



Comparative Clinical Trial on *Aragwadha Erand* and *Trivrutta Eranda Nitya Virechana* in *Gridhrasi* (Lumbago Sciatica Syndrome): A Study Protocol

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Background: At present, the life style is gradually shifting away from healthy living, and therefore people fall victim of various diseases. Sedentary lifestyle, stress, improper posture, continuous jerky movements, long travelling, etc., put maximum pressure on the spine and lower portion of the pelvis. About 80–90% of people get affected by low back pain and 5% of those become victims of sciatica.

Aim: Studying the effect of *Trivrut Eranda Tailam* and *Aragvadha Eranda Tailam Virechana* in *Gridhrasi* (Lumbago sciatica syndrome).

Objectives: To study the effect of *Trivrut Eranda Tailam* in *Gridhrasi*, To study the effect of *Aragvadha Eranda Tailam* in *Gridhrasi* and to compare the effect of *Trivrutta Eranda Tailam* and *Aragvadha Eranda Tailam* in *Gridhrasi*.

Methodology: This study will be a Randomized controlled interventional trial to be conducted on 30 participants. The participants will be divided into two groups viz. Group A and Group B. The

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patient in Group A will be given *Trivrutt Eranda Tailam* (15 patients) and Group B will be given *Aragvadha Eranda Tailam* (15 patients).

Results: *Nitya virechan* will be carried out in both these groups. The results will be compared on the basis of SLR test [Straight leg raising test], Lassegue sign, Flip test, Bowstring test and Serum electrolytes used for *Gridhrasi*.

Conclusion: Conclusions will be drawn on the result.

Keywords: *Nitya virechan; Aragvadha eranda; trivrutta eranda; Gridhrasi (Lumbago sciatica syndrome).*

1. INTRODUCTION

At present, the life style is gradually shifting away from healthy living, and therefore people fall victim of various diseases. Sedentary lifestyle, stress, improper posture, continuous jerky movements, long travelling, etc., put maximum pressure on the spine and lower portion of the pelvis. About 80–90% of people get affected by low back pain and 5% of those become victims of sciatica [1]. Low back pain is not a onetime phenomenon; rather it is characterized by the commonest presenting symptom is low back pain with or without the pain radiating down the back of the leg (sciatica) [2]. Sciatica is a crippling disease cause pain in hip and to the whole path of sciatic nerve; it referred down back of the leg and sometimes to the foot. Sciatica is a clinical condition characterized by severe pain started from the low back region and radiating down along the course of the leg. This is common entity encountered in clinical practice [3] [4].

Trauma on lumbosacral spine (*Abhigata*), postural defects (*Vishamachesta*), overloading (*Bharavahana*), abrupt unbalanced movements (*Atichesta*), continuous jerky movements, sedentary lifestyle as well as psychological factors (*Chinta, Shoka*, etc.) are considered as causative factors of the disease [5]. Sciatica is similar to Ayurveda long back described *Gridhrasi*. The etymology of it is suggestive of the typical gait of the patient resembling the Vulture gait. The disease is listed under 80 *Vata* diseases, i.e. *Nanatmaja Vatavyadhi* [6]. The common symptoms of *Gridhrasi* are—pain starts from *Sphik* (buttock) and that radiates through *Kati* (groin), *Prushta* (back), *Uru* (thigh), *Janu* (knee), *Jangha* (calf), and till to *Pada* (foot). The classical symptoms are *Stambha* (stiffness), *Toda* (pricking pain), *Spandana* (twitching), etc. [7]. Another classical clinical investigation is *Sakthiutkshepa Nigraha* (restricted movement of lifting of the leg) told by *Sushruta* [8]. *Vata* caused rigidity, pain and pinning sensation which affect, first, the buttocks and then descends to low-back, knee, calves and legs gradually,

