

Management Of Adolescent Sleep Disorder With Mamsyadi Ghana Vati- A Randomized Controlled Trail

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Abstract:

Background: Improper sleep in children, it impacts the attention, daily activity, impulse control problems, makes the child irritable which further leads to behavioral issues at home and school & overall quality of life of the child. Sleep disorders in the adolescents was 11%.

Aim: To investigate the effect of oral use of *Mamsyadi Ghana Vati* over *Padaabhyanga* with *Ksheerbala Tail* in sleep disorder in Adolescents.

Objective: To evaluate & compare the efficacy of *Mamsyadi Ghana Vati* on *Anidra* in Adolescents.

Materials and Methods: Group A was given *Mamsyadi Ghana Vati* for oral route and Group B was given *Ksheerbalataila* for Local application of *Padaabhyanga* for 15 days in home. Follow up & assess the diagnostic criteria were taken at 7th days, 15th day and 30 days.

Results: Group A observed percentage of changes at 7th, 15th & 30th day was 33.33%, 76.19% & 88.10%. Group B observed percentage of changes at 7th, 15th & 30th day was 8.8%, 41.03% & 56.41%.

Conclusion: Both the group were significant in the management of *Anidra* in Adolescents but *Mamsyadi Ghana Vati* was highly significant with p=0.001, when compared over *Padaabhyanga* with *Ksheerbalataila* (p=0.002).

Keywords: *Anidra*, Insomnia, *Mamsyadi Ghana Vati*, *Ksheerbalataila*, *Padaabhyanga*.

INTRODUCTION:

Insomnia causes like evacuation of doshas from body and head by purgation, emesis, suffering from fear complex, anxiety, anger etc. exposure to dust/smoke, physical exercise, blood- letting, fasting, uncomfortable bed etc.¹

In one of the studies global prevalence in 13 years or more was found as difficulty in falling asleep or staying asleep in 25% of subjects with 7% of them frequent symptoms. It was found in a study that as per DSM-IV criteria the prevalence of current insomnia was 9% and the lifetime prevalence in children between ages 13-16 years was observed to be 11%.²

The factors that affect the incidence of insomnia are age, sex, lifestyle and accompanying complaints like severity of pain, cardiac disorders, myopathies etc. Stress, depression, and any psycho-social issues at home and school like ADHD, learning disabilities and lifestyle do have insomnia as symptom.³

Improper sleep-in children can cause diverse consequences. It impacts the attention, daily activity, impulse control problems, makes the child irritable which further leads to behavioral issues at home and school. Thus affects the overall quality of life of the child.

Behavioural insomnia is the most prevalent among all types, and affects 25% of Adolescents, approximately. In behavioural insomnia there is difficulty in initiation of sleep and its maintainance. Thus, the sleep is inadequate. Sedative of Benzodiazepines groups like Lorazepam, Alprazolam and Diazepam etc. on regular uses can cause severe withdrawal symptoms such as seizures, dependence and addiction.⁴

Thus, there is an urgent need for the eradication of the problem of insomnia by efficient management using natural ways and counselling the patient effectively, use of herbal medication and correcting the life style. Hence, *Mamsyadi Ghana Vati* can be use in Adolescents. The drugs *Mamsyadi Ghana Vati* like *Ashwagandha*, *Jatamansi*, *ParsikaYavani* may help in treat *Anidra* safely.⁵

Objectives:

To evaluate the efficacy of *Mamsyadi Ghana Vati* on *Anidra* in Adolescents.

To compare the effect of *Mamsyadi Ghana Vati* over *Padaabhyanga* on *Anidra* in Adolescents.

MATERIALS & METHODS:

Selection of patient: Patient select on the basis of diagnostic criteria, attending OPD and IPD of Department of *Kaumarbhritya*, KLE Ayurveda Hospital, Belagavi, Karnataka were registered, after taking informed consent from parents/ guardian, for the present clinical study.

The study was carried out after obtaining the ethical clearance of **Institutional Ethics Committee(IEC)**(KLE/BMK/MRC/635/2020).

This study has been registered under **Clinical Trial Registry (CTRI)** Reg. no: CTRI/2020/12/029542.

