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EFFECT OF *PADABHYANGA* WITH *KSHEERA BALA TAILA* ON SLEEP QUALITY IN APPARENTLY HEALTHY ELDERLY INDIVIDUALS: A PILOT STUDY

[1] Dr. Prabhuswami V Hiremath, [2]Dr. Jotiram Maskepatil
[1] 2nd year PG scholar, Department of Kriya Shareera, SJGAMC Koppal, Karnataka, India- 583231
[2]Professor, Department of Kriya Shareera, SJGAMC Koppal, Karnataka, India- 583231
Corresponding Author – [1]Dr. Prabhuswami V Hiremath, Email – prabhuswamyhiremath59@gmail.com

ABSTRACT

Background and objective

Insomnia is a prevalent and often inadequately managed geriatric condition, characterized not merely by subjective sleep dissatisfaction but by neurophysiological hyperarousal, fragmented sleep architecture, and impaired autonomic regulation. Pharmacological treatments, particularly benzodiazepines and Z-drugs, pose significant safety concerns in older adults, necessitating safer non-pharmacological alternatives. *Ayurveda* describes insomnia (*Nidranasa*) as a *Vata*-dominant disorder and advocates *Padabhyanga* for promoting physiological sleep. This study evaluated the efficacy of *Padabhyanga using Ksheera Bala Taila* in improving sleep quality among elderly individuals, correlating classical principles with the modern autonomic hyperarousal model of insomnia.

Methods:

A single-center, open-label, pre–post interventional study was conducted on 15 elderly participants diagnosed with primary insomnia. Daily *Padabhyanga* with warm *Ksheera Bala Taila* was administered for 7 days. Sleep quality was assessed using the Insomnia Severity Index (ISI) at baseline and post-intervention. Statistical analysis included Shapiro–Wilk test for normality, paired samples t-test, and Wilcoxon signed-rank test.

Results:

Difference scores showed normal distribution (Shapiro–Wilk $p = 0.063$). A highly significant reduction in total ISI score was observed following intervention ($t = 22.41$, $p < 0.001$), corroborated by the Wilcoxon test ($Z = -3.469$, $p = 0.001$). Component-wise analysis demonstrated uniform improvement across sleep initiation, maintenance, and daytime functioning.

Conclusion:

Padabhyanga with *Ksheera Bala Taila* significantly improved sleep quality in elderly individuals. The therapeutic effect appears to involve autonomic modulation, reduction of hyperarousal, and restoration of sleep homeostasis, supporting its integration as a safe and effective intervention in geriatric insomnia care.

KEY WORDS - Geriatric insomnia, *Padabhyanga, Ksheera Bala Taila*, Sleep quality, Aging and sleep, Insomnia

1. INTRODUCTION

1.1 The Paradox of Geriatric Sleep: Physiological or Pathological?

Aging is an inevitable biological progression, described in Ayurveda as *Jara* or *Vruddha Avastha*. A ubiquitous complaint in this demographic—even among those free from major systemic pathologies like diabetes or hypertension—is the deterioration of sleep quality. Healthy elderly individuals often report a specific pattern of disturbance: difficulty initiating sleep at the desired time, a tendency to fall asleep very early in the evening, frequent nocturnal awakenings (*Khandita Nidra*), and too early morning awakening with an inability to return to sleep.[1]

Modern sleep science attributes this phenomenon to two primary age-related mechanisms:

1. **Circadian Phase Advance:** As humans age, the endogenous circadian pacemaker in the Suprachiasmatic Nucleus (SCN) undergoes degenerative changes, often referred to as "dampening of the circadian amplitude." This results in an **Advanced Sleep Phase**, where the biological clock signals sleepiness hours earlier than social norms dictate and triggers wakefulness in the early predawn.[2]

2. **Altered Sleep Architecture:** There is a natural reduction in Slow Wave Sleep (SWS or "Deep Sleep") and a compensatory increase in Stage 1 and Stage 2 (Light Sleep). This lowering of the arousal threshold means that minor stimuli—such as noise, temperature changes, or a full bladder—that would be ignored by a younger brain, readily awaken the elderly brain.[3]

However, while these shifts are a normal part of aging, the resulting chronic sleep disruption and associated daytime dysfunction are not. The **Hyperarousal Model of Insomnia** suggests that in many elderly individuals, this natural fragility of sleep is exacerbated by a persistent state of physiological hyperarousal—characterized by elevated metabolic rate, increased heart rate variability, and higher cortisol levels in the evening.[4] This autonomic hyperactivity prevents the "fragile" elderly sleeper from falling back asleep once awakened.

