

A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF SANKHA-PUSHPI CHOORNA WITH SAHAPANA OF KSHEERA AND DRAKSHA SWARASA IN NIDRANASHA W.S.R.TO PRIMARY INSOMNIA

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ABSTRACT

Background: Sleep has occupied a special place in human concern. It has been rightly stated by Acharya Charaka that happiness and misery, proper and improper growth, good strength and weakness, potency and sterility, knowledge and ignorance, life and death of an individual depend on the quality of sleep. The condition of Insomnia has tendency to damage the person's daily life, including his social and occupational life. Considering this *Sankhapushpi Choorna* with *Go ksheera* and *Draksha Swarasa* were selected for this study. *Sankhapushpi Choorna* has the property of *Nidrajanana* and *Medhya*. *Ksheera* has the property of *VataPitta Shamana* and *Draksha* has the property of *Pitta Kapha Shamana*, *Rakta Prasadana*.

Methods: The study was Randomized parallel Group comparison clinical study. The study was conducted in 60 subjects for a period of 30 days. Subjective and objective parameters were documented at base line, 7th day, 15th day and on 30th day. Observations were analysed and findings were evaluated by using statistical methods.

Results: This study shows that both *Sankhapushpi Choorna* with *Ksheera* and *Sankhapushpi Choorna* with *Draksha Swarasa* have significant effect in *Nidranasha*.

Conclusion: The result obtained was both *Sankhapushpi Choorna* with *Ksheera* and *Sankhapushpi Choorna* with *Draksha Swarasa* have significant effect in *Nidranasha*. There is no significant difference in effect of *Sankhapushpi Choorna* with *Ksheera* and *Sankhapushpi Choorna* with *Draksha Swarasa*.

Keywords: Sankhapushpi Choorna, Ksheera, Draksha, Nidranasha, Sahapana, Primary Insomnia

INTRODUCTION

Nidra is one among the *Trayopastambha* in Ayurveda and supports the wellbeing of an individual. Sleep disorders are increasing day by day for various reasons related to lifestyle and profession. In India Insomnia has a prevalence of 10% - 48% in the general population of which 18.6% was reported in South India¹. Primary Insomnia is associated with substantial impairment in an individual's quality of life, impacting health, work and healthcare cost. Insomnia left untreated may reduce the mental and physical efficiency and drag the individual towards several psycho-somatic disorders. *Nidranasha* is caused by aggravated *Vayu*, *Pitta*, an aggrieved state of the mind, wasting of *Dhatu*, and trauma². Contemporary management for Insomnia is mainly by tranquilizers, anti-depressants, sedatives and hypnotics. Long term use of these may cause various side effects including drug dependency. *Sankhapushpi*³ is having the properties such as *Tikta Rasa*, *Snigdha*, *Picchila Guna*, *Sheeta Virya*, *Pitta Kapha Hara*, and has the *Karma* as *Nidrajanana*, *Moha Nashaka*, *Rasayana* and *Medhya*⁴. *Go ksheera*⁵ and *Draksha*⁶ are also having the properties of *Nidrajanana*. Having *Madhurarasa*, *Mridu*, *Snigdha*, *Sheeta Virya* and *Vata Pitta Shamaka* properties⁷ and *Madhura Rasa*, *Guru*, *Snigdha*, *Mridu-Guna*, *Seeta Virya*, *Vata Pitta Shamaka* properties and *Karma* as *Rakta Prasadana*, *Dourbalya Nashaka* and *Balya* respectively. *Sahapana* refers to a *Dravya* taken along with the medicine, which enables the medicine to get absorbed into the body and spread its action quickly all over the body⁸.

Materials and Methods

Objectives of the study

1. To evaluate the efficacy of *Sankhapushpi Choorna* with *Ksheera* in *Nidranasha*
2. To evaluate the efficacy of *Sankhapushpi Choorna* with *Draksha Swarasa* in *Nidranasha*
3. To compare the efficacy of *Sankhapushpi Choorna* with *Ksheera* and *Sankhapushpi Choorna* with *Draksha Swarasa* in *Nidranasha*

Source of Data

Sample Source: People suffering from *Nidranasha* visiting OPD and IPD of Kayachikitsa of Alva's Ayurveda Medical College Hospital, Moodbidri.

Drug Source: Raw drugs collected from the source of procurement and identified by experts concerned.

Sankhapushpi (whole plant) *Choorna* prepared at Alva's Pharmacy, Mijar, Moodbidri.

Method of sampling: Lottery Method. Patients diagnosed with *Nidranasha* were randomly allocated into two groups A and B.

Criteria For Selection Of Patients

Diagnostic criteria: Diagnosis made according to the guidelines mentioned in ICD-10⁹.

