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A Comparative Clinical Study to evaluate the effect of Brahmi Taila Shirodhara and Bala Hatadi Taila Shirodhara in the management of Anidra with special reference to primary Insomnia.

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Abstract: Background: Sleep is an important physiological process and basic need for the body. Normal healthy sleep is characterized by various factors. These factors include sufficient duration, good quality, appropriate timing and regularity and the absence of sleep disturbances, and disorders. According to Ayurveda, Nidra among the three Upastambhas for the maintenance of the living organism. Insomnia is commonly seen in the age group of 18-80 years. This study deal to study efficacy of Shirodhara using Brahmi Taila and Bala Hatadi Taila in Anidra. Objectives: The objective of the study was to study the efficacy of Brahmi Taila Shirodhara in the management of Anidra. To study the efficacy of Bala Hatadi Taila Shirodhara in the management of Anidra. To compare the efficacy of Brahmi Taila Shirodhara and Bala Hatadi Taila. Shirodhara in the management of Anidra. Methodology: In this study, 46 patients of 'Anidra' were taken. However, 06 patients were not coming for follow up and they dropped out. In Group-A, 20 Patient of clinically diagnosed cases of Anidra were administered with Shirodhara by using Brahmi Taila for a period of 45 min for 7 days. In Group-B, 20 patients of clinically diagnosed cases of Anidra were administered with Shirodhara by using Bala Hatadi Taila for a period of 45 min for 7 days. Results: Overall, it was observed that Percentage of Relief in Each Patient of 40 Patients of Anidra in Group A was 76.3% while 69.8% in Group B. Average relief in both groups was 73.0% in each patient of Anidra. In Group A & B regarding symptom Jrumbha, Tandra, Shiro Gaurava, Netra Gaurava, Shirodhara using Brahmi Taila and Bala Hatadi Taila intervention having considerably highly significant results. In the Pittsburgh Sleep Quality Index both drugs are equally effective statistically. Conclusion: It is concluded that Brahmi Taila Shirodhara and Bala Hatadi Taila are equally effective in if Shirodhara adopted in Insomnia.

Keywords: Brahmi Taila Shirodhara, Bala Hatadi Taila, Insomnia, Anidra.

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Introduction:

According to Ayurveda, getting good sleep at a proper time is one of the characteristics of a healthy man. Nidra is the leading disorder in the new Era. At present Nidra related disorder are increasing day by day due to the working tendencies at night time has increased and hence excessive stress has increased. Sleep is an important physiological process and basic need for the body just like food, water and air. Sleeping has a crucial role in maintaining the normal motor and cognitive functions of the body. Our body's natural circadian rhythm or biological clock plays an important role in regulating sleep. Vata and Pitta are the Pradhan Doshas contributing to Anidra. Aswapna (Anidra) is included in Vata Nanatmaja Vikaras, hence Vatashamaka treatment should be given for maintaining and promoting health. The Moordhani Tailam i.e. Shirodhara has been considered as an important procedure in management of Anidra. In this study, one group were assigned Shirodhara using Brahmi Taila while another group given Shirodhara using Bala Hatadi Taila for a period of 45 min for 7 days.

Objectives:

1. To study the efficacy of *Brahmi Taila Shirodhara* in the management of *Anidra*.
2. To study the efficacy of *Bala Hatadi Taila Shirodhara* in the management of *Anidra*.

3. To compare the efficacy of *Brahmi Taila Shirodhara* and *Bala Hatadi Taila Shirodhara* in the management of *Anidra*.

Methodology:

Patient suffering from *Anidra* were selected from OPD of S.D.M Trust's Ayurvedic Medical College and Danigond Post Graduation Centre, Padma Hospital and Research Centre, Terdal, Karnataka.

Study design : Comparative Clinical Study.

Sample size : Minimum 40 patients suffering from *Anidra* fulfilling the inclusion criteria of either sex were selected for comparative study.

Selection of Drug:

Bala Hatadi Taila from *Saharsa Yogam, Tailprakara* and *Brahmi Taila* from *Ayurveda Sara Sangraha*

INCLUSION CRITERIA :

1. Patients between age group of 18-60 years.
2. *Anidra* along with patients complaining of *Jrumbha, Tandra, Shiro Gaurava, Netra Gaurava* either some or all.
3. Patients complaining of inability to fall asleep, fatigue, tiredness, reduction in sleep time either any of these for the duration of one month.

