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Research Article

A COMPARATIVE STUDY TO EVALUATE THE EFFECT OF *BALA* AND *SHATAVARI SIDDHA KSHEERA SHIRODHARA* AND *TILA TAILA SHIRODHARA IN ANIDRA* (INSOMNIA)

Rani Pooja[1]*, Wetal.R.Vishakha[2], Gupta Arun[3]

*[1]Panchakarma Vaidya, All India Institute of Ayurveda, Gautam Puri, Sarita Viahar, New Delhi.
[2]Associate Professor, [3]Professor & HOD, Department of Panchakarma, Ch. Brahm Prakash Ayurved Charak Sansthan, Khera Dabar, Najafgarh, New Delhi.

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ABSTRACT

Anidra (Insomnia) means *"na nidra abhavarthe"* i.e. deprivation of sleep or disturbed sleep. It has been found that disturbed sleep or less sleep can lead to various medical conditions includes stroke, obesity, diabetes, hypertension and psychological problems etc. Treatment approach for insomnia in modern medicines includes hypnotics and sedatives which cause drug dependency and leads to ill-effects on health. In *Ayurveda* for the treatment of *Anidra*, *Shirodhara* (Oil dripping) procedure with different liquid media has been mentioned. This study has been designed to evaluate the effect of *Shirodhara* with *Bala* and *Shatavari Siddha Ksheera* and *Tila* oil. **Aim and objectives**: To compare the effect of *shirodhara* therapy between *Bala* and *Shatavari Siddha Ksheera* and *Tila tail* in *Anidra*.

Materials and method: The study was a randomized, parallel group comparative design clinical study. Total 131 patients diagnosed as *Anidra* (Insomnia) as per ICD -10 criteria were selected from Outpatient and in-patient in the department of Panchakarma from Ch. Brahm Prakash Ayurveda Charak Sansthan, New Delhi. India. All the patients were randomly divided into two groups A and B. Group A (66) received *Bala* and *Shatavari Siddha Ksheera Shirodhara*. Group B (60) received *Tila Taila Shirodhara* for 14 days which includes *Shirodhara* for 07 days and follow-up on 14th day. **Result**: In this study overall there was highly significant improvement in sign and symptoms. After treatment relief in group A was 78.99% and in Group B was 77.53%. On intergroup assessment there was no significant results were obtained. **Conclusion:** In this study both groups were equally effective. So, it can be concluded that procedural effect may have main role as compared to drug.

INTRODUCTION

Anidra (Insomnia) means *"na nidra abhavarthe"* i.e., deprivation of sleep or disturbed sleep[1]. According to *Charak "*As proper *Aahar* is required for maintenance of health similarly adequate *Nidra* is required for *Sukha* and *Aarogya*, hence included under *Tryaupasthambha* (three basic supports of life) [2]. *Acharya Charak*, *Sushruta* and *Vagbhatta* have mentioned six, three and seven types of *Nidra* respectively. Out of them one is *Vaikariki Nidra* which can be correlated with sleep disorders occurring due to decrease in *Kapha dosha* or due to any unpleasant condition in the body and mind[3].

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There are various causative factors responsible for *Anidra* among them physical causative factors include dietary articles which possessing dry and rough properties, excessive physical exertion, exercise, fasting, indulgence in sexual intercourse, inadequate administration of *Panchakarma* therapies like *Vamana* (emesis), *Virechana* (purgation), *Nasya* (nasal medications), *Raktamokshana* (bloodletting), and *Dhooma* (medicated smoke). Psychological causes include fear, anxiety, anger, ecstatic state, sorrow, greed, and agitation[5]. Inadequate sleep causes *Jrimbha* (yawning), *Angamarda* (body ache), *Tandra* (drowsiness), *Shiroroga* (head disorders), *Shira* and *Akshi gaurav* (heaviness in eyes and head), *Aalasya* (laziness), *Bhrama* (giddiness), *Apaka* (indigestion), *Moha* (stupor) and *Vatajanya rogas*[6]. As per classic pathogenesis of *Anidra* involves *Vata* and *Pitta Dosha* mainly. The reported prevalence of insomnia is 9% in the general population and about 30% suffer from

