

EVALUATION OF THE EFFECT OF SIRODHARA WITH TRINA PANCHAMOOLA KSHIRA IN PRIMARY INSOMNIA

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ABSTRACT

Sleep or *nidra*, an indicator of good health, is one of the natural instincts of man. Improper sleep includes sleep deprivation, sleep at improper time and excessive sleep. Although different terminologies have been used to describe insomnia in Ayurvedic classics each terminology expresses reduced sleep time as cardinal feature. *Alpanidra* is the term commonly used to denote the state of reduced or disturbed sleep. Primary insomnia can be correlated with *alpanidratha* detailed in Ayurveda. Globally, 10-15% of the adult population is believed to be suffering from primary insomnia or *alpanidratha*. Conventional care for the same is limited to barbiturates and anxiolytics which have a reputation of being addictive and heavily implicated with concurrent side effects like prolonged drowsiness, nausea and fatigue. Hence there arises a need to experiment alternative methods which are easy to administer and safe in terms of adverse effects. This search involves remedies that focuses on non-oral drug regimen narrowed down to the concept of *sirodhara* mentioned in Ayurveda. A randomized controlled trial with two groups was thus planned and implemented at Government Ayurveda College, Thiruvananthapuram. The study group was given *trinapanchamoolakshira* for *sirodhara* and the control intervention was *sirodhara* with non-medicated *kshira*. *Sirodhara* was done for 45 minutes, for 7 days. The study group had 9 members and control group had 7 members. Quantity and quality of sleep was assessed. Proper evaluation before, during, after treatment and on follow up was made. *Sirodhara* with *kshira* was found to be effective in reducing the distress caused by sleeplessness though no statistically significant difference was found between the groups.

Keywords: primary insomnia, barbiturates, *alpanidratha*, *trinapanchamoola*, *sirodhara*.

INTRODUCTION

Nearly one-third of all adults in any particular year are affected by insomnia, a widely reported sleep disorder in developed world. Around 25% patients within chronic insomnia are believed to have primary insomnia¹. In Ayurveda, sleep is considered one among the *upastambha*², a pillar of life and an *adharaniya vega*³, an insuppressible urge. *Anidra* or *Alpanidratha* is well explained in the classics. Acharya Caraka has described *Anidra* as one among the *Vatikananatmaja vikara*⁴. Loss of sleep is a symptom of both *vata* and *pitta vridhi* and *kapha kshaya*.⁵

NEED AND SIGNIFICANCE

Sleep disorders constitute 1-7 % of an average OP consultation⁶. Mostly it constitutes a transient rhythmic disturbance in day to day life. Generally the insomniac depends on non – prescription drugs like barbiturates and CNS depressants. All of them do possess serious side effects to a certain extent like day time drowsiness, mood swings, anorexia, GI irritation and dependence.

Ayurveda offers a number of treatments for *nidranasa*, which are far more safe and reliable. One among them is *sirodhara*⁷, which has proven effects in enhancing serotonin level and resulting in propagation of sleep⁸. The domain of study here is *Sirodhara* with *trinapanchamoolaksheera*. *Trina panchamoola*⁹, a group of drugs told to be superior in *Pitta samanatwa*, incorporated with the principles of *dhara* prepared in the *kshirapakavidhi* was studied.

AIMS AND OBJECTIVES

1. To find out the effect of *sirodhara* in primary insomnia.

2. To compare the action of non-medicated *kshira* and medicated *kshira* used in *sirodhara*.

MATERIALS AND METHODS

The patients diagnosed as having primary insomnia according to DSM IV^{TR}¹⁰ were selected for study from the OPD of Department of Kayachikitsa, Government Ayurveda College, Thiruvananthapuram. The respondents were screened using insomnia screening questionnaire and randomly allocated into study and control group. A detailed case performa was used to record the data regarding personal history and disease. Assessment was done before, during and after treatment using sleep diary and PSQI.

Subjective and Objective parameters were assessed for clinical evaluation. Improvement and changes were recorded in the performa. Sixteen patients registered for the study. On randomization 9 of them were allocated to study group and the rest were kept as control. Those who were diagnosed with primary insomnia, and were willing for undergoing *dhara* in the age group 20-60 years were included in the study. Those with organic sleep disorders, with major psychiatric or systemic illness, with history of substance abuse and those on medication for sleep disturbance were excluded from the study. After screening, every odd numbered participant was allocated into study group and the rest into control group. The study was conducted during January 2012 to March 2013.

