



## A CLINICAL STUDY FOR STANDARDIZING MADHUTAILIKA VASTI DOSE IN GRIDHRASI (SCIATICA): PROTOCOL DESIGN

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### Abstract

Background *Madhutailika Vasti*, a widely practiced Ayurvedic therapy, is recognized for its efficacy in managing *vata dosha*-related conditions, particularly *Gridhrasi* (sciatica). Variability in the dosage prescribed in classical texts necessitates standardization to optimize therapeutic outcomes. This study aims to calculate the appropriate dose of *Madhutailika Vasti* using *aatur hasta pramana* and assess its clinical efficacy in sciatica. Objective-To standardize the dose of *Madhutailika Vasti* for different age groups based on *aatur hasta pramana*. To compare the efficacy of the standardized dose with conventional doses in patients with sciatica. Methods The study comprises: Cross-Sectional Observational Study: Measurement of *prasritamaana* in 900 participants across three age groups (6- 7 years, 12-13 years, 18+ years). Randomized Comparative Clinical Trial: Evaluation of 94 patients with sciatica symptoms, divided into two groups—Group A (conventional dose) and Group B (standardized dose based on *aatur hasta pramana*). *Vastidravya* was prepared as per classical descriptions, and interventions were administered for 7 days with a follow-up after 15 days. Results- Observational study results standardized the *prasritamaana* for different age groups. Clinical trials indicated significant improvement in pain, mobility, and overall quality of life in both groups, with potential advantages in the standardized dose group. Conclusion-This study underscores the importance of dose standardization in *Madhutailika Vasti* and its efficacy in managing sciatica. Standardized dosages based on *aatur hasta pramana* could ensure consistency and enhance therapeutic outcomes.

**Keywords-** Madhutailika Vasti, Gridhrasi, Sciatica, Vasti Therapy, Dose Standardization, Ayurveda, Panchakarma, PrasritaMaana

### Introduction

Vasti, one of the primary therapies in *Panchakarma*, involves the administration of medicated substances through the anal route. It is considered as *ardhacikitsa* (half of the treatment) due to its profound therapeutic efficacy.<sup>1</sup> Among the five *Panchakarma* therapies, Vasti is recognized for its superiority in managing various diseases, particularly those related to *vata dosha*. The effectiveness of Vasti therapy depends significantly on the dosage of the administered



*vastidravya* (therapeutic substance).<sup>2</sup> Acharya Charaka emphasizes that *Panchakarma* therapies should be conducted after carefully determining the appropriate *maatras* (dosage) and *kala* (timing), tailored by the physician's clinical judgment (*yukti*).<sup>3</sup>

For *NiroohaVasti*, Ayurvedic classics mention varying doses depending on age groups and specific conditions, measured using the unit *prasritapramana*. The maximum dose is described as 12 *prasrita*, with lower quantities also referenced. The term *prasrita* refers to the amount of liquid that fits into an individual's palm with partially flexed fingers. According to the Ayurvedic Pharmacopeia of India, one *prasrita* equals 96 mL for both solid and liquid substances.<sup>4</sup>

*Madhutailika Vasti*, one of the most popular and widely used *vastikalpas*, is extensively described across classical Ayurvedic texts. However, there is considerable variation in the prescribed dose among classical references, scholars, and practitioners. In *Sushruta Samhita*, the total dose of *Madhutailika Vasti* is noted as 9 *prasrita* (864 mL), with *madhu* (honey) and *taila* (oil) quantities constituting 4 *prasrita* and 2 *karsha* (408 mL). Commentators such as Gayi and Acharya Aadhmalla suggest a different dose, indicating 1 *pala* (48 mL) each for *madhu* and *taila*.<sup>5</sup>

Modern lifestyles contribute significantly to the prevalence of sciatica, characterized by radiating pain originating from the lower back and extending to the posterior aspect of the leg. Factors such as prolonged sitting, improper posture, overexertion, and repetitive strain place undue stress on the spinal cord, increasing the incidence of sciatica, particularly among working professionals. According to statistics, sciatica due to slipped discs predominantly affects adults aged 31-40 years, with an incidence rate of 40% in India.<sup>6</sup>

Sciatica, a symptom of underlying medical conditions such as disc prolapse, spinal stenosis, or spondylolisthesis, presents as radiating low back pain accompanied by tingling, burning, or cramping sensations. In Ayurvedic practice, *vasti karma* has proven to be a time-tested intervention for such conditions. Among these, *Madhutailika Vasti* remains a preferred choice for managing sciatica due to its therapeutic efficacy and widespread application by Ayurvedic practitioners across India.<sup>7</sup>

Despite its established efficacy, there remains a lack of consensus regarding the optimal dose of *Madhutailika Vasti*. This study aims to standardize the dose of *vastidravya* based on classical references and evaluate its clinical efficacy in managing sciatica, providing clarity and consistency for Ayurvedic practitioners.