repeated pulsation in limbs also symptoms like drowsiness, heaviness and anorexia [9]. Back pain is second only to the common cold as the most frequent reason for visiting a physician and is the most common chronic pain syndrome in industrial countries. It is mostly a self-limited illness. Low back pain accounts for 30-50% of rheumatic complaints encountered by general practitioners. The incidence in the industrial sector in India is 11% in textile workers. The highest prevalence is in persons aged 45 to 65 years. Low back pain becomes chronic only in 3-5% of cases. Radicular pain is one among the most common clinical manifestations of back pain [10]. The disease affects daily, routine activity of victim's life as it restricts the leg movement. Shooting pain occurs from buttock and goes down up to a foot. Victim is having pricking pain (*Toda*), twitching or trembling sensation (*Spandana*) due to stretching of sciatic nerve and paresthesia (*Supti*). Clinical diagnosis is based on history with straight leg raising (SLR) test (*Sakthiutkshepa Nigraha*). Diagnosis conformation is done through X-ray and Magnetic Resonance Imaging (MRI). The treatment of the sciatica is done commonly with analgesics to relieve pain and physiotherapy for regulating the spinal compression. That will help to certain extent but it is not of ultimate cure [11]. Surgeries for this condition is moreover expensive and there are chances of recurrence as well [12,1]. Ayurveda offers ample of options in the management of this painful disorder. In this disease, mainly *Apana Vayu* and *Vyana Vayu* vitiation are observed, but most of the times *Kapha* remains as associated *Dosha*. So for, the treatment of *Gridhrasi*, drug of choice should have *Vatashamaka*, *Kaphashamaka*, *Vatanulomaka*, *Dipana-Pachana* (digestive-carminative), and *Shulaprashamana* properties [13]. *Nitya virechana* is advised in the line of treatment of *Jalodara*, *Kushta*, *Gridhrasi*, *Katishool* etc. *Nitya Virechana* is feasible as well as can be easily given without hospitalization in *alpa bala* patients also [14]. Hence we planned *nitya virechana* for *Gridhrasi*.

2. BACKGROUND

In *Vatavyadhi mrudu virechana* mentioned with *Tilvak Ghrita*, *Saatala Ghrita*, *Eranda Tailam*, etc., with milk. As by the above references defected *vata* is the main causative factor for *Gridhrasi* for that planning treatment with *Sneha Virechana* by the *Trivrutta Eranda Tailam* and *Aragvadha Eranda Tailam*. And *Nitya virechan* (daily purgation) is a type of *virechana* (purgation therapy). Whenever there is a large number of toxins present in the body, we have to remove it in small quantities daily [15] [16]. Preferred drug to treat *Vata* because most of the properties of common *Eranda* drug and respected other drug is opposite to *Vata*. It's hot, unctuous, heavy and laxative properties helps to pacifies *Pakvshaysthavata*, *Anulomak*, *Virechaka* in nature cure constipation by dislodging the encrusted matter. The preparation contains two more ingredients side by side with which it become more potent to pacifying *Vatadosha*. The medicine is administered internally in the dosage of 10ml with luke warm water. It's an effective medicine for *Gridhrasi*.

3. AIM

Studying the effect of *Trivrut Eranda Tailam* and *Aragvadha Eranda Tailam Nitya Virechana* in *Gridhrasi* (Lumbago sciatica syndrome)

4. OBJECTIVES

1. To study the effect of *Trivrut Eranda Tailam* in *Gridhrasi*
2. To study the effect of *Aragvadha Eranda Tailam* in *Gridhrasi*
3. To compare the effect of *Trivrutta Eranda Tailam* and *Aragvadha Eranda Tailam* in *Gridhrasi*.

5. CASE DEFINITION

Patients having cardinal features of the disease such as presence of dull or piercing pain, twitching and stiffness in back, lumber region, buttock, and thigh, back of knee, calf, and feet area in successive order. Along with Positive Straight Leg Raising Test (SLRT) in the affected leg. And radiological investigation lumbago sciatica X-ray.

Research question: Whether *Trivrutta Eranda Tailam* and *Aragvadha Eranda Tailam* are effective in *Gridhrasi* ?

Hypothesis: *Trivrutta Eranda Tailam* and *Aragvadha Eranda Tailam* are effective in *Gridhrasi*.

Null Hypothesis: *Trivrutta Eranda Tailam* and *Aragvadha Eranda Tailam* are not effective in *Gridhrasi*

6. METHODOLOGY

Trial design: Randomized parallel group trial.

Study setting: Patient with *Gridhrasi* (lumbago sciatica) with present criteria will be included in the study from Panchakarma OPD of MGACH & RC, SALOD (H).

7. ELIGIBILITY CRITERIA

7.1 Inclusion Criteria

1. Age group of above 20 and below 60 years
2. Patient having radiating pain in either of lower limbs
3. Irrespective Gender, occupation or economic status
4. Sciatica (ICD-10 criteria M54.3)
5. Lumbago with sciatica (ICD-10 criteria M54.4)
6. Low back pain with Loin pain or Low back strain (ICD-10 criteria M54).