occasional insomnia[8]. It has been found that disturbed sleep or less sleep can lead to various medical conditions includes stroke, obesity, diabetes, hypertension and psychological problems etc. Treatment approach for insomnia in modern medicines includes hypnotics and sedatives which cause drug dependency and leads to ill-effects on health. In *Ayurveda* for the treatment of *Anidra*, *Shirodhara* (Oil dripping) procedure with different liquid media has been mentioned. Keeping all these points this study has been designed to evaluate the effect of *Shirodhara* with *Bala* and *Shatavari Siddha Ksheera* and *Tila* oil. The main aim of this study is to compare the effect of *Shirodhara* therapy between *Bala* and *Shatavari Siddha Ksheera* and *Tila tail* in *Anidra*. Also, to find out whether change in drugs or liquid media plays role in effect of the therapy.

Materials and Methods

Research design: The study was a randomized, parallel group comparative design clinical study.

Ethical Clearance

Before starting the clinical trial on patients of *Anidra* (Insomnia) ethical clearance was taken from the Institutional Ethical Committee (IEC) of Ch. Brahm Prakash Ayurveda Charak Sansthan, Khera Dabar, Najafgarh, New Delhi. Trial no.F1(533)/13/CBPACS/ Admin/IEC/6710 dated 3.01.2019.

CTRI Registration

CTRI Reg. No. was obtained CTRI/2019/03/018093 dated 14.03.2019.

Collection and identification of Drugs

The ingredients *Bala* and *Shatavari* and *Til* Oil were procured from authentic distributors drugs were identified in the Department of Dravyaguna CBPACS, Delhi.

Preparation of Drugs for *Shirodhara*

For *Bala* and *Shatavari Siddha Ksheera dhara* take *Bala* and *Shatavari moola* each 48 grams in quantity. Then 6000ml of water boiled till it reduces to half of its quantity. Further add 1500ml of milk in it and boiled it till the quantity get reduced to 1500ml. After that filter it with the piece of cloth and use it for *Khseera dhara* purpose. *Tila* Oil was after identification and authentication directly used for the procedure.

Inclusion Criteria

1. Patients of chronic insomnia (*Anidra*) i.e. (at least three nights a week for a month or longer) [10].
2. Age group 16 to 50 years.
3. Patients of insomnia with hypertension, depression and anxiety disorders without complications of any other systematic diseases.

Exclusion Criteria

1. Having major psychiatric illness like schizophrenia, Alzheimer's etc.
2. With alcohol dependency.
3. Patients of asthma, malignancies, liver cirrhosis, chronic renal failure.
4. Patients of any acute illness.

Sampling Method

Lottery method random numbers were utilized for the study.

Selection of patient

Patients of *Anidra* were selected from OPD and IPD of Ch. Brahm Prakash Ayurveda Charak Sansthan, New Delhi. Consort guidelines were followed for the reporting of the study.

Total 131 patients diagnosed as *Anidra* (Insomnia) as per ICD -10 criteria were selected from Outpatient and in-patient in the department of Panchakarma from Ch. Brahm Prakash Ayurveda Charak Sansthan, New Delhi. India

Intervention

All the patients were randomly divided into two groups: group A and group B.

Group A (66) received *Bala* and *Shatavari Siddha Ksheera Shirodhara.*

Group B (60) received *Tila Taila Shirodhara*

Both groups received their respective interventions in morning after having light breakfast.

Duration of intervention

14 days which includes *Shirodhara* for 07 days and follow-up on 14th day.

Consent of patients

The nature and design of the study were explained to patients, and informed consent was obtained. During the study, patients were asked to adhere to the treatment protocol and report any adverse events to the investigators at the earliest.

Criteria of Assessment:

All Ayurvedic parameters and Assessment scale was calculated at base line. The sample size was 63 in each group under 5 % alpha error and 90 % power of test. All the patients were assessed for relief in sign and symptoms after the completion of trial.