1. A complaint of difficulty falling asleep, maintaining sleep, or non-refreshing sleep.
2. The sleep disturbance occurs at least three times per week for at least one month.
3. The sleep disturbance results in marked personal distress or interference with personal functioning in daily living.
4. Absence of any known causative organic factor, such as neurological or other medical condition, psycho active substance use disorder or a medication.

Inclusion Criteria: Patients having *Lakshana* of *Nidranasha* and Patients between 16- 60 years of age.

Exclusion Criteria: Insomnia secondary to Major mental disorders, Pregnant Women and Lactating Mothers, Insomnia caused by other Medical conditions.

Study Design: Randomized parallel Group comparison clinical study.

Intervention: Group A – Participants were given with 3g of *Sankhapushpi Choorna* with 50ml of *Ksheera* at night after food for 14 days. Group B - Participants were given with 3g of *Sankhapushpi Choorna* with 50ml of *Draksha Swarasa* at night after food for 14 days.

Observation Period: Patients were assessed with Subjective and objective parameters at baseline and on 7th

day during treatment and on 15th day after treatment and follow up was on 30th day. Total study duration was 30 days.

Assessment Criteria: Primary outcomes were *Angamarda, Shirogurava, Jrumbha, Jadya, Glani, Bhrama* and *Apakti*. Secondary outcomes were the criteria mentioned in Athens Insomnia Scale.

Results

There were 60 patients of *Nidranasha* registered for the study and were randomly allocated into two groups A&B. Group A had 30 patients and Group B had 30 patients. Totally 60 patients completed the clinical trial. In Group A, 30 Patients were given with *Sankhapushpi Choorna* with *Ksheera* and Group B, 30 patients were given *Sankhapushpi Choorna* with *Draksha Swarasa*. Summary statistics have been interpreted for S.D, SE, MD, MEAN, t-value, p-value. Test of results within the group by using paired t-test and between the groups by using unpaired t-test. Subjective parameters that assessed for the study were *Angamarda, Shirogurava, Jrumbha, Jadya, Glani, Bhrama* and *Apakti*. Objective parameters that taken for assessment were Sleep induction, Awakening during night, Final awakening, Total sleep duration, Sleep quality, Wellbeing during the day, Functioning capacity during the day and Sleepiness during the day. Both the individual effect of parameters on baseline, 7th day, 15th day and 30th day in Group A and B were compared. Effect of *Sankhapushpi Choorna* with *Ksheera* and *Sankhapushpi Choorna* with *Draksha Swarasa* on Subjective Parameters were analyzed statistically, difference was significant at the level of ($p < 0.001$). (Table No.1). Effect of *Sankhapushpi Choorna* with *Ksheera* and *Sankhapushpi Choorna* with *Draksha Swarasa* on Athens Insomnia Scale were analyzed statistically, difference was significant at the level of ($p < 0.001$) (Table No.2). While comparing both groups on Subjective parameters *Angamarda, jrumbha* and *jaadya* shows significant values and all other parameters shows insignificant results. (Table No.3). While comparing both groups on Athens Insomnia Scale shows insignificant result with p value 0.65. (Table No.4)

DISCUSSION

Discussion on Observation

Gender Incidence: Majority of patients were female i.e.58.3%. The production of various neuro-endocrinal hormones differs in female during puberty, menstrual cycles, pregnancy, and menopause. The shifting of ratios of hormones can be an unsettling process, this contributing to the inability to fall asleep.

Age: All the patients in this series were between the age of 16 to 60 years. This study shows 46.6% subjects from 16-30 age group, 30% were 31-45 age group and 23.3% subjects from 46-60 age group. It showed that primary insomnia is common in older adults due to certain biological changes like shift in circadian rhythm that make sleep more difficult as we age.

Religion: In this study 48.3% of the patients were Hindus. It does not mean that Hindus are more prone to this disease, this may be due to the fact that the area had more Hindus, and the patients were elected incidentally.

Occupation: In this series maximum no. of patients (21.6%) were housewives and IT professionals- Maybe middle-aged women are having more stress because of nearing to the Menopause. And IT professionals having more stress over work.

Socio economic status: Primary Insomnia has been considered a disease of the intelligent and middle social class, because of the stress. But higher classes and lower-class people are not exposing to mental stress as much. Middle class people do hard mental work. So, it is more common in middle social class.

Marital status: 81.6% of patients were married, it shows that due to family problem and stress in working field may lead to the condition of primary insomnia in them.

Addiction: Clinical study shows that 50% of patients were addicted to Tea/Coffee. Caffeine is an alkaloid which is present in coffee and tea which has a stimulant action on CNS and increased mental activity, thereby causing reduced sleep.

