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Research Article

# A RANDOMISED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFECT OF *AGNIKARMA* AND *KALA BASTI* BY *ERANDMOOLADI NIRUHA* AND *SAINDHVADI ANUVASANA* IN THE MANAGEMENT OF *GRIDHRASI*

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## ABSTRACT

*Gridhrasi* is a *Vata*-dominant disorder described in Ayurveda and is clinically comparable to sciatica, which commonly presents with radiating pain, stiffness, pricking sensation and functional limitation. Ayurvedic management of *Gridhrasi* is done using *Karma Chikitsa* including *Basti* and *Agnikarma*. Although both procedures have been described for managing *Gridhrasi*, evidence on the clinical benefit of combining *Agnikarma* with *Kala Basti* remains limited. Therefore, this study was planned to evaluate the therapeutic effect of *Agnikarma* administered after *Kala Basti* in patients with *Gridhrasi*. **Objective:** To evaluate the efficacy of *Kala Basti* followed by *Agnikarma* with *Panchadhatu Shalaka*, compared with *Kala Basti* alone, in managing *Gridhrasi*. **Methods:** A randomized, active-controlled, open-label clinical study will be conducted in the OPD and IPD of the PG Department of Panchakarma, CBPACS, New Delhi. A total of 50 patients fulfilling the predefined diagnostic and eligibility criteria will be enrolled and randomly allocated into two groups of 25 participants each. Group A will receive *Kala Basti* comprising *Erandmooladi Niruha Basti* and *Saindhavadi Taila Anuvasana Basti* for 16 days, followed by three sittings of *Agnikarma* with *Panchadhatu Shalaka* on days 16, 23, and 30. Group B will receive *Kala Basti* alone for 16 days. Patients will be assessed at baseline and at predefined post-treatment and follow-up time points up to day 48. The primary clinical assessment will include changes in *Gridhrasi* symptoms, while functional status will be evaluated using the ODI and SLR test. **Results:** The results of study will assess changes in individual symptoms and overall clinical response between the two groups. **Conclusion:** The proposed study may help develop feasible evidence based Ayurvedic treatment protocol for management of *Gridhrasi*.

## INTRODUCTION

*Gridhrasi* is characterized by pain extending from the lower back and buttock towards the thigh, knee, leg and foot, often associated with *Ruka* (pain), *Stambha* (stiffness), *Toda* (pricking sensation) and *Muhusphandana* (twitching)[1]. Depending upon *Dosha* predominance, it is described as *Vataja* and *Vata-Kaphaja Gridhrasi* [2].

The clinical presentation of *Gridhrasi* closely resembles sciatica, which is characterized by pain along the distribution of the sciatic nerve and may be associated with sensory disturbances and a positive Straight Leg Raise (SLR) test. Lifestyle factors such as prolonged sitting, faulty posture, inadequate physical activity and dietary irregularities may contribute to the development of such disorders, with *Vata* aggravation. Vitiated *Vata* is considered an important factor in development of painful disorders according to Ayurvedic perspective.[3]

*Bastikarma* is regarded as an important therapy for aggravated *Vata*. *Erandmooladi Niruha Basti* is indicated for pain involving the *Jangha*, *Uru, Pada, Trika* and *Prishtha* regions, corresponding to the symptomatic distribution of *Gridhrasi*[4]. *Saindhavadi Taila* is also indicated in *Vata* disorders, particularly *Gridhrasi*[5]. These classical indications support the selection of *Kala Basti* comprising *Erandmooladi*

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*Niruha* and *Saindhavadi Anuvasana* for the present study.

*Agnikarma* is advocated for the management of severe pain involving structures such as *Snayu*, *Sandhi* and *Asthi*,[6] making it relevant for the painful presentation of *Gridhrasi*. Clinical studies have also indicated its potential therapeutic benefit in this condition.

Despite the individual therapeutic significance of *Bastikarma* and *Agnikarma*, evidence evaluating their combined therapeutic effect in *Gridhrasi* is limited. Therefore, the present randomized clinical study has been planned to evaluate whether *Kala Basti* with *Erandmooladi Niruha* and *Saindhavadi Anuvasana* followed by *Agnikarma* with *Panchadhatu Shalaka* provides greater clinical benefit than *Kala Basti* alone in patients with *Gridhrasi*, with the aim of developing an evidence-based and practically feasible therapeutic approach.

## OBJECTIVES

### Primary Objective

To evaluate the efficacy of *Kala Basti* followed by *Agnikarma* with *Panchadhatu Shalaka* in comparison with *Kala Basti* alone in the management of *Gridhrasi*.