Place of study	KLE Ayurveda Hospital and Research Centre
Source of Data	Patients from <i>Kaumarabhritya</i> OPD and IPD of KLE Ayurveda Hospital, Shahapur, Belagavi
Study Design	Randomized controlled clinical trial
Study Groups	2 Groups: Group A: Trial group (<i>Mamsyadi Ghana Vati</i>), Group B: Control group (<i>Ksheerbalataila</i>)
Sample Size	30, N= 15 In Group A N= 15 In Group B
Intervention Drug	<i>Mamsyadi Ghana Vati</i> , <i>Ksheerbalataila</i>
Study Period	18 Months
Drug Intervention	15 days

Period	
Follow Up	7 th , 15 th , 30 th
AusadhaSevankala	Nishi (Night at bed)

Table 1**Inclusion Criteria:**

1. Age Group 13-16 years of both genders.
2. Adolescents fulfilling the Diagnostic Criteria.

Exclusion Criteria:

1. Age Group below 13 and above 16 years of both genders.
2. Any child on any medication for sleep disorder,
3. Any other drug affecting the expected outcome of the study.
4. At the time of examination if any child was found to have any diseases or any medication that could interfere with the proposed study were excluded.

Diagnostic criteria:

1. Difficulty in initiating sleep.
2. Sleep disturbance causes clinically significant distress or impairment in social, educational, academic, behavioral, or other important areas of functioning.
3. Sleep difficulty occurs at least 3 nights per week
4. Sleep difficulty was present for at least 3 months.
5. Sleep difficulty occurs despite adequate opportunity for sleep.
6. Insomnia is not attributable to the physiological effects of a substance. (Drug abuse, medication)⁶

Statistical methods:

1. Mann-Whitney U test
2. Wilcoxon matched pairs test

Assessment criteria: A special proforma was prepared with a gradation of symptoms and scoring was done by adopting **Athens Insomnia Scale**.^{7,8.}

Total no:2hours of sleep

Grading	Symptoms	BT	7 th Day	15 th Day	30 th Day
<u>0</u>	6 hrs. to 8hrs. (Normal)				
<u>1</u>	4 hrs. to less than 6 hrs.				
<u>2</u>	2 hrs. to less than 4 hrs.				
<u>3</u>	0 to less than 2 hrs.				

Table 2**Table no.3: Difficulty in initiating sleep**

Grading	Symptoms	BT	7 th Day	15 th Day	30 th Day
<u>0</u>	Difficulty in initiating sleep				
<u>1</u>	Sleep within 30min. (Normal)				
<u>2</u>	30 mints to less than 1hr.				
<u>3</u>	1 hr. to less than 2hrs.				

Table 3**Table no.4: Number of awakenings**

Grading	Symptoms	BT	7 th Day	15 th Day	30 th Day
<u>0</u>	No awakening (Normal)				

<u>1</u>	Normal 1 to 2 times				
<u>2</u>	3 to 4 times				
<u>3</u>	More than 4 times				

Table 4**Table no.5: Angamarda (Body ache)**

Grading	Symptoms	BT	7 th Day	15 th Day	30 th Day
<u>0</u>	No body ache (normal)				
<u>1</u>	(Mild) generalized pain on & off during the day				
<u>2</u>	(Moderate) generalized pain throughout the daybut is able to normal activity				
<u>3</u>	(Severe) generalized pain throughout the day enough to affect routine work				

Table 5**Table no.6: Tandra (Drowseness)**

Grading	Symptoms	BT	7 th Day	15 th Day	30 th Day
<u>0</u>	Tandra (Normal)				
<u>1</u>	Occasional for short duration				
<u>2</u>	Intermittent Tandra for long duration				
<u>3</u>	Frequent Tandra throughout the day				

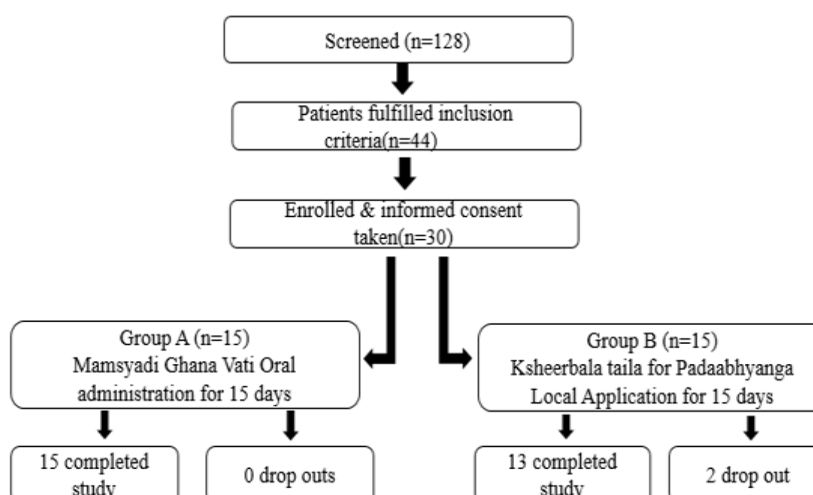
Table 6**Table no.7: Shirshool(Headache)**

