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Research Protocol

Ayurveda Section

Clinical Evaluation of *Vajigandhadi taila matrabasti* versus *Sahacharadi taila* matrabasti in the Management of *Gridhrasi* (Sciatica): A Study Protocol

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ABSTRACT

Introduction: In Ayurveda, *Basti*, or medicated enema, is recognised as a crucial component of *Panchakarma*, constituting half of the therapeutic approach. *Matra Basti*, a specific form of *Basti Karma*, is particularly effective in addressing disorders related to the nervous system, neuromuscular conditions and nutritional imbalances. *Gridhrasi*, commonly known as sciatica, is characterised by pain that extends from the lower back to the legs. These conditions frequently develop due to a variety of factors, such as poor sitting posture, excessive physical strain and a sedentary lifestyle.

Need of the study: In Ayurvedic practice, different medicated oils are prescribed based on the patient and the specific disease condition. Both *Vajigandhadi* oil and *Sahacharadi* oil are Ayurvedic formulations recommended for the treatment of *Gridhrasi* (sciatica) through per rectal administration. However, the comparative efficacy of these two oils in alleviating sciatic pain remains unclear. To address this knowledge gap, the present study will be conducted.

Aim: To compare the efficacy of *Vajigandhadi taila matrabasti* (a form of unctuous enema) with *Sahacharadi taila matrabasti* (another form of unctuous enema) for the management of *Gridhrasi* (sciatica).

Materials and Methods: A randomised controlled clinical trial will be conducted at MG Ayurved College, Hospital and Research Centre located in Salod (H), District Wardha, Maharashtra, India, from December 2022 to December 2025. In this study, a total of 80 participants will be randomly assigned to two groups, each consisting of 40 patients. Participants in group A will receive a *Vajigandhadi taila matrabasti* (a type of unctuous enema) at a dosage of 72 mL, administered rectally after meals for 14 days. Conversely, group-B will receive a *Sahacharadi taila matrabasti* (an unctuous enema) at the same dosage and administration schedule. Parameters will be assessed on the initial day, the 14th day and again after 30 days for follow-up purposes. Statistical analysis will be conducted using R (version 4.3.2) software. Objective parameters will be analysed using Independent t-tests, while subjective parameters will be analysed using Chi-square tests. Results will be presented as mean and standard deviation, with statistical significance at p-value <0.05.

Keywords: Basti, Pain, Rectal enema, Sciatic nerve

INTRODUCTION

In *Gridhrasi*, the affected person's gait is altered as their legs become stressed and slightly curved due to pain, resembling the walk of a *Gridhra* (vulture), from which the name *Gridhrasi* is derived, referring to this radiating pain-dominant disease [1]. The salient features of *Gridhrasi* include *Stambha* (stiffness), *Ruka* (pain), *Toda* (pricking ache) and *Muhuspandan* (twitch) in *Sphik* (buttock), *Kati* (hip), *Uru* (thigh), *Janu* (knee), *Jangha* (calf) and *Pada* (foot) in that order. In the *Kapha-Vataja* type of *Gridhrasi*, *Tandra* (drowsiness), *Gaurav* (heaviness) and *Arochak* (tastelessness) are also present [2].

The characteristics of sciatica resemble those of *Gridhrasi*. Sciatica causes constant aching pain in the lumbar area, radiating to the buttock, calf and foot due to sciatic nerve irritation [3]. The causes of sciatica can include disc herniation or slipped disc, spinal stenosis and spondylolisthesis. The occurrence of sciatica, based on various studies, ranges from 1.6% in the general population to 43% in selected occupational groups [4]. Although Low Back Pain (LBP) is a common complaint that affects 80-90% of individuals during their lifetime, actual sciatica occurs in about 5% of cases. Sciatica typically manifests between the ages of 30 and 50 years [5].

Aacharya Charaka mentioned *Basti* (medicated enema), *Agnikarma* (thermal cautery) and *Siravyadha* (venepuncture) as treatment modalities for *Gridhrasi* [6] (sciatica). Among these, *Basti* (medicated enema) is a primary treatment modality for *Vata Dosha*. It has both *Shodhana* (bio-cleansing) and *Shamana* (pacification) effects. *Basti* (medicated enema) can be of various types, depending on the ingredients and specific needs [7].

