



An Open Labelled Non-Randomized Clinical Evaluation of Vajigandhadi Tail Matra Basti in Gridhrasi – A Study Protocol

Mehta V^{1*} , Mehta A²

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^{1*} Vidhi Mehta, Post Graduate Scholar, PG Department of Panchkarma, Institute for Ayurved Studies and Research, Kurukshetra, Haryana, India.

² Ashish Mehta, Professor and Head, PG Department of Panchkarma, Institute for Ayurved Studies and Research, Kurukshetra, Haryana, India.

Introduction: Gridhrasi is one of the 80 types of Nanatmaja Vatavyadhi, occasionally presenting with Kaphanubandha. The cardinal symptoms include Ruka (pain), Toda (pricking sensation), Stambha (stiffness), and Muhur Spandana (twitching) affecting the Sphika, Kati, Uru, Janu, Jangha, and Pada in sequence, along with Sakthikshepa Nigraha (restricted leg lifting). In Kaphanubandha, additional symptoms like Tandra, Gaurava, and Arochaka are observed. Clinically, Gridhrasi is often correlated with lumbar radiculopathy, which results from lumbar disc herniation, vertebral degeneration, or foraminal narrowing, leading to radiating low back pain, numbness, weakness, and altered reflexes. Acharya Charaka prescribes Siravyadha, Basti Karma, and Agnikarma for its management, with Basti being particularly significant among Panchakarma pro-cedures due to its multifaceted benefits.

Methods: This study aims to evaluate the efficacy of Vajigandhadi Tail Matra Basti in both Vataj and Vata-Kaphaja Gridhrasi. Thirty patients will be selected and divided into two sub-groups:

- **Group A:** Vataj Gridhrasi (n=15)
- **Group B:** Vata-Kaphaja Gridhrasi (n=15)

Treatment interventions will be assessed based on subjective and objective parameters. Statistical methods will be employed for data analysis.

Results: The findings will be analyzed to determine the effectiveness of Vajigandhadi Tail Matra Basti in each subgroup. Comparative assessments based on key clinical parameters will be presented.

Discussion and Conclusion: The final conclusions will be drawn based on observed clinical outcomes and sta-tistical analysis. The study will contribute to understanding the role of Basti therapy in managing both types of Gridhrasi and provide insights into optimizing Ayurvedic interventions for lumbar radiculopathy.

Keywords: Gridhrasi, Vataj Gridhrasi, Vata-Kaphaj Gridhrasi, Matra Basti, Vajigandhadi Taila

Corresponding Author

Vidhi Mehta, Post Graduate Scholar, PG Department of Panchkarma, Institute for Ayurved Studies and Research, Kurukshetra, Haryana, India.
Email: vbmehta14@gmail.com

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Introduction

A variety of *Vatavyadhi* described in *Charaka Samhita* are divided into *Samanyaja* and *Nanatmaja* group. *Gridhrasi* is one of 80 types of *Nanatmaja Vatavyadhi* though, occasionally there is *Kaphanubandha*.^[1] The name itself indicates way of gait shown by patients due to extreme pain just like a *Gridhra* (vulture), it is clear that this disease not only cause pain but also causes difficulty in walking, which is very much frustrating to patient. Though, the disease is present in leg, it disturbs the daily routine and overall life of patient. The cardinal signs and symptoms of *Gridhrasi* are like *Ruka* (pain), *Toda* (pricking sensation), *Stambha* (stiffness) and *Muhur Spandana* (twitching) in *Sphika*, *Kati*, *Uru*, *Janu*, *Jangha* and *Pada* in order and *Sakthikshepa Nigraha* i.e., restricted lifting of leg. In *Kaphanubandha*, there will also be presence of *Tandra*, *Gaurava*, and *Arochaka* along with above symptoms.^[2] In modern science, symptoms of *Gridhrasi* mainly correlated with lumbar radiculopathy. It can be caused by lumbar disc herniation, degeneration of spinal vertebra, and narrowing of foramen from which nerves exit spinal canal. Symptoms include low back pain that radiates into lower extremities in a dermatomal pattern. Other accompanying symptoms can include numbness, weakness, and loss of reflexes, although absence of these symptoms does not exclude a diagnosis of lumbar radiculopathy.^[3] The treatment principle of *Gridhrasi* explained by *Acharya Charaka* is *Siravyadha*, *Bastikarma* and *Agnikarma*.^[4]

Need of Study: There are some research works done regarding various treatment procedures for *Gridhrasi* management with *Vajigandhadi Tail*. But as mentioned, *Gridhrasi Vyadhi* is of two types i.e., *Vataj* and *Vata-Kaphaj Gridhrasi*. There is no specific indication found in textbooks that in which type of *Gridhrasi*, *Vajigandhadi tail* will have better efficacy. So here to fill the knowledge gap, I have selected this topic for my research work.

