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RESEARCH ARTICLE

A COMPARATIVE CLINICAL STUDY OF KANAMULA CHURNA AND SHIRODHARA WITH CHAKRA TAILA IN CASES OF ANIDRA

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ABSTRACT

Anidra is a disorder where the sufferer complains of loss of sleep during its natural time i.e. night. It has been classified under Vata Nanatmaj Vyadhi. Vata plays a key role in producing Anidra. Vata being Satva Rajo Guna Pradhana and Laghu, is quite opposite to the factors inducing sleep e.g. Kapha which is Guru, Manda and Tamoguna Pradhana. Thus, both being diametrically opposite are the causative factors for Nidra (Kapha) and Anidra (Vata). Ayurvedic classics also implicate Pitta as an adjuvant cause in the pathogenesis of Anidra. Pitta is Satva Rajas Guna Pradhana. Thus, it also constitutes of the elements opposite to the Tamah Guna and is instrumental in causing Anidra. A simultaneous Kshaya (decrease in Kapha) accentuates the process. All these factors work at the physiological level to produce Anidra. The Chikitsa sutra of Anidra carries three main measures, Shamana of the vitiated Vata, enhancing the Kapha and putting Manah to peace. Vata Nashana procedures include Snehana in the form of Abhyanga, Tarpan, Dhara. Kapha is enhanced by using Vrinhana, Balya, Rasayana Ahara and Vihara. Manasik Santap can be relieved by using measures for mental relaxation e.g. Shauch, Santosh, Ishwar Pranidhana. Eleven months of intensive trial and study yielded encouraging results. 80-85% patients reported complete relief from the disease, while others had considerable respite. There were no adverse effects as reported by the patients and drug was tolerated quite well. None of the patients reported addiction or dependence and there was no craving after the drug was stopped.

INTRODUCTION

Nidra is a reversible state of unconsciousness occurring naturally and distinguishable from unconsciousness due to organic cause by the fact that the person is easily arousable. Hence Nidra is opposite to wakefulness physiologically occurring for a certain length of time which generally extends for 6-8 hours in normal adults.

A condition where the sufferer complains of loss of Nidra (sleep) during its natural time i.e. Ratri (night) is called Anidra. It is a pathological condition. Naidanik bhavas contributing to the condition of Anidra can broadly be listed under Sharirik (somatic), manas (psychological) and Agantuja in origin. These result in accumulation of concerning doshas (Rajas, Vata and Pitta) and simultaneous Tamah and Kapha kshaya in Monovaha srotasas. Despite the absence of specific Samprapti Ayurvedic texts clearly implicate vitiation of Vata and Pitta doshas and derangement of Manovaha srotasas in pathogenesis of Anidra. Dalhana cleared the picture further; Vata dosha vridhi and Kapha Kshaya occur simultaneously in the body. There can be no nidra without kapha. Such people experience Vaikariki type of Nidra where a person does not get Nidra (sleep) at all (Anidra) and the little Nidra (sleep) he manages is abnormal.[1]

True to Ayurvedic spirit, management of Anidra in various Ayurvedic samhitas is multidimensional. Various modes applied are Ahara (diet), Vihara (behavioural/physical daily activities); Aushadhi (drugs), procedures (therapies) etc.

Anidra (insomnia) is a common sleep complaint. It is a perception that sleep quality is inadequate or non-restorative, despite the adequate opportunity to sleep. It is also associated with a variety of medical, psychiatric and sleep disorders.[2] A comprehensive history and physical examination are essential to determine the etiology of Anidra (insomnia).

The complaint of Anidra (insomnia) encompasses many sleep problems. These include: Difficulty in falling asleep, sleeping too lightly with multiple spontaneous awakening, inability to fall back asleep. On the basis of duration Anidra (insomnia) is divided into three types: Transient (Lasts upto one week), Short term (Lasts 1-6 months), Chronic (Lasting more than 6 months). A world health organization study conducted in 15 centres found a prevalence of approximately 27% for the complaint "difficulty in sleeping".[3]

Various therapies and preparations have been advocated in Ayurvedic samhitas to manage the cases of Anidra. In present drug trial two drug regimes was decided upon for clinical study to explore the extent of usefulness of this regime in cases of Anidra.