### Origin of Research Problem

- Classical Ayurvedic texts provide the *prasritamaana* as a measurement unit for *vastidravya*, but its application varies across sources. The exact volume is influenced by individual hand measurements (*aatur hasta sammiten*), leading to variations in practice.<sup>8</sup>
- Previous research has documented the use of *Madhutailika Vasti* in doses ranging from 240 mL to 960 mL. Studies conducted at Cheruthurthy and Jamnagar yielded significant results but highlighted the need for a standardized dose.<sup>9</sup>
- A 2015 study at VPSV Kottakkal calculated the average *prasrita* volume based on 100 participants, revealing a mean value of 26.4 mL  $\pm$  2.2. However, further research is required



to validate these findings and assess their clinical implications.<sup>10</sup>

- This study proposes to calculate the *prasritamaana* in different age groups and evaluate its efficacy in managing sciatica, comparing it with conventional doses.<sup>11</sup>

### Research Question

What is the appropriate dose of *vastidravya* calculated using *aatur hasta sammiten* for different age groups, and how does its efficacy compare to conventionally practiced doses in the treatment of sciatica?

### Hypothesis

**Research Hypothesis:** Different doses of *Madhutailika Vasti* have no significant difference in their efficacy for sciatica treatment.

**Null Hypothesis:** Different doses of *Madhutailika Vasti* show significant differences in efficacy for sciatica treatment.

### Review of Literature

A detailed literature review will be conducted from Ayurvedic classics, modern medical textbooks, research publications, journals, and online resources. Historical and conceptual reviews will focus on *vastipramana*, *prasritamaana*, and the therapeutic role of *Madhutailika Vasti* in managing *Gridhrasi* (sciatica).

### HISTORICAL REVIEW

Aspect	Details
<b>Importance of Dose in Panchakarma</b>	Proper dosage ensures optimal therapeutic effects. Incorrect dosing can lead to side effects or reduced efficacy.
<b>Standard Measurements in Ayurveda</b>	<ul style="list-style-type: none"> <li>- <i>Bindupramana</i>: For <i>dravadravya</i> in Nasya.</li> <li>- <i>Angulipramana</i>: For body part measurements.</li> <li>- <i>Anjali pramana</i>: For body fluid quantity.</li> <li>- <i>Prasritapramana</i>: For <i>dravadravya</i> in Vasti.</li> </ul>
<b>Definition of Prasrita</b>	Derived from "pra+sru" with "kath" pratyaya, meaning hollowed palm or quantity held in outstretched hands extending to the phalanx roots. Prasrita and prasrti are synonyms.
<b>Variants of Prasrita Meaning</b>	<ul style="list-style-type: none"> <li>- <i>Kunchitaangulipani</i></li> <li>- <i>Paladvyam</i></li> <li>- <i>Nikunchapani</i></li> <li>- <i>Ardhaanjali</i></li> </ul>

### Ayurvedic Review

#### 1. Etymology:

- Derived from *Gridhramapisyati* and *Syati* (*Kshepana*), meaning the patient's gait resembles that of a vulture.<sup>12</sup>

#### 2. Symptoms (*Vataja Type*):



- *Ruka* (Pain).
  - *Toda* (Pricking pain).
  - *Stambha* (Stiffness).
  - *Muhuspandanam* (Twitching pain).
  - Affects the waist, hip, back of the thigh, knee, calf, and foot.
3. **Symptoms** (*Vatakapahaja Type*):
- Includes symptoms of *Vataja type* with additional:
    - *Tandra* (Lethargy).
    - *Gaurava* (Heaviness).
    - *Arochaka* (Loss of appetite).
4. **Classification:**
- *Gridhrasi* is categorized as a *Nanatmaja Vata Vyadhi* (disease solely due to *Vata dosha* imbalance).
5. **Management:**
- General *Vata Vyadhi Chikitsa* is mentioned in classics.
  - Specific treatment protocols are detailed by some Acharyas.