Grading	Symptoms	BT	7 th Day	15 th Day	30 th Day
<u>0</u>	No Shirshool				
<u>1</u>	Occasional				
<u>2</u>	Intermittent, not affect daily routine				
<u>3</u>	Frequent, affecting daily routine work				

Table 7**Ajirna (indigestion)-Yes/No****Table no.8: Overall improvement of patient was assessed as per following gradation**

Grading	Symptoms	BT	7 th Day	15 th Day	30 th Day
<u>0</u>	100% Improvement				
<u>1</u>	75% Improvement				
<u>2</u>	50% Improvement				
<u>3</u>	25% or Less Improvement				

Table 8**Fig. no. 1:Consort Chart:**

**RESULT:****Table:9** Comparison of Group A and Group B with TOTAL HOURS OF SLEEP at different treatment time points by Mann-Whitney U test

Times	Group A				Group B				U-value	Z-value	P-value
	Mean	SD	Median	IQR	Mean	SD	Median	IQR			
Baseline	1.3	0.5	1.0	0.5	1.3	0.5	1.0	0.5	105.00	-0.3920	0.6950
Day 7	1.2	0.4	1.0	0.0	1.3	0.6	1.0	0.5	103.50	-0.4670	0.6400
Day 15	0.3	0.5	0.0	0.5	0.5	0.5	1.0	0.5	71.00	-1.4420	0.1490
Day 30	0.1	0.4	0.0	0.0	0.7	0.6	1.0	0.5	49.50	-2.6390	0.0080*

Table 9**Table:10** Comparison of Group A and Group B with DIFFICULTY IN INITIATING SLEEP at different treatment time points by Mann-Whitney U test

Times	Group A				Group B				U-value	Z-value	P-value
	Mean	SD	Median	IQR	Mean	SD	Median	IQR			
Baseline	1.5	0.7	2.0	0.5	1.7	0.5	2.0	0.5	100.00	-0.5910	0.5540
Day 7	1.0	0.8	1.0	1.0	1.5	0.5	1.0	0.5	74.00	-1.7590	0.0790
Day 15	0.4	0.5	0.0	0.5	0.4	0.5	0.0	0.5	96.00	-0.0820	0.9350
Day 30	0.1	0.4	0.0	0.0	0.4	0.5	0.0	0.5	73.00	-1.5040	0.1330

Table 10**Table:11:** Comparison of Group A and Group B with NUMBER OF AWAKENING at different treatment time points by Mann-Whitney U test

Times	Group A				Group B				U-value	Z-value	P-value
	Mean	SD	Median	IQR	Mean	SD	Median	IQR			
Baseline	0.7	0.7	1.0	0.5	1.0	0.8	1.0	0.1	86.50	-0.9020	0.3670
Day 7	0.7	0.7	1.0	0.5	1.0	0.8	1.0	0.0	85.50	-1.2430	0.2140
Day 15	0.1	0.4	0.0	0.0	0.8	0.7	1.0	0.5	48.50	-2.6760	0.0070*
Day 30	0.1	0.4	0.0	0.0	0.7	0.6	1.0	0.5	49.50	-2.6390	0.0080*

Table 11**Table:12 :** Comparison of Group A and Group B with OVERALL IMPROVEMENT OF PATIENT at different treatment time points by Mann-Whitney U test

Times	Group A				Group B				U-value	Z-value	P-value
	Mean	SD	Median	IQR	Mean	SD	Median	IQR			
Baseline	2.8	0.8	3.0	0.0	3.0	0.0	3.0	0.0	105.00	-1.0000	0.3170
Day 7	1.9	0.7	2.0	0.0	2.7	0.5	3.0	0.5	39.00	-3.3720	0.0010*
Day 15	0.7	0.5	1.0	0.5	1.8	0.7	2.0	0.3	22.50	-3.6840	0.0001*
Day 30	0.3	0.5	0.0	0.5	1.3	0.9	2.0	1.0	42.50	-2.7600	0.0060*

Table 12

Table:13 Comparison different treatment time points with OVERAL IMPROVEMENT OF PATIENT in Group A and Group B by Wilcoxon matched pairs test

Groups	Changes from	% of change	Z-value	p-value
Group A	Baseline-Day 7	33.33	3.0594	0.0022*
	Baseline-Day 15	76.19	3.2958	0.0010*
	Baseline-Day 30	88.10	3.2958	0.0010*
	Day 7-Day 15	64.29	3.2958	0.0010*
	Day 7-Day 30	82.14	3.2958	0.0010*
	Day 15-Day 30	50.00	2.0226	0.0431*
Group B	Baseline-Day 7	8.89	1.8257	0.0679
	Baseline-Day 15	41.03	3.0594	0.0022*
	Baseline-Day 30	56.41	3.1798	0.0015*
	Day 7-Day 15	34.29	2.9341	0.0033*
	Day 7-Day 30	51.43	3.0594	0.0022*
	Day 15-Day 30	26.09	3.1798	0.0015*

DISCUSSION:

➤ Discussion on the study is being done under the following headings.