For subjective parameters grading/scoring pattern was adopted as follows-

Table 1: *Ayurvedic* Scoring adopted for *Anidra*[11]

S.no.	Parameters	Grade
1.	**Sleeplessness**	
1.	No sleeplessness	0

2.	Occasionally	1
3.	Mild	2
4.	Moderate	3
5.	Severe, require medicine	4
2.	**Headache**	
1.	No headache	0
2.	Occasionally	1
3.	Mild	2
4.	Moderate	3
5.	Severe, require medicine	4
3.	**Heaviness**	
1.	No heaviness	0
2.	Occasionally	1
3.	Mild	2
4.	Moderate	3
5.	Severe, require medicine	4

Table 2: Insomnia Severity Index Scale[12]

S. No.	Questionnaire	Score
1.	**Difficulty falling asleep (it takes you to fall asleep after turning-off the lights)**	
i)	None	0
ii)	Mild	1
iii)	Moderate	2
iv)	Severe	3
v)	Very severe	4
2.	**Difficulty staying asleep**	
i)	None	0
ii)	Mild	1
iii)	Moderate	2
iv)	Severe	3
v)	Very severe	4
3.	**Problem waking up too early**	
i)	None	0
ii)	Mild	1
iii)	Moderate	2
iv)	Severe	3
v)	Very severe	4
4.	**How satisfied/dissatisfied are you with your current sleep pattern?**	
i)	Very Satisfied	0
ii)	Satisfied	1
iii)	Moderately Satisfied	2
iv)	Dissatisfied	3
v)	Very Dissatisfied	4
5.	**How noticeable to others do you think your sleep problem is in terms of impairing the quality of your life?**	
i)	Not at all noticeable	0
ii)	A Little	1
iii)	Somewhat	2
iv)	Much	3

v)	Very Much Noticeable	4
6.	**How worried/distressed are you about your current sleep problem?**	
i)	Not at all noticeable	0
ii)	A Little	1
iii)	Somewhat	2
iv)	Much	3
v)	Very Much Noticeable	4
7.	**To what extent do you consider your sleep problem to interfere with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/ daily chores, concentration, memory, mood, etc.) currently?**	
i)	Not interfering at all	0
ii)	A Little	1
iii)	Somewhat	2
iv)	Much	3
v)	Very much interfering	4

Total score categories: 0-7 = No clinically significant insomnia, 8-14 = Sub threshold insomnia, 15-21 = Clinical insomnia (moderate severity), 22-28 = Clinical insomnia (severe).

Statistical analysis

Statistical analysis of the collected data was done. It was analyzed in terms of mean Score (x) Standard Deviation (S.D.), Standard Error (S.E.). For intra-group comparison Paired Student 't' test was carried out and for inter-group comparison unpaired 't' test was carried out at a level of 0.05, 0.02, 0.01, 0.001 of 'P' value. Paired and unpaired student 't' test was done using in built Microsoft software data analysis pack 2010.

Results

In this study total 131 patients were enrolled out of which there were total 05 dropouts. In Group A 03 and in Group 02. So, there were 66 patients in Group A and 60 in Group B.

Table 3: Patient Demographic data

S. No.	Patient Profile		No. of Patients	Percentage %
1.	**Gender**	Male	29	23
		Female	97	77
2.	**Age**	16-25	55	43.6
		26-35	27	21.4
		36-45	30	23.8
		46-50	14	11.1
3.	**Educational Status**	Illiterate	4	3
		Primary	3	2
		Metric	21	16
		Post-metric	98	89
4.	**Occupational Status**	Student	51	40
		Housewife	45	36
		Service	28	22
		Labor	2	1
5.	**Diet**	Vegetarian	58	46
		Mixed	68	54
6.	***Sharirika Prakriti***	Vata-pitta	35	27
		Pitta-Kapha	37	29
		Vata-kapha	54	43
7.	***Mansika Prakriti***	Rajsika	80	63
		Tamsika	46	37
8.	***Koshtha***	Krura	34	27

