Sleep factors	Athens insomnia scale			
	0: No problem	1: Slightly delayed	2: Markedly delayed	3: Very delayed or did not sleep at all
Sleep induction	0: No problem	1: Slightly delayed	2: Markedly delayed	3: Very delayed or did not sleep at all
Awakenings during the night	0: No problem	1: Minor problem	2: Considerable problem	3: Serious problem or did not sleep at all
Final awakening	0: Not earlier	1: A little earlier	2: Markedly earlier	3: Much earlier or did not sleep at all
Total sleep duration	0: Sufficient	1: Slightly insufficient	2: Markedly insufficient	3: Very insufficient or did not sleep at all
Sleep quality	0: Satisfactory	1: Slightly unsatisfactory	2: Markedly unsatisfactory	3: Very unsatisfactory or did not sleep at all

Well-being during the day	0: Normal	1: Slightly decreased	2: Markedly decreased	3: Very decreased
Functioning capacity during the day	0: Normal	1: Slightly decreased	2: Markedly decreased	3: Very decreased
Sleepiness during the day	0: None	1: Mild	2: Considerable	3: Intense

**2. Subjective Criteria**

- *Tandra*
- *Angamarda*
- *Angasada*
- *Arati*
- *Klama*
- *Shirashoola*

**Grading of the symptoms**

- No symptoms - 0
- Mild degree (Occasional complaints) - 1
- Moderate degree (once or twice in 2 – 3 days) - 2
- Severe degree (daily complaints) – 3

This grading was adopted to assess the efficacy before treatment and after treatment.

**Intervention**

Group A: 3gms of *Tagara Churna* with *Mahisha Ksheera*, one hour before to bedtime for 30 days.

Group B: 3gms of *Ashwagandha Churna* with *Mahisha Ksheera*, one hour before to bedtime for 30 days.

**OBSERVATION**

Total 40 patients were taken for the trial. 20 patients in Group A and 20 in Group B. There were no dropouts through out the whole treatment schedule.

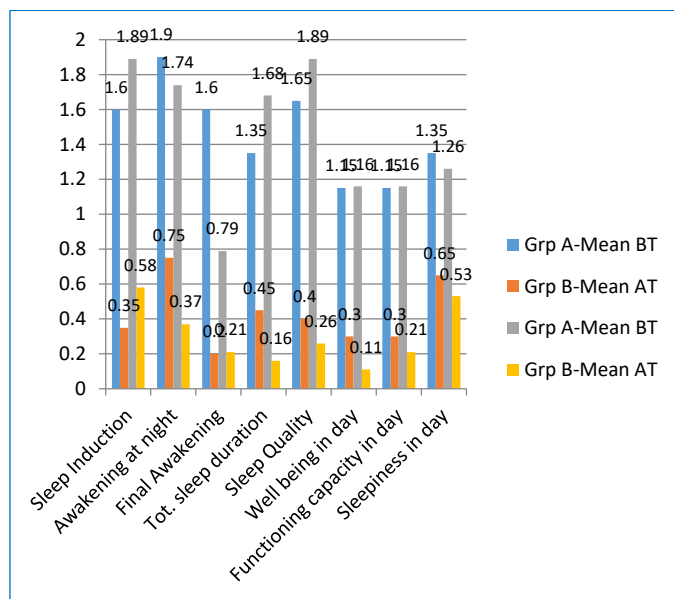
Maximum patients were between the age group of 51-60 years, were males. Data obtained showed that maximum patients were leading a sedentary lifestyle and were from lower middle class family. The data also signifies that most of the patients were married

and maximum patients were addicted to tea and coffee followed by alcohol. It was observed that most of the patients were having *Madhyama Sara* and *Madhyama Satva*.