ETHICAL APPROVAL

The research study was approved by Ethical committee of Government .Ayurveda College, Thiruvananthapuram.

INTERVENTION: PROCEDURE AND DURATION

The procedure studied was *Sirodhara* with *trinapanchamoolakshira*. The intervention was given for 45 minutes for 7 consecutive days. The assessment was made before entering the therapy, during the therapy, after completion of therapy and after thirty days. For the control group, plain *sritakshiradhara* was given in the same format. Informed consent was obtained from all the participants.

PREPARATION OF TRINAPANCHAMOOLA KSHIRA

100g of *Trinapanchamoolachoorna* was boiled in 2.5 litre of milk. When the decoction was sufficiently prepared it was allowed to cool. After the temperature of the *kshira* came down to room temperature, it was administered to the patient according to *dharavidhi*.

DATA COLLECTION

Following parameters were noted systematically for the fulfilment of the objectives of the study:

1. Total Sleep Time : -(TST)
2. Frequency of Nocturnal Awakenings (FNA)
3. Assessment of mood after awakening

By noting the time of going to bed, time taken to fall asleep, number of awakenings, and time taken to go back to sleep and final awakening time, the total sleep time is calculated. An

increase in TST is definitely an indicator of improvement.

Apart from the same, the following instruments were also used to assess various parameters related to insomnia condition.

1. Pittsburgh Sleep Quality Index (Buysse et.al, 1989)¹¹
2. Sleep Assessment Scale (Clark LJ, 2012) ¹²

STATISTICAL EVALUATION

Statistical analysis of data was done using SPSS software. To describe the demographic, clinical and etiological details descriptive statistics were used. Student t test was applied to find the effectiveness of the intervention by comparing the mean scores of the study and control group.

RESULTS

The findings of the study are presented under the following three sub-headings: (a) demographic and clinical data of the participants (b) etiological data and (c) effect of the therapy (intervention)

(a) DEMOGRAPHIC AND CLINICAL DATA OF THE PARTICIPANTS

The mean age of the people participated in the study group was 52.22 years and that of the control group was 46.0 ($t=1.49$, $p<0.05$). There were equal no: of graduates and secondary educated persons in both the groups. A little more than half (55.6%) of the respondents were females in the study. A total of 57.1% were from urban background. Housewives constituted 50% of the sample. Also, 31.3% were professionals and the rest were farmers and manual labourers. Lower middle class constituted 50% of the people

who registered for this study. A total of 31.3% were from upper middle class, with an average monthly income more than 30,000 and 18.8% were poor with a monthly income less than 300. Finally, 56.3% were married, 18.8% were separated from spouses and the rest were unmarried.

Regarding the diet, 81.3 % in the group followed mixed diet; 50 % had *vishamagni*, 25% had increased appetite, and rest had normal appetite. The data shows that maximum number of the patients preferred (75%) *katu- amla-lavana rasa* in their daily food. Majority (81.3%) patients didn't have any sort of addictions and the remaining 18.7 % had history of both smoking and alcoholism. Among the male participants, 42.9% were both alcoholics and smokers and 81.3% were regular consumers of beverages like tea and coffee. All the patients participated in the study had disturbed sleep, which is the typical feature of insomnia. Also, 50% of the patients had regular dreams and the remaining 50% had occasional dreams.

In the current study, 43.8% people had constipated bowel, 18.8 % had loose bowel and 6.3% had irregular bowel habit. Majority (81%) of the patients had to get up more than twice at night due to increased bladder frequency. In the group, 43.8 % don't exercise, 37.5 % regularly exercise and the rest performed mild or moderate exercise. Among the 9 females who took part in the study only 33.3 % was still menstruating and the rest had achieved menopause. The participants were predominantly of *vata-kaphaprakriti* (50%) contrary to the expected

vata/pitta/vata-pitta prakriti. Among the remaining participants, 37.5% were found to have *vata-pitta prakriti* and the rest were *kapha-pitta prakriti*. Most common *sativaprakriti* found in the members of the study was *tamas* and *rajas*. There were 31.3 % of people with *satwa - rajas* combination also.
(b) ETIOLOGICAL DATA

INTERPRETATION

1. Duration of symptoms

The duration of symptoms in 31.3 % patients was less than 6 months. Majority had duration greater than 1 year. There were patients with 13 years and 20 years symptom duration.

2. Mode of onset

Altogether, 68.8% of the patients had gradual onset. Most of them complained of an initial episode of late onset of sleep. In the case of acute onset, there were strong pre- disposing factors that made the person vulnerable.