		Mridu	21	17
		Madhyam	71	56
9.	***Agni* (Digestive Fire)**	Vishama	54	43
		Tikshna	41	32
		Manda	26	21
		Sama	5	4
10.	**Mala (Bowel Movement)**	Clear	98	77
		Constipated	28	13
11.	***Nidana* (Cause)**	Excess Anxiety	56	44
		Family disputes	41	33
		Financial Issues	6	5
		Loss of family members	6	5
		Social Phobia	4	3
		Menopausal Issues	1	1

Table 4: Intra group comparison between Group A and Group B (After treatment)

Parameters	Group	N	Mean			% of Relief	SD (±)	SE (±)	T	P
			BT	AT	DIF					
Sleeplessness	**A**	66	3.12	0.75	2.36	75.72	0.51	0.06	37.2	<0.001
	B	60	3.11	0.88	2.23	71.65	0.67	0.08	25.6	<0.001
Headache	**A**	66	3.01	0.63	2.37	78.89	0.57	0.07	33.5	<0.001
	B	60	3.01	0.88	2.13	70.71	0.56	0.07	29.1	<0.001
Heaviness	**A**	66	2.90	0.57	2.33	80.2	0.47	0.05	39.9	<0.001
	B	60	2.65	0.48	2.16	81.76	0.58	0.07	28.5	<0.001
DFA	**A**	66	3.27	0.81	2.43	74.53	0.55	0.06	37.5	<0.001
	B	60	3.25	0.61	2.63	81.02	0.58	0.07	35.0	<0.001
DSA	**A**	66	3.22	0.80	2.42	75.11	0.55	0.06	35.3	<0.001
	B	60	3.21	0.78	2.43	75.64	0.56	0.07	33.4	<0.001
PWE	**A**	66	2.98	0.62	2.36	79.18	0.54	0.06	35.2	<0.001
	B	60	3.25	0.98	2.26	69.74	0.54	0.07	32.02	<0.001
C.S (satisfied/ dissatisfied)	**A**	66	2.78	0.69	2.09	75.0	0.38	0.04	44.5	<0.001
	B	60	2.65	0.78	1.85	69.81	0.48	0.06	28.7	<0.001
IQL	**A**	66	2.95	0.69	2.27	76.9	0.54	0.06	36.2	<0.001
	B	60	2.98	0.73	2.25	75.41	0.43	0.05	39.9	<0.001
C.S (worried/ distressed)	**A**	66	2.87	0.63	2.24	77.89	0.43	0.05	42.1	<0.001
	B	60	2.76	0.53	2.23	80.72	0.49	0.06	34.6	<0.001
IDF	**A**	66	2.83	0.59	2.24	79.14	0.43	0.05	42.18	<0.001
	B	60	2.7	0.58	2.11	78.39	0.37	0.04	44.02	<0.001

*(DFA (Difficulty in falling asleep), DSA (Difficulty in staying asleep), PWE (Problem in waking up too early), C.S (Current Sleep (satisfied/ dissatisfied)), IQL (Impairment in Quality of Life), C.S (Current sleep (worried/ distressed), IDF (Interference in daily function), Before treatment (BT), After treatment (AT), After follow up (AFU), Differential item functioning (DIF), Standard deviation (SD).)