A. Discussion on observation:

a) **Age:** Pubertal development which includes transition in social and emotional development may create a period of substantial risk for development of insomnia in adolescents, which may be due to hormonal changes.⁹

b) **Sex:** The onset of menses at puberty leads to hormonal changes which may be the cause for sex differences. Depression affects girls more than boys almost double the rate during adolescence.¹⁰

B. DISCUSSION ON RESULT:

a) **Total Hours of sleep, Difficulty in initiating Sleep, Number of Awakening:** Root of the plant contain the compound Triethylene glycol, which promotes sleep. Significant result in increased sleep in the mice. (P=0.05). Valeranone (present in *Jatamansi*) improves sleep structure and perception of sleep-in insomnia and it induces sedation by inhibiting breakdown of GABA in the brain. Furthermore because of *Madhura rasa, Snigdha guna, sitaVirya, Brahman* and *Rasayankarma* it acts as *Vatahara* and *kaphavidhikar* as well as balances the *manshikdoshas*. This might has helped in increasing hours of sleep, improved difficulty in initiating sleep and reducing the number of awakenings during sleep.^{11,12.}

d. **Shirshoola and Angamarda:** *ParasikaYavani* in various experiments have proved to have analgesic and sedative properties. Chemical constituent Hyoscine in *ParasikaYavani* is found effective for the same. Presence of *Madhura rasa, Snigdha, -guru guna, MadhuraVipaka (Ashwagandha)* and *Vatashamaka* properties of the drug has helped in reducing *Shirashula* and *Angamarda*.^{13.}

f. **Tandra:** Tandra is caused by domination of Vata followed by *kaphadosha*. Due to *Madhura, Katu, Tikta rasa* and *KatuVipaka (Parsikayavani and jatamansi)* of drug in *mamsyadighanaVati*, it may have helped in normalizing the deranged *Vata* and clearing the *srotoavrodha* by *kapha*. This may have reduced *Tandra* and improved sleep.¹⁴

g. Ajirna: Hyoscyamine and beta-sitosterol has effective role in anti-spasmodic and anti-colic effect. Furthermore, the drug has carminative properties. Due to *Tikta rasa*, *Laghuguna* and *KatuVipaka*, and *karma* like *Deepan* and *Pachana* it helped in the improvement of *Ajirna*.¹⁵

h. Overall Improvement: The improvement for Group A with p-value 0.001 on day 30 was more significant as compared to Group B with p-value 0.002.

- *Ashwagandha* being *Rasayan*, *Jatamansi* being *medya* and *ParasikaYavani* being *DeepanPachana* they might have collectively worked in overall improvement of insomnia.
- In this study *Mamsyadi Ghana Vati* (p=0.001) was more effective than the *KsheerabalatailaPadaabhyanga*(p=0.002).
- In compare the *Mamsyadi Ghana Vati* Relived the symptoms of insomnia but In *Ksheerbalataila L/A Padaabhyanga* reduced the symptoms.
- In this study age group was 13 to 16 years, in this group insomnia was more prevalent because of the hormonal changes, stress, depression, Puberty, Electronic media, school work etc.¹⁶
- In this study it was observed that after giving medication for 15 days, symptoms reduced however after 15 days withdrawal of medication relapse of symptoms was observed after the 1 month.

C. Probable drug mode of action:

- **Jatamansi:** Lusture to the body & strength it. Promotes palatability & sensory interest, cold in potency & alleviates disease due to *Tridosha*& blood, burning sensation, skin disease. Hot infusion is used to promote sleep.¹⁷
- **Ashwagandha:** it *Tikta*, *kashaya rasa*, *UshnaVirya* leads to reduced *Vata&kapha*, act as a tonic & tissue vitalizer. Act as an analgesic, promote sleep.¹⁸
- **ParasikaYavani:** It *Tikta*, *Katu rasa&UshnaVirya* leads to reduced *kapha&Vata*, *Vedanastapana*, *Deepan*, *Pachana*, *Shula*, *Nidrajanaka* etc.¹⁹

• CONCLUSION:

- In the present study involving 30 subjects, with an intervention of period of 15 days following conclusion can be drawn:
- *Mamsyadi Ghana Vati* was found to be effective in the management of *Anidra* in Adolescents.
- Both the groups showed comparable results. Both the group were significant in the management of *Anidra* in Adolescents but *Mamsyadi Ghana Vati* was highly significant with p=0.001, when compared over *Padaabhyanga* with *Ksheerbalataila* (p=0.002).

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