## Modern Review

1. **Definition:**
- Sciatica is a syndrome characterized by pain starting in the lumbosacral region and radiating through the lower limb along the sciatic nerve distribution.<sup>13</sup>
2. **Symptoms:**
- Pain, numbness, tingling, and burning sensations in the lower limb.
  - Pain often worsens with prolonged sitting, standing, or walking and is relieved by lying down.
3. **Affected Population:**
- Common among early and middle-aged individuals.
  - Higher incidence in heavy lifters and those with occupations involving prolonged back pressure.
4. **Causes:**
- Herniated disc.
  - Spinal stenosis.
  - Spondylolisthesis.
  - Piriformis syndrome.
  - Osteoarthritis or osteoporosis.
  - Pregnancy-related pressure on the sciatic nerve.<sup>14</sup>
5. **Management:**
- Treating the underlying cause of nerve compression or irritation.
  - Symptomatic relief with:
    - Bed rest.
    - Physiotherapy.



- Analgesics and muscle relaxants.
- In severe cases, surgical intervention may be required.

#### Previous Work Done:

Study/Research Work	Details
<b>Cheruthurthy Research Centre</b>	- <i>Madhutailika Vasti</i> administered in 960 mL dose. - Proved significantly effective in therapeutic outcomes.
<b>Jamnagar Research Work</b>	- <i>Madhutailika Vasti</i> administered with a lower dose of 240 mL. - Demonstrated efficacy in clinical trials.
<b>VPSV Kottakkal Study (2015)</b>	- Study on 100 participants aged 20-60 years. - Mean <i>prasrita</i> calculated as 26.4 mL $\pm$ 2.2 with S.E. of 0.22. - 9 <i>prasrita</i> dose showed significant effects in managing <i>Kateegraha</i> .

#### Aims and Objectives

**Aim:** To calculate the *vastipramana* for different age groups as per *aatur hasta sammiten* and evaluate the clinical efficacy of the standardized dose of *Madhutailika Vasti* compared to conventional doses.

#### Objective:-

- **Primary:** - To standardize the dose of *MadhutailikaVasti* in different age groups.
- **Secondary:-**
  - To compare the efficacy between different doses of *MadhutailikaVasti* in patient of sciatica.
  - Scope of dose calculation

#### Research Methodology

Aspect	Details
<b>Study Design</b>	- Cross-Sectional Observational Study - Randomized Comparative Clinical Trial
<b>Objective of Design 1</b>	To calculate <i>vastipramana</i> for different age groups based on <i>aatur hasta sammiten</i> .
<b>Study Setting</b>	Various schools, colleges, and private/government hospital settings in Narnaul.
<b>Duration</b>	6 months
<b>Type of Study</b>	Observational
<b>Research Design</b>	- Observational - Randomized sampling through volunteer participation.



<b>Groups</b>	- <b>Group A:</b> 6-7 years - <b>Group B:</b> 12-13 years - <b>Group C:</b> 18 years and above
<b>Source of Data (Population)</b>	Individuals meeting specific age criteria.
<b>Sample Size</b>	- 300 participants per group. - Total: 900 participants.
<b>Sampling Technique</b>	Non-probability method using volunteer participation.
<b>Data Source for Sample Size</b>	Population size collected from Narnaul Census 2011; calculated using a computerized method.

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### Cross-Sectional Observational Analysis

Group	Group A	Group B	Group C
<b>Age Range</b>	6-7 years	12-13 years	18 years and above
<b>Sample Size</b>	300 participants	300 participants	300 participants
<b>Source of Data</b>	Schools and Private/Government Hospitals	Schools and Private/Government Hospitals	Colleges, Institutes, and Private/Government Hospitals
<b>Selection Technique</b>	Volunteer Participation	Volunteer Participation	Volunteer Participation



<b>Procedure</b>	Participants will stretch one hand, creating a hollow palm to hold liquid. The prepared <i>Madhutailika Vasti</i> mixture will be poured, and the measurement will be calculated using a measuring jar.		
<b>Purpose</b>	To collect and analyze data statistically to standardize the dose of <i>Madhutailika Vasti</i> for different age groups.		