Table 5: Intra group Comparison between Group A and Group B after follow up

Parameters	Group	N	Mean			% of Relief	SD (±)	SE (±)	T	P
			BT	AT	DIF					
Sleeplessness	**A**	66	3.12	0.83	2.28	73.30	0.45	0.05	40.7	<0.001
	B	60	3.11	0.81	2.3	73.79	0.53	0.06	33.5	<0.001
Headache	**A**	66	3.01	0.72	2.28	75.89	0.48	0.06	38.02	<0.001
	B	60	3.01	0.81	2.2	72.29	0.54	0.07	31.2	<0.001
Heaviness	**A**	66	2.90	0.57	2.33	80.2	0.47	0.05	39.9	<0.001
	B	60	2.65	0.43	2.21	83.64	0.49	0.06	35.0	<0.001
DFA	**A**	66	3.27	0.98	2.28	69.9	0.45	0.05	40.7	<0.001
	B	60	3.25	0.75	2.5	76.92	0.53	0.06	36.07	<0.001
DSA	**A**	66	3.22	0.92	2.30	71.36	0.49	0.06	37.7	<0.001
	B	60	3.21	0.86	2.35	73.05	0.48	0.03	37.8	<0.001
PWE	**A**	66	2.98	0.65	2.33	78.17	0.53	0.06	35.3	<0.001
	B	60	3.25	0.95	2.3	70.76	0.53	0.06	33.5	<0.001
C.S (satisfied/ dissatisfied)	**A**	66	2.78	0.75	2.03	72.8	0.46	0.05	35.6	<0.001
	B	60	2.65	0.8	1.85	69.81	0.48	0.06	29.7	<0.001
IQL	**A**	66	2.95	0.71	2.24	75.89	0.46	0.05	39.08	<0.001
	B	60	2.98	0.8	2.18	73.18	0.43	0.05	39.19	<0.001
C.S (worried/ distressed)	**A**	66	2.87	0.62	2.25	78.42	0.44	0.05	41.62	<0.001
	B	60	2.76	0.61	2.15	77.71	0.51	0.06	32.3	<0.001
IDF	**A**	66	2.83	0.57	2.25	79.67	0.44	0.05	41.62	<0.001
	B	60	2.7	0.66	2.03	75.3	0.41	0.05	38.3	<0.001

Intra group comparison

After treatment and after follow up *Bala* and *Shatavari Siddha Ksheera Shirodhara* and *Tila* oil *Shirodhara* was highly significant (P <0.001) on the above mentioned symptoms.

Table 6: Inter-group comparison in Group A and Group B (AT and After follow up)

Parameters	Group	N	Mean	Variance	DF	T	P	Result
Sleeplessness	**A**	66	0.833	0.202	124	0.17	0.8	NS
	B	60	0.816	0.355				
Headache	**A**	66	0.727	0.478	124	0.64	0.5	NS
	B	60	0.816	0.728				
Heaviness	**A**	66	0.575	0.278	124	1.39	0.1	NS
	B	60	0.433	0.385				
DFA	**A**	66	0.984	0.138	124	2.86	0.5	NS
	B	60	0.75	0.292				
DSA	**A**	66	0.924	0.286	124	0.55	0.5	NS
	B	60	0.866	0.388				
PWE	**A**	66	0.651	0.353	124	2.49	0.01	S
	B	60	0.95	0.556				
C.S (satisfied/ dissatisfied)	**A**	66	0.757	0.278	124	0.45	0.6	NS
	B	60	0.8	0.26				
IQL	**A**	66	0.71	0.30	124	0.925	0.3	NS
	B	60	0.8	0.26				
C.S (worried/ distressed)	**A**	66	0.621	0.269	124	0.04	0.9	NS
	B	60	0.616	0.308				
IDF	**A**	66	0.57	0.27	124	0.95	0.3	NS
	B	60	0.66	0.29				

S: Significant, NS: Not Significant

Intergroup Comparison

From the table no.6 it was found that there was statistically significant difference (P<0.01) in the symptom Problem in waking up early. There was no statistically difference found in the rest of the symptoms.