Kanamula Churna mentioned in Anidra was selected for oral therapy[4] and Chakra taila was selected for Shirodhara.[5]

In Ayurvedic literature 'taila' has been advocated as the drug of choice for Vatarogas. Being 'Sukshma' it is easily absorbed and being Vyavayi it is quickly absorbed and metabolised later. After samskara it is capable of curing all the diseases. Considering the conceptual principles, mode of application and maintaining the Vridhi and Kshaya of dosha and dhatu, it was decided to prescribe Chakra taial in a modified manner as Shirodhara in present series of cases of Anidra.

MATERIAL AND METHODS

Plan of Study

For the proposed comparative clinical study, the patients were selected from the OPD and IPD of the State Ayurvedic College and Hospital, Lucknow. Referred patients from other clinics and hospitals were also registered.

Selection and diagnosis of cases

History of the patient (Medical/Social/Personal)

Special attention was paid to the quality and quantity of physical and mental work he/she performed and thereby need of relaxation (amount of time) needed to regain the normal energetic levels. Daily sleep routine i.e. time of going to bed, number of sleep hours, keeping up late, short duration of sound sleep was mapped out. Environmental factors e.g. noisy areas of residence, uncomfortable bed were inquired about.

Emotional stress due to loss of a close associate, a new job, a deadline to fulfill, was also given equal attention. All these facts were assorted under the classical format given in the Ayurvedic texts consisting of predisposing factors for Anidra.

1. ***Kala:*** Time of going to bed and waking up, also multiple awakenings and the afternoon siesta.
2. ***Prakriti:*** Constitutional parameters (Vataja and Pittaja)
3. **Vikriti:** Increase of Vata and Pitta doshas and decrease of Kapha.
4. ***Vikara:*** Any chronic illness e.g. hypertension, renal disease, painful conditions, hyperpyrexia etc.
5. ***Abhighata:*** History of trauma
6. ***Manasika Santapa:*** History of stress, strain, anxiety, fears, worries, excitement etc.
7. ***Kshaya:*** Rasa Kshya - loss of weight to below the normal range or wasting.

Therapeutic history - History of drug intake, procedural complications of Vamana, Virechana, Nasya etc. and Upavasa (fasting).

Detailed Information about the Symptom Complex

Lakshanas - Patients were examined on the basis of a specific proforma especially prepared for the purpose. Classically mentioned Lakshanas/upadravas of nidranasha were used as the spectrum of clinical features to be sought in a patient of Anidra. They are as follows:

1) Jrimbha 5) Shirogaurav 9) Bhrama
2) Angamarda 6) Akshigaurav 10) Apakti
3)Tandra 7) Jadya/Jadata 11) Vata Rogas
4) Shiroroga8) Glani

Laboratory Investigations-To differentiate idiopathic Anidra from Anidra due to organic disease, laboratory investigations both routine and specific were advised, before registering the patients and after the completion of trial period. Also specific investigations to monitor the effects of the trial drug on the patients were advised at 15 days interval.

1. Complete haemogram: Hb, TLC, DLC, ESR, Blood sugar: - Fasting & PP
2. Routine urine (Routine & Microscopic) and stool examinations (Ova & cyst)
3. Fundoscopy

Specific investigations advised if possible and as and when required are as follows:

1. SGPT
2. Serum creatinine
3. Blood arterial gases
4. Computerised axial tomography head
5. Polysomnography

Inclusion Criteria-The patients having complaints of Anidra least three consecutive nights, resulting at least six symptoms (Jrimbha, Angamarda, Tandra, Shiroroga, Shirogaurav, Akshigaurav, Jadya, Glani, Bhrama, Apakti & Vata Roga) mentioned as Upadravas of Nidranasha by Charak.

Exclusion Criteria-Patients having prolonged practice of Langhana (fasting), Abhighata janya rogas (diseases due to traumatic injury), Chirakari rogas (chronic diseases e.g. Tamaka shwasa, Hridroga, Mutraghata, Kampavata, Unmada, Ashthila Pratyashihila etc.) and cases of drug dependence were not included in study.

Selection of Drug

1. Kanamula Churna was selected for oral therapy.
2. Chakrataila for daily Shirobhyanga, to counter Shirorogas and provide strength to the mastishka and Indriyas.

