

Clinical study to evaluate the effect of Katu Taila Pratimarsha Nasya w.s.r. to quality of sleep

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Background: Sleep is considered essential for every individual's well-being. Ayurveda particularly emphasizes the significance of quality sleep on both mental and physical health. Recognizing the crucial role of sleep, this study aims to evaluate the efficacy of Katu Taila Pratimarsha Nasya in enhancing sleep quality.

Material and Methods: A total of 30 patients were included in this study, all placed in a single group. The participants received Katu Taila Pratimarsha Nasya treatment for 30 consecutive days, administered in the evening before sunset, a time aligned with the natural aggravation of Vata Dosha. Each participant was given a dosage of 2 Bindu (drops) in each nostril.

Results: Pratimarsha Nasya was found highly effective ($p < 0.001$) on Global PSQI Score, on Sleep Quality Scale, self-developed Sound Sleep Scale as well as on Sukhama Probodhashcha (Awaken freshly).

Conclusion: The administration of Katu Taila Pratimarsha Nasya has demonstrated a significant improvement in overall sleep quality. Key aspects such as the ability to fall asleep and the ease of waking up, showed positive changes. Based on these findings, it can be concluded that incorporating Katu Taila Pratimarsha Nasya into a daily routine is beneficial. The recommended dosage is "2 Bindu" in each nostril, administered once in the evening. This practice could be a valuable addition for those seeking to enhance their sleep quality and overall well-being.

Keywords: Nasya, Ayurveda, Sleep disorder, Insomnia, Katu Taila

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Introduction

In *Ayurveda* sleep is considered as an essential factor for health and longevity. *Ayurveda* uses number of concepts to prevent illness and promote health. *Nidra* is a part of daily rituals and it is regarded by *Ayurveda* as one of the three *Upstambha* (Co-pillars) that sustains life and it is an essential phenomenon for our body to be in a sound state.[1] Any irregularity in the sleep pattern poses various threats to the physical and mental health of body. [2] *Acharya Charaka* has stated that happiness, misery, nourishment, emaciation, strength and weakness, virility and impotence, the knowledge and ignorance as well as existence of life and its cessation all these depends upon proper and improper sleep i.e. they are positively attainable if sleep is present, if sleep is disturbed the outcomes could be adverse.[3]

Stressed lifestyle, progress of technology, disordered eating habits, demanding working profile and different other stress interfering the normal sleeping habits of people as a result of which quality of sleep is affected. Administration of medicine or medicated oil through the nose is known as *Nasya*. [4] *Ayurveda* classics explained *Nasa* as the only route to the head. So, any medicine which is administered through the nose can influence the head directly.[5] *Pratimarsha Nasya* is a type of *Nasya* which should be practiced daily as a procedure of *Dincharya*. It is described as the most convenient and well tolerated form of *Nasya*. [6] *Acharya Sushruta* and *Acharya Vagbhatta* has mentioned that use of *Pratimarsha Nasya* daily during evening hours (*Sayamkala*) leads to *Sukhanidra-Prabhodanama*. [7,8] Here in this study we have used *Katu Taila Pratimarsha Nasya* and the final prepared *Murchita Katu Taila* has the quality to penetrate the *Sukshma Srotas* i.e., most fine channels. Regular practice of *Katu Taila Nasya* leads to *Sukhnidra-Prabodhanama* along with other symptomatic effects such as prevention from premature greying of hairs, appearance of wrinkles and chloasma on face. Use of *Katu Taila Nasya* also promotes smooth functioning of sense organs and lightness in upper region. To achieve these benefits of *Katu Taila*, it was chosen as a drug for *Nasya Karma*. [9] Keeping in mind the above concept, this research work had been planned with an aim to understand effects of *Pratimarsha Nasya* and clinically observing it.

Material and Methods

Selection Criteria

Consent: Written and informed consent of apparently healthy volunteers was taken before inclusion in the trial.

Selection of Volunteers: Apparently healthy volunteers were randomly selected from O.P.D. of *Swasthavritta*, R.G.G.P.G. Ayu. College & Hospital Paprola, Distt. Kangra (H.P.) - 176115.

Inclusion Criteria

1. Volunteers willing for trial.
2. Age group 18-60 years irrespective of sex, race, religion and socioeconomic status.

Exclusion Criteria

1. Volunteers not willing for the trial.
2. Volunteers below 18 years and above 60 years.
3. Volunteers having any associated chronic ailments like Pregnant and Lactating mothers, Diabetes mellitus, Cardiac disorders, Dyslipidaemia, Renal disorders, Alcoholic liver disease.
4. Pregnant and lactating mothers.