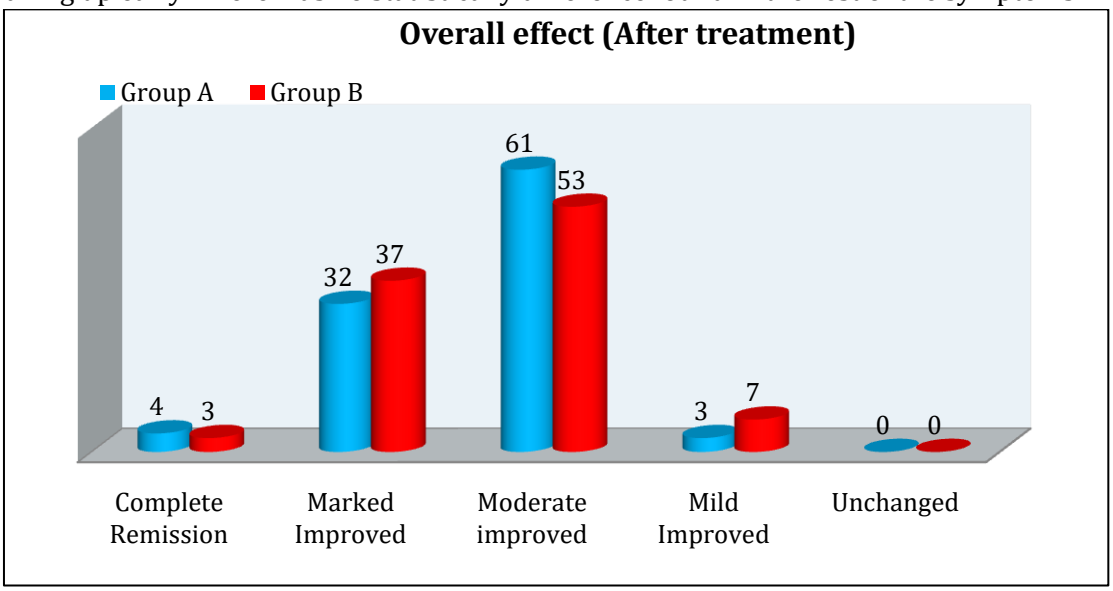

Table 7: Overall effect of therapy in both the groups after treatment

Overall effect	Group A (in %)	Group B (in %)
Complete Remission	04	03
Marked improved	32	37
Moderate Improved	61	53
Mild improved	03	07
Unchanged	00	00
Total	100	100

Figure No.1: After treatment in *Bala* and *Shatavari siddha Ksheeradhara* group A 3% patients were having mild improvement, in 61% there was moderate improvement, in 32% patients there were marked improvement and in 4% patients there were complete remission. Whereas in *Tila Taila Shirodhara* Group 7% patients were having mild improvement, in 53% patients were having moderate improvement, in 37% there was marked improvement and in 3% there was complete remission.