3. Presence of financial stress

In the study, only one fourth of the patient complained of financial stress. In the presentation of primary insomnia, there is no relevance for accounting of a stress factor. Hence, the lack of financial stress points into the accuracy of diagnosis.

4. Job satisfaction

Within the employed group, 50 % complained lack of job satisfaction.

5. Marital issues

Among the 12 married people, 41.7 % had incompatibility issues with their spouse.

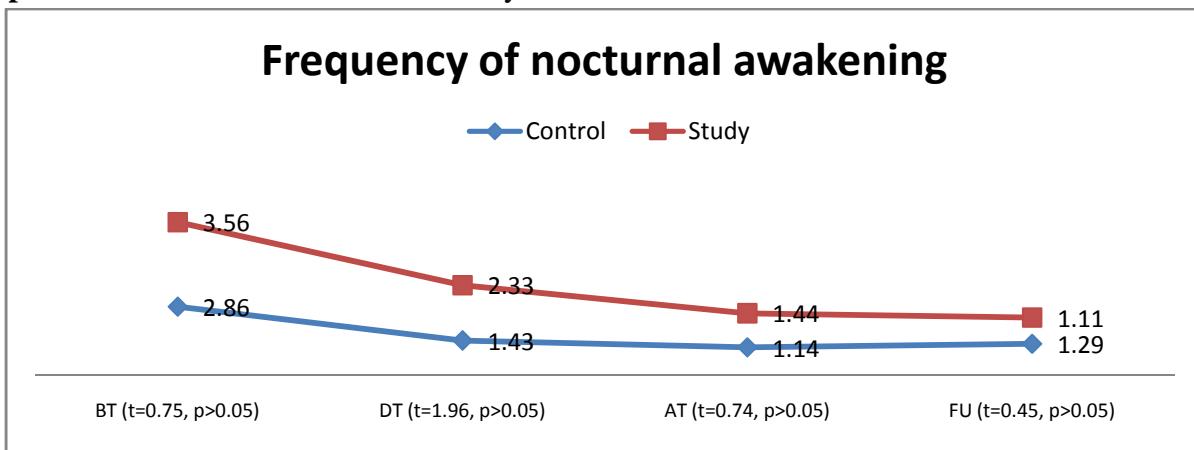
6. Living alone

In the group, out of 16 only 2 were found to be living alone.

7. Seasonal influence

In 37.5 % participants there was an increase in symptoms during hot climate. But the data is not sufficient to derive a relation between environment and sleeplessness.

Graph 1: Mean FNA score across the study



BT – Before treatment, DT – During treatment, AT – After treatment, FU – Follow-up

Mean FNA in the study group was 3.56 before the treatment, while in control group it was 2.86 (Graph: 1). There was a considerable decrease in no: of nocturnal awakenings in both the groups during treatment, but the difference was not significant statistically among the groups ($t=1.96$, $p>0.05$). The therapy was found to be effective in handling the frequency of nocturnal awakenings since the mean showed a tendency to decline after

(c) EFFECT OF THE THERAPY

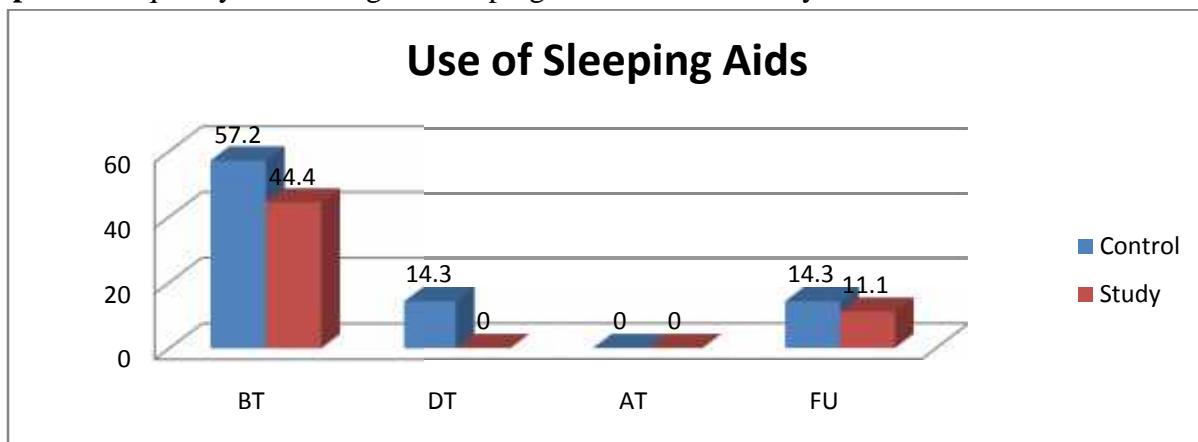
The effect of therapy was measured on the basis of statistical evaluation of the following variables:

1. Frequency of nocturnal awakening (FNA)

the treatment in both the groups though not statistically significant ($t=0.74$, $p>0.05$). In the follow up period, the mean of FNA remained low, but there was no significant difference ($t=0.45$, $p>0.05$) between the study and control groups. It could be inferred that *trinapanchamoolaksheeradhabra* and *ksheeradhabra* was equally good in reducing nocturnal awakenings.

2. Use of sleep aids

Graph 2: Frequency of the usage of sleeping aids across the study



BT – Before treatment, DT – During treatment, AT – After treatment, FU – Follow-up

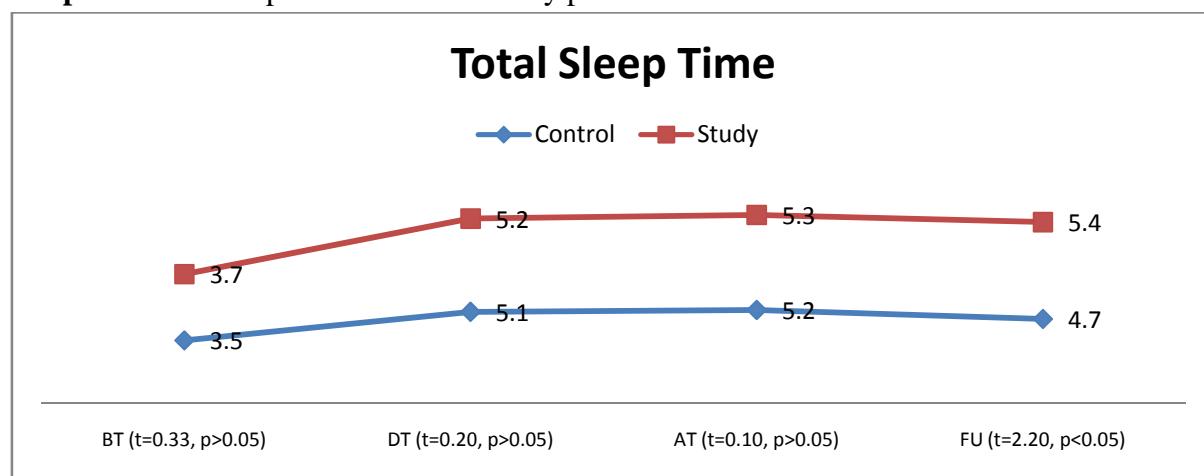
Use of sleeping pills / aids was assessed to know the severity of the illness prior to the therapy. Before treatment, 44.4 % in the study group and 57.1 % in the control group were using sleeping aids – mostly sleeping pills, with prescription and as OTC. After the treatment, the sleep aids were nil in both the groups. But during follow up, there was a marginal increase in the usage of sleep aids (Graph: 2).

3. Mood on awakening

Before starting the therapy, all the participants in the study group and 57.1% in the control group experienced depressed mood on awakening. During treatment, both the groups responded well. After the treatment, the study group had only 11.1% participants with sad mood while getting up and in the control group it was zero. Follow up data showed a slight increase in the no: of patients with sad mood on awakening in the study group.

4. Total Sleep Time (TST)

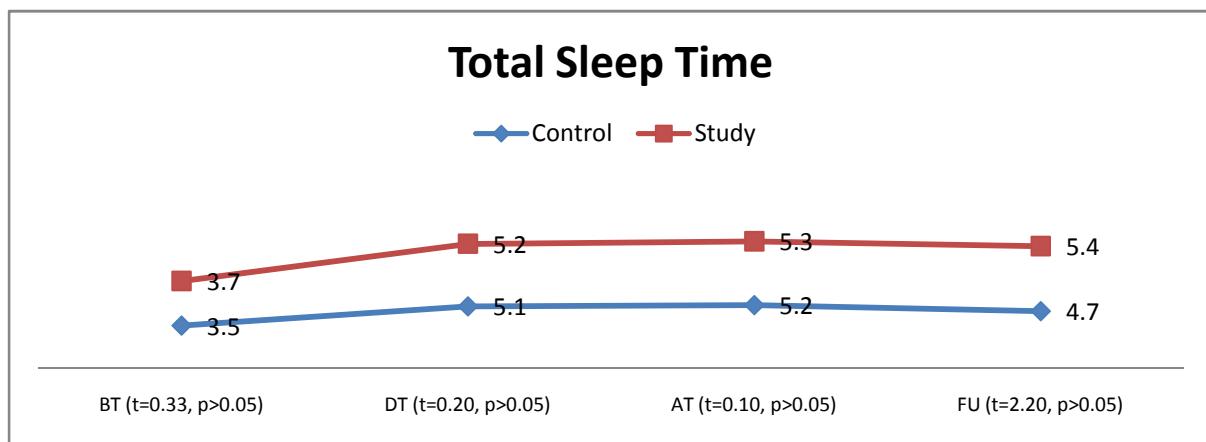
Graph 3: Total sleep time across the study period