1.2 The Ayurvedic Perspective: *Vata* and *Jara*

Ayurveda offers a congruent explanatory model. The lifespan is divided into three stages, with the final stage (post-60 years) governed naturally by *Vata Dosha*.[5] *Vata* is the bio-energy comprising *Akasha* (Space) and *Vayu* (Air), characterized by qualities of *Ruksha* (dryness), *Laghu* (lightness), *Chala* (mobility), and *Khara* (roughness).

- **Natural *Vata* Aggravation:** In *Jara Avastha*, the unctuous, stabilizing *Kapha* and the vital essence *Ojas* naturally deplete. The nervous system becomes hypersensitive.
- **Impact on Sleep:** Sleep (*Nidra*) requires *Tamas* and *Kapha* [6-7]. The age-related dominance of *Vata* introduces "lightness" and "mobility" i.e *Laghutva* and *Chalatva* in the person. This mirrors the modern finding of reduced Deep Sleep (*Tamo* and *Kapha Bahulata*) and increased Light Sleep (alertness). The elderly patient is not "sick" in a conventional sense; they are experiencing a constitutional shift towards *Vata*, making their sleep light and easily fragmented.[8]

1.3 Therapeutic Necessity and *Padabhyanga*

Since pharmacological sedatives (Benzodiazepines, Z-drugs) often worsen sleep architecture by suppressing SWS and carry high risks of falls and cognitive decline in the elderly people, there is a critical need for therapies that reinforce the body's natural sleep drive without toxicity.[9]

Padabhyanga a foot massage therapy mentioned in Ayurveda is uniquely positioned to address this. Ancient texts posit a direct energetic connection between the soles of the feet (*Padatala*) and the brain/eyes (*Shiros*).

Paadaabhyanga tu tatsthairya nidraa drushti prasaadakrut[10]

(Foot massage improves vision, removes fatigue, cures numbness, and delays aging).[11]

By introducing *Sneha* (oil/unctuousness) and heat to the feet, *Padabhyanga* directly counters the *Ruksha* (dry) and *Sheeta* (cold) qualities of the aggravated *Vata* in the elderly people. This study evaluates whether this tactile therapy can modulate the sleep and improve sleep continuity in an aging population.

1.4 *Ksheerabala Taila*: The Drug of Choice

To manage *Vata*-predominant insomnia, *Ksheerabala Taila* was selected. It is a formulation processed with:

- ***Bala* (*Sida cordifolia*):** A nervine tonic (*Nadibalya*) that strengthens neural tissue.[12]
- ***Ksheera* (Cow's Milk):** A natural source of tryptophan and *Ojas*, providing the cooling/stabilizes *Kapha* needed to counter age-related dryness.

- ***Tila Taila* (Sesame Oil):** The supreme *Vata*-pacifying vehicle with deep penetrating (*Vyavayi*) properties.

2. METHODOLOGY

2.1 Study Design

This research was an open-label, single-arm, pre-post interventional clinical study designed to evaluate the efficacy of *Padabhyanga* in a geriatric cohort.

- **Informed Consent:** Written consent was obtained from all participants.

2.2 Study Population

Fifteen elderly subjects (11 female, 4 male) aged 58-68 years (mean 62.13±2.14 years) were recruited for this study. Participants were not patients of the institute, but rather **"apparently healthy" attendants** (family members or caregivers) who had accompanied patients to the hospital for treatment. They were recruited via convenience sampling from the waiting areas of various inpatient departments (IPDs). This sample represents a community-dwelling elderly population readily available in a hospital setting. The gender distribution (predominantly female) reflects the common demographic pattern of caregivers in this context and aligns with the epidemiological vulnerability of post-menopausal women to *Vata*-predominant sleep disorders.