7.2 Exclusion Criteria

1. Age below 20 years and above 60 years
2. Any lesion of sciatic nerve (ICD-10 criteria G57.0)
3. Any lesion of due to inter-vertebral disc disorder (ICD-10 criteria M51.1)

Interventions: Total duration of intervention will be the same for both groups and follow up will be on 15 days in both groups. Table 1.

Criteria for discontinuing or modifying allocated interventions: If the symptoms get aggravated during treatment such subject will be withdrawn from study and treated free of cost till becomes alright.

Follow Up: 15 days

Statistical analysis: The progressions from pattern will be dissected by utilizing Paired and Unpaired 't' Test for target standards.

Table 1. Methodology

Group	Group A	Group B
Sample size	15	15
Intervention	<i>Nitya virechana</i> with <i>Trivrutta Eranda taila</i>	<i>Nitya virechana</i> with <i>Aragvadha Eranda Tailam</i>
Dose	10 ml/Daily morning	10 ml/Daily morning
Anupana	Luke warm water	Luke warm water
Duration	15 days	15 days
Total duration	30 days	30 days

Table 2. Drugs for Virechan**a. Composition of Trivrutta Eranda Tailam**

Sr. No.	Sanskrit name	Botanical Name	Parts Used
1.	Trivrutta	<i>Operculina terpepethum L.</i>	Root
2.	Eranda	<i>Ricinus communis L.</i>	Seeds

b. Composition of Aragwadha Eranda Tailam

Sr. No.	Sanskrit name	Botanical Name	Parts Used
1.	Aragvadha	<i>Cassia fistula L.</i>	Fruit
2.	Eranda	<i>Ricinus communis L.</i>	Seeds

Table 3. Drugs ingredients

Sr. No.	Drug	Rasa	Guna	Virya	Vipaka	Doshaghnata
1.	<i>Trivrutta</i>	<i>Katu</i>	<i>Ruksha</i>	<i>Ushna</i>	<i>Katu</i>	<i>Kaphgna</i>
2.	<i>Eranda</i>	<i>Katu</i>	<i>Guru</i>	<i>Ushna</i>	<i>Madhur</i>	<i>Vata</i>
		<i>Tikta</i>	<i>Laghu</i>	<i>Sheeta</i>	<i>Katu</i>	<i>Pitta</i>
		<i>Madhur</i>	<i>Snigdha</i>			<i>Kapha</i>
		<i>Kashaya</i>	<i>Tikshna</i>			
			<i>Sukshma</i>			
3.	<i>Aragvadha</i>	<i>Madhura</i>	<i>Guru</i>	<i>Sheeta</i>	<i>Madhura</i>	<i>Vatahara,</i> <i>Pittahara,</i> <i>Kaphahara</i>

Time duration till follow up: The patient will be followed up during treatment 15 days

Follow up period: 0th – 15th days

Time schedule of enrolment, interventions: *Nitya virechan* procedure will be carried out within 15 days with *Trivrutt Eranda Tailam* and *Aragvadha Eranda Tailam* .

Recruitment: 30 (15 in each group) patients will be selected by lottery strategy, and PI will assign and enlist the patient.

Methods: Data collection, management, and analysis.

Data collection methods: Assesment criteria

8. SUBJECTIVE PARAMETERS**8.1 Ruk (pain)**

1. No pain: 1
2. Continue pain: 2
3. Mild pain but no difficulty in walking: 3
4. Moderate pain and slight difficulty in walking: 4
5. Severe pain with severe difficulty in walking: 5

8.2 Toda (pricking sensation)

1. No pricking sensation: 1
2. Continue pricking sensation: 2
3. Mild pricking sensation: 3
4. Moderate pricking sensation: 4
5. Severe pricking sensation: 5

8.3 Stambha (stiffness)

1. No stiffness: 1
2. Sometimes for 5–10 min: 2
3. Daily for 10–30 min: 3

8.4 Spandana (twitching)

1. No twitching: 1
2. Sometimes for 5–10 min: 2
3. Daily for 10–30 min: 3
4. Daily for 30–60 min: 4
5. Daily more than 1 h: 5

8.5 Objective Criteria

1. SLR test [Straight leg raising test]
2. Lassegue sign [17]
3. Flip test [18]
4. Bowstring test [19]
5. Serum electrolytes

Data management: The information passage coding will be finished by PI

Statistical methods: Unpaired, paired t test and Wilcoxon sign rank, Wilcoxon rank sum test, using SPSS software.

For objective criteria unpaired t-test will be applied.

For subjective criteria Chi-square test will be applied.

Others tests will also be applied if required.

Suitable change can be made if required during course of study for better.