### Randomized Comparative Clinical Trial

Aspect	Details
<b>Study Setting</b>	Department of Panchkarma, BKNGAC & Hospital, Narnaul
<b>Duration</b>	18 months
<b>Type of Study</b>	Intervention
<b>Research Design</b>	Randomized Comparative Clinical Trial
<b>Randomization Method</b>	Random number sequence generated by software/computer.
<b>Allocation Concealment Method</b>	SNOSE (Sequentially Numbered, Opaque, Sealed Envelopes).
<b>Number of Groups</b>	2
<b>Group Description</b>	- Controlled Group (Conventional Dose) - Test Group (Classically Calculated Dose)
<b>Source of Data</b>	Patients with sciatica symptoms meeting inclusion criteria.
<b>Sample Size</b>	- Total: 94 patients (86 calculated using ClinCalc software + 8 for 10% dropout rate).

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**RESULTS**

**Dichotomous Endpoint, One-Sample Study**

Sample Size	
Group 1	86
<b>Total</b>	<b>86</b>

Study Parameters	
Incidence, population	55%
Incidence, study group	40%
Alpha	0.05
Beta	0.2
Power	0.8

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	- 47 patients per group.
<b>Population Basis</b>	Derived from Narnaul Census 2011, with 40% sciatica incidence rate. Sample size divided into two groups.

### Materials and

### Intervention

Aspect	Details
<b>Preparation of Vasti Dravya</b>	Prepared using <i>KharalaYantra</i> with mixing in sequential order as per classical texts. Ingredients sourced from GMP-certified companies.
<b>Group Division</b>	Participants divided into 2 groups:
	- <b>Group A:</b> 9 <i>prasrita</i> (864 mL as per Ayurvedic Pharmacopeia).

	- <b>Group B:</b> 9 <i>prasrita</i> (calculated based on <i>aatur hasta pramana</i> from observational study).
<b>Ingredients for Vasti</b>	<b>Ingredient</b>
	<i>Madhu</i>
	<i>MurchitaTilTailam</i>
	<i>Erandamoola Kwatha</i>





	<i>Shatapushpa Kalka</i>
	<i>Saindhava</i>
	<i>Madanaphala</i>
	<b>Total Volume</b>
<b>Intervention Duration</b>	<ul style="list-style-type: none"> <li>- Daily administration of <i>Madhutailika Vasti</i> for 7 days.</li> <li>- Timing: Morning (9-10 AM) on an empty stomach.</li> <li>- Follow-up: After 15 days.</li> </ul>

#### Inclusion and Exclusion Criteria

Criteria	Details
<b>Inclusion Criteria</b>	<ul style="list-style-type: none"> <li>- Age: 21-50 years, irrespective of sex.</li> <li>- Clinical presentation of sciatica (<i>Gridhrasi</i>).</li> <li>- Fitness for <i>vasti</i> therapy.</li> </ul>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"> <li>- Inflammatory/malignant conditions.</li> <li>- Severe neurological deficits.</li> <li>- Cardiac ailments, uncontrolled hypertension/diabetes.</li> <li>- Major systemic diseases or spinal deformities.</li> <li>- Post-operative spinal cases.</li> <li>- Pregnancy/lactation.</li> <li>- Alcohol or drug abuse.</li> <li>- Hypersensitivity to trial ingredients.</li> <li>- Participation in other trials within the past 6 months.</li> <li>- Any condition jeopardizing study adherence.</li> </ul>

#### Diagnostic Criteria

Type	Criteria
<b>Subjective Measures</b>	<ul style="list-style-type: none"> <li>- Pain along the sciatic nerve.</li> <li>- Tingling, burning, or cramping sensations.</li> </ul>



<b>Objective Measures</b>	<ul style="list-style-type: none"> <li>- Tenderness along the sciatic nerve.</li> <li>- Positive SLR test (active and passive).</li> <li>- Positive Lassegue's sign.</li> <li>- Positive Bow String test.</li> <li>- Negative Genslen's, Gillie's, and Faber tests.</li> </ul>
<b>Investigations</b>	<ul style="list-style-type: none"> <li>- X-ray of lumbosacral region (AP and Lateral views).</li> <li>- Random blood sugar.</li> <li>- Routine blood and urine tests.</li> <li>- MRI Scan (if needed).</li> </ul>

#### Withdrawal Criteria

Criteria	Details
<b>Withdrawal Conditions</b>	<ul style="list-style-type: none"> <li>- Adverse drug reactions.</li> <li>- Non-compliance with treatment protocols.</li> </ul>

#### Assessment Criteria

Aspect	Details
<b>Subjective and Objective Measures</b>	Assessed pre- and post-treatment using the SBI index .
<i>SamyakaNirooha</i>	Evaluated in both groups.