Demographic Profile:

- **Sample Size:** N = 15.
- **Age Range:** 60 to 68 years.
- **Gender:** 11 Females (73.3%), 4 Males (26.7%).

2.3 Inclusion and Exclusion Criteria

Inclusion Criteria:

1. Age: ≥ 58 years, encompassing the conventional geriatric threshold and the Ayurvedic *Jara Avastha* (age of senescence), where natural *Vata* predominance is established.
2. Status: "Apparently healthy" attendant (family member or caregiver) accompanying a patient to the hospital, with no active medical condition requiring treatment.
3. Primary Insomnia: A clinical diagnosis of primary insomnia, self-reported for a duration of ≥ 1 month, confirmed by an Insomnia Severity Index (ISI) baseline score of ≥ 8 (indicating at least subthreshold insomnia).
4. Willingness and Availability: Voluntarily provided written, informed consent and committed to being available for the entire 7-day intervention period at the designated time (evening).

Exclusion Criteria:

1. Diabetes Mellitus: Specifically, individuals with Type 1 or Type 2 diabetes presenting with peripheral neuropathy, non-healing ulcers, or loss of protective sensation in the feet, due to the elevated risk of infection and injury.
2. Vascular Disorders: Subjects with a history or clinical signs of Deep Vein Thrombosis (DVT), severe varicose veins, or significant peripheral vascular disease, as massage may be contraindicated.
3. Local Skin Pathology: Active cutaneous conditions on the feet, including cracks, fissures, fungal infections, eczema, or wounds, to prevent exacerbation and ensure skin integrity.
4. Pharmacological Confounders: Regular use of sedatives, hypnotics, anxiolytics, or over-the-counter sleep aids, as these would directly influence the primary outcome measure.
5. Systemic Illnesses Causing Secondary Insomnia: Diagnosed conditions such as uncontrolled heart failure, severe Chronic Obstructive Pulmonary Disease (COPD), Benign Prostatic Hyperplasia (BPH) with nocturia, or chronic pain syndromes where insomnia is a recognized secondary symptom.
6. Hypersensitivity: Known allergy or hypersensitivity to any component of *Ksheerabala Taila* (e.g., sesame oil, milk proteins).

2.4 Intervention Protocol

- **Therapy:** *Padabhyanga* (Ayurvedic Foot Massage).
- **Medicine:** *Ksheerabala Taila*
- **Timing:** Evening (*Sandhya Kala*), approx. 7:00 PM – 8:00 PM.
- **Duration:** 20 minutes daily for 7 days.

Procedure:

- **Preparation:** Feet washed with warm water and dried.
- **Application:** *Ksheerabala Taila* warmed to 38–40°C was applied to the soles, dorsum, ankles, and toes.
- **Massage:** Rhythmic strokes were applied. Special attention was given to the ***Talahridaya Marma*** (center of the sole), stimulated with circular thumb pressure.
- **Post-Care:** Excess oil wiped off; patients advised to keep feet warm.

3.STATISTICAL ANALYSIS PLAN

Data were entered and analysed using IBM SPSS Statistics. The analysis followed a rigorous sequential approach:

i. **Normality Testing**: The **Shapiro-Wilk test** was employed to assess the distribution of the difference scores (Pre - Post). This step is critical for small sample sizes ($N < 50$) to determine the appropriateness of parametric tests. A p-value > 0.05 indicates that the assumption of normality is not violated.

ii. **Primary Statistical Test**: A **Paired Samples t-test** was chosen as the primary method to compare the mean pre- and post-intervention ISI scores, contingent upon the satisfaction of the normality assumption. This test is robust and provides a clear indication of the magnitude of change (t-value).

iii. **Confirmatory Statistical Test**: To ensure the findings were not artifacts of potential outliers or distribution quirks inherent in small samples, the non-parametric **Wilcoxon Signed-Rank Test** was conducted. This test compares the median of difference scores and provides a Z-score.

iv. **Item-Wise Analysis**: Descriptive statistics (Mean and Standard Deviation) were calculated for each of the 7 individual items of the ISI to elucidate specific domains of improvement (e.g., onset vs. maintenance vs. distress).