Period of Study: Total duration of clinical trial was 30 days.

Follow-Up: On 15th day within the intervention period that is 30 days.

Sample size: Total 30 volunteers were registered for the clinical trial.

Study schedule: Two *Bindu* of *Katu Taila* in each nostril every evening (before sunset) as a daily regimen for 30 days.

Bindu: It is defined as the total quantity of collected *Taila* that dribbles down when the first two digit of index finger (proximal and middle phalanges) are dipped in to *Taila*. [10]

Observation

In the present study, total 30 volunteers were randomly selected among which all volunteers completed the study. The observation of volunteers was carried out before and after the completion of trial for 1 month.

Criteria for assessment: Effect of therapy was compared before and after the trial on following criteria-

International as well as self-made sleep quality scale.

1. Pittsburgh Sleep Quality Index (PSQI)
2. Sleep quality scale
3. Self-made scale on *Sukhama Nidra* (Sound sleep)
4. *Sukhama Probodhashcha* (Awaken freshly) were used for sleep quality assessment
5. Criteria for assessment of Characteristics of *Vridhdha*, *Heena* and *Sama Vata Dosha*.

Results

For statistical analysis of the trial, subjective parameters were accessed with "Wilcoxon Sign Rank Test". P value less than 0.05($p < 0.05$) was considered statistically significant.

A) Assessment on the basis of PSQI Scale.

Table 1: The table below shows the improvement in terms of the mean values of B.T., A.T., mean difference, % change and P value in component (1-4) among 30 A.H.V.

Components	Mean B.T.	Mean A.T.	Mean Difference (B.T-A.T.)	%age Change	P value	Sig.
Component 1 Subjective sleep quality	2	0.6	1.4	70%	<0.001	HS
Component 2 Sleep latency	1.6	0.83	0.8	50%	<0.001	HS
Component 3 Sleep duration	1.7	0.6	1.1	64.7%	<0.001	HS
Component 4 Sleep efficiency	1.4	1.03	0.37	26.4%	<0.001	HS

HS - Highly Significant

Effect of Katu Taila Pratimarsha Nasya in 30 apparently healthy volunteers on component(1-4)

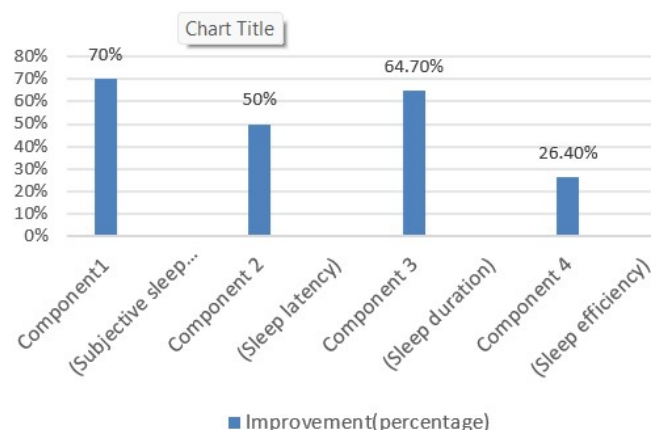


Table 2: The table below shows the improvement in terms of the mean values of B.T., A.T., mean difference, % change and P value in component (5-7) among 30 A.H.V.

Components	Mean B.T.	Mean A.T.	Mean Difference (B.T-A.T.)	%age Change	P value	Sig.
Component 5 Sleep disturbance	1.6	1.3	0.3	18.8%	0.004	MS
Component 6 Use of Sleep medication	1.3	0.93	0.37	28.5%	0.002	MS
Component 7 Daytime dysfunction	1.5	1.24	0.26	17.33	0.008	MS

MS - Moderately Significant

Effect of Katu Taila Paratimarsha Nasya in 30 apparently healthy volunteers on component(5-7)

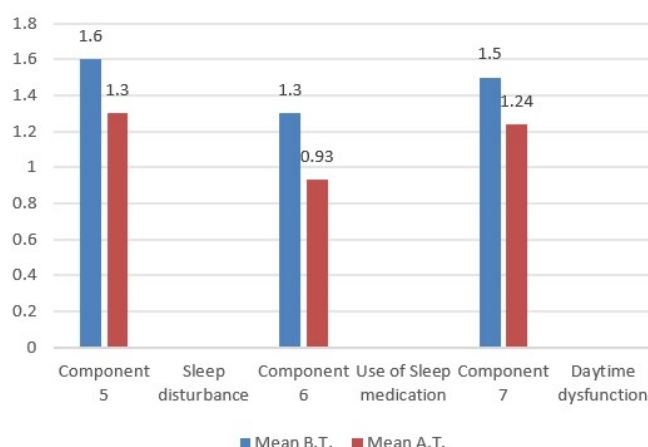


Table 3: The table below presents the mean values for B.T., A.T., mean difference, % change and P value in the evaluation of Global PSQI Score among 30 A.H.V.