4. Patients already diagnosed for primary insomnia with duration of one month.
5. Patients fit for *Shirodhara*.

B) EXCLUSION CRITERIA:

1. Anidra due to other conditions like *Madatyā* and *Abhighata*.
2. Pregnant women, Severe Psychiatric disorders.

Treatment:

Group A: In this group 20 Patient of clinically diagnosed cases of *Anidra* were administered with *Shirodhara* by using *Brahmi Taila* for a period of 45 min for 7 days.

Group B: In this group 20 Patient of clinically diagnosed cases of *Anidra* were administered

with *Shirodhara* by using *Bala Hatadi Taila* for a period of 45 min for 7 days.

Shirodhara procedure:

Abhyanga of patients done over the face, neck, shoulder and chest. Gauze is tied around the head above the eyebrows of the patient. After closing the eyes cotton was kept over the eye lids and it was tied with proper bandage. Ear plug applied. Then Patient asked to lie in supine position on the *droni* with a pillow under the neck and the *shirodhara* device placed near his head. Eyes were covered to protect from oil with cotton and gauze. *Brhami* and *bala Hatadi Oil* heated just above body temperature (38° - 40°C) and poured into the *Dharapatra*. A continuous stream of oil allowed to fall on the entire forehead around 40-45 minutes. The oil recollected from the *droni*, reheated and poured back into the *Dharapatra*.

Observation & Results:

Table No.1 Gender Wise Distribution of Patient of *Anidra*

Gender	Group-A		Group-B		Total	
	n	%	n	%	n	%
Male	10	50.0	13	65.0	23	57.50
Female	10	50.0	7	35.0	17	42.50

In this study, 10[50%] patients were male and 10[50%] patients were female in Group-A while 13[65%] patients were male and 7[35%] patients were female in Group-B. Totally 17[42.5%] were

female and 23[57.5%] were male while more male was recruited in study it may be due random selection of patients.

Graph.1 Gender Wise Distribution of Patient of Anidra.

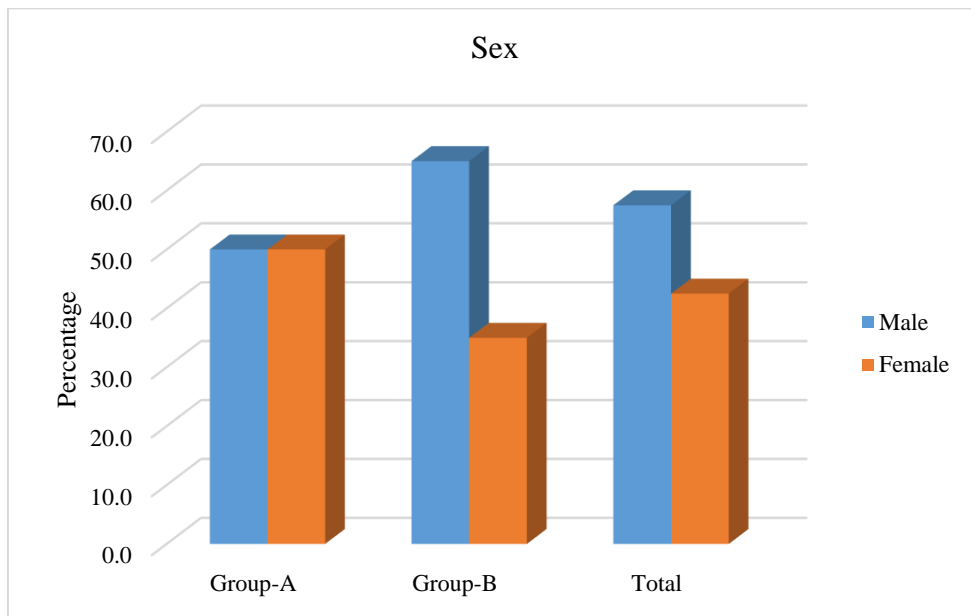
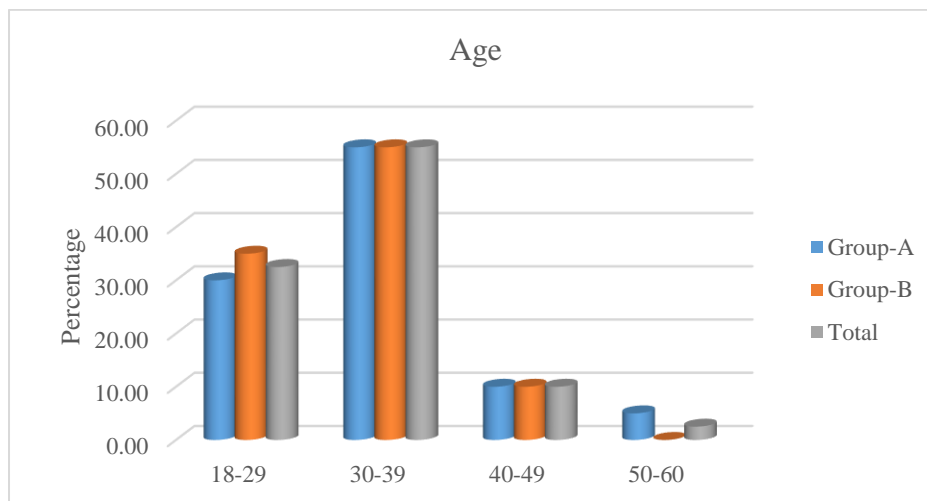