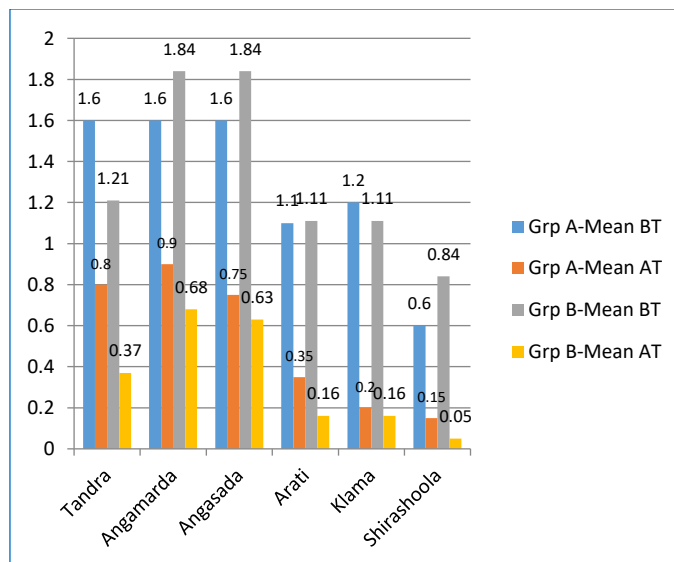
**RESULT**

At the beginning of study most of the patients reported sleep difficulties in the various forms such as delayed sleep induction etc. Improvement in the following symptoms of *Nidranasha* were assessed before and after treatment.

**Graph 1: Effect of therapy on Objective parameters in Group A & B.**



**Graph 2: Effect of therapy on Subjective criteria in Group A & B.**



**Table 1: Overall result of Athens Insomnia Scale in between both the groups**

Overall result of AIS			Difference in the means (In %)	Paired t test/Wilcoxon matched paired test	Remark
	Mean	±SD			
<b>Group A</b>					
BT	11	2.95		t=15.379	p<0.001*
AT	3.4	1.67	7.6 (69.1%)		
<b>Group B</b>					
BT	11	3.49		* t=13.071	P<0.001*
AT	2.3	1.42	8.7(79.09%)		
*: Highly significant					

The overall effect of AIS in Group A showed highly significant result with mean score before treatment being 11±2.95 and mean score after treatment being 3.4±1.67.

The overall effect of AIS in Group B showed highly significant result with mean score before treatment being 11±3.49 and mean score after treatment being 2.3±1.42.

**Table 2: Overall result of Subjective criteria in between both the groups**

Overall result of Criteria			Difference in the means (In %)	Paired t test/Wilcoxon matched paired test	Remark
	Mean	±SD			
<b>Group A</b>					
BT	7.7	2.68		Z= 3.749	p<0.001*
AT	3.15	1.73	4.55(59.1%)		

<b>Group B</b>					
BT	7.55	3.50		t=8.402	P<0.001*
AT	1.95	1.54	5.6(74.17%)		
*: Highly significant					

The overall effect of Subjective criteria in Group A showed highly significant result with mean score before treatment being 7±2.68 and mean score after treatment being 3.15±1.73.

The overall effect of Subjective criteria in Group B showed highly significant result with mean score before treatment being 7.55±3.50 and mean score after treatment being 1.95±1.54.

All the patients with *Nidranasha* considered for the study showed improvement in all the parameters in both the groups. However *Ashwagandha Churna* showed more significant result when compared with *Tagara Churna*. Changes within the group were also found to be significant.

## DISCUSSION

### On Athens Insomnia Scale

Athens Insomnia Scale (AIS) is used to assess the results of the study. AIS is divided into 8 components which indicate eight traits of sleeplessness. They are as follows:

#### 1. Sleep Induction

This denotes the time taken by the patient to fall asleep after lying on bed. The results obtained shows that in both the groups change were highly significant. However by observing the differences in mean scores we can say that the result is best in Group A (78.1%) than in Group B (69.3%).

#### 2. Awakening during night

This indicates disturbance in sleep during night in terms of awakening without any reason or getting up for micturition. Result obtained shows that in both the groups changes were highly significant. However,

by observing the differences in mean scores we can say that the result is best in Group B (78.73%) than in Group A (60.5%).

### 3. Final Awakening

This indicates the time when the patient finally wakes up from his sleep in the morning, and does not go back to sleep again. Results obtained shows that in both the groups changes were highly significant. However, by observing the difference in mean scores we can say that the result is more significant in Group A (87.5%) than in Group B (73.42%).

### 4. Total Sleep Duration

It indicates the number of hours patients are sleeping during night. The results obtained show that in both the groups changes were highly significant. However, by observing the difference in mean scores we can say that the result is more significant in Group B (90.5%) than in Group A (66.6%).

### 5. Sleep Quality

This denotes the rating given by the patient about the quality of sleep he experienced, whether he is satisfied with his sleep or not. The results obtained show that in both the groups changes were highly significant. However, by observing the difference in mean scores we can say that the result is more significant in Group B (86.2%) than in Group A (75.7%).