In Ayurvedic literature taila has been advocated as the drug of choice for Vatarogas.[6] Being 'Sukshma' it is easily absorbed and being Vyavayi is quickly assimilated and metabolized later.[7-9] After Samksara it is capable of curing all the diseases.[6,10]

Considering the conceptual principles, mode of application and maintaining the balance related to Kshaya of dosha and dhatu it was decided to prescribe Chakra taila in a modified manner as Shirodhara in present series of cases of Anidra.

Kanamula Churna-Pippalimula- 2 gm orally/day HS with Gur 5.5 gm upto 8 weeks

Chakratail **(**Madhuyashti, Kshirvidan, Saral Kastha, Devadaru, Laghu Panchamula - in equal part & Til taial) Shirodhara 750ml/day, 10 days consecutively and thrice in a period of 8 weeks with a gap of 10 days between two cycles (10+10+10+10+10+10).

Method of Trial

For the purpose of study patients were divided in two groups randomly and all the patients were asked to stop all the

previous medication if any. The total period of study was eight weeks.

Group I: This group was advised oral therapy only with Kanamula Churna

Group II: This group was administered Shirodhara with Chakratail. In addition oral therapy mentioned in group I was also advised. The cases were assessed on weekly basis.

Assessment of Result

The result of present study was assessed under following categories:

- **Arogya:** Complete recovery: Patients returning to satisfactory sleep with proper circadian rhythms, without any Lakshana/Upadrava.
- **Kinchit Arogya.** Improved - obvious improvement in onset, maintenance rhythm and finally satisfaction from sleep, with minimum Lakshna/Upadrava.
- **Anarogya:** No improvement in symptoms.
- **Roga Vriddhi:** Increase in intensity and/or frequency of the symptoms.

Results of study were assessed clinically by changes in symptoms and complaints.

Follow Up: The patients were assessed in follow up care every 15 days as long as possible.

Observations

Based on 50 established cases of insomnia interesting observations have come forth.

Incidence of the disease in different age groups revealed that insomnia is most common in the age group 41-50 years (15, 30%). The age group 20-30 years (14, 28%) is the next most prone to develop Anidra (insomnia). Males are more prone to develop Anidra (insomnia) (29, 58%) than females (21, 42%). All the females who registered for the study were housewives so statistically Anidra was found more commonly in housewives (18, 36%). Majority of the registered patients were Hindus (48, 96%) so statistically in this set of patients, Hindus were predominant. Incidence of Anidra was found to be maximum (31, 62%) among vegetarians. Married people were found to be overwhelmingly prone (39, 78%) to Anidra. Majority of the registered patients (27, 54%) were addicted to tea. Anidra was found to be more common in educated people (47, 94%). People living in congested surroundings were found to be more prone to Anidra (42, 62%). People with no daily exercise were more prone to suffer from Anidra (36, 72%). People with vata pittaja and rajas prakriti were found to suffer more from Anidra (37, 74%).

Those with medium appetite were more prone to Anidra (25, 50%) while people with poor appetite were not for behind (17, 34%).

Clinical symptomatology as described in Ayurveda was found to be present in all the patients 100% in various combinations. Of the eleven symptoms four namely Jrimbha, Angmarda, Shirogaurav and Akshigaurava were found in all the patients (50, 100%). Shiroroga was found in (46, 92%). Tandra, Apakti, Jadya, Bhrama, Vatarogas and glani were found in 41 (82%), 32 (64), 24 (48%), 24 (48%), 20 (40%), 5 (10%) respectively.

Considering the sleep hygiene, levels majority of the patients showed good sleep hygiene. Among the patients, 45 (90%) had no recent change in the sleep schedule, 28 (56%) patients had adequate bed comfort. Majority of patients, 34 (68%) did not take any day time naps. Snoring was absent in 37 (74%). Of the 50 patients registered 22 (44%) did not use bed for any other purpose. None of the registered patients witnessed any apneoas or gasping during sleep. The number of patients with rest as a pre-bed time activity was maximum 31 (62%). Hence sleep hygiene was at optimum levels in majority patients registered for Anidra.