Review of Literature

Classical *Ayurveda* literature including *Brihatrayi*, *Laghutrayi*, and *Nighantu's* along with modern text books will be reviewed for study. Website like PubMed, Google scholar, Scopes, Articles, Journals and Research papers will be screened for the information regarding the subject.

Drug Review

Vajigandhadi Tail (reference: *Gada Nigrah, Kayachikitsa Khand/Vatvyadhi Rogadhikar/178*)^[5]

Content: *Ashwagandha, Bala, Shunthi, Bilwa, Agnimanth, Patala, Gambhari, Shyonak, Shalparni, Prishniparni, Brihati, Kantkari, Gokshur, Erand tail*

Source of Data

Patients visiting *Panchakarma* outpatient department and indoor patient department of Shri Krishna Govt. Ayurvedic College and Hospital, Kurukshetra Haryana and full filling the inclusion criteria shall be enrolled for the study after obtaining informed consent.

Aim and Objectives

Aim

To develop a single drug modality in both types of *Gridhrasi* i.e. *Vataj* and *Vata-kaphaja Gridhrasi*.

Objectives

1. To evaluate effectiveness of *Vajigandhadi tail matra basti* in *Vataj Gridhrasi*.
2. To evaluate effectiveness of *Vajigandhadi tail matra basti* in *Vata-kaphaj Gridhrasi*.
3. To observe the best effect of *Vajigandhadi tail matra basti* in both type of *Gridhrasi*.

Research Questions

- Does *Vajigandhadi Tail* has similar effect in both type of *Gridhrasi* (*Vataj Gridhrasi* and *Vata-kaphaj Gridhrasi*)?

Hypothesis

Research Hypothesis

H1: *Vajigandhadi tail* has no significant difference in *Vataj* and *Vata-kaphaj Gridhrasi*.

Null Hypothesis (H0)

H0a – *Vajigandhadi Tail* has significant difference in *Vataj* and *Vata-Kaphaj Gridhrasi*.

H0b – *Vajigandhadi Tail* has no effect in *Vataj* and *Vata-Kaphaj Gridhrasi*.

Study Design:

Type of trial : Interventional

Purpose : Treatment

Masking : Open label
 Method of Randomization: Non-randomization
 Timing : Prospective
 End point : Efficacy
 No. of groups : 1 group (2 subtypes)
 Subjects : 30 (15 in each subtype)
 Allocation : Selection of patient according to criteria
 Phase of trial : Phase 2
 Duration of Trial : 18 months
 Statistical tool : Appropriate tool will be applied

Methodology

The study will be conducted in Institute for Ayurved Studies & Research, Kurukshetra, Haryana, India.

Posology

Quantity of Dravya

Kalka Dravya: Ashwagandha, Bala, Shunthi, Dashmoola - 1 part

Jala: 16 parts

Erand Tail: 4 parts

Procedure: Prepare Tail with above drugs viz. Kalka Dravyas, Sneha (Erand Tail), and Drava Dravya (Jala) taken in specified quantity.

Inclusion criteria:

1. Patients willing to sign the consent form.
2. Patients between the age sub-group of 30-50 years of either sex.
3. Patients presenting with clinical features of Gridhrasi and Lumbar Radiculopathy.
4. Patients with chronicity of disease less than 3 years.
5. Patients fit for Basti Karma (Basti Yogya).

Exclusion criteria:

1. Subjects with chronicity of disease more than 3 years.
2. Subjects of either sex age below 30 years and above 50 years.
3. The patients unfit for Basti Karma (Basti Ayogya).
4. Patients having systematic pathologies like cardiac disease, renal diseases and hypertension (already diagnosed).
5. Subjects with uncontrolled diabetes, systemic disorders and endocrine disorders (already diagnosed).

6. Patients having tuberculosis of spine, spinal tumors, vertebral fractures, surgical conditions, hyper uricemia and auto immune disease like rheumatoid arthritis, ankylosing spondylitis (already diagnosed).
7. Pregnant and lactating women.

Withdrawal Criteria:

1. Patient himself wants to withdraw from the clinical trial.
2. During the course of trial if any serious condition or any serious adverse effect occurs this requires treatment.

Plan of Study

Table 1: Sub-group

Sub-Group	A (Vataj Gridhrasi)	B (Vata-Kaphaj Gridhrasi)
Symptoms	1. Stambh (stiffness) 2. Ruk (pain) 3. Tod (pricking pain) in Sphik, Kati, Prushth, Uru, Jaanu, Jangha, Pada (respectively) 4. Spandan (twitching sensation)	1. Stambh (stiffness) 2. Ruk (pain) 3. Tod (pricking pain) in Sphik, Kati, Prushth, Uru, Jaanu, Jangha, Pada (respectively) 4. Spandan (twitching sensation) 5. Tandra (drowsiness) 6. Gauravta (heaviness) 7. Aruchi (anorexia)
Name of drug	Vajigandhadi Tail	Vajigandhadi Tail
Number of patients	15	15
Dose	60 ml	60 ml
Duration	15 days	15 days
Timing	After lunch	After lunch
Route of administration	Anal	Anal

Statistical Analysis

The observations and result will be analyzed and presented on the basis of respective and applicable statistical.