The simplest form of *Basti* (medicated enema) selected for the present study is *Matrabasti* (a type of unctuous enema). The quantity of *Matrabasti* (a type of unctuous enema) is one-quarter of *Anuvasana Basti* (oil enema), which amounts to 1½ *pala* [8]. *Aacharya Charaka* considered the dose of *Matrabasti* (a type of unctuous enema) to be equivalent to *Hrasva Snehamatra* (a small dose of oral unctuous intake). According to *Aacharya Charaka*, *Matrabasti* (a type of unctuous enema) is suitable for those who are emaciated due to overworking, engaging in physical workouts, weightlifting, long journeys, travelling in vehicles and indulgence with women, as well as for those suffering from *Vata* disorders [8].

Vajigandhadi Taila is recommended for the treatment of *Gridhrasi* (sciatica), as suggested by *Yogaratnakara*. Its *Vatahara* (which alleviates *Vata*) and *Brimhana* (nourishing) properties may help address the pathogenesis of the disease [9].

Both *Vajigandhadi taila* and *Sahacharadi taila* are recognised for their effectiveness in treating *Gridhrasi*; however, their relative efficacy has yet to be determined. The compositions of these oils show minimal variation, with *Vajigandhadi taila* consisting of a total of 13 ingredients, while *Sahacharadi taila* comprises four ingredients. Nonetheless, each oil possesses unique components

and characteristics that differentiate them [10,11]. Hence, the present study aims to compare the efficacy of *Vajigandhadi taila matrabasti* (a type of unctuous enema) versus *Sahacharadi taila matrabasti* (a type of unctuous enema) for the management of *Gridhrasi* (sciatica).

Primary objectives:

1. To assess the efficacy of *Vajigandhadi taila matrabasti* (a type of unctuous enema) in the management of *Gridhrasi* (sciatica).
2. To assess the efficacy of *Sahacharadi taila matrabasti* (a type of unctuous enema) in the management of *Gridhrasi* (sciatica).

Secondary objectives: To compare the efficacies of *Vajigandhadi taila matrabasti* (a type of unctuous enema) and *Sahacharadi taila matrabasti* (a type of unctuous enema) in the management of *Gridhrasi* (sciatica).

Null hypothesis: *Vajigandhadi taila matrabasti* (a type of unctuous enema) will be equally or less effective than *Sahacharadi taila matrabasti* (a type of unctuous enema) in the treatment of *Gridhrasi* (sciatica).

Alternate hypothesis: *Vajigandhadi taila matrabasti* (a type of unctuous enema) will be more effective than *Sahacharadi taila matrabasti* (a type of unctuous enema) in the treatment of *Gridhrasi* (sciatica).

REVIEW OF LITERATURE

The contemporary professional environment often leads to improper seating, overexertion, abrupt movements during travel and sports, increased reliance on technology, higher body weight and mental stress. These elements can significantly contribute to undue pressure on spinal structures, which is a notable factor in the development of sciatica. Given the seriousness of this condition, it is imperative to pursue effective and safe treatment options. *Gridhrasi* represents a complex lifestyle challenge that necessitates appropriate management strategies. Consequently, exploring safer management alternatives is of considerable significance. *Basti* is widely endorsed by distinguished practitioners for its effectiveness in addressing this condition, as it involves the administration of medicine through the anal orifice.

In a clinical study involving 32 patients diagnosed with *Gridhrasi*, participants were randomly assigned to one of three treatment groups. Group A consisted of eight patients who received *Kati Basti* using *Sahacharadi taila*; group B, comprising 13 patients, underwent *Matra Basti* with *Sahacharadi taila*; and group C included 11 patients who received *Rasna Guggulu*. The treatment spanned 14 days. All groups exhibited improvements; however, *Matra Basti* resulted in more significant relief for the majority of cardinal and associated signs and symptoms compared to *Kati Basti* [10]. Similarly, in another study conducted in 2015, the effects of *Vajigandhadi taila matrabasti* and *Til taila matrabasti* were assessed among 30 patients suffering from *Gridhrasi*. Participants were divided into two groups and received treatment over nine days. Evaluations of subjective parameters indicated statistically significant improvements. Objective assessments also demonstrated meaningful enhancements, except for knee and ankle jerk reflexes. While group A exhibited a marginally better clinical response than group B, this difference did not attain statistical significance [11].