Majority of the people kept lying in bed when unable to sleep 32 (64%). Majority of patients had chronic insomnia (37, 74%). Of the 21 female patients registered, 12 (57.14%) were menopausal. Manah santap was present in all the cases of Anidra. Majority of the patients had social marital - and work related stress (15, 30%). Most common site of bed among the patients of Anidra was North (16, 32%) and Head to feet orientation was East to West (26, 52%).

RESULTS

Considering symptomatology in Group I, the general condition of majority of patients 28 (93.33%) was fair before the treatment. In Group II, all the 20 (100%) patients had a fair general condition prior to the treatment and none of the patients in both the groups had a good general condition. After the treatment all the patients 50 (100%) improved to the good category.

Majority of the patients had both onset and maintenance anidra (insomnia); 27 (90%) in Group I and 17 (85%) in Group II. This improved considerably in both the Groups and all the patients 50 (100%) fell under none category i.e. none of the patients had any type of anidra after treatment.

For an overwhelming majority of patients (29, 96.67%) in Group I and 20 (100%) in Group II no procedure succeeded in bringing sleep before the treatment. After the treatment no procedure was required in all 30 (100%) patients in Group I.

Variable	Group	Before Treatment (Mean ± SD)	After Treatment (Mean ± SD)	Change after Treatment (Mean ± SD)	't'	Y
Grading Day time effects	I	7.70±1.02	0±0	(-)7.70±1.02	41.26	<0.001
	II	7.95±1.23	0.15±0.68	(-)7.80±1.61	21.68	<0.001
Duration of Onset (in ks)	I	2.28±0.52	0.53±0.13	(-)l. 75±0.52	18.40	<0.001
	II	2.44±0.69	0.36±0.27	(-)2.08±0.67	13.76	<0.001
Duration of Sleep (in hrs)	I	3.90±0.31	6.80±0.41	2.90±0.48	33.05	<0.001
	II	3.70±0.47	6.75±0.55	3.05±0.51	32.76	<0.001
Number of Nocturnal awakenings	I	2.63±0.99	1.13±0.35	(-)1.50±0.90	9.13	<0.001
	II	2.85±1.09	1.00±0.0	(-) 1.85±1 .09	7.59	<0.001
Interval between two episodes	I	0.80±0.99	55.70±11.24	54.90±11.57	25.98	<0.001
	II	1.50±1.31	54.35±14.46	52.85±14.48	16.43	<0.001

In Group II, while 17 (85%) patients did not require any procedure to fall asleep after the treatment, 3 patients (15%) still required meditation etc.

There was no satisfaction from sleep in all 50 (100%) patients prior to the treatment. Post-treatment it improved to reach adequate levels in all 50 (100%) patients.

Vital Statistics

Variable	Group	Before Treatment (Mean + SD)	After Treatment (Mean + SD)	Change after Treatment (Mean + SD)	't[1]	V
Pulse rate (per minute)	I	75.73+3.55	72.00+0.00	3.73+3.55	5.76	0.001
	II	75.30+5.99	72.50+1.93	2.80+5.37	2.33	<0.05
Systolic BP (mmHg)	I	123.60+11.26	124.73+9.12	1.13+5.35	1.16	NS
	II	125.80+14.48	123.50+9.33	2.30+8.11	1.27	NS
Diastolic BP (mmHg)	I	80.73+8.16	81.33+6.29	0.64+5.04	0.65	NS
	II	79.40+7.76	79.00+6.41	0.40+4.73	0.38	NS
Respiration rate (per minute)	I	21.20+20.27	20.27+1.64	0.93+1.14	4.47	0.001
	II	20.90+1.82	20.10+1.52	0.80+1.05	3.42	0.001
Temperature (°C)	I	Normal	Normal	No change		
	II	Normal	Normal	No change		

Overall assessment

Group	Arogya		Kinchit Arogya		Anarogya		Roga Vridhi	
	No.	%	No.	%	No.	%	No.	%
Group I	24	80	6	20	-	-	-	-
Group II	17	85	3	15	-	-	-	-

Statistically, there was no significant difference in the results in two groups. But arogya is slightly better in the group II where Shirodhara was used concurrently with the oral drug therapy. This may be correlated with the fact that Shirodhara is a procedure for Snehana karma. This is Vatanashana and Kapha Vardhaka in action which results in decrease in vitiated Vata and enhancement in Kapha which results in nidrajanan effect. This added to the efficacy of the Kanamula churna thus providing better results.