Global PSQI Score	Mean B.T.	Mean A.T.	Mean Difference (B.T-A.T.)	%age Change	P value	Significance
	10.73	6.4	4.33	40.35%	<0.001	Highly Significant

B) Assessment on the basis of Sleep Quality Scale.

In this study, it was observed that *Pratimarsha Nasya* with *Katu Taila* produced highly significant results in the following 13 questions out of total 28 questions i.e.

- Q1. Difficulty falling asleep.
- Q8. Refreshed after asleep.
- Q10. Headache due to poor sleep.
- Q12. Sleep more after waking up.
- Q13. Enough sleep hours.

- Q16. Vigorous after sleep.
 Q18. Fatigue if relieved after sleep.
 Q19. Mistake at work due to poor sleep.
 Q20. Sleep satisfaction.
 Q22. Hard to concentrate at work due to poor sleep.
 Q23. Interference of Sleepiness in daily life.
 Q25. Difficult getting out of bed.
 Q27. Clear head after sleep.

Effect of Katu Taila Pratimarsha Nasya in 30 apparently healthy volunteers on Global PSQI Score

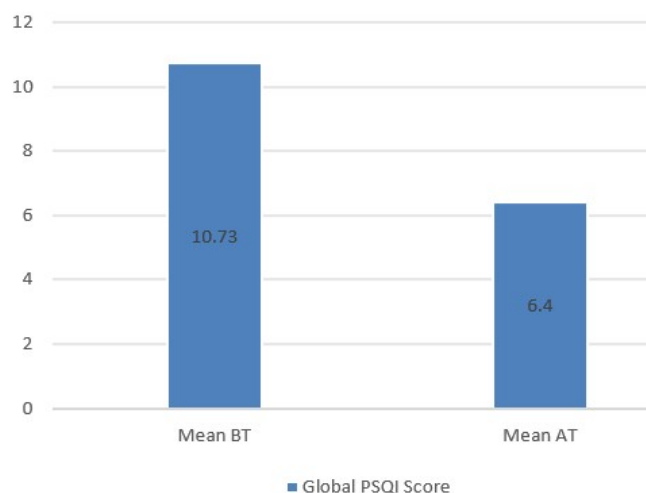


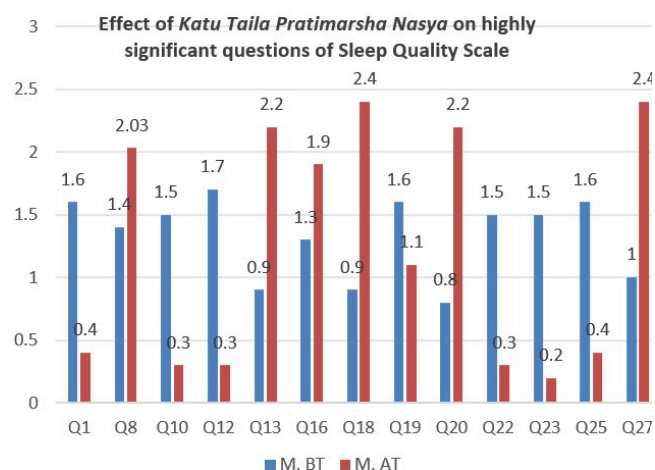
Table 4: The given table shows the mean B.T., A.T., mean difference, percentage change and P-value for Questions which shows highly significant results.

Sleep Quality Scale Q.	Mean B.T.	Mean A.T.	Mean Difference(B.T.-A.T.)	%age Change	P value	Sig.
Q1	1.6	0.4	1.2	75 %	<0.001	HS
Q8	1.4	2.03	-0.63	45%	<0.001	HS
Q10	1.5	0.3	1.2	80%	<0.001	HS
Q12	1.7	0.3	1.4	82.35%	<0.001	HS
Q13	0.9	2.2	1.3	59%	<0.001	HS
Q16	1.3	1.9	-0.6	46.15%	<0.001	HS
Q18	0.9	2.4	-1.5	58.33%	<0.001	HS
Q19	1.6	1.1	0.5	29.4%	<0.001	HS
Q20	0.8	2.2	-1.2	54.5%	<0.001	HS
Q22	1.5	0.3	1.2	80%	<0.001	HS
Q23	1.5	0.2%	1.3	86.88%	<0.001	HS
Q25	1.6	0.4	1.2	75%	<0.001	HS
Q27	1	2.4	-1.4	58.33%	<0.001	HS