Additionally, a study involving 40 patients with *Gridhrasi* compared the efficacy of *Vyoshadi taila Matra Basti* to that of *Sahacharadi taila matrabasti* over seven days. Comprehensive assessments were conducted both before and after treatment. Group A reported a 51.47% reduction in pain (*Ruk*), stiffness (*Sthambha*), pricking sensation (*Toda*) and heaviness (*Gaurava*), alongside notable improvements in active and passive straight leg raising tests, Bragard's test and lumbar movements. Conversely, group B exhibited a 40.49% reduction in *Ruk, Sthambha* and *Toda*, demonstrating improvements in similar functional tests, although it did not achieve statistically significant advancements in *Gaurava*, left lateral flexion and left rotation. The study concluded that *Vyoshadi taila Matrabasti* was more effective in alleviating symptoms of *Gridhrasi* and provided longer-lasting results [12].

An open-label clinical study employing a pre-and post-test design examined the effects of two types of *Kati Basti* on a cohort of 90 patients with *Gridhrasi* over a 14-day treatment period. The results revealed similar rates of relief across various assessment parameters for both groups, with the most significant improvements observed in functional ability [13].

MATERIALS AND METHODS

A randomised controlled clinical trial will be conducted at Mahatma Gandhi Ayurved Medical College, Hospital and Research Centre, Salod, Wardha, Maharashtra, India, from December 2022 to December 2025. Ethical clearance approval has been obtained from the Institutional Ethics Committee (MGACHRC/IEC/January-2022/436) and the trial is registered with the Clinical Trial Registry of India (CTRI/2022/12/048093). Informed consent will be obtained from each participant after providing detailed information about the intervention in their native language. All consent materials will be provided to participants as hard copies and confidentiality will be maintained throughout the study. Participants will be assigned to groups using simple randomisation via computer-generated random numbers. This single-blind study will mask treatment allocation from the participants.

Inclusion criteria: The inclusion criteria for this study are:

- Patients who provide written informed consent;
- Patients of either sex aged between 18 and 55 years;
- Clinically diagnosed cases of *Gridhrasi* (sciatica);
- Patients testing positive (≤70 degrees) for the Straight Leg Raising (SLR)/Lasegue's sign [14]. Patients must also have a pain level of ≥4 on a scale of 0 to 10 (VAS).

Exclusion criteria: The exclusion criteria are:

- Known cases of tuberculosis or neoplasm of the spine and hip joint;
- Ankylosing spondylitis or fractures secondary to fractures;
- Deformities and congenital defects of the spine and hip joints;
- Patients with neurological deficits such as sensory loss, foot drop, limb muscle wasting and bowel/bladder incontinence;
- Patients with uncontrolled diabetes mellitus and/or those diagnosed with complications of diabetes mellitus, such as neuropathy, nephropathy, retinopathy, etc.;
- Patients with a known history of severe cardiovascular diseases;
- Patients with concurrent serious hepatic dysfunction, renal dysfunction, uncontrolled pulmonary dysfunction (such as asthmatic and COPD patients), or other severe concurrent diseases;
- Non ambulatory patients with monoparesis, paraplegia, or hemiplegia;
- Pregnant or lactating women;
- Patients with evidence of malignancy;
- Patients who are menstruating.

Sample size calculation: The sample size for the study is determined using G power software. Considering a 10% dropout rate, with the Type I error level set at 5% and 80% power for the study, the final sample size is calculated to be 80 participants, with 40 in each group.

Study Procedure

The necessary raw materials for the formulation of medicated oils were acquired from the market and the drugs were subsequently

prepared and standardised at Dattatraya Ayurveda Rasashala (an analytical laboratory affiliated with the institution). The preparation of the Ayurvedic oils, *Vajigandhadi taila* and *Sahacharadi taila*, was conducted in the pharmacy following a systematic procedure, as specified in the Ayurvedic Pharmacopoeia of India (API) [15].

Vajigandhadi taila consists of *Withania somnifera, Sida cordifolia, Aegle marmelos, Dashamoola* and *Ricinus communis* oil [Table/Fig-1] [16]. *Sahacharadi taila* comprises *Barleria prionitis, Cedrus deodara, Zingiber* officinale and *Sesamum indicum* oil [Table/Fig-2] [16].

S. No.	Sanskrit name	Botanical name	Parts used	Quantity
1	*Ashwagandha*	*Withania somnifera*	Root	1 part
2	*Bala*	*Sida cordifolia*	Root	1 part
3	*Bilwa*	*Aegle marmelos*	Bark	1 part
4	*Bilwa*	*Aegle marmelos*	Root	1 part
5	*Agnimantha*	*Premna mucronate*	Root	
6	*Shyonaka*	*Oroxylum indicum*	Root	
7	*Patala*	*Stereospermum suaveolens*	Root	
8	*Gambhari*	*Gmelina arborea*	Root	
9	*Brihati*	*Solanum indicum*	Root	
10	*Kantakari*	*Solanum xanthocarpum*	Root	
11	*Gokshura*	*Tribulus terrestris*	Root	
12	*Shalaparni*	*Desmodium gangeticum*	Root	
13	*Prishnaparni*	*Uraria picta*	Root	
14	*Eranda*	*Ricinus communis*	Seed (oil)	4 part

[Table/Fig-1]: Contents of *Vajigandhadi taila* [16].