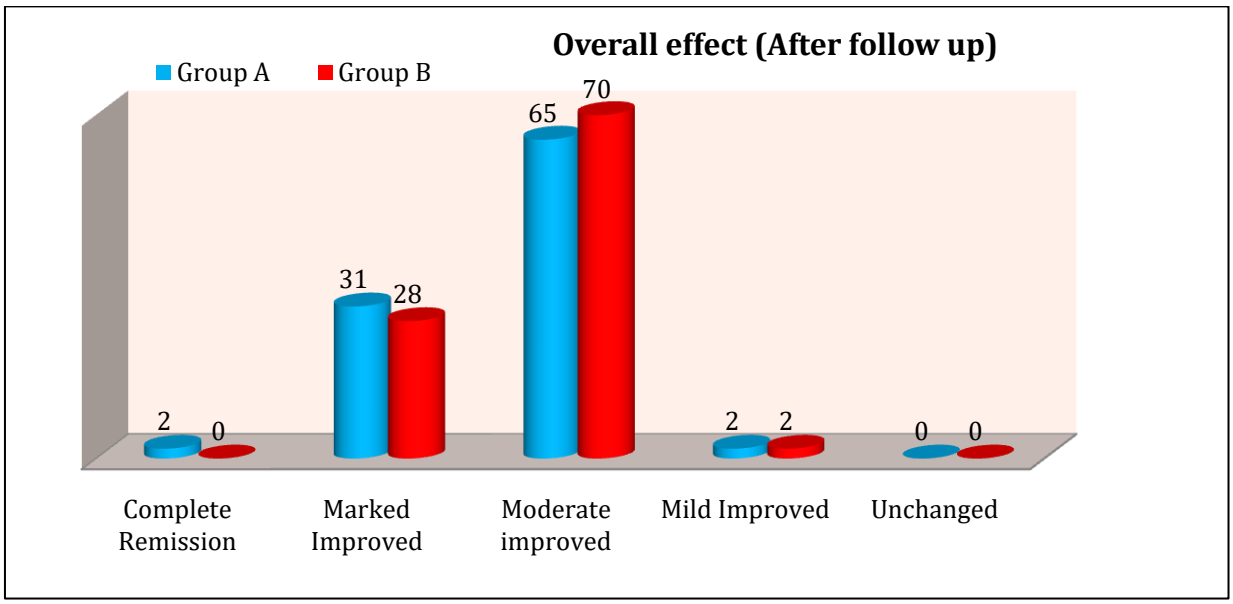

Table 8: Overall effect of therapy in both the groups after follow up

Overall effect	Group A (in %)	Group B (in %)
Complete Remission	02	00
Marked improvement	31	28
Moderate Improved	65	70
Mild improved	02	02
Unchanged	00	00
Total	100	100

Figure No.2: After follow up it was found that in group A in 2% patients there were mild improvement, in 65% patients there were moderate improvement, in 31% marked improvement was observed and in 2% patients there were complete remission Likewise in group B there was 2% patients in which mild improvement was seen. In 70% patients there were moderate improvement, in 28% patients marked improvement was observed.

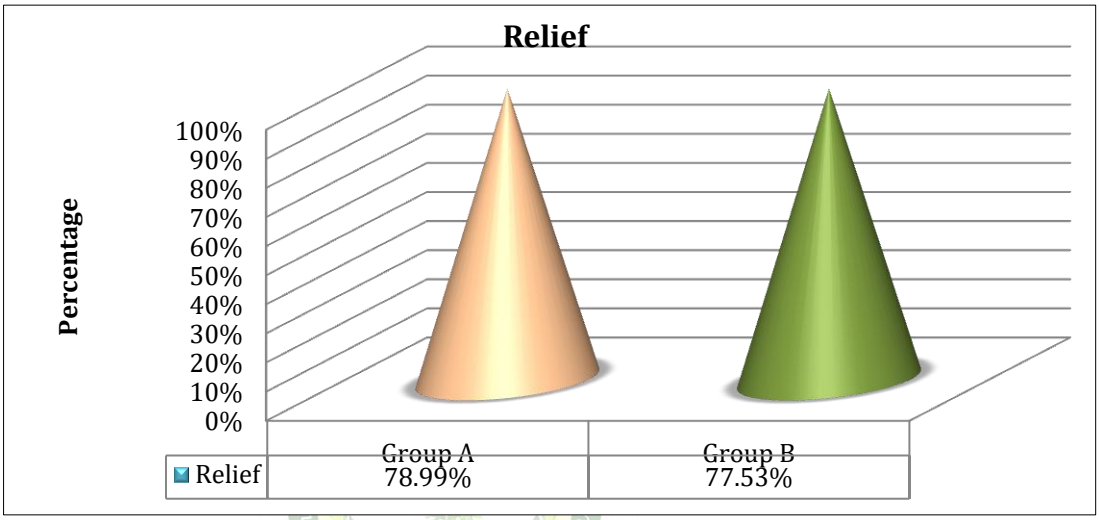

Figure No.3: After treatment relief in group A was 78.99% and in Group B was 77.53%.

Table 9: Comparison of overall relives obtained in both groups after treatment

Group	Total no. of patients	Relief
A	66	78.99%
B	60	77.53%

Figure no.4: (A- *Bala* and *Shatavari siddha ksheera shirodhara* B-*Tila taila shirodhara*)