Table No.2 Age Wise Distribution of Patient of Anidra

Age (yrs)	Group A		Group B		Total	
	n	%	n	%	n	%
18-29	06	30.0	07	35.0	13	32.5
30-39	11	55.0	11	55.0	22	55.0
40-49	02	10.0	02	10.0	04	10.0
50-60	01	05.0	0	0.0	01	2.5
Total	20	100	20	100	40	100

Graph 2: Age wise distribution of Patients of Anidra

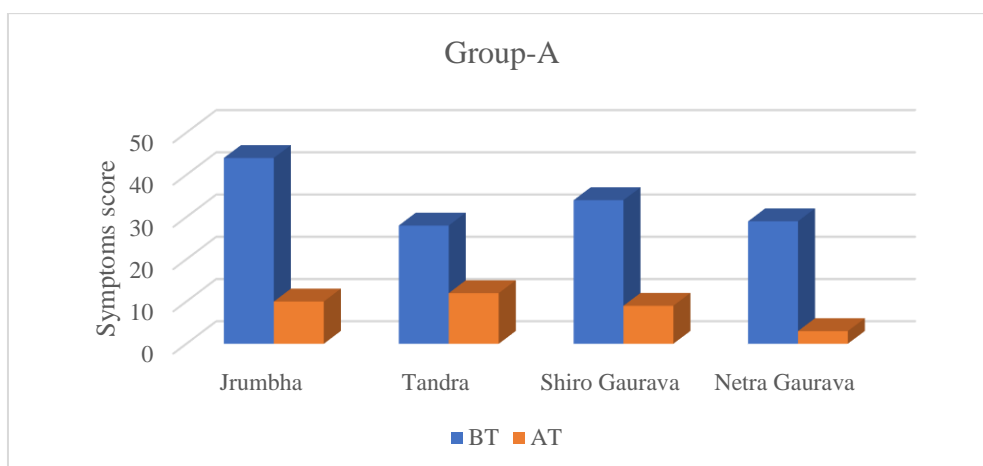


CLINICAL OBSERVATIONS:**Table No.3 Percentage of Relief (Subjective Criteria) in Each Symptom of 40 Patients of Anidra .**

Sr. No	Symptoms	(Group-A)			(Group-B)		
		BT	AT	% of Relief	BT	AT	% of Relief
1	Jrumbha	44	10	77.3	42	17	59.5
2	Tandra	28	12	57.1	30	11	63.3
3	Shiro Gaurava	34	9	73.5	35	6	82.9
4	Netra Gaurava	29	3	89.7	24	4	83.3
	Average			74.4			65.8

In Group-A percentage of relief noted in Jrumbha was 77.3%, while in other symptoms like Tandra percentage of relief was noted as 57.1%, 73.5% in Shiro Gaurava and 89.7% in Netra Gaurava. Average relief in all symptoms in Group A was 74.4%.

In Group-B, the percentage of relief noted in Jrumbha was 59.5%, while in other symptoms like Tandra percentage of relief was noted as 63.3%, 82.9% in Shiro Gaurava followed by 83.3% in Netra Gaurava. Average relief in all symptoms in Group A was 65.8%.