Considering these facts we find that the present drugs used for the trial have produced a significant improvement in all the cases of Anidra in both groups. Patients of both the groups reported benefit in various aspects. Each and every aspect related to this disease was touched by the clinical trial.

There was an overall improvement in the patients regarding ability to fall asleep, maintain sleep and satisfaction from sleep. A complete multifaceted recovery process was initiated by the treatment which was evident in an improved general condition, reduced day time effects and absence of addiction, dependence and relapse.

DISCUSSION

Anidra, the psychosomatic disorder of modern civilization is purely a vatic (neurological) disease of worldwide prevalence. In Ayurvedic classics Anidra is commonly related to involvement of manovaha srotasas and indriyas resulting in impaired ability to concentrate, poor memory, reduction in working capability, stamina and leads to behavioural changes in human beings. In Ayurvedic classics murdha is the seat of prana vayu and tarpak shleshma. When these two vital elements are in equilibrium the manovaha srotasas and indriyas are able to perform in coordination and the phenomenon of nidra also occurs physiologically. When Vata, vitiated due to its naidanik hetus moves to reside in Uttamanga; manovaha srotasas and indriyas are involved and functional capacity of tarpak shleshma decreases qualitatively and quantitatively. Thus increase in vata and kapha kshaya leads to Anidra. In clinical practice variety of drugs are available to treat those types of cases symptomatically, the Ayurvedic approach to treat Anidra is multidimensional and counteracts the Naidanik Bhavas of Anidra. The present drug trial composed of dual therapeutic procedure i.e. oral drug therapy and locally Shirobhyanga in established cases of Anidra.

The probability of pharmacological actions of these procedures was hypothetically estimated on the basis of Ayurvedic principles and qualities of trial drugs. The constituents of these preparations presumably act in the manner discussed below.

Kanamula Churna with Gur (Anupana) **-** Both the drugs act on mahasrotas particularly the sthana of vata, because they are Rochan, Deepan, Pachan and Vatanuloman. So these drugs pacify the vitiated vata and somehow control the doshaya vikara of this disease. Side by side the drugs are Balya Brinhan Brishya and Rasayana. Thus they promote the function of Kapha Dosha (Tarpak Shleshma) and are Kaphavardhak in nature. Pippali Mula is also Medhya, hence it nourishes the manovaha srotasas and indriyas and thereby improves the function and increases the Tama Bhava during Ratrikala. Pippalimula is katu in rasa, snigdha, laghu tikshna in guna ushma in virya madhura in vipaka. Its nidrajanan properties can be attributed to its snigdha guna and madhura vipaka. It can also be perceived to be nidrajanan due to its prabhava.

Chakrataila used for Shirodhara **-** Chakra taila contains Kshirvidari, Madhuyashti, Devdaru, Saral Kashtha, Gokshur, brihati, kantakari, shalparni, prishniparni. Snehan karma like abhyanga, tarpana, murdha taila, lepan, shirodhara are the karmas (procedures) applied externally on the Uttamanga, the seat of buddhi, gyana, smriti, chetana and Viveka acts upon the sharirik and manasika doshas improves the function of manovaha srotasas and ultimately contributes to a change in life style in a human being. Most of the drugs are Madhura in rasa, guru, snigdha in guna and ushna in veerya, vata-pittaghna in action. Thus, these drugs are Kapha vardhak (tarpak shleshmd) in properties. Side by side some of the drugs are Balya, Vrishya, Nadibalya, brinhan, rasayan and medhya. So the combination of medicated oil Chakra tail used for shiro dhara in cases of Anidra definitely performs the classical views i.e. Vata hara, Snehan, Tarpan Karm at the site - manovaha srotas and indriyas. Thus, this procedure treats the unbalanced state of vitiated pran vayu and subdued Tarpak shleshma to a state of equilibrium and promotes the nidrajanan prabhava.