Mode of action of Herbs

In Group A the drugs used were *Bala*, *Shatavri* and Milk. *Bala* is mentioned as *Balya* and *vatahara* in *Agrya dravya*[13]. It possess *Madhura rasa, Snighdha guna* and *Sheeta virya* along with *Balya* and *Vrishya* properties due to which it pacifies *Vata-pitta dosha*[14]. Through various researches it was found that *bala* possess antioxidant properties and it has been proven as adaptogenic and immunomodulator[15,16]. Whereas *Shatavari* is having *Madhura-tikta rasa*, *Madhura vipak* and *Sheeta virya* along with this it is mentioned as *Balya*, *Medhya* and *Rasayan* with *Vata* and *Pitta shamak* properties[17]. In this trial *Ksheera* has been taken which is having *Nidrajanna* effect along with this it possess *Snigdha*, *Guru, Sthira guna* and *Rasayan* properties as well its helps in *Manah prasadan* effect and helpful in inducing sleep[18]. The drug used in Group B is *Tila* oil which possesses *Kashaya*, *Madhura*, *Tikta* and *Katurasa*, along with this *Snigdha*, *Ushna* and *Guru guna* also it is *Balya medhya* and *Agni vardhak* and pacify *vata Dosha*[19]. In pathology of *Anidra* mainly vitiated *Dhatu* is *Vata- pitta* and *Rasadhatu*. So, in this group all the three drugs used in *Shirodhara* helps in *Rasadhatuposhana* and *Vardhan* due to the *Balya, Rasayan, Dhatupushti karma* properties possessed by them. So, in Group A the effect was more as compared to Group B.

Probable mode of action of *Shirodhara*

It was found that overall relief was more in *Bala* and *Shatavari Sidhha Ksheera* Group as compared to *Tila* oil group. However both groups were found to be highly significant. Means both groups i.e., *Bala* and *Shatavari Ksheera shirodhara* and *Tila* oil *Shirodhara* were equally effective in the treatment of *Anidra*. This can be understood in these ways:

Shirodhara's mechanism can be deduced at the following levels:

The consequence of impulse generation.

1. Temperature's Impact
2. Absorption via the scalp
3. During the procedure, the dim light has an effect.

1. Effect of Impulse Generation- In *Shirodhara* therapy, a continuous stream of liquid is poured over the forehead, creating a steady pressure. Through the hollow sinus, this constant pressure amplifies and creates impulses, which are then sent within via cerebrospinal fluid[20]. This impulse activates sleep-regulating parts of the brain, causing Melatonin, GABA, and Serotonin levels to normalize, as well as a drop in Histamine, Acetylcholine, and Dopamine levels. The temperature of the liquid poured over the forehead in this therapy is usually higher than the temperature of the body. According to one study, a slight local increase in temperature causes neuronal activity, which is linked to sleep patterns, and suppressing this causes awake. Mild skin warming has also been linked to sleep-like activity in the cerebral cortex and the reticular formation of the midbrain [21].
2. Absorption through the scalp vein- Drugs are absorbed through the scalp vein after being poured locally for 30-45 minutes in *Shirodhara*. Drugs enter the systemic circulatory system through emissary veins in the scalp[22]. One study in Japan found that drug delivery through the scalp is a viable route for drug administration. *Shirodhara* may thus aid in achieving the desired results [23].
3. *Shirodhara* therapy is performed under dark light, which has an effect on the procedure. The explanation for this could be that melatonin hormone is released more under dim light, which aids in sleep initiation [24]. As a result, this therapy must be performed in a suitable environment.

CONCLUSION

Anidra is a *Vata nanatmaj vikara* with main *Dosha* involved are *Vata* and *Pitta*. *Bala* and *Shatavari Ksheera Shirodhara* was more effective than *Tila taila shirodhara* as it contains *Madhura- Tikta rasa*, *Guru*, *Snigdha guna*, *Sheeta virya* and *Madhura vipaka* along with this it possess chemical constituent having antioxidant, immunomodulator and adaptogenic properties. In this study both groups were equally effective. So, it can be concluded that procedural effect may have main role as compared to drug. Also it can be concluded that *Anidra* can be best treated by *Shirodhara* which is anon pharmacological intervention and can reduce the chances of adverse effect caused by pharmacological drugs like sedatives and hypnotics.

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***Address for correspondence**
Dr. Rani Pooja,
Panchakarma Vaidya,
All India Institute of Ayurveda,
Gautam Puri, Sarita Viahar, New Delhi.
Email: pathakpooja773@gmail.com