Graph 3 : Percentage of Relief in Symptoms Score in Group-A

Graph 4 : Percentage of Relief in Symptoms Score in Group-B

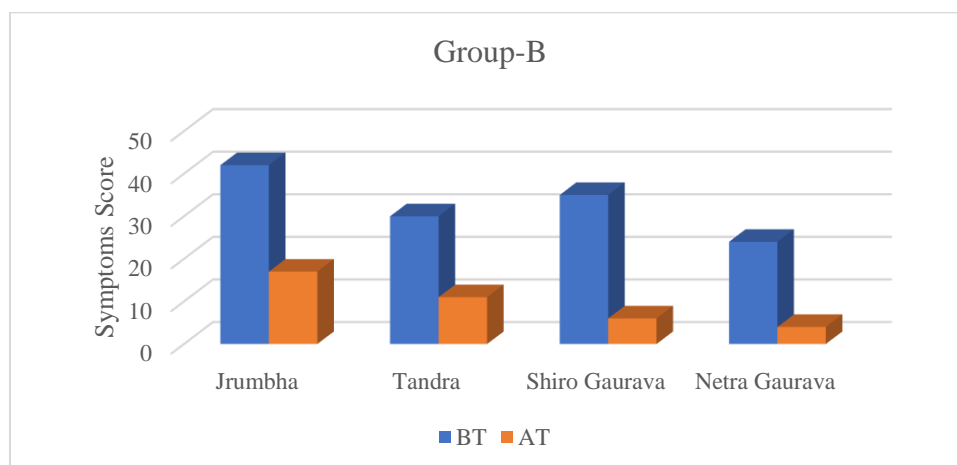


Table No.4 Wilcoxon Signed Rank Test for the Symptoms in Group-A:

Sr. no	Symptoms	Mean		±SD		Median		Sum of +Ranks	p value
		BT	AT	BT	AT	BT	AT		
1	Jrumbha	2.20	0.50	0.52	0.69	2	0	190	<0.001
2	Tandra	1.40	0.60	0.94	0.68	2	0.5	66	<0.001
3	Shiro Gaurava	1.70	0.45	0.98	0.51	2	0	132	<0.001
4	Netra Gaurava	1.45	0.15	1.05	0.37	2	0	120	<0.001

Table No.5 Wilcoxon Signed Rank Test for the Symptoms in Group-B:

Sr.no	Symptoms	Mean		SD		Median		Sum of +Ranks	p value
		BT	AT	BT	AT	BT	AT		
1	Jrumbha	2.10	0.85	0.55	0.75	2	1	147	<0.001
2	Tandra	1.50	0.55	1.05	0.60	2	0.5	126	<0.001
3	Shiro Gaurava	1.75	0.30	1.02	0.47	2	0	120	<0.005
4	Netra Gaurava	1.20	0.20	1.06	0.41	1	0	88	<0.001

Table No. 6 Comparison between Two Group w.r.t Symptoms Score of 80 Patients in Anidra.

Sr.no.	Symptoms	Mean		SD		Median		Mann Whitney		p value
		Gr-A	Gr-B	Gr-A	Gr-B	Gr-A	Gr-B	U'	U	
1	Jrumbha	1.70	1.25	0.80	1.07	2	1	252.5	147.5	0.156
2	Tandra	0.80	0.95	0.89	1.00	1	1	228	172	0.454
3	Shiro Gaurava	1.25	1.45	1.07	1.05	1	2	220	180	0.595
4	Netra Gaurava	1.30	1.00	0.98	1.08	1	1	230	170	0.421

Comparison between Two Group w.r.t Symptoms Score:

The Difference between before treatment and after treatment score of both groups compared by 'Mann-Whitney U Test'. It was found that the sum of rank of Group-A for the symptom Jrumbha Test statistic (U) was 252.5 and U was 147.5, where the test statistic U was not lies between Population Mean ± 1.96 SD which was not significant at 5% level of significance as $p = 0.156 (p > 0.05)$ Therefore the difference between Symptom Score of Jrumbha of Group-A and Group-B is statistically not significant, so therefore we can conclude that in the symptom

Jrumbha both drugs are equally effective statistically.