BT – Before treatment, DT – During treatment, AT – After treatment, FU – Follow-up

It is counted as the hours of actual sleep deducted from the total time spent in bed. It is a marker of adequate sleep. From graph 3, initially the average TST was 3.78 hours in the study group and 3.56 hours in control group. During the treatment there was an increase in mean TST score (5.22 and 5.14 respectively). After treatment, this further increased without any statistically significant difference ($t=0.10$, $p>0.05$) between the groups. During follow up, there was significant difference ($t=2.20$, $p<0.05$) found between the groups; the group with *Trinapanchamoolaksheeradhara* improved in total sleep hours. The average hours of sleep didn't touch the optimum level, but it reduced the patients discomfort considerably.

Graph 4: Pittsburg Sleep Quality Index scores across the study



BT –Before treatment, DT – During treatment, AT – After treatment, FU – Follow-up

6. SAS Score

The average Sleep Assessment Scale (SAS) Score of the study group was 9.0 and that of control group was 8.71 before treatment. During treatment there was a score reduction in both the groups. Immediately after the

5. PSQI Score

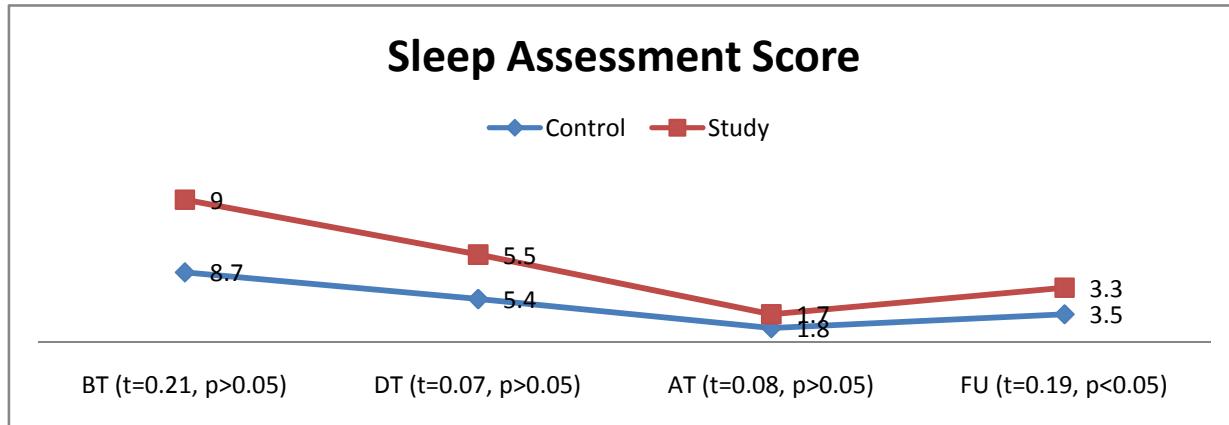
Pittsburgh sleep quality index is a diagnostic tool used to grade the distress caused by insomnia. In the current study (graph: 4) it was used for diagnostic purpose as well as for assessing the efficacy of treatment. Before treatment, the mean PSQI score of study group was 15.89 and 15.00 in control group. There was a decrease in the mean score during and after the therapy in both groups. There was a better result observed in the control group. In the follow up, there were almost similar scores in both groups. Once again, equal efficacy of both medicated and non medicated *ksheeradhara* was witnessed.

therapy the score improved to the maximum, 1.73 in study group and 1.86 in control group ($t=0.08$, $p>0.05$) indicating a considerable change in relieving the signs and symptoms of insomnia. But during follow up, the score showed a slight increase in both groups, suggestive of the lack of sustained action of

ksheeradhara. Here too, there was no statistically significant difference ($t=0.19$,

$p>0.05$) among the groups.