### Secondary Objective

1. To assess the effect of *Agnikarma* following *Kala Basti* on the clinical features and functional disability associated with *Gridhrasi*.
2. To compare the overall clinical response between the two treatment groups.

### Hypothesis

### Alternate Hypothesis (H1)

*Kala Basti* followed by *Agnikarma* with *Panchadhatu Shalaka* is more effective than *Kala Basti* alone in the management of *Gridhrasi*.

### Null Hypothesis (Ho)

*Kala Basti* followed by *Agnikarma* with *Panchadhatu Shalaka* is as effective as *Kala Basti* alone in the management of *Gridhrasi*.

## METHODS

### Study Design

A randomised, active-controlled, open-label clinical study.

### Study Setting

OPD and IPD of the Postgraduate Department of Panchakarma, Ch. Brahm Prakash Ayurved Charak Sansthan (CBPACS), Khera Dabar, New Delhi, India.

### Study Population

Patients diagnosed with *Gridhrasi* and fulfilling the predefined inclusion and exclusion criteria will be enrolled in the study.

### Sample Size

A total of 50 participants will be enrolled and equally allocated into two groups, with 25 participants in each group. The sample size was calculated using the ClinCalc sample size calculator[7].

### Eligibility Criteria

### Diagnostic Criteria

Patients will be diagnosed with *Gridhrasi* based on the following clinical features:

1. Presence of *Ruka, Toda, Stambha and Spandana* in the *Sphika, Kati, Uru, Janu, Jangha* and *Pada*[8] regions.
2. Tenderness along the course of the sciatic nerve.
3. Positive Straight Leg Raise (SLR)[9] test, with elevation between 30° and 70°.

### Inclusion Criteria

Participants fulfilling the following criteria will be included:

- Patients willing to participate and provide written informed consent.
- Patients clinically diagnosed with *Gridhrasi*, irrespective of subtype.
- Patients of either gender.
- Age between 20 and 60 years.

### Exclusion Criteria

Patients will be excluded if they:

- Have contraindications to *Bastikarma* or *Agnikarma*.
- Have major systemic or serious diseases such as Pott's disease, AIDS or malignancy.
- Have spondylolisthesis, sacroiliac arthritis or herpes simplex associated with radiating pain.
- Are debilitated or have multiple wounds or vertebral fractures.
- Are pregnant.

### Withdrawal Criteria

Participants will be withdrawn from the study if:

- They voluntarily choose to discontinue participation.
- They develop an acute illness or complication requiring discontinuation of the intervention.
- Any other condition arises that necessitates withdrawal from the study.

### Recruitment and Selection

Eligible patients attending the OPD and IPD of the Department of Panchakarma will be screened according to the predefined diagnostic and eligibility criteria. Participants willing to participate will be enrolled after obtaining written informed consent.

**Randomisation**

Participants will be randomly allocated into two groups in a 1:1 ratio using computer-generated simple randomization.

**Blinding**

Due to the procedural nature of the interventions, blinding of participants and investigators will not be feasible. Outcome assessment will be performed using predefined clinical and functional assessment parameters.

**Intervention Groups**

- Group A- *Kala Basti* followed by *Agnikarma*: Participants will receive *Kala Basti* comprising *Erandmooladi Niruha* and *Saindhavadi Anuvasana* for 16 days, followed by three sittings of *Agnikarma* with *Panchadhatu Shalaka.*
- Group B- *Kala Basti* alone: Participants will receive *Kala Basti* comprising *Erandmooladi Niruha* and *Saindhavadi Anuvasana* for 16 days.

**Duration and Assessment**

The total study duration for each participant will be 48 days, including treatment and follow-up. Assessment will be performed at baseline (day 0), post-treatment (day 16), (day 30) and final follow-up (day 48).

**Study Drug**

The interventions used in the present study will comprise *Erandmooladi Niruha Basti, Saindhavadi Taila Anuvasana Basti* and *Agnikarma* with *Panchadhatu Shalaka.*

**Outcome Measures**

The efficacy of the interventions will be assessed using subjective and objective parameters at baseline and subsequent assessment points.