HS - Highly Significant

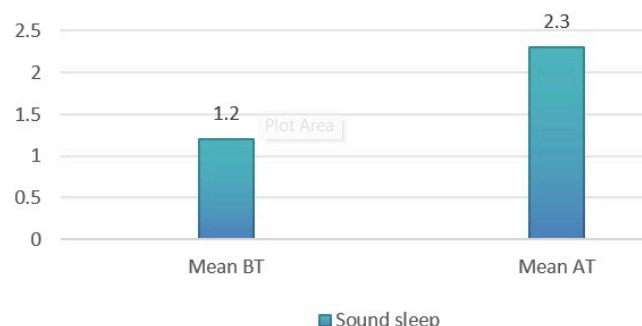
Table 5: The given table shows the % change in terms of improvement.

Scale	Mean A.T.	Mean B.T.	Mean Difference (A.T.-B.T.)	% change
Sukhama Nidra (Sound sleep)	2.3	1.2	1.1	91.66



C) Assessment on the basis of Self developed Sound Sleep

Effect of Katu Taila Pratimarsha Nasya on Sound sleep scale.



D) Assessment on the basis of Scale on symptomatic effect - Waking up refreshed.

Table 6: The given table shows the mean B.T., A.T., mean difference, percentage change and P-value for Questions which shows highly significant results.

Symptomatic effects	Mean A.T.	Mean B.T.	Mean Difference (A.T.-B.T.)	%change	P value	Sig.
Sukhama Probodhashcha (Waking up refreshed)	2.4	1.3	1.1	84.61%	<0.001	HS

HS - Highly Significant

E) Assessment by characteristics of Vriddha, Heena and Sama Vata Dosha.

To assess *Doshika* pattern in volunteers under this study a symptomatic proforma has been designed from *Ashtanga Sangraha* (A.S. Su. 19/3-9)[11] and this pattern has been observed in following manner.

- Three major groups i.e., *Vriddha Vata*, *Heena Vata*, *Sama Vata*, all are given equal points i.e., 100 each.

2. The number of characteristics in *Vridhdha Vata* was 19, *Heena Vata* was 9 and *Sama Vata* was 5.
3. To calculate characteristics in *Vridhdha Vata*, *Heena Vata*, *Sama Vata* the values are following.

Here value = 100/Number of characteristics in the group

(A) Each characteristic in *Vridhdha Vata* is assigned an equal value of 5.26 % (100/19).

(B) Each characteristic in *Heena Vata* is assigned an equal value of 11.11% (100/9).

(C) Each characteristic in *Sama Vata* is assigned an equal value of 20% (100/5).

Effect of *Katu Taila Pratimarsha Nasya* on the basis of Scale on symptomatic effect -Waking up refreshed

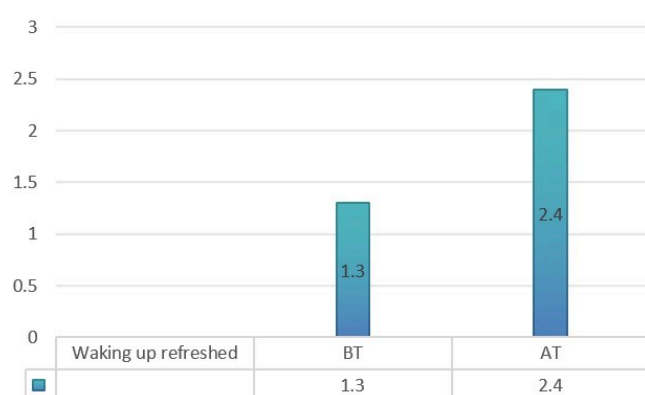
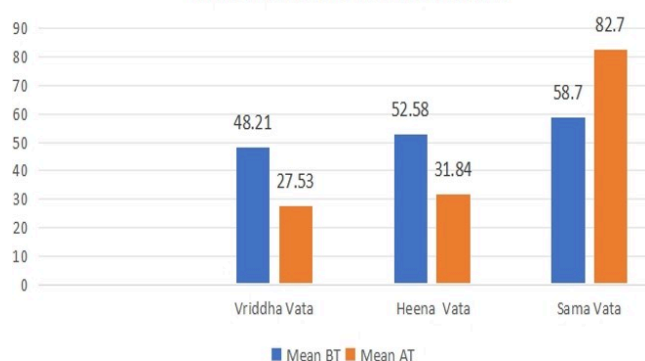


Table 7: Statistical representation of effect of *Katu Taila Paratimarsha Nasya* on characteristics of *Vridhdha*, *Heena* and *Sama Vata* in 30 apparently healthy volunteers.