Likewise, in other symptoms viz. Tandra, Shiro Gaurava and Netra Gaurava the test statistics U was not lies between Population Mean ± 1.96 SD which was not significant at 5% level of significance as $p > 0.05$. So therefore, we can conclude that in these symptoms, trial Group-A and Group B intervention are equally effective statistically. So, from this we can conclude both groups are equally effective statistically for the symptoms of Anidra viz. Jrumbha, Tandra, Shiro Gaurava and Netra Gaurava.

Table No.7 Wilcoxon Signed Rank Test for the Pittsburgh Sleep Quality Index in Group-A:

Sr.no.	Parameters	Mean		SD		Median		Sum of +Ranks	p value
		BT	AT	BT	AT	BT	AT		
1	Sleep quality	2.15	0.55	0.59	0.60	2	0.5	153	<0.001
2	Sleep latency	1.45	0.40	0.94	0.60	2	0	131	<0.001
3	Sleep duration	2.05	0.70	0.60	0.66	2	1	166.5	<0.001
4	Sleep efficiency	1.65	0.15	0.93	0.37	2	0	136	<0.001
5	Sleep disturbance	1.65	0.55	0.93	0.69	2	0	128	<0.001
6	Use of sleep medication	1.80	0.85	0.62	0.75	2	1	91	<0.001
7	Day time Dysfunction	1.70	0.75	0.98	0.79	2	1	75	<0.005

Table No.7 Wilcoxon Signed Rank Test for the Pittsburgh Sleep Quality Index in Group-B:

Sr.no.	Parameters	Mean		SD		Median		Sum of +Ranks	p value
		BT	AT	BT	AT	BT	AT		
1	Sleep quality	2.00	0.75	0.73	0.64	2	1	161	<0.001
2	Sleep latency	1.75	0.60	0.85	0.68	2	0.5	154	<0.005

3	Sleep duration	1.45	0.35	0.94	0.49	2	0	91	<0.001
4	Sleep efficiency	1.30	0.20	1.03	0.41	1.5	0	91	<0.001
5	Sleep disturbance	1.65	0.50	0.81	0.69	2	0	120	<0.001
6	Use of sleep medication	1.80	0.70	0.62	0.66	2	1	153	<0.001
7	Day time Dysfunction	1.80	0.50	0.89	0.61	2	0	120	<0.005

Table No. 8 Comparison between Two Group w.r.t PSQI parameters of 40 Patients in Anidra.

No.	Parameters	Mean		SD		Median		Mann Whitney		p value
		Gr-A	Gr-B	Gr-A	Gr-B	Gr-A	Gr-B	U'	U	
1	Sleep quality	1.60	1.25	0.94	1.07	2	1	240.5	159.5	0.27
2	Sleep latency	1.05	0.95	0.89	1.00	1	1	208.5	191.5	0.82
3	Sleep duration	1.35	1.45	0.93	1.05	1.5	2	210.5	189.5	0.78
4	Sleep efficiency	1.50	1.00	1.00	1.08	2	1	250.5	149.5	0.17
5	Sleep disturbance	1.10	0.30	1.12	0.47	1	0	293	107	<0.05
6	Use of sleep medication	0.95	1.15	0.89	0.99	1	1	237	163	0.31
7	Day time Dysfunction	0.95	1.20	1.15	0.77	1	1	232.5	167.5	0.38

Comparison between Two Group w.r.t Pittsburgh Sleep Quality Index :

The Difference between before treatment and after treatment for PSQI score of both groups compared by 'Mann-Whitney U Test'. It was found that the sum of rank of Group-A for the criteria Sleep quality, Test statistic (U') was 240.5 and U was 159.5, where the test statistic U was not lies between Population Mean ± 1.96 SD which was not significant at 5% level of significance as $p = 0.27$ ($p > 0.05$) Therefore the difference between Sleep quality Score of Group-A and Group-B is statistically not significant, so therefore we can

conclude that in the criteria Sleep quality both drugs are equally effective statistically.

Similarly, in the parameters Sleep latency, Sleep duration, Sleep efficiency, Sleep disturbance, use of sleep medication and Day time Dysfunction Test statistic (U') were and the test statistic U was not lies between Population Mean ± 1.96 SD which was not significant at 5% level of significance as ($p > 0.05$).

Discussion:

Gender: In this study, totally 17[42.5%] were female and 23[57.5%] were male while more male

was recruited in study it may be due random selection of patients.

