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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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 Aragavadha 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
patient in Group A will be given Trivutt 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 (Abhigahata), 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), 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 Sakthikshepa 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 (Sakthikshepa 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 planed 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 Aragavadha 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 Trivrutta Eranda Tailam and Aragavadha Eranda Tailam Nitya Virechana in Gridhrasi (Lumbago sciatica syndrome)

4. OBJECTIVES

1. To study the effect of Trivrutta Eranda Tailam in Gridhrasi
2. To study the effect of Aragavadha Eranda Tailam in Gridhrasi
3. To compare the effect of Trivrutta Eranda Tailam and Aragavadha 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 Aragavadha Eranda Tailam are effective in Gridhrasi?

Hypothesis: Trivrutta Eranda Tailam and Aragavadha Eranda Tailam are effective in Gridhrasi.

Null Hypothesis: Trivrutta Eranda Tailam and Aragavadha 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 fallow 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 | Nitya virechana with Trivrutta Eranda taila | Nitya virechana with Aragvadha Eranda Tailam |
| 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     | Operculina terpethum L. | Root |
| 2.      | Eranda        | Ricinus communis L. | Seeds |

b. Composition of Aragvadha Eranda Tailam

| Sr. No. | Sanskrit name | Botanical Name | Parts Used |
|---------|---------------|----------------|------------|
| 1.      | Aragvadha     | Cassia fistula L. | Fruit |
| 2.      | Eranda        | Ricinus communis L. | Seeds |

Table 3. Drugs ingredients

| Sr. No. | Drug | Rasa | Guna | Virya | Vipaka | Dosha gnata |
|---------|------|------|------|-------|--------|-------------|
| 1.      | Trivrutta | Katu | Ruksha | Ushna | Katu | Kaphagna |
| 2.      | Eranda | Katu | Tikta | Madhura | Kappha |
|         |       | Kulth | Lalgkha | Sheeta | Kappha |
| 3.      | Aragvadha | Madhura | Sheeta | Madhura | Vatahara |
|         |       | Guru | Tikshna | Kappha |

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: Assessment 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 Gridhrasi 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 sthansamshraya in Asthi-Sandhi take place and produces Asthivahasrotodusti . So Sainhik Mrudu Samshodhana given by Charak, because in Gridhrasi saman aushadhi could not because it is krucchasasya 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 majavaha 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 Pakshayasthavata, 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, Sukhma, Snigdha gunas that’s why with this qualities it reaches deeper dhatus like asthi and maja 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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