Prakriti: The *Deha Prakriti* of the patients suffering from primary insomnia was assessed, based on the physical, psychological and behavioral factors mentioned in Ayurvedic classics. In this study maximum

patients belong to *Vatapitta Prakriti*. This is obvious as *Nidranasha* is caused due to *Vata* vitiation. And also, it is revealed that the majority of patients has *Rajasika Prakriti* followed *Rajasika satvika* property.

Chronicity: Majority of the patients were having chronicity ranging from 6months to 1year may be due to lack of sleep hygiene.

Dietary habits: 91.6% patients of this series were mixed dietarians and remaining 8.6% were vegetarian- as a greater number of patients are from costal belt and their dietary habit is mixed.

Specific Hetu: Out of 60 patients, specific *Hetu* of *Nidranasha* was *Chinta* which was observed in 25% of patients. As *Chinta* is said to be the direct cause for *Nidranasha* as they provoke *Raja*, *Vata*, *Pitta* and decreases *Satva*, *Tama* and *Kapha* and cause *Nidranasha*. *Chinta* or stress activates the HPA system, activation of HPA and/ or the sympathetic nervous system results in wakefulness and these hormones including Corticotropin-releasing hormone (CRH), Adreno corticotropic hormone (ACTH), Cortisol, Corticosterone, Nor-adrenaline and Adrenaline are associated with attention and arousal.

Discussion on Result

In the clinical trial the given drug Group A and B (the interventions done in group A and B) had very good response in relieving the symptoms, which were also statistically significant. Both *Sankhapushpi Choorna* with *Ksheera* and *Sankhapushpi choorna* with *Draksha swarasa* showed statistically significant difference in all the assessment criteria. Further it was accepted that, there was no significant statistical difference in the effect of *Sanhkapushpi Choorna* with *Ksheera* and *Sanhkapushpi Choorna* with *Draksha swarasa* in *Nidranasha*.

On comparison between 2 groups in assessment criteria there was statistical difference seen for *Angamarda*, *Jrumbha* and *Jaadya*. All other subjective and Objective parameters showed no statistically significant difference between the groups.

Probable mode of action of Drugs

Sankhapushpi: Rasa of *Sankhapushpi* i *Tikta Rasa* with *Snigdha*, *Picchila guna*, *Sheeta Virya* and *Madhura Vipaka*. Main chemical constituent is

Alkaloids contains-convolamine, convoline, phylalabine, convoline, convosine, Convolvine, confoline, convolidine, sankhapushpine, β -sitosterol, Scooletin, kaempferol, N-hexacosanol, Hydroxy cinnamic acid. Also, volatile oils, Fatty acids, fatty alcohols, hydrocarbons, myristic acids, palmitic acids and linoleic acids are found. The flavonoids, glycosides and alkaloids help soothe our nervous system by bringing relief to mental fatigue. Thiopental sodium present in the *sankhapushpi* also may contribute for inducing sleep.

Milk: It contains amino acid known as tryptophan which help to induce sleep. Milk also contains melatonin, a hormone that regulate the sleep wake cycle.

Draksha: Rasa of *Draksha* is *Madhura Rasa* with *Guru*, *Snigdha*, *Mridu guna*, *Sheeta Virya*, and *Madhura Vipaka*. *Madhura rasa* helps in the *shamana* of *Vata Dosha*.

CONCLUSION

Nidranasha is included in 80 *vata roga* caused due to the morbidity of the *Vata* and *Pitta Dosha* and *Mano Dosha Rajas* involving *Rasa Dhatu*, commonly associated with *Angamarda*, *Shirogaurava*, *Jrumbha*, *Jadya*, *Glani*, *Bhrama* and *Apakti*. Both *Sankhapushpi Choorna* with *Ksheera* and *Sankhapushpi Choorna* with *Draksha Swarasa* showed statistically significant effect in all the criteria.

On comparison between the two groups post treatment with assessment criteria there is statistical difference only for *Angamarda*, *Jrumbha*, *Jaadya*. All other subjective and Objective parameters show statistically insignificant difference. Hence the conclusion drawn was, there was no significant difference in the effect of *Sankhapushpi choorna* with *Ksheera* and *Sankhapushpi choorna* with *Draksha swarasa* in *Nidranasha*.