S. No.	Sanskrit name	Botanical name	Parts used	Quantity
1	*Sahachar*	*Barleria prionitis*	Whole plant	1 part
2	*Devadaru*	*Cedrus deodara*	Heartwood	1 part
3	*Nagar*	*Zingiber officinale*	Rhizome	1 part
4	*Til*	*Sesamum indicum*	Seed (oil)	4 part

[Table/Fig-2]: Contents of *Sahacharadi taila* [16].

To prepare the Ayurvedic oils, a mixture was created by combining one part of *Kalka* (herbal paste), four parts of sesame oil and 16 parts of *Kwatha*. This mixture was then subjected to a slow boiling process to yield the final oil product. A sample of the resultant oil underwent examination in the analytical laboratory affiliated with the institute for drug standardisation. Upon passing all quality assessments, the oil was subsequently packaged and sealed.

Group A will receive *Vajigandhadi taila Matrabasti* (72 mL) rectally after meals for 14 days. Group B will receive *Sahacharadi taila matrabasti* (72 mL) rectally after meals for 14 days. The treatment duration will be 14 days, followed by a 16-day follow-up period. Assessments will be conducted at baseline (day 0), day 14 and day 30 [Table/Fig-3].

Groups	Group-A	Group-B
Sample size	40	40
Intervention	*Vajigandhadi taila matrabasti*	*Sahacharadi taila matrabasti*
Dose	72 mL	72 mL
Duration of intervention	14 days	14 days
Follow-up period	16 days	16 days
Total duration (intervention+follow-up)	30 days	30 days

[Table/Fig-3]: Schedule of enrollment and intervention.

Interventions may be discontinued or modified due to voluntary withdrawal of participants or the emergence of adverse events, drug sensitivities, or other medical issues. Affected participants will be offered complimentary treatment until the resolution of the issue.

Outcomes

Subjective parameters:

a. *Toda* (pricking sensation)
b. *Stambha* (stiffness)
c. *Suptata* (numbness)
d. *Spandana* (throbbing)
e. *Tandra* (stupor)
f. *Gaurava* (heaviness)
g. *Aruchi* (anorexia)

These subjective symptoms, as described in Ayurvedic medicine, will be assessed using a self-reported scale categorising symptom severity as mild, moderate, or severe.

Objective parameters:

- **Visual Analogue Scale (VAS) for pain in the last 48 hours [17]:** The visual analogue scale is a pain rating scale that helps to assess the intensity of pain in patients on a scale of 0 to 10.
- **Roland-Morris Disability Questionnaire (RDQ-23) [18]:** The Roland-Morris Disability Questionnaire will help to assess the patient's disability before treatment and their improvement after treatment. It is recognised as the most frequently utilised outcome measure in studies assessing interventions for LBP. Scores on the RDQ can range from 0 to 24, with higher scores indicating a greater level of disability. Participants respond to a series of statements by marking a box to indicate their agreement, selecting those that accurately reflect their condition on the day of assessment, while leaving boxes blank for statements that do not apply. The final score is calculated by summing the number of checked items.
- **Straight Leg Raising test (SLR):** The straight leg raise test is performed with the patient in a supine position. The examiner gently raises the patient's leg by flexing the hip while keeping the knee extended. The angle at which pain occurs is noted; pain between 30° and 70° of leg elevation suggests nerve root irritation or disc herniation [14].

Femoral Nerve Stretch test (FNS) [19]: To perform the femoral nerve stretch test, a patient lies in a prone position. The knee is passively flexed to the thigh and the hip is passively extended. The femoral nerve tension test is used to screen for nerve root impingement or compression in the upper lumbar spine (L2-L4).

STATISTICAL ANALYSIS

Statistical analysis will be performed using R (version 4.3.2). Objective parameters will be analysed using Independent t-tests, while subjective parameters will be analysed using Chi-square tests. Data will be presented as means and standard deviations and statistical significance will be set at $p<0.05$.

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