**Subjective Parameters**

The following clinical features of *Gridhrasi* will be assessed using predefined grading criteria:

**Classical Symptoms**

| S.No | Sign & Symptoms | Criteria | Score |
|---|---|---|---|
| 1 | *Ruka* (Pain) | • No pain<br>• Painful movement without limping<br>• Painful movement with limping, but without support<br>• Painful, can walk only with support.<br>• Painful, unable to walk<br>• Severe pain, needs medication. | 0<br>1<br>2<br>3<br>4<br>5 |
| 2 | *Stambha* (Stiffness) | • No stiffness<br>• Mild stiffness for 5-10 minutes<br>• Moderate stiffness for 10-60 minutes<br>• Severe stiffness more than 1 hour | 0<br>1<br>2<br>3 |
| 3 | *Toda* (Pricking Pain) | • No pricking sensation<br>• Mild pricking sensation<br>• Moderate pricking sensation<br>• Severe pricking sensation | 0<br>1<br>2<br>3 |
| 4 | *Aruchi* (Anorexia) | • Normal taste feeling to eat food on time<br>• No feeling to have food even if hungry<br>• *Bhaktadvesha*: Irritability to touch, smell, seeing and listening about food<br>• *Abhaktachhanda:* Aversion to food because of anger, stress, etc. | 0<br>1<br>2<br>3 |
| 5 | *Tandra* (Drowsiness) | • No drowsiness<br>• Mild with no interference in daily activities<br>• Moderate with manageable interference in daily activities<br>• Severe with unmanageable interference in daily activities | 0<br>1<br>2<br>3 |
| 6 | *Gaurva* (Heaviness) | • No feeling of heaviness<br>• Mild with no interference in daily activities.<br>• Moderate with manageable interference in daily activities<br>• Severe with unmanageable interference in daily activities. | 0<br>1<br>2<br>3 |

| | | | |
|---|---|---|---|
| 7 | *Suptata* (numbness) | • Absent<br>• Mild<br>• Moderate<br>• Severe | 0<br>1<br>2<br>3 |

**ODI (Oswestry Disability Index):** Assessment of functional disability with ODI Questionnaire[10]

**Objective Parameter**

**Straight Leg Raise (SLR) Test**

SLR will be assessed as an objective measure of functional limitation associated with *Gridhrasi*. The test will be graded according to the predefined scoring criteria based on the angle of leg elevation. The diagnostic criterion for inclusion is a positive SLR between 30° and 70°.

**Assessment Schedule**

The outcome parameters will be recorded at:

- Day 0 – Baseline assessment
- Day 16 – Post *Kala Basti* assessment
- Day 30 – Post-*Agnikarma* assessment
- Day 48 – Follow-up assessment

The overall clinical response will be determined from changes in subjective and objective parameters between baseline and post-treatment/follow-up assessments.

**Data Collection and Management**

Data will be collected using a standardized patient assessment sheet prepared for the study. Baseline demographic, clinical, and assessment data will be recorded before treatment initiation, followed by documentation of outcome measures at the predefined assessment points. The assessment will include the selected parameters, the Oswestry Disability Index (ODI), and the Straight Leg Raise (SLR) test and changes in classical symptoms.

**Statistical Analysis Plan**

Data will be analyzed using appropriate statistical methods. Within-group changes will be assessed using the paired t-test for normally distributed data or the Wilcoxon signed-rank test for non-normally distributed data. Between-group comparisons will be performed using the unpaired t-test or Mann–Whitney U test, as appropriate. Statistical significance will be considered at $P < 0.05$.

Statistical software: The data will be entered, tabulated and analyzed using appropriate statistical software.

**Ethics Approval and Consent**

Ethical approval has been obtained from the Institutional Ethics Committee, CBPACS, New Delhi. We will obtain written informed consent from all participants. Participation will be voluntary and withdrawal will be permitted at any stage.

**Safety Monitoring**

All adverse events will be documented and managed according to institutional guidelines. Participants developing severe adverse events will be withdrawn and provided appropriate medical management.

**Expected Results**

Both groups are expected to show improvement in the clinical features of *Gridhrasi*, including pain, stiffness, pricking sensation and functional disability. *Kala Basti* followed by *Agnikarma* with *Panchadhatu Shalaka* is expected to demonstrate greater overall improvement than *Kala Basti* alone, particularly in pain and functional outcomes.

**DISCUSSION**

*Gridhrasi* is a *Vata*-dominant disorder for which *Basti* and *Agnikarma* are traditionally used. This study will compare *Kala Basti* followed by *Agnikarma* with *Panchadhatu Shalaka* versus *Kala Basti* alone to assess their comparative clinical effectiveness. The findings may provide evidence for an effective Ayurvedic approach to managing *Gridhrasi*.

**Dissemination Plan**

The study findings will be disseminated through publication in a peer-reviewed scientific journal and presentation at relevant academic and scientific forums. The study will maintain participant confidentiality during reporting and publication.

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