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Table 1: Statistical Results For Subjective Parameters

Parameters	Group	BT mean	DT	MD	%	S.D	S.E	t- value	p-value
<i>Angamarda</i>	A	2.33	D7	0.77	33.04	0.43	0.07	9.76	<0.001
			AT	1.46	62.6	0.68	0.12	11.78	<0.001
			AF	2.07	88.8	1.04	0.19	10.79	<0.001
	B	1.4	D7	0.77	33.04	0.43	0.07	9.76	<0.001
			AT	1.46	62.6	0.68	0.12	11.78	<0.001
			AF	2.07	88.8	1.04	0.19	10.79	<0.001
<i>Shirogourava</i>	A	2.4	D7	0.83	34.58	0.37	0.06	12.04	<0.001
			AT	1.6	66.66	0.62	0.13	14.1	<0.001
			AF	2.16	90	0.87	0.16	13.57	<0.001
	B	2.1	D7	0.43	20.47	0.5	0.09	4.7	<0.001
			AT	1.3	61.9	0.59	0.1	11.94	<0.001
			AF	2.13		0.77	0.14	15.05	<0.001
<i>Jrumbha</i>	A	2.1	D7	0.7	33.3	0.46	0.08	8.23	<0.001
			AT	1.37	65.23	0.8	0.15	9.25	<0.001
			AF	1.87	89.04	1.19	0.21	8.56	<0.001
	B	0.87	D7	0.2	22.9	0.4	0.07	2.69	<0.001
			AT	0.63	72.4	0.8	0.14	4.28	<0.001
			AF	0.8	91.9	0.99	0.18	4.39	<0.001
<i>Jaadya</i>	A	2.13	D7	0.76	35.6	0.43	0.07	9.76	<0.001
			AT	1.46	68.5	0.68	0.12	11.78	<0.001
			AF	1.9	89.2	1.02	0.18	10.11	<0.001
	B	0.7	D7	0.3	42.8	0.46	0.08	3.52	<0.001
			AT	0.66	94.2	0.66	0.12	5.52	<0.001
			AF	0.7	100	0	0	5.46	<0.001
<i>Glani</i>	A	1.7	D7	0.66	38.8	0.47	0.08	7.6	<0.001
			AT	1.13	66.4	0.86	0.15	7.21	<0.001
			AF	1.43	84.1	1.04	0.19	7.54	<0.001
	B	0.9	D7	0.13	14.4	0.34	0.06	2.11	<0.001
			AT	0.73	81.1	0.58	0.1	6.88	<0.001
			AF	0.9	100	0	0	6.92	<0.001
<i>Bhrama</i>	A	0.56	D7	0.36	64.2	0.49	0.08	4.09	<0.001
			AT	0.53	94.6	0.68	0.12	4.28	<0.001
			AF	0.56	100	0.77	0.14	4.01	<0.001
	B	0.63	D7	0.56	88.8	0.5	0.09	6.15	<0.001

			AT	0.63	100	0.49	0.08	7.07	<0.001
			AF	0.63	100	0.49	0.08	7.07	<0.001
Apakti	A	1.43	D7	0.46	32.1	0.5	0.09	5.03	<0.001
			AT	0.9	62.9	0.88	0.16	5.57	<0.001
			AF	1.26	88.1	1.31	0.23	5.29	<0.001
	B	1.43	D7	0.4	27.9	0.49	0.09	4.39	<0.001
			AT	0.93	65	0.78	0.14	6.51	<0.001
			AF	0.25	17.4	1.09	0.2	6.81	<0.001

Table 2: Statistical Results On Objective Parameters

Assessment criteria	Mean score				%	SD	SE	t value	p value
	BT			BT-AT					
Athens in-somnia scale		DT-7	9.8	3.7	27.4	3.09	0.56	6.54	<0.001
	13.5	AT-15	4.66	8.83	65.4	4.43	0.81	10.91	<0.001
		AF-30	0.9	12.6	93.33	5.32	0.97	12.95	<0.001

Table 3: Statistical Results While Comparing the Subjective Parameters

Parameters	Group	Mean	MD	Unpaired t test			
				S.D	S.E	t value	p value
Angamarda	Group A	0.86	0.5	0.5	0.09	3.63	<0.001
	Group B	0.36		0.55	0.1		
Shirogourava	Group A	0.8	0.06	0.55	0.1	0.52	0.6
	Group B	0.86		0.43	0.07		
Jrumha	Group A	0.73	0.5	0.52	0.09	3.77	<0.001
	Group B	0.23		0.5	0.09		
Jaadya	Group A	0.66	0.63	0.54	0.09	6.01	<0.001
	Group B	0.03		0.18	0.03		
Glani	Group A	0.56	0.4	0.67	0.12	2.81	0.007
	Group B	0.16		0.37	0.06		
Bhrama	Group A	0.03	0.03	0.18	0.03	1	0.32
	Group B	0		0	0		
Apakti	Group A	0.53	0.03	0.57	0.1	0.22	0.82
	Group B	0.5		0.57	0.1		

Table 4: Statistical Results While Comparing the Objective Parameters

Groups	Mean	Deference in mean	Unpaired t test			
			SD	SE	't' value	P value
Group A	4.66	0.4	2.98	0.54	0.44	0.657
Group B	3.89		3.89	0.71		

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