Discussion on Epidemiological Observations

Based on 50 established cases of insomnia interesting observations have come forth. Incidence of the disease in different age groups revealed that insomnia is most common in the age group 41-50 years (15, 30%). In our social set up

people belonging to this age group experience maximum mental stress, be it marital, social work related or financial boundations. Secondly, a simultaneous increase in Vata dosha ensues which is mentioned in Ayurvedic classics too. Vata vriddhi is well known as the main causative factor of Anidra. Males are more prone to develop Anidra (insomnia) (29, 58%) than females (21, 42%). Although times have changed, work profile of males still remains busier and stressful. Clearly mental stress is higher in males. Incidence of Anidra was found to be maximum (31, 62%) among vegetarians. Non vegetarian's diet is Kaph vardhak ahara, Mamsarasa finds special mention in the Ahara plan advocated by the classics. Non vegetarians thus have a higher threshold for acquiring Anidra. It being a Kaphavardhak and nidrajanan diet provides them with the required protection. Also, we find that the vegetarian diet is Satvik and non-vegetarian diet is highly tamasik. Nidra is tamogunapradhana while satvik people get a little sleep, as is mentioned in ayurvedic texts. The information provided by the data conforms to the above facts. Married people were found to be overwhelmingly prone (39, 78%) to Anidra. This is clearly due to high level of responsibilities and mental stress. Majority of the registered patients (27, 54%) were addicted to tea. Tea is a stimulant. Hence addiction to tea can cause Nidranash or Anidra. These figures also conform to the above fact.

Anidra was found to be more common in educated people (47, 94%). They handle jobs that require greater mental labour and hence involve more stress than the physical labour. Also an educated person faces more social stigma, uncertainty of employment, clash between ambitions and real achievements. Thus mental stress which is a naidanik bhava for Anidra is greater in educated people.

People living in congested surroundings were found to be more prone to Anidra (42, 62%). Congested localities have high disturbance level and social obligations. People living in overcrowded areas were generally from lower income group or people below poverty line who usually are involved in intense physical labour during the day. Thus they have no time for cares or tensions about the future. Lower mental stress levels save these people from falling prey to Anidra despite overcrowded surroundings.

People with no daily exercise were more prone to suffer from Anidra (36, 72%). Daily exercise helps to keep a healthy body which in turn is a prerequisite for a healthy mind. One can get physiological sleep only if manovaha srotas and indriyas are healthy. This is the cause why those with regular exercise were only (5, 10%) of the patients. People with vata pittaja and rajas prakriti were found to suffer more from Anidra (37, 74%). This conforms to the theory of Anidra in ayurvedic classics. Vata, pitta and rajas guna are most important factors causing Anidra. Hence prakriti with combination of these three is most likely to suffer from this disorder. Those with medium appetite were more prone to Anidra (25, 50%) while people with poor appetite were not for behind (17, 34%). With low appetite dhatuposhana and nutrition suffers. Thus rasa dhatu becomes Aposhit deficient and causing Anidra.

It was found that people belonging to middle class were greatly prone to suffer from Anidra. It is the middle class people who face social and work related stress along with marital stress and deadlines. There is a great difference between requirements and achievements resulting in dissatisfaction and stress. Thus mental stress being greater, in middle class people suffers more from Anidra.

CONCLUSION

The action of drug was excellent and nidrajanan effect was achieved within 4 weeks in majority of the cases. All the patients 100% could successfully go to sleep without the aid of any procedure, sleep inducing drugs etc. or with simple meditation and drinking milk after the trial. Both sleep hours and sleep maintenance increased significantly in the patients of two groups after the drug trial. General condition of all the patients (100%) improved significantly after the drug trial. There was a significant decrease in both systolic and diastolic blood pressure in these patients after the drug trial. No adverse effect was observed in any of the patients and the drug was very well tolerated by all in the prescribed dose. Patients did not develop any dependence or addiction for the drug as was observed in the follow up. No patient has reported any relapse till date. Kana mula churna with anupana of gur is deepan pachan and vatanashan, side by side it enhances the actions balya, brinhan, brishya, rasayan. Chakratail used for shirodhara promotes the action snehan, tarpon, nadibalya brishya medhya and rasayana thus vata pittaghna in nature and improves the functioning of Uttamanga and Pranayatan. The dual therapeutic approach applied in the clinical trial establishes a homeostasis between the vitiated Vata (prana vayu) and depleted Kapha (Tarpak shleshma) at the site of Nadisthana murdha. This phenomenon lies beneath its Nidra janana prabhava.

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