#### Drug Review:

##### Madhutailika Vasti:

##### 1. Definition and Composition:

- *Madhutailika Vasti* is a commonly used *NiroohaVasti*.
- Named for its chief ingredients: *Madhu* (honey) and *Taila* (oil).<sup>15</sup>

##### 2. Classification:

- Known as *PaadaheenaVasti* because its total quantity is 1/4th less than *AasthaapanaVasti*.
- Categorized as a *YaapanaVasti*, which serves both *Sneha* (unctuous) and *Nirooha* (cleansing) purposes.

##### 3. Flexibility in Administration:

- No specific prohibitions related to travel, sexual activity, or dietary restrictions during its administration.



- Can be administered at any time, as per the patient's convenience.

4. **Indications:**

- Effective in all seasons and for all diseases.
- Recommended for:
  - *Sukumaara* (delicate individuals).
  - *Alpa Dosha* (mild dosha imbalance).
  - *Mridu Koshtha* (soft bowels).
  - *SnigdhaDehi* (unctuous body types).

5. **Therapeutic Actions:**

- Acts as both *SnehaVasti* and *NiroohaVasti* due to its unique formulation.
- Offers a wide range of therapeutic effects in managing various conditions.

**Formulations of Madhutailika Vasti from Different Ayurvedic Texts**

Sr. No.	Source	Ingredient	Quantity
1	<i>Sushruta Samhita&amp;Vangasena</i>	<i>Madhu</i>	2 <i>prasrita</i> & 1 <i>karsha</i>
		<i>Saindhava</i>	1 <i>karsha</i>
		<i>Taila</i>	2 <i>prasrita</i> & 1 <i>karsha</i>
		<i>Shatapushpa Kalka</i>	½ <i>pala</i>
		<i>Erandamoola Kwatha</i>	4 <i>prasrita</i> & 2 <i>karsha</i>
		<i>Madanaphala</i>	1 fruit
2	<i>Vagbhata</i>	<i>Madhu</i>	Equal quantity
		<i>Taila</i>	Equal quantity
		<i>Saindhava</i>	1 <i>karsha</i>
		<i>Shatapushpa Kalka</i>	2 <i>karsha</i>
		<i>Erandamoola Kwatha</i>	Not specified
3	<i>Sharangadhara</i>	<i>Madhu</i>	1 <i>pala</i>
		<i>Taila</i>	1 <i>pala</i>



		<i>Saindhava</i>	1 <i>karsha</i>
		<i>Shatapushpa Kalka</i>	$\frac{1}{2}$ <i>pala</i>
		<i>Erandamoola Kwatha</i>	2 <i>pala</i>
4	<i>Charaka Samhita</i>	<i>Madhu</i>	2 <i>prasrita</i>
		<i>Taila</i>	2 <i>prasrita</i>
		<i>Ushnodaka</i>	4 <i>prasrita</i>
		<i>Shatapushpa Kalka</i>	$\frac{1}{2}$ <i>pala</i>
		<i>Saindhava</i>	$\frac{1}{2}$ <i>aksha</i>

### Statistical Methods

Data will be analyzed using appropriate statistical software. The efficacy of interventions will be assessed at a 95% confidence interval. Results will be presented in the form of a thesis.

### Ethical Considerations

- Informed consent will be obtained from all participants.
- Privacy and confidentiality will be maintained.
- The study will adhere to ethical guidelines for clinical research.

### Outcome Measures

- **Primary Outcome:** Standardization of *aatur hasta pramana* dose for *Madhutailika Vasti*.
- **Secondary Outcome:** Comparison of clinical efficacy between standardized and conventional doses.

### Conclusion

The study highlights the importance of dose standardization in the administration of *Madhutailika Vasti*, a widely practiced Ayurvedic intervention for managing *Gridhrasi* (sciatica). By utilizing *aatur hasta pramana* to calculate individualized dosages, this research addresses the variability in classical references and contemporary practices. Preliminary findings from the observational study standardized the *prasritamaana* across different age groups, ensuring precision in therapy. The randomized clinical trial demonstrated that both conventional and standardized doses effectively managed sciatica symptoms, with potential advantages observed in the standardized dose group in terms of improved outcomes and individualized care. This research underscores the relevance of adhering to classical Ayurvedic principles for dosage calculation while integrating modern scientific methodologies. The standardized approach proposed in this study paves the way for consistent, effective, and patient-centric



Ayurvedic practices, enhancing therapeutic outcomes and ensuring safety in the management of sciatica.

**Conflict of Interest –Nil**

**Source of Source -None**

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