Age: As per inclusion criteria of patients were selected having age between 18 years to 60 yrs. and distributed it in four-sub age groups. Out of 40 patients' number of patients found in age group 18-29 were 13[32.5%], in age group 30 to 39 yrs. were 22[55%], in 40 to 49 yrs. age group were 04[10%], and 01[2.5%] patient from age group 50-60 yrs. of Anidra was observed.

Clinical findings : In Group-A, regarding symptom Jrumbha, Tandra, Shiro Gaurava, Netra Gaurava, p value was <0.001 which was statistically considerably highly significant ($p < 0.001$). In Group-B, regarding symptom Jrumbha, Tandra, Shiro Gaurava, Netra Gaurava, p value was <0.001 which was statistically considerably highly significant ($p < 0.001$).

It was found that the difference between Symptom Score of Jrumbha, Tandra, Shiro Gaurava, Netra Gaurava of Group-A and Group-B is statistically not significant, so therefore we can conclude that in these symptoms of Anidra both drugs are equally effective statistically. So, from this we can conclude both groups are equally effective statistically for the symptoms of Anidra viz. Jrumbha, Tandra, Shiro Gaurava and Netra Gaurava.

It was found that criteria Sleep quality, Sleep latency, Sleep duration, Sleep efficiency, Sleep disturbance, use of sleep medication and Day time Dysfunction, the difference between

Score of Group-A and Group-B is statistically not significant, so therefore we can conclude that in the criteria of PSQI score both drugs are equally effective statistically.

Mode of action of Shirodhara:

Imbalance of prana, udana and vyana vayu, sadhaka pitta and kalpa can produce stress and tension which are the usual triggering factors of the Insomnia. Shirodhara re-establishes the functional integrity between these three subtypes of doshas through its mechanical effect. Agnya chakra (the space between the two eyebrows) is the seat of pituitary and pineal gland. As we know the pituitary gland is one of the main glands of the endocrine system and exhibits its action on human body for various functions, etc. Shirodhara stimulates it by its penetrating effect, which decreases the brain cortisones and adrenalin level, Synchronizes the brain wave (alpha wave) and strengthens the mind which is usually disturbed in Insomnia. By Shirodhara, patient feels relaxation, both physically and mentally. Relaxation of the frontalis muscle tends to normalize the entire body activity and achieves a decrease activity of sympathetic nervous system with lowering of heart rate, respiration, oxygen consumption, blood pressure, brain cortisones and adrenalin levels, muscle tension and probably increase in alpha brain waves. It strengthens the mind and spirit and this continues even after the relaxation. Special stimulation of different nerve plexus, glands and

brain cells accompanies mental functions of different levels. Shirodhara which contain many drugs like Brhami and Bala hatadi tail drugs may stimulate the endocrine, nervous and immune system and thereby it may reduce Anidra. Further large study can be done on more sample to generalized the results. Theses drug can also be studied for their pharmacokinetic studies. Study can also be done with other procedure of Panchakarma to obtain more efficacy of drug. The limited size of sample was not sufficient to conclude the efficacy of the intervention.

Conclusion:

Sleep is one of the basic needs of life and requirement for Health and longevity. Mutual relationship between Vata and Rajas causes Rajo Guna Vruddhi, which intern cause suppression of effect of Tamas at the psychological level leading to loss of sleep. In Group A regarding symptom Jrumbha, Tandra, Shiro Gaurava, Netra Gaurava, Shirodhara using Brahmi Taila intervention having considerably highly significant results. In Group B regarding symptom Jrumbha, Tandra, Shiro Gaurava, Netra Gaurava, Shirodhara using Bala Hatadi Taila intervention having considerably highly significant results. It was found that the difference between Symptom Score of Jrumbha, Tandra, Shiro Gaurava, Netra Gaurava of Group-A and Group-B is statistically not significant, so therefore we can conclude that in these symptoms of Anidra both drugs are equally effective statistically. In the Pittsburgh

Sleep Quality Index both drugs are equally effective statistically. Percentage of Relief in Each Patient of 40 Patients of Anidra in Group A was 76.3% while 69.8% in Group B. Average relief in both groups was 73.0% in each patient of Anidra. Overall, it is concluded that Brahmi Taila Shirodhara and Bala Hatadi Taila are equally effective in if Shirodhara adopted in Insomnia.

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