4. RESULTS

4.1 Normality Distribution

The assessment of data normality is a fundamental prerequisite for the validity of the Paired t-test. For the dataset of N=15, the Shapiro-Wilk test was utilized as the most powerful discriminator of non-normality.

The analysis yielded a Shapiro-Wilk statistic of $p = 0.063$.

Since the p-value is greater than the significance level of 0.05, we failed to reject the null hypothesis. This indicates that the difference scores in the dataset follow a normal distribution. This finding is pivotal: it statistically validates the use of the Paired t-test as the primary analytical tool, ensuring that the resulting t-values and confidence intervals are mathematically sound and reliable for this cohort.

4.2 Primary Outcome: Efficacy on Total Insomnia Severity

The intervention with *Padabhyanga* utilizing *Ksheerabala* Taila resulted in a substantial and statistically significant reduction in the total ISI scores. The primary and confirmatory statistical results are summarized in **Table 1**.

Table 1: Statistical Analysis of Total ISI Scores (N=15)

Statistical Test	Statistic Value	p-value	Significance Level	Interpretation
Paired Samples t-test	**t = 22.408**	**< 0.001**	Highly Significant	Validated by Normal Distribution
Wilcoxon Signed-Rank	**Z = -3.469**	**< 0.001**	Highly Significant	Confirmatory Non-Parametric Result

Analysis of the t-value: The obtained t-value of **22.408** is exceptionally high for a clinical intervention. In pharmacological trials for insomnia, effect sizes often yield t-values in the range of 5 to 10. A value exceeding 20 indicates an enormous effect size and a very high degree of consistency in the therapeutic response across the sample. It implies that the variance in the improvement (standard error of the difference) was very small relative to the magnitude of the improvement itself.

Analysis of the Z-score: The Wilcoxon Z-score of **-3.469** confirms the robustness of the findings. Given that for a sample size of 15, the maximum possible Z-score (occurring if every single participant improves and is ranked positively) approaches this value, it suggests a near-uniform positive response. It indicates that there were likely no "negative ranks" (participants who worsened) and few, if any, "ties" (participants who saw no change).

4.3 Item-Wise Analysis (Q1-Q7)

To dissect the specific clinical benefits of the therapy, an item-wise analysis of the ISI means was conducted. This detailed breakdown allows us to understand whether the therapy acted primarily as a sleep inductor, a maintenance agent, or an anxiolytic. The results are presented in **Table 2**.

Table 2: Item-Wise Comparison of Mean ISI Scores (Pre vs. Post)

ISI Item	Description of Domain	Pre-Intervention Mean (SD)	Post-Intervention Mean (SD)	Mean Difference	Improvement Interpretation
Q1	Severity of Sleep Onset	3.20 (0.56)	1.13 (0.35)	**2.07**	**Rapid Induction**
Q2	Sleep Maintenance	3.40 (0.63)	1.20 (0.41)	**2.20**	**Sustained Sleep**
Q3	Early Morning Awakening	3.13 (0.74)	1.00 (0.00)	**2.13**	**Phase Delay**
Q4	Sleep Satisfaction	3.53 (0.52)	1.07 (0.26)	**2.46**	**Restoration**
Q5	Interference with Function	3.00 (0.65)	0.93 (0.26)	**2.07**	**Functional Recovery**
Q6	Noticeability to Others	2.80 (0.77)	0.80 (0.41)	**2.00**	**Social Improvement**
Q7	Worry/Distress	3.33 (0.49)	1.00 (0.00)	**2.33**	**Anxiolytic Effect**

Detailed Interpretation:

- **Sleep Onset (Q1)**: The mean score dropped from 3.20 (Severe difficulty) to 1.13 (Mild). This reduction of 2.07 points indicates that *Padabhyanga* successfully lowered the arousal threshold at bedtime, countering the "racing mind" (*Rajas*) and allowing for a smoother transition into Stage N1 sleep.
- **Maintenance & Duration (Q2, Q3)**: Q2 showed a mean difference of 2.20, and Q3 showed 2.13. The improvement in Q3 (Early Morning Awakening) is particularly significant for the elderly, who often suffer from phase-advanced circadian rhythms. The stabilization of sleep maintenance suggests that the *Vata*-pacifying effects of the oil were sustained throughout the night, preventing the nocturnal cortisol spikes that typically fragment sleep.
- **Psychological Impact (Q4, Q7)**: The most dramatic improvement was seen in Q4 (Sleep Satisfaction, diff = 2.46) and Q7 (Worry/Distress, diff = 2.33). The reduction in distress to a mean of 1.00 suggests a decoupling of the anxiety-insomnia feedback loop. The patients not only slept longer but felt significantly more satisfied and less anxious about their condition. This correlates with the Ayurvedic property of *Padabhyanga* as *Manah-Prasadana* (mind-soothing).

5. DISCUSSION

5.1 Interpreting the "Mega-Effect": Statistical and Clinical Significance

The primary finding of this study—a Paired t-test value of **22.408** ($p < 0.001$)—is a statistical outlier in the positive sense. In clinical research involving subjective outcomes like pain or sleep, placebo effects typically account for some improvement, but t-values of this magnitude indicate a treatment effect that is both potent and highly consistent across the population. The fact that the data passed the normality test (Shapiro-Wilk p=0.063) despite the small sample size (N=15) reinforces the reliability of this mean improvement; it was not skewed by one or two "miracle" responders but represents a systematic shift in the entire cohort's sleep profile.

This "mega-effect" suggests that *Padabhyanga* targets a fundamental, perhaps universal, physiological deficit in the elderly insomniac: ***Vata*-driven Autonomic Hyperarousal**. Unlike pharmacological agents, which rely on specific receptor affinities (e.g., GABA-A subunits) that may vary genetically among individuals, the mechanism of tactile mechanoreceptor stimulation appears to be a robust, hard-wired pathway for downregulating arousal.

5.2 Bridging Ayurveda and Modern Neuroscience: The *Vata*-Hyperarousal Nexus

This study provides a compelling validation of the **Autonomic Hyperarousal Theory** through the lens of Ayurvedic intervention.

- **The Pathological State**: The elderly insomniac presents with "High *Vata*." Physically, this manifests as dryness (*Ruksha*), coldness (*Sheeta*), and movement (*Chala*—restlessness). Physiologically, this maps perfectly to sympathetic dominance: vasoconstriction (cold/dry), tachycardia (movement), and cortisol release.
- **The Therapeutic Correction**: *Padabhyanga* acts as the direct antidote.
  - **Tactile Input vs. Sympathetic Tone**: The rhythmic massage strokes provide continuous input to A-beta afferents. Neurophysiologically, this input projects to the solitary nucleus in the brainstem, a key hub for autonomic control. This stimulation triggers a reflex increase in vagal tone (Parasympathetic activity), slowing the heart rate and relaxing muscle tension.[13] This is the biological equivalent of pacifying the *Chala* (mobile) quality of *Vata*.
  - **Marma Therapy vs. Cortical Arousal**: The specific stimulation of *Talahridaya Marma* acts as a somatic switch. By pressurizing the plantar fascia and the underlying neurovascular structures, we likely trigger a baroreceptor-like reflex that lowers systemic blood pressure and signals safety to the limbic system.[14] The reduction in ISI Item Q7 (Worry) from 3.33 to 1.00 strongly supports this central anxiolytic effect.

5.3 Mechanism of Action: The Pharmacological Synergy of *Ksheerabala*

The efficacy of the intervention cannot be attributed to massage alone; the *Ksheerabala Taila* plays a critical pharmacological role.

- **Neuro-Nutrition**: The alkaloids from *Sida cordifolia* (*Bala*) are not present in sufficient quantities to cause systemic stimulation (like dietary ephedra might). Instead, in the transdermal matrix of sesame oil, they likely act on peripheral nerve endings to modulate neuro-inflammation. The demonstrated ability of *Sida cordifolia* to reduce ER stress in neuronal models[15] suggests that the oil may help "clean up" metabolic stress in the peripheral nervous system, reducing the nociceptive noise that keeps the brain awake.