Name of Characteristics	Mean B.T.	Mean A.T.	Mean Difference (B.T.-A.T.)	% Change	P value	Significance
Vridhdha Vata	48.21	27.53	20.68	42.89	<0.001	HS
Heena Vata	52.58	31.84	20.74	39.4	<0.001	HS
Sama Vata	58.7	82.7	-24	40	<0.001	HS

HS - Highly Significant

Effect of *Katu Taila Pratimarsha Nasya* on Ch. of *Vridhdha*, *Heena* and *Sama Vata* in 30 A.H.V.



Discussion

Assessment by PSQI Scale.

Katu Taila Pratimarsha Nasya has *Vata Shamaka* property, as *Chala Guna* of *Vata* balance it helps to reduce excessive thinking, mental activity and making it easier to fall asleep. By pacifying *Vata Dosha*, it reduces stress and mental agitation encouraging relaxation and calming the nervous system. This promotes deep sleep, therefore improving sleep duration, overall quality of sleep and Global PSQI score.

Assessment by Sleep Quality Scale.

In this study, it was observed that *Pratimarsha Nasya* with *Katu Taila* produced highly significant results in 13 out of 28 questions i.e. on: Q1, Q8, Q10, Q12, Q13, Q16, Q18, Q19, Q20, Q22, Q23, Q25, Q27. These results were observed to be improved by 75%, 45%, 80%, 82.35%, 59%, 46.2%, 58.3%, 29.4%, 54.5%, 80%, 86.88 %, 75% and 58.33%, respectively. It might be because as people are getting better and longer sleep, they are waking up feeling more rested, energized, refreshed and with a clear head. This helps the volunteers get out of bed more readily, being more focused at work, make fewer mistakes and experience fewer headaches from sleep deprivation. All of these factors, along with satisfactory sleep indicate noticeable improvement in quality of sleep.

Assessment by *Sukhama Nidra* Scale (Sound sleep).

The study showed that among 30 volunteers, an effect on sound sleep was observed at 91.66% ($p < 0.001$), which is statistically highly significant. It might be because, as we know *Vata Dosha* is one of the factors that may affect the quality of sleep. *Katu Taila* pacifies *Vata Dosha* in the body and because of continuous use, *Katu Taila* improves sleep quality, duration and depth thus promoting sound sleep.

Assessment by *Sukhama Probodhashcha* (Awaken freshly)

Waking up refreshed was improved by 84.61%, which is highly significant. It might be because the *Vata Dosha* pacifying property of *Katu Taila* promotes sound sleep along with the pacification of *Kapha Dosha*, which reduces *Ama* and *Guruta* in the body. As individuals sleep soundly at night, it promotes a sense of freshness in the morning.

Assessment by characteristics of *Vridhdha*, *Heena* and *Sama Vata*.

It may be due to the fact that, as per *Ayurvedic* classics, *Vata Dosha* naturally vitiate in the evening. When *Katu Taila Pratimarsha Nasya* is taken in the evening, the body's *Vata Dosha* is pacified and eventually results in the balancing of *Sama Vata Doshika* pattern by incrementation in *Heena Vata* and reduction in *Vridhdha Vata Doshika* pattern.

Conclusion

Two drops of *Katu Taila* as *Pratimarsha Nasya* in bilateral nostrils once a day (evening hours) for a period of 30 days is found highly effective ($p < 0.001$) on Global PSQI Score (especially in subjective sleep quality, sleep latency, sleep duration and sleep efficiency). Highly significant ($p < 0.001$) on Sleep Quality Scale with improvements in 13 questionnaires (Q1, Q8, Q10, Q12, Q13, Q16, Q18, Q19, Q20, Q22, Q23, Q25, Q27) out of 28. On self-developed Sound Sleep Scale 91.66% ($p < 0.001$) improvement was observed. Found highly effective ($p < 0.001$) in *Sukhama Prabodhashcha* (waking up refreshed). It was also found highly efficacious ($p < 0.001$) to pacify *Vridhdha Vata* to show incremental changes in *Heena Vata* resulting in *Sama Vata* which is a balance condition. On the base of these evidences, it is being concluded that Sleep is essential for our physical and mental health which helps to enhance our overall quality of life, "In today's fast paced world, where time is of essence, *Katu Taila Pratimarsha Nasya* is emerged as a highly effective to improve quality of sleep. In addition to this it is a low-cost procedure which is safe, less time consuming, simple to be used without any assistance of professionally skilled person and can be practiced at home easily.

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