9 EXPECTED RESULTS

Primary outcome: We will see the impact of *nitya virechana* on subjective parameters during treatment. Information will be communicated as a standard mistake of mean at 5 % Level of confidence. It is hypothesized that *Trivrutta Eranda Tailam* and *Aragwadha Eranda Tailam nitya virechan* will be more effective in subjective with no any adverse effect.

Secondary outcome: We will see the effect of *Trivrutta Eranda Tailam* and *Aragwadha Eranda Tailam Nitya Virechana* on objective parameters such as SLRT, Lassegue sign, Flip test, Bowstring test and Serum electrolytes.

10. DISCUSSION

In the Human body lumbar spine is the pillar of all the muscles and nerves tree. In that any kind

of structural deformity makes a trouble for human being. And worldwide also it is the site of most of costly orthopedic difficulty for the world's developing countries rather than developed country, as well as industrialized countries. It is site of miracles well said. The nervous system with that the autonomic nervous system works side by side under the lumbar spine area so it is very difficult to treat as well as very carefully to handle such situation. With the heavy schedule busy, professional and social life having usual sitting posture in the office, in the industrial area work did their continuous work with same posture of back and leads to overexertion, jerk on back .that exerts a pressure on vertebral column leads to get injury to the spine as well nerve compression too. And reflects the tremendous to the back and with compression developing the radiating pain to lower limbs either side. In *Gridharsi* there is pain which goes throughout lower back region and radiates to lower limbs, that gets stiffness, restricted movements, numbness, and tingling sensation in the leg. Degenerative disc disease may irritate the nerve root and cause sciatica, as can mechanical compression of the sciatic nerve, such as from spondylolisthesis, spinal stenosis or arthritis in the spine [20-26]. *Acharya Charaka* mentioned *Gridhrasi* in *Vata Nanatmaja Vyadhi*. In *Gridhrasi*, *Ruka*, *toda*, *spandan* on lower back and lower limbs are the chief complaints related with *stambha*, In the disease *Gridhrasi hetu dosha* is *vata sthansamshtaya* in *Asthi-Sandhi* take place and produces *Asthivahasrotodusti* . So *Sainhik Mrudu Samshodhana* given by *Charak*, because in *Gridharsi saman aushadhi* could not because it is *krucchasadya* and in *madhyam roga marga*. *Gridhrasi* is a *Madhyama marga gata vatavyadhi* in which vitiated *vata dosha* settle in *asthi* and *sandhis* as a result *Khavaigunya* in *asthivaha* and *majjavaha srotasa* so the leading to *Vata prakopa*. Main symptoms of *Gridhrasi* are *Ruka*, *Stambha*, controlled movement of leg, Pain during flexion and extension. So the drugs choice for the current study are *Eranda*, *Aragvadha*, and *Trivrutta* . It's hot, unctuous, heavy and laxative properties helps to pacifies *Pakvshaysthavata*, *Anulomak*, *Virechaka* in nature cure constipation by dislodging the encrusted matter which are opposite to *vata dosha*. Hence it pacifies *vata*. That's why *Mrudu samshodhana* i.e *Virechana* has been considered as the treatment for *Vata vyadhi* given by *Acharya charak*, *Bhavprakash*, and *Chakra data*. *Eranda taila* has been mentioned as chief *sneha* of vegetable origin and *Taila* has *vatashamaka guna*. *Taila* has got

Usna, Snigdha, Sukshma, Snigdha gunas that's why with this qualities it reaches deeper *dhatu* like *asthi* and *majja* and piercing through minute channels. *Taila* is *Vedanasthapana, Snehana, Sandhaniya, Deepana, Balya, Rasayana, Ropaniya* etc. so with the result it can be use in *Vata* disorders.

Strength: If proposed study will results in the positive outcome then it will be established new mode of management for the *Gridhrasi*. In society, we will be provided economical and effective hypoglycemic management for *Madhumeha*.

11. CONCLUSION

Conclusion will be mentioned after the analyzing data.

LIMITATIONS

Will be convincing the patients for *nitya virechan* for 15 days and for hospitalization.

ETHICAL APPROVAL

Research ethics approval; approval from research ethics committee has taken. No. DMIMS (DU)/IEC/2017-18/6382.

CONSENT

The made consent will be taken from the patient before starting the assessment. During the investigation the classification of every patient will be kept up. With all the data model assent structure and other related documentation will be given to members.

Dissemination policy: The information will be dispersed by paper distribution. Creation qualification rules and any proposed utilization of expert scholars.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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