Time Duration till Follow up

In both the sub-groups initially 15 days of treatment and follow up period 22nd and 29th day.

Criteria For Assessment

A. Subjective Parameters:

Table 2: Ruk (Pain)

No pain	0
Occasional pain (1-2 hours per day)	1
Mild pain (no difficulty in walking)	2
Moderate pain (slightly difficulty in walking)	3
Severe pain (severe difficulty in walking)	4

Table 3: Stambha (stiffness)

No stiffness	0
Stiffness for few minutes after sitting for long duration but relieved by mild movements	1
Stiffness more than 1 hour or more than once in a day but routine works are not disturbed	2
Stiffness lasting for more than 1 hour or many times a day mildly affecting the daily routine	3
Episodes of stiffness lasting for 2-6 hours / Daily routines are hampered severely.	4

Table 4: Suptata (numbness)

No numbness	0
Occasionally once in a day for few minutes	1
Daily once in a day for few minutes	2
Daily for 2 or more times/30-60 minutes	3
Daily more than 1 hour/Many times a day.	4

Table 5: Spandana(throbbing/pulsating)

No Throbbing/Pulsation at all	0
For few minutes occasionally which is relieved spontaneously	1
Daily once in a day for few minutes	2
Many times in a day affecting daily routine	3
Daily for many times severely hampering daily routine.	4

Table 6: Aruchi(anorexia)

Normal taste in food, feeling to eat food in time	0
Feeling to take food but not having taste	1
Anannabhilasha- not feeling to take food even if hungry	2
Bhaktadvesha- irritability to touch, smell, seeing and listening about food	3
Abhaktachanda - Aversion to food because of anger, stress etc.	4

Table 7: Tandra(drowsiness)

No drowsiness	0
Mild drowsiness occasionally but does not affect daily routine	1
Moderate drowsiness frequently many times in a day that hamper daily routine	2
Moderate drowsiness whole day and need to take rest so can't work	3
Severe drowsiness whole day also at mental level reduced alertness etc.	4

Table 8: Gaurava(heaviness)

No feeling of heaviness	0
Occasional feeling of heaviness not affecting the normal movements	1
Frequent feeling of heaviness affecting the normal movements	2
Feeling of heaviness throughout the day severely affecting the normal movements	3
Feeling of heaviness throughout the day totally hampering normal movements.	4

B. Objective Parameter:**Table 9: SLR Test**

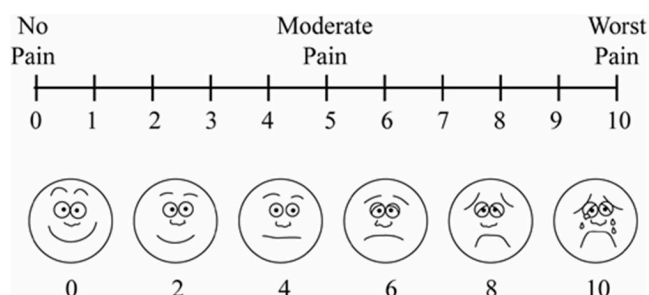
Equal to or greater than 90°	0
71°- <90°	1
51°-70°	2
31°-50°	3
<30°	4

Walking distance: For this purpose. Patients will be asked to walk 20 meters distance on a plain way. Time will be recorded by the help of a stop watch in seconds. The walking time will be noted before and after treatment.

Table 10: Walking distance

0-20 seconds	0
21-40 seconds	1
41-60 seconds	2
More than 60 seconds	3

VAS scale: For Pain Gradings as following:



Primary outcomes: Improvement in subjective and objective parameters

Secondary outcomes: The comparative efficacy of treatment in both the sub groups.

Data Management: Data coding will be done by Principal investigators.

Statistical Methods: Unpaired and Paired t-test.

Consent or Assent: Subjects will be given detail information regarding their treatment in their own language. Then written consent will be taken from patients before starting the study.

Approval: Approved by IEC, URC of the concerned University. Trial is registered under Clinical Trials Registry - India [6]

Dissemination Policy: Will be in the form of paper publication, presentation and monograph.

Strengths: If proposed study will result in the positive outcome, then it will be established new mode of management for the both type of *Gridhrasi*.

Results

Results of the treatment will be tabulated and analyzed statistically with relevant tests and level of significance will be reported.

Discussion and Conclusion

Conclusion will be mentioned after the analyzing data.

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