### 6. Well-being during the day

This denotes that patient has trouble engaging in social activity during the day time. Results obtained shows that in both the groups changes were highly significant. However, by observing the difference in mean scores we can say that the result is more significant in Group B (90.5%) than in Group A (73.9%).

### 7. Functioning capacity during the day

This indicates patient has trouble keeping up enough enthusiasm for the things which has to be done. The results obtained shows that in both the group changes were highly significant. However, by observing the difference in mean scores we can say that the result is

more significant in Group B (81.9%) than in Group A (73.9%).

### 8. Sleepiness during the day

It indicates that patients is having trouble staying awake while driving, in class, eating meals. The results obtained shows that in both the group changes were highly significant. However, by observing the difference in mean scores we can say that the result is more significant in Group B (57.9%) than in Group A (51.8%).

## Discussion on Subjective Parameters

### 1. Tandra

The results obtained shows that in both the group changes were highly significant. However, by observing the difference in mean scores we can say that the result is more significant in Group B (69.4%) than in Group A (50.1%).

### 2. Angamarda

The results obtained shows that in both the group changes were highly significant. However, by observing the difference in mean scores we can say that the result is more significant in Group B (63.04%) than in Group A (43.7%).

### 3. Angasada

The results obtained shows that in both the group changes were highly significant. However, by observing the difference in mean scores we can say that the result is more significant in Group B (65.7%) than in Group A (53.1%).

### 4. Arati

The results obtained shows that in both the group changes were highly significant. However, by observing the difference in mean scores we can say that the result is more significant in Group B (85.8%) than in Group A (68.1%).

### 5. Klama

The results obtained shows that in both the group changes were highly significant. However, by observing the difference in mean scores we can say

that the result is more significant in Group B (85.58%) than in Group A (83.3%).

#### 6. Shirashoola

The results obtained shows that in both the group changes were highly significant. However, by observing the difference in mean scores we can say that the result is more significant in Group B (94.04%) than in Group A (75%).

#### Discussion on overall results

The results obtained shows that in both the group changes were highly significant. However, by comparing the difference in mean scores ( AIS:- Group A 69.1% and Group B 79.09% , Subjective Criteria:- Group A 59.1% and Group B 74.17% ) it is clear that Group A (*Ashwagandha Churna*) has shown more significant result than Group B (*Tagara Churna*).

#### Probable mode of action

In 40 patients of *Nidranasha*, the significant symptomatic relief was observed in most of the symptoms after administration of *Ashwagandha Churna* when compared to *Tagara Churna*. *Kaphadosha* and *Tamas* are responsible for *Nidra*, whereas *Rajas* and *Vatadosha* are responsible for *Nidranasha*. *Tagara* and *Aswagandha* have similar *Rasa*, *Guna*, *Veerya* and *Vipaka*. The *Rasa* being *Katu*, *Tikta* and *Kashaya* are *Pitta Shamaka* and due to *Ushna Virya* of the drugs they are *Vata Shamaka*. Both the drugs have *Vatahara* and *Nidrajanaka* properties by virtue of which these have shown significant therapeutic result. These drugs were given along with *Mahisha Kshira*. Milk possessing *Madhura Rasa*, *Snigdha*, *Guru*, *Shlakshna*, *Picchila*, *Manda Gunas*, *Sheeta Virya*, *Madhura Vipaka*, *Vatapittahara* and *Shleshmakrit* properties, it can act as an excellent sleep promoting adjuvant. *Mahishakshira* has been regarded as "*Agyadravya*" in promoting sleep in our classics. *Ashwagandha* having *Madhura Rasa* as its *Anurasa* probably have shown better result than *Tagara*. An attempt has been made to manage this disease by an Ayurvedic regimen. In

trial period of 40 patients of *Nidranasha*, no patient developed any side effect

#### CONCLUSION

*Nidra* is essential phenomenon for long healthy life. According to modern science, sleep is said to nourish and repair the damages to the tissues caused by various catabolic activities of the body. *Nidranasha* effectively represents insomnia. *Vatavridhi* along with *Kapha Kshaya* is responsible for *Nidranasha*. *Manasika Nidanas* like *Atichinta*, *Bhaya* are the main causative factors of the disease. Both the groups have shown effective results but when compared, *Ashwagandha Churna* has shown better result than *Tagara Churna*.

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