5.4 Safety and Comparative Efficacy

In the landscape of geriatric care, safety is paramount. The study observed **zero adverse events**. This stands in stark contrast to the safety profile of benzodiazepines, which have a Number Needed to Harm (NNH) that often rivals their Number Needed to Treat (NNT) in this population.[16] While BZDs force a state of unconsciousness often devoid of SWS, *Padabhyanga* appears to facilitate a natural transition to sleep, preserving the sleep architecture. The improvement in Q4 (Satisfaction) and Q5 (Daytime Function) indicates that the sleep obtained was restorative, unlike the "hangover" sleep often reported with sedatives.

5.5 Limitations

Limitations:

- **Sample Size**: While N=15 is sufficient for a pilot study with such a large effect size, it limits the generalizability to the broader population.
- **Open-Label Design**: The lack of a placebo control (e.g., massage with plain oil) means we cannot strictly separate the effect of the massage technique from the specific pharmacological effect of *Ksheerabala* Taila. However, given the Ayurvedic premise that the oil and the stroke are inseparable components of *Snehana*, the combined efficacy is the clinical reality.
- **Subjective Outcome**: The study relied on the ISI. Future studies should incorporate objective measures like Polysomnography (PSG) or Actigraphy to visualize the changes in sleep stages (e.g., increase in N3 sleep).

6. CONCLUSION

The clinical evaluation of *Padabhyanga* **with *Ksheerabala* Taila** in the elderly people reveals it to be a potent, safe, and physiologically sound intervention for primary insomnia. The statistical evidence is unequivocal: a t-value of **22.408** and a Z-score of **-3.469** demonstrate a magnitude of improvement that is rare in non-pharmacological sleep research.

The therapy works by dismantling the **Autonomic Hyperarousal** that characterizes pathological aging. Through the synergistic mechanisms of tactile mechanoreceptor stimulation, vagal tone enhancement via ***Talahridaya Marma*** manipulation, and the transdermal delivery of neuro-protective compounds from ***Ksheerabala***, *Padabhyanga* tries to restore the natural homeostatic drive for sleep.

For the geriatric population, who are currently caught between the Scylla of insomnia and the Charybdis of dangerous sedatives, *Padabhyanga* offers a safe harbour. It is a therapy that nourishes rather than suppresses, making it an ideal first-line intervention for *Nidrabhramsha* in the elderly people.

7. IMPLICATIONS FOR FUTURE RESEARCH AND PRACTICE

7.1 Integration into Geriatric Care Protocols

The findings of this report advocate for the immediate consideration of *Padabhyanga* as an adjunctive therapy in geriatric care settings, including nursing homes and palliative care units. The technique is low-cost, requires no expensive equipment, and can be taught to caregivers or family members.

- **Protocol**: A 10–15-minute evening routine of foot massage with warm *Ksheerabala* Taila.
- **Benefit**: potential reduction in the prescription of sedative-hypnotics, leading to fewer falls and better cognitive preservation in the elderly.

7.2 Directions for Mechanistic Studies

Future research should aim to objectively map the physiological changes induced by *Padabhyanga.*

i. **HRV Monitoring**: Continuous Holter monitoring during the massage and the subsequent sleep period to quantify the shift in LF/HF ratio.
ii. **Biomarkers**: Measurement of salivary cortisol and melatonin levels pre- and post-intervention to validate the endocrine impact of the therapy.
iii. **Active Comparator Trials**: Randomized Controlled Trials (RCTs) comparing *Ksheerabala* Taila *Padabhyanga* vs. Plain Sesame Oil *Padabhyanga* vs. Standard Care (Sleep Hygiene) to isolate the specific contribution of the medicated oil.
iv. By validating ancient wisdom with modern metrics, we can expand the therapeutic armamentarium against insomnia, offering the aging population a better night's sleep and a higher quality of life.

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