Group 5: Sleep Assessment Score (SAS) across the study



BT – Before treatment, DT – During treatment, AT – After treatment, FU – Follow-up

DISCUSSION

Alpanidratha is due to increased *rukshatha* in the body which results from *soumyadhathukshaya*, attributed to the rise in *vata* and *pitta* and subsequent *sleshmasoshana*. The increased *rukshatha* when combined with *rasavahasrotodushti* (*rasa kshaya*) due to *athichinthanadinidana*, manifests somatically as *nidranasa* or *alpanidratha*. A careful estimation of factors promoting *nidra*, reveals the importance of *manas*.

klaanthamanah is told to be *nidrahetu*, but *klama* is “*sleshmatamo bhava*”. Here there is reasonable *sleshmakshaya* and that accounts to the failure in initiation of sleep. *Tamas* enables the individuals to attain a ground level when all their energy (*satwa* and *rajas*) are spent on daytime activities. The bodily exhaustion signals *tamas* to take control and as a result the *indriyas* and *manas* are slumbered into a

timed stupor. But when there is *vatavriddhi* (as norms in *vardhakya*) or *pitta vridhi* (in *grishma*) or *vatapitavridhi* (as in *manovikaras* like *krodha*, *soka*, *bhaya* and in *jwaradivyadhis*) or *satwagunadhidhya* (as in *adhyayana*, *dhyana*, as norms of *rishicharya*), *rajovridhi* (as in stress or excitement) and *tamonasa* (obviously due to *jagrathavastha* of *mana* due to *satwarajoaadhikya*) there will be disturbance to this rhythm.

By definition of primary insomnia, the condition shouldn't be associated with any organic illness or psychiatric disease which makes it purely somatic. That implies the condition which we are dealing is a *vata-pitta vridhi* and that too of a chronic nature. By default *vata* – *paitikaaadhikya* tends to be acute. Here we don't observe any associated symptoms involving acuteness. Then we have to assume that the condition is subtler than similar *Vata* – *pitta dushti*. And hence, there is

no need of vigorous *brimhana*. *Samana* therapy with an acute and chronic impact is apt.

Efficacy of trinapanchamoolaksheeradhabra in insomnia

The intervention done was found to be effective in reducing the symptoms of insomnia like frequent nocturnal awakening, depressed mood on awakening and difficulty in falling asleep.

The sleep quality was improved in both groups. Both the study and control interventions proved equally useful in withdrawing sleep aids. Qualitative and quantitative evaluation of sleep couldn't elicit any statistically valid difference between the groups. The study group had a better total sleep time in the follow up period compared to the control group, indicating the sustained effect of *trinapanchamoola* in increasing sleep hours.

Probable mode of action

Probable mode of action of drug based on its therapeutic properties: *Trinapanchamoola* is *Madhura* and *Kashaya rasa* predominant. *Acharya Vaghbata* includes roots of *Kusa*, *Ikshu*, *Darbha*, *Sara* and *Sali* in this group. This *gana* is extreme *sitavirya*, *snigdthaguna* and *madhuravipaka*. Although mainly indicated in *mutrakrichra*, this group of drugs with their *pittaharatva* would really prove beneficial in *nidranasa* where *pitta kopa* is inevitable. Moreover, the idea that *gana* can be formulated in any of the *panchavidhakashayakalpana* lead to the

choice of *kalpana* as *ksheerapaka*. *Ksheera* with its pharmacological properties like *seethaveerya*, *snigdha* – *guru guna* and *madhuravipaka*, do pacify both *vata* and *pitta* and is thus exactly opposite to the *doshavikalpa* that is happening in *nidranasa*. Further cow's milk with its *rasayana* and *jeevaneeyaguna* will surely soothe the functioning of *indriyas* and thereby pave way for the proper initiation of sleep. The relative *kaphavridhi* occurring due to the use of *ksheera* also promotes the *tamoguna* to initiate sleep.

CONCLUSION

Ksheeraseka told in the classics as a remedy for sleeplessness, is found to be effective in inducing, maintaining and restoring sleep in people with sleep disorder. It can be chosen as an easy remedy for providing adequate sleep in patients with sleep disturbances mostly in an in- patient set up where *takradhara* require a lot of pre-operative preparations and *tailadhara* being costly. Sustained impact on total sleep time gives us a hope in providing an alternate to barbiturates and other sleep inducing CNS depressants.

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